



THE SOUTH AFRICAN CODE OF MARKETING PRACTICE FOR HEALTH PRODUCTS CODE & GUIDELINE, VERSION 17.1 (November 2024).

This Code of Marketing Practice (the "Code") is the official Code of the Marketing Code Authority (MCA). Companies that are members of the MCA have committed to comply with this Code, which is applicable to all Health Products which are subject to registration in terms of the Medicines and Related Substances Act 101 of 1965 as amended, irrespective of whether the products have been registered or called up for registration.

Companies may have standards which are stricter in which case these standards will be applied by members.

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

Guidelines to the Code assist in the interpretation and application of the Code. They can be obtained from www.marketingcode.co.za.

The version control history of amendments to the Code is referenced at the end of the Code document.

For further information on the MCA or the Code enforcement provisions, please contact info@marketingcode.co.za.



Table of Contents

1	CHAPTER 1: PREAMBLE	1
2	CHAPTER 2: OBJECTIVES OF THE MCA	2
3	CHAPTER 3: APPLICATION, SPIRIT, AND INTERPRETATION OF THE CODE AND RECORD-KEEPING	3
3.1	Preamble	3
3.2	Application	4
3.3	Interpretation	5
3.4	Guidance on determination of FMV	8
3.5	Promotion of Health Products	9
3.6	Provision for Self-Regulatory Enforcement	10
3.7	Record-keeping	10
4	CHAPTER 4: COMPANY REPRESENTATIVES	11
4.1	Professionalism	11
4.2	Training	11
4.3	Medical Scientific Liaison (MSL)	11
4.4	Responsibility for Product Information	11
4.5	Provision of Services by Company Representatives	12
4.6	Scientific/Product Queries	13
4.7	Adverse Events/Product Technical Complaints/Usability Issues Reporting	14
4.8	Gaining Interviews with HCPs	14
4.9	Respect for HCPs and Others	14
4.10	Operating Room or Clinical Environment	15
5	CHAPTER 5: PROMOTION AND ADVERTISING	16
5.1	The promotion of Health Products shall:	16
5.2	General Principles	16
5.3	Advertising and Promotional Material	19
5.4	Information to be Provided to HCPs	19
5.5	Professional Information/Patient Information Leaflet and Instructions for Use	20
5.6	Minimum Requirements for Advertisements and Promotional Material	20
5.7	Artwork and Visual Representations	21
5.8	Information, Claims and Comparisons	23
5.9	Substantiation	29
5.10	Endorsements, Testimonials and Quotations	30
5.11	Journal Advertising	33
5.12	Disparaging Claims	34



5.13	Disguised Promotion	34
5.14	Market Research	35
5.15	Clinical Trials	35
5.16	Provision of Reprints of Journal Articles	35
5.17	Distribution of Advertisements and Promotional Material	36
5.18	Detailed Briefing Material	36
5.19	Communication and Electronic/Digital Media	37
5.20	Unapproved Indications	41
6	CHAPTER 6: APPROVAL OF PROMOTIONAL MATERIALS AND ACTIVITIES	44
6.1	Approval of Promotional Items and Activities	44
6.2	Proof of Approval	45
6.3	Reapproval of Promotional Material	46
6.4	Retention of Documentation/Record keeping	46
7	CHAPTER 7: INDUCEMENTS, DONATIONS AND SPONSORSHIP	48
7.1	Inducements	48
7.2	Donations and Corporate Social Investment	48
7.3	Sponsorship	50
7.4	Grants and Financial Support	50
8	CHAPTER 8: SAMPLES AND BANDED PACKS	52
8.1	Health Products	52
8.2	Personal Care Products	52
9	CHAPTER 9: COMPETITIONS	53
9.1	Competitions for HCPs	53
9.2	Consumer Competitions	53
10	CHAPTER 10: MEETINGS AND EVENTS WITH HCPs	55
10.1	General principles	55
10.2	CPD Meetings	59
10.3	Medical or Scientific Congresses, Conferences or Seminars	60
10.4	Transparency Related to Sponsorships	62
10.5	Hospitality for Administrative Staff during Meetings	62
11	CHAPTER 11: PROMOTIONAL ITEMS AND GIFTS	63
11.1	Promotional Aids	63
11.2	Items for Patients and Patient Organisations	66
12	CHAPTER 12: CONTRACTING AND REIMBURSING HEALTHCARE PROFESSIONALS	68
12.1	Contracted Services	68
12.2	Payment Exclusions	69
12.3	Patient Registries	69



13	CHAPTER 13: MEETINGS AND EVENTS INVOLVING PATIENT ORGANISATIONS	71
13.2	Contracted Services	71
14	CHAPTER 14: RELATIONS WITH CONSUMERS AND THE MEDIA	72
14.1	Advertising of Medicines in Schedule 2 & above, Class C & D Devices & IVDs	72
14.2	Advertising of Schedule 0 and 1 Medicines, Class A and B Medical Devices	72
14.3	Requests from Individual Consumers	72
14.4	Information Available to Consumers	72
14.5	Patient Education	74
15	CHAPTER 15: MATTERS SPECIFIC TO MEDICAL DEVICES AND IVDS	75
15.1	Demonstrations	75
15.2	Performance Evaluations, Appraisals and Training	75
15.3	Loan or Placed Equipment	77
16	CHAPTER 16: ENFORCEMENT OF THE CODE	82
16.1	IPASA Members	82
16.2	General Principles	82
16.3	Referral of Complaints	82
16.4	External Remedies	82
16.5	Repeat Complaints Received by the MCA	83
16.6	Enforcement Structures	83
16.7	Powers of an Adjudicating Committee	83
16.8	Powers of an Appeal Committee	86
16.9	Company-to-Company Complaints Process	87
16.10	General Rules Pertaining to Complaint and Appeal Documentation	88
16.11	Powers of the Executive Officer	89
16.12	Lodging of a Formal Complaint with the MCA	91
16.13	Nominated Complainant	91
16.14	Exchange of Complaint-Related Documentation between the Parties	92
16.15	Adjudication Process	92
16.16	Lodging an Appeal	94
16.17	Exchange of Appeal-Related Documentation between the Parties	95
16.18	Appeal Hearings	95
16.19	Validity of Proceedings	97
16.20	Publication of Outcomes	97
16.21	Non-Compliance with Rulings or Undertakings	98
16.22	Ex Parte Opinions	99
17	CHAPTER 17: TRADE ASSOCIATION AFFILIATION	101
17.1	Trade Associations involved in development of the Code	101



17.2	Trade Associations and Companies represented by the MCA since 2021	101
18	CHAPTER 18: RECORD OF UPDATES TO THE CODE	102



ACRONYMS

CCCO:	means Company Code Compliance Officer
CME:	Continuing Medical Education
CPA:	The Consumer Protection Act 68 of 2002
CPD:	Continuing Professional Development.
CTAC:	Code Technical Advisory Committee.
FFS:	Fee for Service.
FMCG:	Fast Moving Consumer Goods
FMV:	Fair Market Value
HCP:	Healthcare Practitioner
IFPMA:	International Federation of Pharmaceutical Manufacturers and Associations
IPASA:	Innovative Pharmaceutical Association of South Africa
MCA:	Marketing Code Authority
MSL:	Medical Scientific Liaison (staff)
PHARMISA:	Pharmaceuticals Made In South Africa
POPIA:	Protection of Personal Information Act 4 of 2013
SOP:	Standard Operating Procedure
SAAHA:	South African Animal Health Association
SALDA:	South African Laboratory Diagnostics Association
SAMED:	South African Medical Device Association
SCA:	Self Care Association of South Africa



GLOSSARY

1. In the Code:

- 1.1 words and phrases that are defined in the Medicines Act have the meanings assigned to them in this Act unless otherwise stated or inconsistent with the context;
- 1.2 words and phrases that are defined in the Code have the meanings assigned to them in the Code unless inconsistent with the context;
- 1.3 any word or phrase defined in any section hereunder, shall bear the same meaning throughout the remainder of this Code;
- 1.4 unless specifically otherwise provided, any number of days prescribed shall be determined by excluding the first and including the last day or, where the last day falls on a day that is not a Business Day, the next consecutive Business Day;
- 1.5 unless the context indicates otherwise, any use of the word "includes" or "including" in relation to a defined or generic word or expression, on the one hand, and one or more enumerated examples or specific items, on the other, is not to be construed as limiting the defined or generic expression to the examples or items so enumerated;
- 1.6 a word in the singular includes the plural, and vice versa;
- 1.7 a reference to the one gender shall include the other gender;
- 1.8 'chapter' refers to a chapter in the Code;
- 1.9 'section' refers to a section in the Code;
- 1.10 section headings are for convenience and reference purposes only and are not to be used in the interpretation of any of the provisions to which they relate;
- 1.11 information is not without legal force and effect merely on the grounds that it is wholly or partially in the form of a data message as defined in the Electronic Communications and Transactions Act 25 of 2002.
- 1.12 where a document is required to be signed and it is sent by electronic means and/or stored electronically, an advanced electronic signature shall not be required.

2 The following definitions from the Medicines Act are included for ease of reference:

- 2.1 (Draft) **Category D** means medicines as classified in sub-regulation 9(2), intended for use in humans or animals which are, without further manipulation, ready for administration, including packaged preparations where only a vehicle is added to the effective medicine. Category D medicines include Discipline-specific medicines and health supplements for both human and veterinary use.
- 2.2 **Clinical Trial** means an investigation in respect of a Medicine for use in humans or animals that involves human participants or animals and that is intended to
 - 2.2.1 discover, or verify the clinical, pharmacological or pharmacodynamic effects of the Medicine;
 - 2.2.2 identify any adverse events;
 - 2.2.3 study the absorption, distribution, metabolism and excretion of the Medicine;or



2.2.4 ascertain its safety or efficacy.

- 2.3 (Draft) **Complementary Medicine** means a Category D medicine. Category D medicines are divided into Discipline-specific medicines and Health Supplements. The Discipline-specific category D medicines for human use are those identified in class 33 of Annexure 1 and the Health Supplements in class 34 of Annexure 1.
- 2.4 (Draft) **Discipline-specific medicine** means a category D medicine contemplated in sub-regulation 9(2)(A). Discipline-specific medicines for human use are identified in class 33 of Annexure 1 and for veterinary use in class 29 of Annexure 2. [Previously called complementary medicines].
- 2.5 (Draft) **Health Supplement** means a category D medicine. Health Supplements for human use are identified in class 34 of Annexure 1 and for veterinary use, in class 29 of Annexure 2.
- 2.6 **Instructions for Use** means Instructions for Use of Medical Devices as stipulated in Regulation 23 of the Regulations relating to Medical Devices and IVDs.
- 2.7 In Vitro Diagnostic (IVD) means a Medical Device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.
- 2.8 **Medical Device** means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, including Group III and IV Hazardous Substances contemplated in the Hazardous Substances Act, 1973 (No Act 15 of 1973)
- 2.8.1 intended by the manufacturer to be used, alone or in combination, for humans or animals, for one or more of the following:
- 2.8.2 diagnosis, prevention, monitoring, treatment or alleviation of disease;
- 2.8.3 diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- 2.8.4 investigation, replacement, modification or support of the anatomy or of a physiological process;
- 2.8.5 supporting or sustaining life;
- 2.8.6 control of conception;
- 2.8.7 disinfection of Medical Devices; or
- 2.8.8 providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and
- 2.8.9 which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human or animal body, but which may be assisted in its intended function by such means.
- 2.9 **Medicine**
- 2.9.1 means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in:



2.9.2 the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in humans; or

2.9.3 restoring, correcting or modifying any somatic or psychic or organic function in humans; and

2.9.4 includes any veterinary Medicine.

2.10 **Patient Information Leaflet** means the information pertaining to a Medicine as provided for in Regulation 12 of the General Regulations, written in a manner that is easily understandable to the patient.

2.11 **Professional Information** means the information about a medicine as provided for in Regulation 11 of the General Regulations.

2.12 **User** means a Person that uses a Medical Device or IVD.

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

3.1 **Advertisement** in relation to any Medicine, scheduled substance, Medical Device or IVD, means any written, pictorial, visual or other descriptive matter or verbal statement or reference

3.1.1 appearing in any newspaper, magazine, pamphlet, electronic media (including radio and television) or other publication;

3.1.2 distributed to members of the public; or

3.1.3 brought to the notice of members of the public in any manner whatsoever, which is intended to Promote the sale of that Medicine, scheduled substance, Medical Device or IVD, and "Advertise" has a corresponding meaning.

Advertisement includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to Promote the sale, use or supply of a Health Product.

For the purposes of the Code, the definition of "**Advertisement**" includes: Advertising to HCPs; advertorials; branded materials relating to Health 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; outdoor Advertising; digital applications; 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 in retail outlets; call centres and 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; light box Advertising as well as any other form of Promotion.



- 3.2 **Appellant** means the party to a complaint appealing against a decision of an Adjudicating Committee.
- 3.3 **Appellee** means the party against whom an appeal is filed.
- 3.4 **Artificial Intelligence (AI)**, means the ability of a digital computer or computer-controlled robot to perform tasks commonly associated with intelligent beings. (Brittanica) Refer also to 5.2.15)
- 3.5 **Board** means the Board of the MCA.
- 3.6 **Business Day** means any day other than a Saturday, Sunday or public holiday in terms of the laws of the Republic of South Africa.
- 3.7 **Call Up** means Health Products, identified as requiring registration in terms of Section 14(3) of the Medicines Act, which permits their sale, supply and use in the Republic of South Africa.
- 3.8 **Code** means The South African Code of Marketing Practice for Health Products.
- 3.9 **Constitution** means the Constitution of the MCA.
- 3.10 **Consumer** means a Person:
- 3.10.1 to whom a Health Product is Promoted in the ordinary course of a Company's business;
 - 3.10.2 to whom a Health Product is supplied (which includes sold, rented, leased and exchanged); or
 - 3.10.3 who uses, in any manner whatsoever, or consumes a Health Product,
 - 3.10.4 including a member of the general public and a patient.
- 3.11 **Company** means a manufacturer, importer, wholesaler, distributor or retailer of Health Products.
- 3.12 **Company Code Compliance Officer** means any natural person 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 compliance with the Code. Every Company shall authorise or appoint a person as the Company Code Compliance Officer.
- 3.13 **Complainant** means the party lodging a complaint for an alleged breach or contravention of the Code.
- 3.14 **Company Representatives** means all relevant personnel, including representatives and other members of staff of, and others retained by way of contract or third-party agreement by the Company, who interact with HCPs and Consumers with regard to Health Products, or play a role in organising, reviewing and approving Promotional Material and activities and/or events intended for HCPs and Consumers or are involved in training with respect to Health Products. Company Representatives include healthcare sales representatives and FMCG sales representatives, agents, merchandisers and Promoters.
- 3.15 **CPA** means the Consumer Protection Act 68 of 2008 and Regulations and Notices issued in terms of this Act.



- 3.16 **Electronic Communication** means any text, voice, sound, audio-visual or image message sent over an electronic communications network, which is stored in the network or in the recipient's terminal equipment until it is retrieved by the recipient and includes telephone, mobile phone, SMS, e-mail, [mobile] messaging, and facsimile machines, data messages or any form of electronic communication as defined in the Electronic Communications and Transactions Act, Act 25 of 2002.
- 3.17 **Electronic/Digital Media** includes the Internet, websites, applications, social media, electronic signage and e-commerce.
- 3.18 **Evaluation of Medical Devices and IVDs** means the assessment and analysis of data pertaining to a Medical Device or IVD to establish or verify the clinical safety and/or performance of the device when used, as intended, by the manufacturer.
- 3.19 **Executive Officer** means the Executive Officer of the MCA.
- 3.20 **FFS or Fee-for-Service/Honorarium** means a payment or an award granted or reimbursement provided in recognition of a special service by a Person. An FFS/Honorarium shall be paid at fair market value for speeches, articles, appearances or other services rendered in terms of a written agreement, which may take into consideration, amongst others, the qualifications and expertise of a speaker, the availability of such expertise in the health sector, and the complexity of the subject. The FFS/Honorarium, which shall be determined by the Company may be subject to scrutiny by the MCA should it be the subject of a complaint in terms of the Code. Where the FFS/Honorarium offered or provided is not in terms of a written agreement, the value shall not exceed the value of an occasional gift as determined by the Board from time to time.
- 3.21 **FMCGs or Fast-Moving Consumer Goods** are products that are sold quickly and at relatively low cost. Examples in the healthcare space include schedule 0 products in both Category A (medicines such as paracetamol and aspirin) and Category D (complementary medicines and health supplements). Many FMCGs have a high consumer demand and high turnover rate. FMCGs are sold across various channels from pharmacy to retail and grocery to spaza stores.
- 3.22 **Guidelines** means the Guidelines to the Code, which contain supplementary information compiled and updated regularly by the MCA to guide the interpretation of the Code.
- 3.23 **Health Products** means Medicines, scheduled substances, Complementary Medicines, Medical Devices, and IVDs as regulated by the Medicines Act.
- 3.24 **Healthcare Professional (HCP)** includes persons registered with any statutory council regulating healthcare practitioners, including the Health Professions Council of South Africa (HPCSA), the South African Veterinary Council (SAVC), the Allied Health Professions Council of South Africa (AHPCSA), the South African Nursing Council (SANC) and the South African Pharmacy Council (SAPC), and includes both clinical and non-clinical persons registered with these councils such as medical practitioners, nurses, technicians, research coordinators, pharmacists and pharmacists' assistants, as well as clinical engineers registered with the Engineering Council of South Africa.



- 3.25 **Health establishment** means the whole or part of a public or private institution, facility, building or place, whether for profit or not, that is operated or designed to provide inpatient or outpatient treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative or other health services as defined in the NHA.
- 3.26 **Hospitality** in relation to the Code means, relating to or denoting the business of providing meals and refreshments, travel, or accommodation to HCPs, Customers, conference delegates, or other official visitors.
- 3.27 **HPCSA** means the Health Professions Council of SA established in terms of section 2 of the Health Professions Act 56 of 1974.
- 3.28 **Industry** means all Companies and includes their licence holders, agents, contractors, third-party distributors/marketers, contracted events' organisers and/or any third party acting on their behalf.
- 3.29 **Institution** means an organisation, establishment, foundation, society, or the like, devoted to the Promotion of a particular cause. This includes private hospitals and clinics.
- 3.30 **Launch** means the introduction of a Health Product for the first time.
- 3.31 **MCA or Marketing Code Authority** means the juristic body established as a voluntary association to create a mechanism for the self-regulation of Companies, subject to the Code, and through which the enforcement of the Code takes place.
- 3.32 **Medicines Act** means the Medicines and Related Substances Act 101 of 1965 and Regulations and notices issued in terms of this Act, as well as, guidelines, directives, notices, , codes or any enforceable document issued by the Regulatory Authority and includes any legislation that amends or repeals and replaces the Medicines Act.
- 3.33 **Member** means a member of the MCA.
- 3.34 **Minimum Requirements** means the legislated requirements for written Advertisements as set out in the General Regulations for Medicines and the Regulations relating to Medical Devices and IVDs for Medical Devices and IVDs.
- 3.35 **NHA** means National Health Act, 61 of 2003.
- 3.36 **Nominated appellant** means the person envisaged in Section 16.12 who lodges an appeal in a matter where a Nominated Complainant has acted on behalf of the MCA.
- 3.37 **Nominated Complainant means** a person nominated by the Board in terms of Section 16.12 to lodge a complaint on behalf of the MCA when a transgression of the Code has been identified by the Executive Officer.
- 3.38 **Off-label Use** means the use of any Health Product for a purpose or indication not approved by the Regulatory Authority and not included in the approved Professional Information/Patient Information Leaflet/Instructions for Use or other official Health Professional Information. **On-label use** has the opposite meaning.
- 3.39 **Panels of Experts** means those persons appointed by the Board by virtue of their expertise to serve on adjudicating, appeal or Ex Parte Committees.



- 3.40 **Person** includes a body corporate, partnership, association, organisation, entity or trust.
- 3.41 **POPIA** means the Protection of Personal Information Act 4 of 2013 and Regulations and Notices used in terms of this Act
- 3.42 **Promotion** in relation to a Health Product includes the marketing and advertising (unless otherwise required by the context) of such a Health Product. **Promote** has a corresponding meaning.
- 3.43 **Promotional Activity** means any activity associated with Health Product Promotion and excludes a Promotional Event.
- 3.44 **Promotional Aids** means non-monetary items given away free of charge to Promote a Company or Health Product.
- 3.45 **Promotional Events** means events organised in association with the Promotion of a Health Product. Continuing Professional Development (CPD) or Continuing Medical Education (CME) events complying with the requirements of the Code are not considered Promotional Events.
- 3.46 **Promotional Material** includes Promotional Aids, detail aids, leave-behind documentation, booklets and advertorials, and includes the items listed under the definition of Advertisement, irrespective of the medium used, which includes Electronic/Digital Media.
- 3.47 **Registry** means an organised 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 serving one or more predetermined scientific, clinical, or policy purpose.
- 3.48 **Regulatory Authority** means the body appointed to regulate Health Products in terms of the Medicines Act or any succeeding legislation, which is currently the South African Health Products Regulatory Authority (SAHPRA).
- 3.49 **Reimbursement service** means the provision of assistance in the preparation of a motivation for Reimbursement of a product by Medical Schemes
- 3.50 **Respondent** means the party against whom a Complainant has lodged a complaint for an alleged breach or contravention of the Code.
- 3.51 **Responsible Pharmacist** means a natural person who is a pharmacist and who shall be responsible to the Pharmacy Council for complying with the provisions of the Pharmacy Act and other legislation applicable to services which specifically pertain to the scope of practice of a pharmacist, and the legislation applicable to the pharmacy under his/her personal supervision.
- 3.51 **Retailer** means a business supplying Health Products directly to Consumers and includes FMCG retailers.
- 3.53 **Right of Sale** refers to the authorisation given in terms of Section 14(3) of the Medicines Act to sell a Health Product.



- 3.54 **Sanction Policy Document** means the document published by the Board from time to time with respect to the sanctions that may be imposed for contraventions of the Code.
- 3.55 **Social Media** means the collective of online communications channels dedicated to community-based input, interaction, content-sharing and collaboration. These channels typically include but are not limited to platforms such as: Facebook, X, Instagram, TikTok, LinkedIn, YouTube, Snapchat, Reddit, Tumblr, Blogs, Pinterest and WhatsApp.
- 3.56 **Social Media Influencer** means a content creator on social media with a social media following and who have established credibility in a specific industry. Social media influencers develop a following by sharing content to entertain, inform, and connect them with their followers. This line of communication allows influencers to generate conversations on social media and drive engagement with their audiences. Social media channels used by influencers include but are not limited to, for example, Instagram, YouTube, blogs and Facebook.
-



CHAPTER 1: PREAMBLE

- 1.1 Whereas; the Constitution of South Africa contains rights and obligations that apply to all persons whether natural or juristic, the advertising and promoting of health products are to be done in a way that respects these rights, especially those found in the Bill of Rights, and upholds the dignity of all persons. Alleged infringements of Constitutional rights are to be referred to the appropriate institutions rather than to the MCA
- 1.2 Whereas the National Drug Policy (1996) provides that "the advertising and marketing of drugs shall be in keeping with the National Drug Policy and in compliance with national regulations, as well as voluntary industry standards. All Promotion-making claims shall be reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation and in good taste. They shall not contain misleading or unverifiable statements or omissions likely to induce medically unjustifiable drug use or to give rise to undue risks. Promotional material shall not be designed to disguise the real nature. Promotion in the form of financial or material benefits shall not be offered to healthcare practitioners or sought by them to influence them in the prescription of drugs. Scientific and educational activities shall not be deliberately used for Promotional purposes"; and
- 1.3 Whereas Section 18C of the Medicines Act empowers the Minister, after consultation with the relevant industries and other stakeholders, to make Regulations relating to the marketing of Medicines, Medical Devices or IVDs, and such Regulations shall also provide for Codes of Practice for relevant industries; and
- 1.4 Whereas Regulation 21 of the Regulations relating to Medical Devices and IVDs provides requirements for the Advertising of Medical Devices and IVDs; and
- 1.5 Whereas Regulation 42 of the General Regulations to the Medicines Act provides requirements for the Advertising of Medicines;
- 1.6 Various Companies in the 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 and the enforcement of the Code has been entrusted to the MCA as provided herein and in the Constitution.
- 1.7 The Executive Officer acts as the custodian of the Code.



CHAPTER 2: OBJECTIVES OF THE MCA

The Objectives of the MCA are described in the MCA Constitution.



CHAPTER 3: APPLICATION, SPIRIT, AND INTERPRETATION OF THE CODE AND RECORD-KEEPING

3.1 Preamble

The National Department of Health, the 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 the cornerstone of healthcare. Accurate information about Health Products is integral to providing quality healthcare services.

- 3.1.1 The ethical Promotion of Health Products is vital in ensuring that Healthcare Professionals (HCPs) and Consumers have access to accurate and substantiated information, that Consumers have access to appropriate Health Products and that Health Products are prescribed and used in a manner that provides the maximum healthcare benefit to Consumers.
- 3.1.2 The industry has an obligation and a responsibility to provide accurate information and education about its Health Products to HCPs and Consumers in order to establish a clear understanding of the appropriate use of the products. Industry relationships with HCPs shall support, and be consistent with, the professional responsibilities HCPs have towards their patients.
- 3.1.3 All Companies shall maintain high ethical standards when conducting Promotional Activities.
- 3.1.4 Considering the provisions of Section 18C of the Medicines Act with regard to Codes of Practice for the relevant industries, the MCA intends this Code to be acknowledged as such for the Industry. Various Health Product trade associations and Companies have adopted it. This signifies the Industry's commitment towards ensuring that the Promotion of Health Products to HCPs and Consumers is carried out in a responsible, ethical and professional manner and based on substantiated information.
- 3.1.5 The industry is committed to educational and Promotional efforts that benefit Consumers, and to Promotional programmes and collaboration that enhance the rational use of Health Products and fair competition in their Promotion. The Industry seeks to preserve the independence of the decisions taken by HCPs.
- 3.1.6 The MCA shall take cognisance of other professional and industry codes applicable to the Health Products sector and professions with which this sector interacts. The MCA has the power to align its administration with that of other codes in force in the Health Sector at any point in time.
- 3.1.7 All Companies shall comply with the applicable legal, regulatory and professional requirements and with the letter and the spirit of the Code.



3.2 Application

3.2.1 The Code applies to the following:

- 3.2.1.1 all Companies that are Members, including their licence holders, agents, contractors, third-party distributors/marketers, contractual event organisers and/or any third party acting on their behalf;
- 3.2.1.2 all non-members of the MCA to the extent that they may influence the demand for Health Products, including retailers, wholesalers and distributors that agree to be subject to the Code; and
- 3.2.1.3 all Health Products, irrespective of registration by the Regulatory Authority, Unregistered Complementary Medicines, Medical Devices and IVDs shall be evaluated against the relevant legislation and guidelines, where approved Professional Information/Patient Information Leaflet/Instructions for Use do not yet exist, for purposes of the Code.
- 3.2.1.4 The following specific activities of Companies, including their licence holders, agents, contractors, third-party distributors/marketers, contractual event organisers and/or any third party acting on their behalf, are subject to the Code:
 - 3.2.1.4.1 all Advertising, Promotion, Promotional Activities and/or communication directed at influencing any Consumer, HCP or seller of Health Products, who in the course of their professional or other activities may prescribe, purchase, supply, administer, loan, rent or lease a Health Product or recommend its use;
 - 3.2.1.4.2 all Advertising and/or Promotional Material directed at Consumers to provide information about the Health Products available for self-medication or use;
 - 3.2.1.4.3 all Advertising and Promotion in relation to the Promotion of a Health Product and any activities directly or indirectly related to it, which may reflect on the Promotional practices of the Industry, including sponsorships, patient information-sharing, meetings and hospitality; and
 - 3.2.1.4.4 Interactions between the Industry and HCPs and the Industry and Consumers as envisaged in the Medicines Act.

3.2.2 The Code does not apply to the following:

- 3.2.2.1 factual, accurate, informative announcements and reference material not intended for Promotional purposes concerning registered Health Products and relating for example, to adverse reactions and warnings;



- 3.2.2.2 product labels, packaging materials and Professional Information/Patient Information Leaflets/Instructions for Use or other Regulatory Authority-approved information. These are subject to regulation by the Medicines Act;
- 3.2.2.3 the Promotion of Stock Remedies as defined under the Fertilisers, Farm Feeds, Agricultural Remedies and Stock Remedies Act 36 of 1947;
- 3.2.2.4 issues relating to the pricing, bonussing, sampling and perverse incentives governed by the legislation and in codes issued in terms of legislation, including the Medicines Act;
- 3.2.2.5 Company sales incentives; and
- 3.2.2.6 Clinical Trials of Health Products.

3.3 Interpretation

- 3.3.1 The provisions of the Code shall be interpreted both in terms of the letter and spirit of the Code.
- 3.3.2 If there is inconsistency between the Code and a provision of any law, the law shall prevail.
- 3.3.3 The Guidelines are supplementary information, which must be used in the interpretation of the Code. The examples contained in the Guidelines which are inserted in the text following the relevant Code provision, are intended to illustrate and clarify the meaning of the provisions of the Code. They are not exhaustive and as such, do not cover all possible situations covered by the provisions of the Code. The Guidelines are secondary to Code requirements. The Guidelines will be updated regularly by the MCA, as part of its mandate to ensure education, application and enforcement of the Code.
- 3.3.4 Any Person or Committee interpreting and applying the Code shall consult the Guidelines for guidance on the application of Code principles in practical situations. An interpretative approach that harmonises the Code and Guidelines shall be followed. In cases of irreconcilable conflict between the Code and the Guidelines, the Code shall prevail and recommendations may be made by structures of the MCA, including the adjudication, appeal and Ex Parte Committees, about any amendments that should be considered by the relevant MCA structures to correct such irreconcilable conflicts.
- 3.3.5 Any review of Advertising and/or Promotional Material or Promotional Events covered by this Code, shall give consideration not only to the impression created by an Advertisement, Promotional Material or Promotional Activity, but also to the impression likely to be gained from a brief or partial exposure to such Advertisement, Promotional Material or Promotional Activity as well as the



probable impact upon the reasonable person to whom the Advertisement, Promotional Material or Promotional Activity is directed.

3.3.6 Rulings made by the enforcement structures of the MCA as provided for in the Code establish precedents on what constitutes acceptable practices in the marketing and Promotion of Health Products.

3.3.7 The following principles shall guide the interpretation of this Code:

3.3.7.1 Companies, including their licence holders, agents, contractors, third-party distributors/marketers, contractual event organisers and/or any third party acting on their behalf, shall comply with the Code, applicable professional and good practice codes and all the applicable laws and regulations, including the CPA and POPIA.

3.3.7.2 Companies shall adhere to ethical business practices and socially responsible Industry conduct and shall not use any form of compensation, payment, reward, benefit or inducement, which is not legally due, or which is given on the understanding, whether express, implied or tacit, that the recipient will engage or refrain from engaging in certain behaviour in a manner which is either:

3.3.7.2.1 illegal; and/or

3.3.7.2.2 contrary to the ethical or professional rules or norms in order to procure the sale, loan, lease or prescription of their Health Products; and/or

3.3.7.2.3 which in the opinion of the MCA may adversely affect the interests of any Consumer or group of Consumers.

3.3.8 Principle-based Decision-making for Approval of Promotions

3.3.8.1 The Code provides rules and guidance on what constitutes ethical marketing practices. Where no applicable rule can be found in the Code, the Compliance Officer and the commercial team of the company are encouraged apply the principles of the Code and to assess if the activity is ethically "right" to approve.

3.3.8.2 In some cases, as in the case of the determination of Fair Market Value (FMV), competition law prevents the Code from prescribing a value. Companies must therefore have their own internal system to determine FMV.

3.3.9 Basic principles and questions that can guide decision-making and challenging or ambiguous situations.

3.3.9.1 The patient must be at the heart or centre of all activities.

3.3.9.1.1 Is the patient at the centre/heart of this activity?



- 3.3.9.1.2 Would the patient's interests (such as the need to receive the best care for their needs) or rights (such as right to accurate, scientific information on a product) be negatively impacted by the activity?
- 3.3.10 Activities must not compromise HCP independence in making treatment decisions.
 - 3.3.10.1 Does the activity incentivise or intend to incentivise the HCP to recommend/prescribe/use a particular product and hence compromise independent judgement?
 - 3.3.10.2 Does the HCP stand to receive direct or indirect financial gain from the activity and hence compromise their independent judgement?
- 3.3.11 Promote the approved, appropriate and rational use of your product.
 - 3.3.11.1 Is the material or activity in line with the relevant approved/registered Professional Information or Instructions for Use? (e.g. no claims made that are not in the Professional Information or Instructions for Use).
 - 3.3.11.2 Is the activity in line with the Medicines Act? (e.g. is the audience appropriate with regard to the scheduling or the category of the product).
 - 3.3.11.3 Does this activity respect the independent decision-making of the relevant stakeholders?
- 3.3.12 Act lawfully, ethically and with integrity
 - 3.3.12.1 Is the material or activity legal / legitimate?
 - 3.3.12.2 Is the material or activity factual, accurate, and balanced? Check that material does not mislead.
 - 3.3.12.3 What is the actual intent of the activity? Is the intent clear or designed to mislead? Examples: market research; phase 4 studies etc.
 - 3.3.12.4 Is the intent to promote a particular product or is it legitimate research?
 - 3.3.12.5 Is the intent of a CPD meeting to educate HCPs or to promote a product? (Note: Different approaches apply but both are permissible).
 - 3.3.12.6 Is there any active or passive participation e.g. by staff or consultants, to hide or misrepresent the true intent of the activity?



3.3.13 Be transparent

3.3.13.1 All the information that leads to the approval and execution of this activity should be disclosed. This will involve at least (refer Chapter 6):

3.3.13.1.1 documenting all transactions and information related to the activity such as invitations, payments, instructions; and

3.3.13.1.2 recording all financial transactions in an agreement signed by the company and the recipient and kept on file in the company for 5 (five) years.

3.3.13.2 Will the activity appear as ethical/acceptable when viewed by patients / public / regulator / competitors?

3.3.13.3 Has the determination of the FMV been substantiated in writing? (See separate guidance on determination of FMV in Section 3.4).

3.3.13.4 Will this activity strengthen confidence and trust in the pharmaceutical industry?

3.3.13.5 Has consideration been given to what could go wrong and measures put in place to ensure correct procedures are followed?

3.4 Guidance on determination of FMV

3.4.1 Contracting of HCPs

3.4.1.1 Reimbursement of HCPs must comply with the Code.

3.4.1.2 The Code provides for the contracting of HCPs for certain activities. Competition law dictates that the MCA cannot prescribe an amount for FMV. Companies must therefore determine and substantiate the FMV for reimbursing an HCP. HCPs may not be reimbursed for time out of their practice. Refer to the Code for guidance on contracting with HCPs.

3.4.1.3 Questions to consider in determining FMV could include:

3.4.1.3.1 Does the Code allow the engagement with HCPs that is intended in the activity?

3.4.1.3.2 Does the activity require special experience or qualifications of the HCP?

3.4.1.3.3 How many similarly competent HCPs would be available to do the presentation?

3.4.1.3.4 Does the HCP have international standing and experience?

3.4.1.3.5 What is the "value" to the company of the audience being addressed?



3.4.1.3.6 What amount of time would be involved in preparation or research by the HCP?

3.4.1.3.7 How much time will be spent on the actual activity?

3.4.2 Contracting social media influencers

3.4.2.1 The Code provides for the contracting of social media influencers at FMV. All promotion done by the social media influencer shall comply with the Medicines and Related Substances Act. The paid partnership and company involvement shall also be transparent.

3.4.2.2 In considering the acceptable FMV fee for a social media influencer, account may be taken of the number of followers, the nature and scope of the influencer's market, the platform, and the objectives of the campaign.

3.4.2.3 An HCP can be contracted as a social media influencer. The HCP cannot however promote a specific Health Product (thus no mention of a Health Product can be made by the HCP to the consumer). They are only allowed to promote disease awareness and educate the public.

3.4.2.4 If an HCP is contracted as a social media influencer, the paid partnership should be transparent and should not be misleading.

3.5 Promotion of Health Products

3.5.1 The promotion of Health Products:

3.5.1.1 shall be in accordance with the Medicines Act;

3.5.1.2 shall comply with the terms of registration, where relevant; be consistent with the particulars listed in its Regulatory Authority-approved product documentation (e.g. the Professional Information/Patient Information Leaflet/Instructions for Use), where applicable. Indications, which have not been approved may not be Promoted and may not deviate from, be in conflict with or go beyond the evidence submitted in the application for registration; and

3.5.1.3 shall not occur before the Health Product is registered in terms of Section 15 of the Medicines Act, unless Section 14(3) of the Medicines Act applies.

3.5.2 The principles underpinning the interactions with HCPs and Consumers as well as Advertising and Promotion in the Code apply equally to all Health Products.

3.5.3 Section 15 of the Code deals with specific activities related to Medical Devices and IVDs only.



3.5.4 Companies subject to the Code that seek to circumvent the Code by engaging or using third parties, such as licence holders, agents, contractors, distributors/marketers and/or event organisers, Social Media Influencers, including but not limited to dispensing system software or ordering system vendors, shall be regarded as infringing the Code.

3.6 Provision for Self-Regulatory Enforcement

3.6.1 The Code is based on the principle of Industry self-regulation through enforcement procedures, which are in line with international standards and practice.

3.6.2 The process of enforcement and the relevant bodies responsible for enforcement are set out in the Constitution and Chapter 16 of this Code.

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

3.7 Record-keeping

3.7.1 Whenever the Code specifies that records must be kept, such records shall be kept by the relevant Party for a period of at least 5 (five) years.



CHAPTER 4: COMPANY REPRESENTATIVES

4.1 Professionalism

- 4.1.1 Company Representatives shall conduct the Promotion of Health Products in a professional manner.
- 4.1.2 Companies and company representatives shall refrain from creating a negative perception or giving an incorrect impression about the Industry to other stakeholders, including Consumers, Consumer associations, the press, HCPs and government officials, by offering excessive Hospitality or the manner in which they gain interviews with HCPs.

4.2 Training

- 4.2.1 Companies shall ensure that all their customer facing Company Representatives are familiar with the Code and trained and certified by the MCA in the application of the Code.
- 4.2.2 All Board members, CTAC members, and panellists should be Code certified once in 24 (twenty-four) months.
- 4.2.3 All Company Representatives shall have appropriate scientific knowledge, and in the case of Category D Medicines, knowledge of the relevant disciplines of Complementary Medicine, and of Health Supplements to be able to provide precise and complete information about the Health Products they Promote or services they offer.
- 4.2.4 All training material must be approved by the Company Code Compliance Officer.

4.3 Medical Scientific Liaison (MSL)

- 4.3.1 Company Medical Scientific Liaison (MSL) personnel provide scientific and medical information and information on the efficacy and safety of the Health Products to HCPs and Customers to ensure the appropriate and safe use of such Health Products. MSL personnel shall therefore have a scientific or medical background or relevant scientific or medical experience.
- 4.3.2 It is recommended that MSL personnel should not report into marketing and sales departments.

4.4 Responsibility for Product Information

- 4.4.1 Companies are responsible for the information about their Health Products irrespective of it being issued by themselves or their third-party service providers.



Guideline to Section 4.4

Note 1

Communications of scientific information to HCPs or Consumers

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

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

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

4.5 Provision of Services by Company Representatives

- 4.5.1 The provision of any services by Company Representatives shall be in accordance with detailed written instructions provided by the Company. The written instructions shall set out the role of the Company Representative in providing the service and cover patient privacy and confidentiality issues. Where patient contact may be involved, instructions on how information is to be given to the recipients or patients shall be included. The written instructions shall not advocate, either directly or indirectly, any course of action, likely to result in a breach of the Code.
- 4.5.2 The provision, delivery or demonstration of medical and educational goods and/or services for the benefit of patients or HCPs shall in no way be linked to the promotion of products and must not have a promotional objective. These services can only be provided if they are legitimately needed in order to ensure the safe and effective use of the product.
- 4.5.3 Company Representatives shall not offer Reimbursement Services to facilitate product changes. Refer also to note 5.
- 4.5.4 Neither the Company nor the Company Representatives shall be given access to data/records that could identify, or could be linked to, any particular patient unless written informed consent has been received from both the HCP and patient.
- 4.5.5 Companies shall ensure that patient confidentiality is maintained at all times.

Guideline to Section 4.5

Note 1: Provision of Services by Company Representatives

The nature of the service provider, the person associated with the provision of medical and educational goods and services, is important i.e. is the service provider a Health Product representative of the Company or is the service provider some other appropriately qualified person, such as a sponsored registered nurse? If the goods and services require patient contact, for example



either directly or by identification of patients from patient records and the like, then Health Product representatives must not be involved. Only an appropriately qualified person, for example a sponsored registered nurse, not employed as a Health Product representative, may undertake activities relating to patient contact and/or patient identification.

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

Note 2: Promotional activities by Company Representatives

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

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

Note 3: Value-added services

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

Note 4: Access to patient records

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

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

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

Note 5 to 4.5.3: Reimbursement Services

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

4.6 Scientific/Product Queries

- 4.6.1 Inquiries from HCPs and Consumers with regard to the use of Health Products shall be handled by appropriately qualified personnel.



- 4.6.2 Unsolicited queries from HCPs on Off-label Use may be answered by regulatory, medical or other appropriately qualified personnel only (and not by sales and marketing Company Representatives).
- 4.6.3 Unsolicited queries from Consumers on any Off-label Use shall be referred to their treating HCPs.
- 4.6.4 Where a specific request is made by a Consumer or a member of a Consumer's family about a Health Product, which has been prescribed, the Company may clarify matters using a Patient Information Leaflet or other patient aid but shall otherwise recommend enquirers to consult their HCPs.
- 4.6.5 Companies shall ensure that their response to any public enquiry is not Promotional.
- 4.6.6 The company shall keep a record of unsolicited requests for literature from HCPs. This information should not be conveyed to HCPs by the Marketing or Sales Department or by medical representatives.

4.7 Adverse Events/Product Technical Complaints/Usability Issues Reporting

- 4.7.1 Company Representatives shall refer any information that they receive relating to the use of the Health Products that they Promote, and particularly reports of adverse events, product technical complaints and usability issues to the scientific service or other relevant department within their Companies.

4.8 Gaining Interviews with HCPs

- 4.8.1 Company Representatives shall not employ any inducement or subterfuge to gain an interview with an HCP.
- 4.8.2 No compensation, payment, reward or benefit shall be paid or offered for the granting of an interview by an HCP.
- 4.8.3 Donations to charities in return for Company Representatives gaining interviews are prohibited.
- 4.8.4 Company Representatives shall take reasonable steps to ensure that they are not misleading in respect of their identity or the Company that they represent.

4.9 Respect for HCPs and Others

- 4.9.1 Company Representatives shall ensure that the frequency, timing and duration of calls on HCPs, pharmacies, hospitals, other healthcare facilities, medical schemes and the like, and including the manner in which they are made, do not cause inconvenience.
- 4.9.2 Company Representatives shall respect the wishes of any individuals on whom they would like to call and observe the arrangements in force at any practice organisation or establishment.



4.10 Operating Room or Clinical Environment

- 4.10.1 Company Representatives who visit operating rooms or clinical environments shall be appropriately trained on operating room/clinical environment protocol(s).
- 4.10.2 Company Representatives shall not give clinical, diagnostic or surgical advice or recommend treatment, even if this is by direct request of the surgeon, operating room staff or any other HCP.

Guideline to Section 4.10

Note 1: Operating Room or Clinical Environment

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

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

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

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



CHAPTER 5: PROMOTION AND ADVERTISING

5.1 The promotion of Health Products shall:

- 5.1.1 be in accordance with the Medicines Act;
- 5.1.2 comply with the terms of registration, where relevant; be consistent with the particulars listed in its Regulatory Authority-approved product documentation (e.g. the Professional Information/Patient Information Leaflet/Instructions for Use), where applicable. Indications, which have not been approved may not be Promoted and promotional material may not deviate from, be in conflict with or go beyond the evidence submitted in the application for registration; and
- 5.1.3 not occur before the Health product is registered in terms of Section 15 of the Medicines Act, unless Section 14(3) of the Medicines Act applies.
- 5.1.4 all Companies shall comply with the applicable legal, regulatory and professional requirements and with the letter and the spirit of the Code.

5.2 General Principles

5.2.1 Self-Medication

- 5.2.1.1 The Advertising and/or Promotion of self-medication shall not encourage Consumers to discontinue the use of prescribed Medicines, Complementary Medicines or Health Supplements.
- 5.2.1.2 Advertising and/or Promotion of self-medication shall not suggest that the relevant Health Product is a foodstuff, cosmetic or other non-medicinal product.
- 5.2.1.3 Although it is acceptable to indicate that self-medication is palatable, Advertising and/or Promotion shall make it clear that it is a Health Product. This is to be contextualised with reference to the nature of the product concerned.
- 5.2.1.4 Advertising and/or Promotion shall encourage the responsible and appropriate use of self-medication and shall not encourage individuals to self-diagnose or self-medicate exclusively. It shall not encourage self-diagnosis where medical intervention is required. Particular care shall be taken where symptoms are generalised, and a diagnosis is made by the exclusion of more serious complaints or where the use of the Health Product could mask the symptoms of a more serious condition.
- 5.2.1.5 An Advertisement for self-medication shall not refer, either expressly or by implication, to products used, or assisting in, the treatment of serious forms of disease, conditions, ailments or defects unless prior approval is given by the Regulatory Authority.



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

Guideline to Section 5.2.2

Note 1: Weight management/slimming/body image

1. *A weight reduction regime in which the intake of energy is lower than its output is the most common self-treatment for achieving weight reduction. Any claims made for the effectiveness of a weight reduction method or product must be backed by appropriate evidence. Testimonials that are not supported by trials do not constitute substantiation.*
 1. *Marketers must show that weight reduction is achieved by loss of body mass before claims are made for a weight reduction aid or regimen. Combining a diet with an unproven weight reduction method does not justify making weight reduction claims for that that method.*
 2. *A statement to the effect of: 'Only effective when used in conjunction with a kilojoule controlled balanced diet' should be included on the label and in the advertisement for a product intended for weight loss/management.*
- 5.2.3 Advertisements shall not suggest that using a Health Product may enhance normal good health (except in the case of Health Supplements when permitted by Guidelines of the Regulatory Authority).
- 5.2.4 Advertisements shall not suggest that a Health Product is a substitute for a healthy diet and lifestyle and shall not undermine current healthy-lifestyle advice.
- 5.2.5 Advertising and/or Promotion shall not be aimed principally or exclusively at children under 12 years of age.
- 5.2.6 Advertisements should encourage Consumers to share information with HCPs so that they can ensure that the Health Products prescribed or recommended are suitable for the intended Consumer.
- 5.2.7 Advertising and/or Promotion shall neither 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.
- 5.2.8 Advertising and/or Promotion shall not offer a virtual diagnosis, advice, prescription or treatment of Consumers, including by correspondence.
- 5.2.9 Advertising and/or Promotional Material may refer to the prevention of symptoms and use of a Health Product in chronic conditions, if this is in line with the registered indication. The Advertisement shall make it clear under which circumstances the use of the Health Product is appropriate. This is particularly important in therapeutic areas where individuals may be asymptomatic.



- 5.2.10 Advertising and/or Promotion shall not encourage, either directly or indirectly, the indiscriminate, unnecessary or excessive use of any Health Product.
- 5.2.11 Advertising shall not contain improper, alarming or misleading claims about a recovery.
- 5.2.12 An Advertisement and/or Promotion shall not offer any personal incentive to a Healthcare Professional, or non-healthcare person, to recommend or supply Health Products to patients or consumers in a Health Establishment.
- 5.2.13 Statements, representations or tie-off lines for direct to consumer promotions shall not be made for the purpose of encouraging Consumers to ask their HCPs to prescribe/recommend a specific Health Product. It is recommended that consumers be encouraged to seek advice from their HCPs. Advertising and/or Promotion shall not refer to a “college”, “hospital”, “institute”, “laboratory” or similar establishment, unless the establishment genuinely exists and has approved the endorsement or use of the name in the Promotional material or Advertisement.
- 5.2.14 Material issued by Companies relating to Health Products, but not intended as Promotional Material for those Health Products, such as corporate advertising, press releases, market research material and financial information to inform shareholders, shall not contravene the Code or the relevant statutory requirements.
- 5.2.15 Artificial Intelligence (AI) means the use of artificial intelligence per se in the marketing and promotion of health products is not prohibited by the Code. It is important for company compliance officers to ensure that the Law and the Code's ethical principles are complied with when applied to AI generated content.

Guidelines to 5.2.15

Principles to be applied in making compliance decisions related to AI-generated content.

1. *Accountability means taking responsibility for the use of AI systems used by the company. This includes proper governance, the use of safeguards/controls that address potential problems and having plans in place to deal with unexpected problems.*
2. *Human control means that there should be an appropriate level of human supervision and influence based on the assessed risk to individuals. AI should not be given total freedom in making decisions.*
3. *Fairness and minimisation of bias*
4. *Privacy, security, and safety by design*
5. *Transparency in and how AI is used by the company*
6. *Ethical use of data*
7. *Substantiation of statements and referencing*



Recommendation: individual company standards should be articulated in a specific policy document (SOP) in order to provide guidance on the minimisation of corporate risk.

5.3 Advertising and Promotional Material

- 5.3.1 Companies shall not be involved in Promotional schemes, which are hazardous to Consumers or which bring or may bring the Industry into disrepute.
- 5.3.2 Postcards, other exposed mailings or material, envelopes or wrappers shall not carry matter, which may be regarded as Advertising and/or Promotional Material to Consumers and which is contrary to the relevant legislation.

Guideline to Section 5.3

Note 1: Reply paid cards

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

5.4 Information to be Provided to HCPs

- 5.4.1 When Company Representatives Introduce a Medicine or a class C or D Medical Device or IVD to an HCP or potential User for the first time, they shall provide a copy of the latest Regulatory Authority-approved Professional Information/Patient Information Leaflet/Instructions for Use to the HCP or potential User. On subsequent occasions, such information shall be made available on request.
- 5.4.2 If discussion on a Health Product is initiated by the HCP on whom a Company Representative calls, the Company Representative shall make available the approved Professional Information/Patient Information Leaflet/Instructions for Use or other approved information on that Health Product as soon as possible after the request.

Guideline to Section 5.4

Note 1: High standards, suitability and taste

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

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

- *the use of imagery of a sexual nature for the explicit purpose of attracting attention to the material;*



- *the provision of rubber stamps/stickers to HCPs for use as aids to prescription writing;*
- *the provision of private prescription forms pre-printed with the name of a Health Product; and*
- *teaser Advertising whereby Promotional Material is intended to “tease” the recipient by eliciting an interest in something which will be following or will be available at a later date without providing any actual information about the Health Product in question.*

Note 2: Public interest criteria

The following should be taken into account:

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

5.5 Professional Information/Patient Information Leaflet and Instructions for Use

- 5.5.1 All Advertising and/or Promotional Material shall be based on the current Regulatory Authority-approved Professional Information/Patient Information Leaflet/Instructions for Use.
- 5.5.2 Where the Health Product is not registered, but enjoys the Right of Sale, Advertising and Promotional Material shall be based on the Professional Information/ Patient Information Leaflet/Instructions for Use or otherwise be in accordance with the Medicines Act and relevant guidelines and annexures as applicable to Category D Medicines and or medical devices.

5.6 Minimum Requirements for Advertisements and Promotional Material

- 5.6.1 Advertisements shall comply with the Minimum Requirements.
- 5.6.1.1 The minimum information required by the legislation shall:
- 5.6.1.2 form part of the Promotional Material (with the exception of Promotional Aids and/or elements which do not contain Promotional claims) and shall not be supplied separately;
- 5.6.1.3 be provided in a clear and legible manner;
- 5.6.2 Advertisements should not be flippant;
- 5.6.3 Advertisements must be consistent with



- 5.6.3.1 the most recent Regulatory Authority approved Professional Information/ /Patient Information Leaflet/Instructions for Use; or
- 5.6.3.2 the Medicines Act, where the Health Product is not registered, but enjoys the Right of Sale and no regulatory authority approved Professional Information/Patient Information Leaflet/Instructions for Use is available.
- 5.6.4 Advertisements must display the minimum information prescribed by legislation on the first or last page, in the case of any printed Promotional Material consisting of more than two pages;
- 5.6.5 Advertisements must not be false or misleading when each page is read in isolation in the event of an Advertisement containing two or more pages;
- 5.6.6 Advertisements should include the statement, "For full prescribing information, refer to the Professional Information approved by the medicines regulatory authority." This applies to all forms of Advertising and/or Promotional Material, including written, audio-visuals and Internet Advertisements and Promotional Material relating to Health Products, directed at HCPs, where there is approved Professional Information. This does not apply to Promotional Aids where no claim is made.
- 5.6.7 Promotional Material shall be identifiable and shall include either the date or a code number identifying the version of the Professional Information/Patient Information Leaflet/Instructions for Use on the basis of which the Promotional Material was drawn up or last revised, approved and recorded.
- 5.6.8 Each Promotional piece for Health Products shall be able to stand alone. A loose insert is regarded as a stand-alone Promotional piece and shall comply with the Code.
- 5.6.9 Advertisers are encouraged to convey the message that Health Products should be treated with respect and may not be suitable for everybody.
- 5.6.10 Advertisers are encouraged to use and to promote the use of the SAHPRA online medicine information database at <https://medsinfo.sahpra.org.za>.
SAHPRA has published a toolkit to provide support for use of this directory.

5.7 Artwork and Visual Representations

- 5.7.1 All artwork, including illustrations, graphs, tables, logos, and trade dress, shall comply with the letter and spirit of the Code.
- 5.7.2 Artwork shall not be misleading about the nature of a Health Product or any claim or comparison and shall not detract from any safety aspects.



- 5.7.3 Graphs and tables shall be presented in such a way as to give a clear, fair, and balanced view of the matters they cover, and shall not be included unless they are relevant to the claims or comparisons being made.
- 5.7.4 Children shall not be depicted in conjunction with Health Products not authorised for use in children.
- 5.7.5 No artwork, including illustrations, shall show children under the age of 12 using or within reach of Health Products without adult supervision.
- 5.7.6 Advertising shall not use misleading, alarming or improper visuals to represent changes in the human body.
- 5.7.7 Visuals shall not imply that a Health Product may be used to treat more serious forms of disease than the registration of the Health Product allows.
- 5.7.8 Advertisements shall not use inappropriate imagery or use imagery out of context.
- 5.7.9 Pictograms shall not be used to depict opinions or interpretations.

Guideline to Section 5.7

Note 1: Artwork and visual representations.

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

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

Anatomical drawings, graphs and tables must not mislead.

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

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

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

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



5.8 Information, Claims and Comparisons

5.8.1 Comparisons

5.8.1.1 The use of comparisons in the Promotion of Health Products shall only be permitted 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, where:

5.8.1.1.1 the trademarks, proprietary names, other distinguishing marks, Health Products, services, activities or circumstances of a competitor are not discredited or denigrated;

5.8.1.1.2 Health Products or services are not presented as imitations or replicas of goods or services bearing another Company's trademark or trade name;

5.8.1.1.3 they are not misleading or disparaging;

5.8.1.1.4 they are substantiated and not left open to interpretation.

5.8.1.1.5 they are intended for the same needs or purpose;

5.8.1.1.6 one or more material, relevant and representative feature(s) which is/are capable of substantiation is/are compared; and

5.8.1.1.7 no confusion is created.

5.8.1.2 No unfair advantage shall be taken of the reputation of a brand, trademark, proprietary name or other distinguishing mark of another Company.

5.8.1.3 Trademarks/trade names or Company names of another Company shall only be mentioned with written permission from the other Company, unless doing so is permitted by intellectual property law and/or common law.

5.8.1.4 Hanging (open-ended) comparisons shall not be allowed.

5.8.1.5 Points of comparison shall be factual and reflect the body of scientific evidence.

5.8.1.6 Comparisons shall not imply that the Health Products with which comparisons are being made are harmful or ineffectual.

Guideline to Section 5.8.1

Note 1: Hanging comparisons

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



Note 2: Price comparisons

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

5.8.2 Accuracy, Balance and Fairness

- 5.8.2.1 This section applies to information or claims of a medical or scientific nature and also to information or claims relating to price lists and market share amongst others.
- 5.8.2.2 Information, claims and comparisons used in Promotional Material and activities, shall be accurate, balanced, fair, objective and unambiguous, based on an up-to-date evaluation of all the evidence, and reflect that evidence.
- 5.8.2.3 All claims in Promotional Material shall be capable of standing alone and shall not be qualified by the use of footnotes and the like.
- 5.8.2.4 Information, claims and comparisons or the manner, in which they are portrayed, shall not be misleading directly or by implication, distortion or undue emphasis.
- 5.8.2.5 Material shall be sufficiently comprehensive to enable the recipients/readers to form their own opinion of the therapeutic value of the Health Product.
- 5.8.2.6 Promotional Material shall not be misleading about the nature of the Health Product, its ingredients or indications and shall encourage the rational use of a Health Product by presenting it objectively and without exaggerating its properties.
- 5.8.2.7 Exaggerated or all-embracing claims shall not be made, and superlatives shall not be used, with the exception of cases where those limited circumstances in which they relate to a clear fact about a Health Product and are substantiated.

Guidelines to Section 5.8.2

Note 1: Accuracy, balance and fairness of claims

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

Note 2: Superlatives

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



as there are too many variables to enable such a sweeping claim to be proven.

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

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

In certain circumstances, the use of the word 'the' can imply a special merit, quality or property for a Health Product that is unacceptable under this section if it cannot be substantiated. Great care needs to be taken with the use of the words 'unique' and 'ultimate'. Although in some circumstances the word 'unique' may be used to describe some clearly defined special feature of a Health Product, in many instances it may simply imply a general superiority, which is unacceptable.

Note 4: Absolute risk and relative risk

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

Note 5: Use of pharmaco-economic data

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

Note 6: Emerging opinions

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

Note 7: Use of statistical data

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

5.8.3 Claims of Novelty and Uniqueness



- 5.8.3.1 A Health Product, or any of its attributes, shall not claim to be unique unless the claim is substantiated.
- 5.8.3.2 Use of the word “unique” shall not be misleading.
- 5.8.3.3 Advertising and/or Promotional Material shall not be misleading about the novelty of the preparation of the Health Product.

5.8.4 Claims relating to formulation

5.8.4.1 Non-content claims

- 5.8.4.1.1 Advertising and/or Promotional Material shall not state that a Health Product does not contain an active ingredient used in competitor Health Products other than as permitted by the Regulatory Authority.

5.8.4.2 Reference to specific properties of ingredients

- 5.8.4.2.1 Claims shall not imply that an active ingredient or Health Product has some special merit, quality or property unless this can be substantiated.
- 5.8.4.2.2 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 Regulatory Authority for inclusion in the Professional Information/ Patient Information Leaflet of the Health Product.

5.8.4.3 Unknown active ingredient

- 5.8.4.3.1 Advertising and/or Promotional Material shall not suggest, either directly or indirectly, that a Health Product contains an unknown active ingredient.

5.8.4.4 Pharmacokinetic properties

- 5.8.4.4.1 Advertising and/or Promotional claims relating to speed of absorption, dissolution, distribution or any other pharmacokinetic particulars shall be acceptable where they are supported by evidence and in line with the Health Product's registration dossier. Such evidence shall, however, not be extrapolated to claims that a Health Product offers improved efficacy or onset of action, without supporting evidence to substantiate such claims.

Guideline to Section 5.8.4.4

Note 1: Speed of absorption claims (5.8.4.4)

All speed of absorption and speed of action claims must be in line with the approved Professional Information. For indications such as, but not limited to, pain and fever,

'fast' is taken to mean that the Health Product works within about 30 minutes,



'immediate benefit' as within 10 seconds,

'all day relief' if the Health Product works for at least 10 hours, and

'all night relief' if the Health Product works for at least 8 hours.

5.8.4.5 Herbal products

5.8.4.5.1 Advertising and/or Promotional Material shall not suggest that a Health Product is herbal, unless all the active ingredients are plants or extracts of plants. "Herbal" may only be used to describe those elements that are of plant origin e.g. "herbal ingredient". Where a formulation contains herbs and other non-herbal ingredients, only the claim "contains herbal ingredients" may be made.

5.8.4.6 Natural Ingredients

5.8.4.6.1 "Natural" used in the context of "Natural Ingredient"¹ means, essentially, ingredients provided by nature, not the work of man or interfered with by man.

5.8.4.6.2 It shall be misleading to use the term "natural" to describe ingredients employing chemicals to change their composition or incorporating the products of new technologies, which are the product of the chemical industry or extracted by chemical processes including additives and flavourings.

5.8.4.6.3 The word natural must not be used in Advertising and/or Promotional material to suggest the safety, quality or efficacy of a Health Product.

5.8.4.6.4 Advertising and/or Promotional Material shall not claim that a Health Product is "natural", but where applicable it may be stated that a product contains natural ingredients.

5.8.5 Claims relating to Efficacy, Effectiveness and Performance

5.8.5.1 An Advertisement for a self-medication must not refer, either expressly, or by implication, to products used in, or assisting in, the treatment of serious forms of disease, conditions, ailments or defects unless prior approval is given by the Regulatory Authority.

5.8.5.2 Efficacy, effectiveness or performance claims shall state clearly whether the Health Product is suitable for use over extended periods of time or where it is indicated for disease risk reduction or prevention.

¹ UK Food Standards Agency, Jul 2008. Criteria for the Use of the Terms Fresh, Pure, Natural etc. in Food Labelling



5.8.5.3 Advertising and/or Promotion shall not claim guarantees about a Health Product's effects, safety or quality.

5.8.5.4 Advertising and/or Promotional material can refer to the prevention of symptoms and the use of a Health Product in chronic conditions, if this is in line with the registered indication. The Advertisement shall make it clear under what circumstances the use of the Health Product is appropriate. This is particularly important in therapeutic areas where individuals may be asymptomatic.

5.8.6 Use of the word "Safe"

5.8.6.1 The word "safe" or its grammatical derivatives or equivalents or words containing references to safety shall not be stated in such a way as to imply that a Health Product has no side effects, toxic hazards or risk of addiction.

5.8.6.2 The word "safe" shall not be used without scientific qualification and substantiation.

5.8.7 Use of the words "The" and "Ultimate"

5.8.7.1 Use of the words "the" and "ultimate" shall not be misleading.

5.8.8 Use of the word "New"

5.8.8.1 The word "new" shall only be used to describe a Health Product, pack presentation or therapeutic indication, which has been available in the South African market for less than 12 months. This includes new formulations, flavours, new pack sizes and design.

5.8.9 Use of the word "Serious"

5.8.9.1 "Serious" shall only be used to describe disease forms, conditions, ailments or defects which are:

5.8.9.2 generally accepted not to be appropriate for diagnosis and/or treatment without consulting a suitably qualified HCP, and/or

5.8.9.3 generally accepted to be beyond the ability of the average Consumer to evaluate accurately and treat safely without regular supervision by a qualified HCP.

Guideline to Section 5.8

Note 1: Exaggerated or misleading claims

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



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

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

Note 3: Sales claims

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

5.9 Substantiation

- 5.9.1 All information claims or comparisons shall be capable of substantiation.
- 5.9.2 No substantiation shall be required for claims in the Professional Information/Patient Information Leaflet/Instructions for Use, which have been approved by the Regulatory Authority.
- 5.9.3 For Complementary Medicines, the substantiation of any product claim shall be in accordance with the requirements of the Medicines Act.
- 5.9.4 All references shall be listed in the Advertisement or Promotional Material. Refer also to Guideline 5.19
- 5.9.5 Referencing shall be of a standard recognised by scientific journals.
- 5.9.6 Upon any request, a Company shall, without delay, provide the reference material related to the Promotional Material.
- 5.9.7 When Promotional Material refers to data, including unpublished data on file, the relevant part of this data shall be provided on request without delay.
- 5.9.8 Where confidential data on file, such as information relating to trade secrets, sensitive commercial information or information of a competitive nature, is involved, in the case of a dispute, the material may be given to an independent arbitrator acceptable to both parties for assessment. The arbitrator shall make an assessment whether the unpublished data support the statement(s) made in the Promotional Material. Alternatively, the information may be shared on conditions acceptable to both parties.

Guideline to Section 5.9.

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

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



are likely to be acceptable:

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

Note 2: Data in support of a claim

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

5.10 Endorsements, Testimonials and Quotations

5.10.1 Endorsements and Testimonials

5.10.1.1 Advertising and/or Promotional Material shall not contain any recommendation of a Health Product by scientists, HCPs, community or institutional pharmacies unless substantiated.

5.10.1.2 Claims or views shall not be ascribed to authors when these no longer represent the current views of the authors concerned or current best practice.

5.10.1.3 The name, photograph, film, video, television or radio Advertisement, or any other reproduction of an HCP shall not be used in any way intended to infer recommendation by any doctor, pharmacist or other HCP of a specific health product.

5.10.1.4 The use of HCPs for Promotion, Promotional material, endorsements or testimonials should take place within the scope set by the professional codes applicable to such HCPs. Refer to Note 3 below.



5.10.1.5 Testimonials shall be current and represent the genuine views of the relevant person.

Guideline to Section 5.10

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

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

Note 2: Testimonials

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

Note 3: Representations from HCPs

(The following extracts from the HPCSA guidelines are included for information and guidance in applying the MCA Code].

The HPCSA ethical rules give guidance on registered practitioners advocating or promoting the use of any medicines or medical devices in terms of ethical rule 23 of the Ethical Rules document.

Rule 23 states:

- *23(1) A practitioner shall not participate in the manufacture for commercial purposes, or in the sale, advertising or promotion of any medicine or medical device or in any other activity that amounts to selling medicine or medical devices to the public or keeping an open shop or pharmacy,*
- *23(2) "A practitioner shall not engage in or advocate the preferential use or prescription of any medicine or medical device which, save for the valuable consideration he or she may derive from such preferential use or prescription, would not be clinically appropriate or the most cost-effective option."*

Note 4: Reporting unprofessional behaviour of persons registered with the HCP

Any unprofessional conduct by HPCSA registered practitioners should be reported to the HPCSA for investigation, please follow the link:

<https://hpcsasonline.custhelp.com/app/home>

to formally lay a complaint against the registered practitioner/s on the HPCSA's online portal in order for the matter to be considered and a determination be made by the relevant Professional Board.

5.10.2 Quotations

5.10.2.1 Any quotation chosen by a Company for use in Promotional Material shall comply with the requirements of the Code.

5.10.2.2 Quotations from medical and scientific literature shall accurately reflect the intention and meaning of the author(s).



- 5.10.2.3 Unpublished, personal communication or opinions shall not be used unless the Company is able, on request to supply written substantiation, based on scientific data.
- 5.10.2.4 Quotations from any study shall not be misleading about the study's overall significance to the reported outcomes.
- 5.10.2.5 Quotations taken from public broadcasts, for example radio, television or the Internet, or from private occasions, such as medical conferences or symposia relating to Health Products, shall not be used without the formal permission of the speaker unless there is a published record of the proceedings and this is given accurately as a reference.
- 5.10.2.6 Advertising and/or Promotional material 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 an HCP, provided there is evidence that this is the case.

5.10.3 Influencer Marketing

- 5.10.3.1 Influencer Marketing is used by social media influencers to endorse specific products, or to draw attention to diseases, conditions or symptoms. This may be unsolicited, where an influencer makes an unsolicited post about a particular product or brand, or solicited, where an influencer is paid for content creation and the use of their feed in order to endorse a particular product or brand.
- 5.10.3.2 Where influencer marketing is employed by companies for the endorsement of Health Products, it is imperative that this does not extend beyond what is permitted in terms of the Medicines Act. The choice of influencer should also be appropriate for the product and the influencer should not encourage, either directly or indirectly, the indiscriminate, unnecessary or excessive use of the product. Cognisance should at all times be taken of the nature of the Health Product so that its endorsement is appropriate and in accordance with the approved Professional Information/Patient Information Leaflet/Instructions for Use or other approved information for the product.
- 5.10.3.3 Furthermore, company and solicited third party social media feeds related to the Health Product should be continuously monitored to ensure that any inappropriate posts for example, off-label use or unapproved claims are removed as soon as possible and within 24 (24 hours) hours. All reasonable attempts should be made, when this comes to the attention of a company, to remove or correct any



identified unsolicited third-party social media feeds with inappropriate or incorrect content.

5.10.3.4 Active monitoring should also be employed to identify reports of any Adverse Drug Reactions (ADRs) or Adverse Events (AEs) which should then be managed in accordance with legislated requirements and the company's Standard Operating Procedures (SOPs).

5.10.3.5 As with print media, paid for or sponsored content must be clearly identified as such to ensure that there is full disclosure and transparency and that audiences are not misled in any way about the true nature of the posting.

5.10.3.6 An influencer's endorsement of the Health Product should also be genuine, and this should be a primary consideration during the selection of an appropriate influencer.

5.10.3.7 Companies should ensure that they have a written contract in place with any paid influencers that includes the following information:

5.10.3.7.1 the details of the engagement/brief, including the required content and timing of the social media post/s;

5.10.3.7.2 The remuneration (cash or cash equivalent), must be at FMV (Refer also to 3.4.2 FMV guidance for social media influencers) and details and conditions of payment recorded;

5.10.3.7.3 the obligation to publish only own content or to clearly disclose or credit the content creator, if and when the content is not self-created;

5.10.3.7.4 the influencer's post should include a disclaimer that the patient / consumer should consult their HCP for further information; and

5.10.3.7.5 any mandatory disclosures and adherence to industry specific regulations that may apply.

5.10.3.8 All Companies involved in the social media marketing of Health Products shall have relevant policies and SOPs in place to ensure compliance with all relevant legislation and codes of practice.

Refer also to 5.19.2

5.11 Journal Advertising

5.11.1 Loose inserts: An Advertisement taking the form of a loose insert in a journal shall not be of a size larger than the page size of the journal itself, printed on one or both sides.



5.11.2 Advertorial: Advertisements in journals shall not resemble editorial matter unless clearly identified as an advertorial or sponsored feature.

5.11.3 Prescribing information: Where the prescribing information appears overleaf in a journal advertisement, a reference to where it can be found shall appear in a legible font size, on either the first or the last page.

Guideline to Section 5.11

Note 1: Journals with an international distribution

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

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

Note 2: Professional Information and Patient Information Leaflet

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

5.12 Disparaging Claims

5.12.1 Health Products and activities of other Companies shall not be disparaged in any way including:

5.12.1.1 the safety, quality, efficacy, effectiveness, and performance;

5.12.1.2 the effectiveness of the official process by which the Health Product obtained market authorisation (e.g., registration, Right to Sale);

5.12.1.3 generic or original Health Products in general;

5.12.1.4 the health professions and the clinical and scientific opinions of their members; and

5.12.1.5 an ingredient or treatment type.

5.12.2 Market research activities and the like shall not contain or lead to disparaging comments about competitors or their Health Products.

5.13 Disguised Promotion

5.13.1 Promotional Material and activities shall not be disguised.

5.13.2 Post-marketing surveillance studies, post-authorisation studies, observational and non-interventional studies and the like shall not be disguised Promotion.



5.13.3 Market research activities and the like shall not be disguised Promotion.

5.13.4 Promotional Material sent under the guise of personal communication shall be inappropriate.

5.13.5 Envelopes shall not be used for the dispatch of Promotional Material if they bear words implying that the contents are non-Promotional.

5.14 Market Research

5.14.1 Market research shall be conducted with the objective of gaining legitimate insights.

5.14.2 Material related to Health Products and their uses, used in market research, whether of Promotional nature or not, and sponsored by a Company shall clearly indicate by whom it has been sponsored.

5.14.3 Where market research is carried out by an agency on behalf of a Company, the agency shall reveal the name of its client to the MCA or the Regulatory Authority, where requested. When commissioning market research, Companies shall take appropriate steps to ensure such information is provided on request.

5.15 Clinical Trials

5.15.1 Clinical Trials are not subject to the Code

5.15.2 All Clinical Trials must have a legitimate scientific purpose and be conducted in accordance with the legislation.

5.15.3 Post-marketing surveillance studies, post-authorisation studies, observational/non-interventional studies and the like must not be disguised Promotion.

5.16 Provision of Reprints of Journal Articles

5.16.1 Unsolicited articles shall be considered as Promotion and shall comply with the Code.

5.16.2 Unsolicited reprints of articles in journals shall only be provided to HCPs if the Health Products, which are the subject of these articles, are "On-label" and have been published in a peer reviewed publication in line with good principles of scientific review and publication.

5.16.3 When providing a reprint of an article about a Health Product, it shall be accompanied by the prescribing information.

5.16.4 If a non-peer-reviewed article is requested by an HCP, a copy may be provided on written request or in accordance with the provisions of the Code pertaining to the issuing of scientific or medical information.



5.17 Distribution of Advertisements and Promotional Material

- 5.17.1 Promotional Material shall only be sent or distributed to those Persons or categories of Persons whose need for, or interest in, the particular information, can reasonably be assumed or who may legally receive such materials.
- 5.17.2 A Company requested by an addressee to cease or limit the volume of Promotional Material shall respect the wishes of the addressee.
- 5.17.3 Mailing lists shall be kept up to date. Requests from HCPs to be removed from Promotional mailing lists shall be complied with promptly and no name shall be restored other than at the explicit request of the HCP or with his/her permission.

5.18 Detailed Briefing Material

- 5.18.1 Companies may prepare detailed briefing materials for the use of Company Representatives, which may include technical aspects and/or the details of each Health Product they will Promote and instructions about how the product should be Promoted.
- 5.18.2 Briefing material shall comply with the relevant requirements of the Code, be consistent with the Professional Information/Patient Information Leaflet/Instructions for Use of the Health Product and shall be approved by the Company Code Compliance Officer.

Guideline to Section 5.18

Note 1: Electronic detailing

1. *The principles embodied in the Code apply equally to electronic detailing (“detailing” or “e-Detail aid”) using such devices as iPads, tablets, etc. Care should be taken to ensure that all text complies with the requirements of the legislation and the Code and is easily legible from a comfortable distance.*
2. *Care should be taken when each page is viewed separately that the information is not false or misleading when read in isolation.*
3. *Placement of mandatory requirements such as, generic names, p-values, statements of significance, etc. should follow the same principles of the Code and should be clearly visible on the screen – they cannot only be visible within an animated feature such as a pop-up, etc.*
4. *The reference “refer to approved Professional Information for full prescribing information” is no longer mandatory if the full Professional Information is directly accessible from within the eDetail aid.*
5. *It is possible to give emphasis to a specific part of the content/area of a tablet screen through the use of light boxes, stretching/enlarging graphs etc.*
6. *Content must not be constructed in such a way that there is loss of context by obscuring critical elements, for instance, a claim remains visible, but a related qualifier statement, or other descriptive text that provides context, is hidden by a pop-up screen.*
7. *Qualifying statements should follow the same principles embodied in the Code.*



They should be linked to the relevant claim with a readily identifiable asterisk or similar device.

8. *Qualifying statements must appear directly below or adjacent to the claim, and must be in prominent text such that the text size for the qualifying statement is larger than the other minimum text size on the screen. A qualifying statement should always be visible when its corresponding claim is on the screen.*
9. *The qualifying statement must not be hidden by pop-ups, if a section of the screen is enlarged, or positioned such that a person has to scroll further down the page to see it.*
10. *Other mandatory information should all be no more than 2 clicks away from any one screen (i.e. could access via a menu bar) or appear as part of the e-detailer e.g. at the end of each 'chapter/section' of information where an e-detailer is so designed.*

5.19 Communication and Electronic/Digital Media

- 5.19.1 Electronic Promotion of Health Products by means of any form of Electronic Communication or the use of Electronic/Digital Media for Promotional purposes shall comply with all aspects of the Code.
- 5.19.2 Electronic Communication and Electronic/Digital Media personal information (as defined in the Protection of Personal Information Act) shall not be used for Promotional purposes, unless, on first contact being made with the relevant Person/ HCP a clear directive option to opt out is provided for that person and his/her decision is subsequently respected by the Company and no further electronic communication is sent.
- 5.19.3 The option to opt out shall also be provided in all subsequent communications, even if the addressee has not opted out after the first contact.
- 5.19.4 These provisions are subject to the provisions of the applicable legislation such as the Consumer Protection Act and the Protection of Personal Information Act.
- 5.19.5 Any electronic forms of Promotion, including those using digital applications and the Social Media, must be considered in context, i.e. is the information medical, educational or Promotional? If the Promotional material is for HCPs it must include:
 - 5.19.5.1 a reference to refer to the approved Professional Information/Patient Information Leaflet/Instructions for Use, before prescribing, within the body of the Advertisement
 - 5.19.5.2 In the event that the Health product is promoted to an HCP for the first time by electronic means, the approved Professional Information/Patient information leaflet/Instructions for Use may be provided as an integral part of the promotional material or by using a direct hyperlink or any other suitable means of transmission. On subsequent occasions, the Professional Information/Patient



Information Leaflet/Instructions for use should be made available on request.

5.19.6 When linking Promotional Material to Professional Information/Patient Information Leaflet/Instructions for Use on a third party site, a pop-up box warning them that they are leaving the Company-controlled site is not required.

5.19.7 Internet

5.19.7.1 All material contained on a website directed at HCPs are subject to the provisions of the Code and the website must be a secure site, designed to allow access to HCPs only.

5.19.7.2 In the case of an Internet Advertisement, the statement, "For full prescribing information, refer to the Professional Information/Patient Information Leaflet/Instructions for Use approved by the Regulatory Authority", shall be in the form of a direct link between the first page of the Advertisement and relevant legislation.

5.19.7.3 It should be clear when the reader is leaving the site or is being directed to a site that the Company has not developed or is not responsible for.

5.19.7.4 Any references or linkages to reputable information sources shall only be to those sources, which provide valuable educational material to enhance the quality use of Health Products. When making such a reference or linkage, a clear screen displaying the following statement shall appear before the reference material is accessed: "The information the reader is about to be referred to may not comply with the South African regulatory requirements. Information relevant to the South African environment is available from the Company and in the Professional Information/Patient Information Leaflet/Instructions for Use approved by the Regulatory Authority."

5.19.7.5 References and links shall not be made to any non-compliant sites.

5.19.8 Audio-visual material

5.19.8.1 Audio-visual material includes audio material, and refers to, for example, films, video recordings, sound bites and interactive data systems.

5.19.8.2 The minimum information required by legislation shall be provided either by way of a document made available to all Persons to whom the material is displayed or distributed, or by inclusion in the audio-visual recording or in the interactive data system itself.

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



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

Guideline to Section 5.19

Note 1: Electronic journals

1. *The first part of an advertisement in an electronic journal, such as the banner, is often the only part of the Advertisement that is seen by readers. It must therefore include a clear, prominent statement as to where the minimum information can be found. This should be in the form of a direct link.*
2. *The first part is often linked to other parts and in such circumstances, the linked parts will be considered as one advertisement. If the first part mentions the Health Product name, then this is the most prominent display of the brand name and the non-proprietary name of the Health Product or a list of the active ingredients using approved names where such exist, must appear immediately adjacent to the most prominent display of the brand name. The size must be such that the information is easily readable.*
2. *The requirement that Promotional Material and activities should not be disguised should also be borne in mind.*

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

A Company may wish to provide promotional and educational material to HCPs via an application downloaded on mobile media platforms (electronic devices). If the application contains Product Promotional Material, it must be a secure application that is designed to allow access only to HCPs. Examples of acceptable Smartphone Apps include, but are not limited to medical dictionaries, access to clinical papers, conference proceedings or planners, and dose calculators. A clear, prominent statement as to where the minimum information can be found must be included as part of the promotional material. The minimum information should be provided in the form of a direct link.

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

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

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

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



Note 3: QR Codes/2D Codes

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

Note 4: Social Media (Refer also to 5.10.3)

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

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

whether discussion boards need to be monitored and how regularly;

provision for discussion boards to be shut down at any time

how to manage an inappropriate conversation;

establishing rules for participants joining a discussion forum that:

outline what is inappropriate conversation (e.g. offensive language, racist comments, promotion of a product) and that conversations may be monitored;

describe whether any content would be excluded from the media, and the process for excluding it;

responsibilities for reporting of monitoring and reporting of Adverse Events reported via this media.

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

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

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

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

Note 5: Company-controlled websites for HCPs

A mechanism such as a password protected site or other entry system will comply with the requirements of this section. An entry system such as a provider number will also be acceptable. The password to gain access to a restricted



access site should not be a word that will be easily identifiable, such as the product name.

Note 6: Minimum information on audio-visual material

1. Where details of the requirement for inclusion of "minimum information" is shown in the audio-visual material as part of the recording, it must be of sufficient clarity and duration to be heard or seen by the listener/viewer. The minimum information must be an integral part of the Advertisement. It is not acceptable for the Advertisement and the minimum information to be separated by any other material.
2. Publications and Advertisements may be affixed to the side of the audio-visual device or included on the box containing the audio-visual material. The minimum information must, however, be made available for any Advertisement for a Health Product appearing on audio-visual material or in an interactive data system or on the Internet, including journals on the Internet.

Note 7: Webinars

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

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

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

5.20 Unapproved Indications

- 5.20.1 Upon receipt of unsolicited requests from HCPs, MSL personnel from Companies may provide information on unapproved Health Products or subjects not covered by the approved Professional Information/Patient Information Leaflet/Instructions for Use, such as unapproved indications.



- 5.20.2 An indication/use of a Health Product that has not been approved by the Regulatory Authority shall not be Promoted in South Africa (including at international conferences held in South Africa) unless Section 14(3) of the Medicines Act is applicable.
- 5.20.3 Information provided with regard to Off-label Use, shall comply with the relevant legislation and the Code.
- 5.20.4 Under no circumstances may the availability of information on unapproved Health Products and indications from the Company's medical department or via medical information services (including medical information websites) be Promoted to HCPs. This does not preclude the provision of the contact details for medical services or medical information services (including medical information websites) for HCPs. However, these contact details shall only be provided along with a general statement such as "For more information contact/visit ...".
- 5.20.5 Any information provided about unapproved Health Products or indications shall be selected and/or prepared by the Company's medical department and any resulting dialogue with the HCP about an unapproved Health Product or indication shall take place with the Company's medical department personnel and not with a member of a commercial/sales function or team.

Guideline to Section 5.20

Note 1: Provision of information during medicine development

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

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

1. *Medical schemes require advance information about the introduction of new medicines or changes to the existing medicines in order to review the reimbursement status before approval for reimbursement. Information that may be provided includes:*
 - *Health Product that contains a new active substance, or active substances prepared in a new way (e.g. biotechnology);*
 - *Health Product that has a new registered indication;*
 - *Health Product that has a novel and innovative means of administration.*
2. *Information may be directed to policy-makers in which case the registration status of the product, must be clearly indicated.*
3. *Only factual information and Company logos instead of product promotional logos should be used.*

Note 3: Promotion at international conferences

The display and provision of Promotional Material for unregistered medicine



and/or indications is permitted at international meetings in South Africa provided the following conditions are met:

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



CHAPTER 6: APPROVAL OF PROMOTIONAL MATERIALS AND ACTIVITIES

6.1 Approval of Promotional Items and Activities

- 6.1.1 A Company shall appoint a Company Code Compliance Officer. The Company Code Compliance Officer shall be either the responsible pharmacist and/or a natural person responsible for enforcement of the Code at the Company and/or the Company's compliance with the Code.
- 6.1.2 The Company Code Compliance Officer shall be certified in Code competency at least once every 2 (two) years by the MCA and shall ensure that Company Representatives are similarly certified.
- 6.1.3 The Company Code Compliance Officer shall be responsible for the approval of all Promotional Material, briefing material, training material, meetings and activities.
- 6.1.4 Each Company shall have a SOP for the approval of material, meetings, activities and other matters as provided for in the Code, which includes:
 - 6.1.4.1 CPD or similar professionally-required educational events;
 - 6.1.4.2 the presentation of scientific or Promotional Material;
 - 6.1.4.3 journal club meetings organised and/or sponsored by a Company (wholly or partly); and
 - 6.1.4.4 an event, part(s) of an event, a speaker or an attendee who is sponsored by the Company.
- 6.1.5 Meetings that fall within the ordinary scope of the day-to-day activities of Company Representatives are not subject to approval.
- 6.1.6 The Executive Officer may, either in response to a formal complaint or for any other reason, monitor and review the Advertising and/or Promotional Material issued by Companies, including copies of the certificates/proof of approval authorising such material and copies of briefing instructions furnished to Company Representatives.
- 6.1.7 The Executive Officer may request a Company to submit copies of any Advertising and/or Promotional Material, including copies of the certificates/proof of approval authorising such material as well as copies of the briefing instructions furnished to Company Representative to the MCA for scrutiny.
- 6.1.8 The purpose of the discretionary monitoring and review of Advertising and/or Promotional Material by the Executive Officer shall be to ensure that the Advertising and/or Promotional Material does not contravene the provisions of the Code and that appropriate compliance procedures are in place. Where the



Executive Officer is of the opinion that there has been a breach of the Code, a Nominated Complainant may be appointed subject to the provisions of Section 16.12.

6.2 Proof of Approval

6.2.1 The proof of approval is the document, recording the details of the approval by the Company Code Compliance Officer.

6.2.2 The proof of approval shall state that:

6.2.2.1 the Company Code Compliance Officer has examined the final form of the material or arrangements for an event;

6.2.2.2 it is in accordance with the requirements of the relevant Advertising and/or Promotional regulations and this Code;

6.2.2.3 it is not inconsistent with the Health Product registration and the Professional Information/Patient Information Leaflet/Instructions for Use; and

6.2.2.4 it is a fair, truthful and accurate presentation of the facts about the Health Product.

6.2.3 For the purposes of proof of the approval of events, the following information and documentation, where applicable, shall be retained:

6.2.3.1 details of the programme, both scientific/educational and entertainment/ hospitality;

6.2.3.2 details of invitations;

6.2.3.3 rationale for the choice of venue(s);

6.2.3.4 the rationale for the meeting or sponsorship;

6.2.3.5 speaker/panelist and participant selection processes and the selection criteria

6.2.3.6 Details of the FFS/Honoraria paid; and

6.2.3.7 the anticipated costs associated with the event, as well as that associated with all entertainment and hospitality. Records of actual costs shall be retained by the Company's finance department and available for auditing purposes.

6.2.4 For the purposes of proof of the approval of Promotional Material, the material shall be preserved in the approved format with information indicating the Persons to whom it was addressed, the method of dissemination and the date of first dissemination.



Guideline to Section 6.2

Note 1: Certification of travel arrangements

When certifying meetings that involve travel inside or outside South Africa, the Company Code Compliance Officer must ensure that all the arrangements are examined, including the programme, the venue, the reasons for using that venue, the intended audience, the anticipated cost and the nature of the hospitality and the like. This would include travel arrangements for speakers. It would also include any arrangements to sponsor travel or accommodation for delegates to a local conference where the money is paid to the professional body organising the conference, or sponsorship of travel or accommodation for delegates to an international conference.

Note 2: Joint ventures and co-promotion

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

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

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

6.3 Reapproval of Promotional Material

- 6.3.1 Promotional Material that is still in use shall be reapproved at intervals no longer than 2 (two) years to ensure that it continues to conform to the relevant legislation and the Code.

6.4 Retention of Documentation/Record keeping

- 6.4.1 The SOP and related documentation shall be available for auditing by the MCA or the Regulatory Authority, where required.
- 6.4.2 All documents/material relating to Promotional Material or activities, including the agenda of an event, irrespective of the nature of the campaign or event, shall be retained as per Section 3.7.
- 6.4.3 Companies shall preserve all proofs of approval pertaining to Code compliance and the relevant accompanying information after the final use of the Promotional Material or the date of the meeting and produce them on request to the MCA or the Regulatory Authority as per Section 3.7.



Documents may be stored electronically subject to the provisions of the Electronic Communications and Transactions Act.



CHAPTER 7: INDUCEMENTS, DONATIONS AND SPONSORSHIP

7.1 Inducements

- 7.1.1 There shall be no personal and/or unjustifiable enrichment of HCPs or their staff.
- 7.1.2 No gift, benefit in kind, rebate, discount, kickback, donation or any other pecuniary advantage shall be offered or given to HCPs, administrative staff, government officials, Consumers or any other Person as an inducement to prescribe, lease, borrow, supply, stock, dispense, administer, use or buy any Health Product, unless excluded from s18A of the Medicines Act in terms of s36 of the Medicines Act..
- 7.1.3 Payments by Companies for services or facilities within a HCP's working environment are prohibited. This includes providing any type of payment for services or facilities, including but not limited to paying for parking, coffee machines, Wi-Fi, transport, upgrade of equipment or work environments, directly or indirectly, including but not limited to providing cash equivalents, personal services or any type of services unrelated to the HCP's profession and that confers a personal or other benefit to the HCP and his / her patients. This excludes services specifically allowed under the Code. A HCP's working environment includes, but is not limited to his/her consulting rooms, a hospital or clinic where he/she provides medical services from time to time, theatre or any other working environment which may be perceived as where the HCP conducts regular business within the scope of his/her profession.

Guideline to Section 7.1.

Note 1: Pharmacy Council

The SA Pharmacy Council (SAPC) "Rules Relating to the Code of Conduct for Pharmacists" prohibits pharmacists, interns and pharmacists' assistants from accepting or paying any financial gain or other valuable consideration in return for the sale or supply of any goods, substances or materials used by the HCP in the practice. The definition of sell in the Pharmacy Act includes Advertise.

Note 2: The Health Professions Council of South Africa (HCPSA)

The Health Professions Council of South Africa (HCPSA) Guidelines prohibits the doctor from accepting such services or facilities. **

7.2 Donations and Corporate Social Investment

- 7.2.1 Financial donations or other appropriate donations to charities or Institutions may be made, if these are properly recorded and approved by the responsible person in each Company or organisation.
- 7.2.2 Donations, grants and benefits in kind to institutions, organisations or associations are only allowed provided that they:
- 7.2.2.1 are made for the purpose of supporting healthcare or research;



- 7.2.2.2 are documented and kept on record by the donor/grantor; and
- 7.2.2.3 do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific Health Products?
- 7.2.2.4 are not made for the purposes of promoting Health Products.
- 7.2.3 Donations may only be made to organisations subject to the applicable legislation.
- 7.2.4 The donation shall be made directly to the relevant organisation and must not be paid directly to any HCP or HCP's administration staff.
- 7.2.5 Acknowledgement by the recipient organisation of a donation must be restricted to an appropriate statement of support
- 7.2.6 Companies shall ensure that there is no conflict/potential conflict of interest between the Company and the recipient.
- 7.2.7 A donation shall not constitute a payment that would otherwise be unacceptable under the Code.
- 7.2.8 Companies shall have an agreement with the relevant organisation in terms of which disclosure of the donation is incumbent on both parties.
- 7.2.9 Donations in lieu of FFS/Honoraria are not permitted.
- 7.2.10 Companies are encouraged to make any information about donations, grants or benefits in kind publicly available.

Guideline to Section 7.2

Note 1: Donations to charities

1. *No donations may be made to hospitals or clinics as an incentive to prescribe any Health Product.*
2. *Charitable donations must not be tied in any way to past, present or potential future use of the Company's Health Products or related services.*
3. *All donations to a charity or non-profit organisation should be appropriately documented. For example, a written request should be submitted by the charitable organisation, detailing the purpose of the charity and the nature of its activities.*
4. *Charitable donations to a bona fide organisation should not be made in response to requests made by HCPs unless the HCP is an employee or officer of the organisation and submits the request on behalf of the organisation.*
5. *It would not be appropriate for a Company to support the favourite charity of a HCP in response to a request by that HCP.*
6. *Companies should have no control over the final use of funds provided as charitable donations to charitable and other non-profit organisations.*



7.3 Sponsorship

- 7.3.1 Companies may sponsor medical education or training, or similar services provided by other organisations. Sponsorship material shall be accurate, contain balanced information on the subject and include a clear indication of which Company has produced the sponsored material.
- 7.3.2 Nothing shall be offered or provided in a manner or in conditions that would interfere with the professional independence of an HCP.
- 7.3.3 Refer also to Section 10.3 regarding the sponsorship of HCPs.

7.4 Grants and Financial Support

- 7.4.1 The Code recognises the significant contribution of the Industry to the knowledge of the proper and effective use of Health Products through the financial support of HCP activities.
- 7.4.2 A Company may provide a grant or financial support provided that the grant or financial support is given only to a healthcare practice, Institution or health related organisation and not directly to an individual HCP.
- 7.4.3 The decision to provide a grant or financial support to a healthcare practice, Institution or health related organisation shall meet one or more of the following purposes:
 - 7.4.3.1 education, training or academic;
 - 7.4.3.2 medical research;
 - 7.4.3.3 activities that improve the quality use of Health Products; or
 - 7.4.3.4 the improvement of patient outcomes.
- 7.4.4 A grant or financial support shall not be conditional upon an HCP, institution or health related organisation recommending, prescribing, dispensing or administering any Health Product of the offeror.
- 7.4.5 Clear guidelines, which can be publicly disclosed, where required, shall be developed in relation to the award of grants and financial support.
- 7.4.6 A written agreement shall be in place to outline the nature of the grant or financial support provided.

Guideline to Section 7.4

Note 1: Faculty expenses for HCPs visiting South Africa

1. Grants to conference sponsors to cover the costs of reasonable honoraria, travel, lodging, and meals for HCPs visiting South Africa who are bona fide conference attendees and/or speakers are acceptable.



2. *HCPs should generally not be reimbursed directly for costs incurred related to the scientific components of the conference. Reimbursement of expenses may only be made through a practice account and on production of original invoices and subject to Section 10.3.*



CHAPTER 8: SAMPLES AND BANDED PACKS

8.1 Health Products

- 8.1.1 The supply of Health Product(s) as samples shall comply with the Medicines Act.
- 8.1.2 Sampling of any medicine (from OTC to Prescription) plus any complementary medicines and health supplement in any form to both the consumer and healthcare professional is a violation of S18B of the Act, and is prohibited.

8.2 Personal Care Products

- 8.2.1 Personal care products may not be provided together with any scheduled Medicines.

Guideline to Section 8.1.2

Note 1: Banded pack for Schedule 0 products

Banded packs are permissible.

The products banded together must be Schedule 0 products but may be different dosage forms or different products.

The products must also be available for sale as single items so as not to exclusively force purchase of the banded products.

Banded packs must comply with legal requirements e.g. Banding packs of paracetamol may result in the combined packs exceeding the maximum paracetamol limit in a pack for a Schedule 0 and as such will not be permissible.

Note 2: Basketing promotions for Schedule 0 products

Basket promotions are permissible (products are not banded together but sold separately).

- 3. The products promoted together must be Schedule 0 products, but may be different dosage forms or different products.*
- 4. As S0 medicines are exempted from bonusing, discounting and rebating (S18A), it is permissible to have promotions such as "buy two products and pay a discounted price" or "buy three for the price of two".*



CHAPTER 9: COMPETITIONS

9.1 Competitions for HCPs

9.1.1 Competitions for HCPs shall be permissible provided that:

- 9.1.1.1 the competition is based on medical or Health Product knowledge or the acquisition of scientific knowledge;
- 9.1.1.2 individual prizes or educational items offered benefit the patient and/or are relevant to the HCP's practice or business;
- 9.1.1.3 entry into a competition is not dependent upon prescribing, ordering or recommending a Health Product and no such condition shall be made or implied;
- 9.1.1.4 the value of the prize does not exceed the limits set by the MCA Board from time to time;
- 9.1.1.5 cash or cash equivalents (e.g. vouchers) are not allowed for the completion of a survey. or as a prize for a competition; and
- 9.1.1.6 the competition complies with the relevant legislation such as the Consumer Protection Act, where applicable.

Guideline to Section 9.1

Note 1: Competitions and quizzes for HCPs

1. *The use of competitions, quizzes and such like for the purposes of sales promotion is an acceptable form of promotion.*
2. *Any competition must be in good taste and must not involve any subject matter that is inappropriate for the promotion of a health product as required under Section 9.1.*
3. *Participation in competitions and quizzes related to the promotion of Schedule 2-6 Health Products is limited to HCPs only.*
4. *The maximum value per prize in a promotional competition for HCPs is R 2 000 (inclusive of VAT) per event or Promotional Activity.*
5. *The total value of all prizes for a competition for HCPs must not exceed R40 000 (inclusive of VAT).*
6. *If the prize is congress sponsorship, it may cover bona fide conference fees, accommodation and travel for the winner only and will be subject to the Code requirements for sponsorship.*

9.2 Consumer Competitions

9.2.1 Competitions for Consumers shall be permissible provided that:

- 9.2.1.1 entry into consumer competitions is not dependent on the conditional purchase of a Health Product



- 9.2.1.2 consumer competitions may not offer a Health Product as a prize;
- 9.2.1.3 the value of the prize does not exceed the limits set by the MCA Board from time to time;
- 9.2.1.4 the competition relates only to Schedules 0 and 1 Medicines or Classes A and B Medical Devices and
- 9.2.1.5 the competition complies with the relevant legislation such as the Consumer Protection Act, where applicable.

Guideline to Section 9.2

Note 1: to Section 9.2

Until such time as the legislation around the control of Complementary /Category D Medicines (Discipline-specific medicines and Health Supplements) is finalised and implemented by SAHPRA, the MCA Code sections 9.2.1.1 and 9.2.1.3 on Consumer Competitions will not apply to Category D medicines.

Note 1: Value of competition prizes

1. *The total value of the prizes for a consumer competition must not exceed R100 000 (inclusive of VAT); and each individual prize may not exceed R5 000 (inclusive of VAT).*
2. *A donation of any nature linked to the competition needs to be included in the total prize money.*
3. *Competitions to wholesalers, the FMCG trade, spaza store owners, retailers, forecourt owners and the like are to be treated in the same manner as a competition to a HCP with similar criteria applying.*

Note 2: Competitions open to Consumers

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



CHAPTER 10: MEETINGS AND EVENTS WITH HCPs

10.1 General principles

10.1.1 Companies, organisations or individuals shall be permitted to organise or sponsor meetings and events, including CPD events and product launches, subject to the following requirements:

10.1.1.1 the merit and focus of the meeting or event is clearly of a scientific and/or educational nature;

10.1.1.2 no stand-alone entertainment or other leisure, social or sporting activities is planned, arranged or funded by Companies as these are unrelated to the Promotion of scientific or educational objectives;

10.1.1.3 the venue and Hospitality is secondary to the meeting or event both in time allocation and focus;

10.1.1.4 programmes and events are conducted in clinical, educational, conference, or other settings, including hotel or other commercially available meeting facilities conducive to the scientific or educational objective of the event and the effective transmission of knowledge.

10.1.1.5 hospitality is modest and appropriate;

10.1.1.6 invitations are not extended to spouses or other guests of HCPs, i.e. any costs incurred by spouses or other guests shall not be reimbursed or paid for by the Company. In exceptional cases, such as where the health needs of the HCP (e.g. disability), the costs of travel, meals and accommodation and registration fees of an accompanying person who is considered to be a caregiver may be provided;

10.1.1.7 inappropriate benefits, including excessive Hospitality, is not offered and/or extended to HCPs; and

10.1.1.8 any reasonable, actual costs related to the attendance of meetings, which may have been incurred by HCPs, may be reimbursed.

Guideline to Section 10.1

Note 1:

Illustrative summary of examples of what may be acceptable or not when interacting with HCPs. This is not an exhaustive list. Refer back to the requirements of the Code when approving promotional items and events.



	Medical Education content	Company/ corporate branded event-related items of general utility*	Promotional product content	Product branded promotional aids, brand reminders
Company-sponsored medical educational event	√	√	X	X
Third-party educational event (dependent on 3 rd party agreement)	√	√	X	X
Advisory Board meeting – clinical / medical	√	√	X	X
Advisory Board meeting – commercial advisory board	√	√	√	√
Clinical Investigator meeting	√	√	X	X
Trade display	√	√	√	√
Medical representative detailing healthcare professional	X Should be provided by medical personnel	√	√	√

**Examples of event-related items of general utility: pens, notepads, lanyards, token bags.*

Note 2: Venues

1. Programmes requiring 'hands on' training in medical procedures should be held at training facilities, medical institutions, laboratories, or other appropriate facilities.
2. It is inappropriate to host HCPs at venues that would be considered holiday destinations and which are distant from their normal place of practice, unless it is a bona fide educational meeting, conference or congress, endorsed by a Professional Healthcare Association.



Note 3: The reasonableness of hospitality

Hospitality should be limited to reasonable hotel accommodation and meals, coffee breaks, and a conference dinner or cocktail reception which all HCP delegates are expected to attend.

Note 4: International travel

Companies may sponsor business class travel for HCP's only for

1. Faculty members presenting at a congress irrespective of day of arrival.
2. HCPs attending advisory boards and clinical investigations irrespective of day of arrival.
3. Business class airfares may not be exchanged for two Economy tickets so that a companion/spouse may accompany the HCP.
4. It is not appropriate to pay for travel expenses for guests or spouses/partners of HCPs or for any other person who does not form part of the trainees or invited attendees at such a meeting.
5. Travel should be arranged by the sponsoring company (or their designated travel agent) and should be restricted to the designated meeting dates (dependent on the travelling time involved, which may include arriving 48 hours before the meeting, and departing soon thereafter).
6. An official agenda should be prepared for the meeting.

Note 5: Local travel

1. Where there are objective reasons to support the need for out-of-town travel to facilitate the exchange of information, reasonable travel costs, including economy class airfares for the attending HCPs who reside outside of the main centre or centres where such training takes place, may be reimbursed. The only exception for economy class travel locally will be a documented medical condition that necessitates business class travel.
2. It is not appropriate to pay for travel expenses for guests or spouses/partners of HCPs or for any other person who does not form part of the trainees or invited attendees at such a meeting.

Note 6: Any other travel

For any other travel, economy class travel is the standard class travel that companies may offer HCPs to attend both local and international events, including congress attendance and site visits. Business class travel may however be provided for flights with flying time longer than 6 hours.

Note 7: Conference Programme

1. International events: An event is 'international' when participants are practicing in different countries. A national meeting with international speakers will still be considered national if all the participants are practicing in the same country.
2. The schedule of the scientific conference programme:

For a full day event, the detailed programme should contain a minimum of six hours of medical educational content (excluding lunch and other breaks).



3. *The availability of the programme in advance:*

The programme should be available at least 60 days prior to the event and contain sufficient information to enable an evaluation of the scientific value of the sessions and permit Companies to notify each sponsored HCPs hospital administration (in the case of public sector HCPs / registrars) and as may be the case for HCPs working for private sector hospitals, superiors or HCP societies / associations.

4. *The relevance of the programme:*

The programme content should directly relate to the specialty and/or medical practice of the HCP who will attend the conference or have a sufficiently reasonable relationship to justify the attendance of the HCP. Agenda content relating to non-scientific topics, such as leadership skills, practice management, and speaking and presentation skills are acceptable if they are kept to a minimum.

Note 8: Geographic location

1. *No Company may organise or sponsor an event that takes place outside its home country unless:*
 - *most of the invitees are from outside of its home country and, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the event in another country, or;*
 - *given the location of the relevant resource or expertise that is the object or subject-matter of the event, it makes greater logistical sense to hold the event in another country.*
2. *The time of the year should be taken into account in determining if a geographic location is appropriate.*
3. *The geographic location should not be the main attraction of the conference. The image of the location among Consumers, media and authorities may not be perceived as a purely luxury, touristic/holiday and/or entertainment venue.*

Note 9: Meals

1. *Modest meals may be provided as an occasional business courtesy consistent with the following limitations:*

The meal should be incidental to the bona fide presentation of scientific, educational, or business information and provided in a manner conducive to the presentation of such information. The meal should not be part of an entertainment or recreational event.

Meals may occur at the HCPs' place of business. However, in some cases the place of business may be a patient care setting that is not available for, or conducive to, such scientific, educational, or business discussions.

2. *In other cases, it may be impractical or inappropriate to provide meals at the HCPs' place of business, for example,*

where the medical technology cannot easily be transported to the HCPs' location,

when it is necessary to discuss confidential product development or improvement information, or



where a private space cannot be obtained on-site.

3. Meals may only be provided to HCPs who actually attend the meeting. Meals for guests of HCPs or for any other person who does not have a bona fide professional interest in the information being shared at the meeting is not allowed.
4. No hospitality can be provided to Health Care Professionals attending individually a virtual third party organized event or a company organized event. Hospitality can be provided to a group of HCPs attending a virtual event together, organized by a member company because this can be considered a face-to-face meeting.

Note 10: Hospitality and accommodation at congresses

1. The level of accommodation offered must be appropriate, modest in nature, and the costs involved must not exceed that level that the recipients would normally accept when paying for themselves.
2. The appropriateness of accommodation: Companies may not pay for or reimburse HCP lodging expenses at top category or luxury hotels.
3. The accommodation must be limited to the duration of the conference – accommodation and/or other services provided to HCP delegates should not cover a period of stay beyond the official duration of the conference.
4. The registration fee: The registration fee should cover only the scientific programme and authorised activities and hospitality.

Note 11: HCPs unconnected to any congress

It is inappropriate to host or sponsor meals or receptions for large groups of HCPs that are entirely unconnected to any Congress, business premises or educational event.

10.2 CPD Meetings

10.2.1 CPD meetings shall meet the following requirements in addition to other requirements stipulated in the Code:

- 10.2.1.1 No Health Product Promotion is allowed in the meeting room. Company-branded items/Promotional Materials are permissible;
- 10.2.1.2 Speakers may only use the International Non-Proprietary Name (INN) of Health Products during CPD events. Companies shall inform speakers that the use of trade names is not permitted;
- 10.2.1.3 The Health Product Promotional Material displayed outside of the meeting room is not visible to Consumers if it is not permissible to Promote such Health Product directly to them;
- 10.2.1.4 For local CPD events and Health Product launches held in major cities, reasonable travel arrangements or reimbursement of actual travel expenses may be made to ensure that the HCPs not



residing/practising in major cities are able to access the applicable information; and

10.2.1.5 The criteria for the selection of attendees/invitees are transparent and available on request for scrutiny by the MCA.

10.2.2 Companies shall not pay HCPs for their time when they attend the CPD events under the guise that such events are scientific meetings or advisory board meetings. Guidelines on contracting and reimbursing HCPs are referred to in Chapter 12 of the Code.

10.3 Medical or Scientific Congresses, Conferences or Seminars

10.3.1 The Code recognises the contribution of the Industry in providing medical education to facilitate better patient care and outcomes through sponsorship of HCPs to attend local and international medical educational and scientific events.

10.3.2 Meetings organised by Companies or any Person on their behalf at venues outside South Africa that are educational and scientific in nature and involve South African HCPs shall be acceptable.

10.3.3 Sponsorship shall be provided to an HCP to attend an educational event provided the event relates directly to the HCP's area of expertise.

10.3.4 Where a Company undertakes the sponsorship of an HCP, the following requirements shall be met:

10.3.4.1 The sponsorship shall be set out in a written agreement;

10.3.4.2 The sponsorship shall not be conditional on the HCP recommending, prescribing, dispensing or administering a Company's Health Product(s);

10.3.4.3 The sponsorship may cover registration fees as well as travel, accommodation, and Hospitality costs of the HCP;

10.3.4.4 Documented criteria shall be in place for determining which HCPs should receive support; and

10.3.4.5 The final determination of for which HCP is to be sponsored shall be made by the Company's Code Compliance Officer.

10.3.5 The decision to sponsor any HCP must be capable of withstanding public and professional scrutiny.

10.3.6 For medical or scientific congresses, conferences and seminars held in South Africa or internationally, whether these are arranged by a South African or international group, the following rules shall be observed:



- 10.3.6.1 The rationale for any meeting or sponsorship to attend a meeting shall be transparent, valid and cogent;
 - 10.3.6.2 Consideration shall be given to the educational programme, overall cost, facilities offered by the venue, nature of the audience, the hospitality provided and the like;
 - 10.3.6.3 As in the case of any meeting, it shall be the programme that attracts delegates and not the associated hospitality or venue;
 - 10.3.6.4 Any associated events shall be subordinate in time and nature to the sponsored meeting, congress, conference or seminar;
 - 10.3.6.5 Payment of registration fees, travel and accommodation cost shall be made to the professional associations/organisers or the appropriate administrative staff and not directly to the HCP, 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;
 - 10.3.6.6 No payment shall be made to the HCP or administrative staff for time spent at the event;
 - 10.3.6.7 Sponsorship of congress organised events, other than recreational and sporting events, shall be permitted;
 - 10.3.6.8 Invitations shall not be extended to spouses or other guests i.e. any costs incurred by spouses or other guests may not be reimbursed or paid for by the Company;
 - 10.3.6.9 The meeting and event shall be appropriate to the field of practice of the HCPs invited to attend;
 - 10.3.6.10 Sponsored HCPs shall not be involved in the direct Promotion of specific Health Products; and
 - 10.3.6.11 The program shall be available at least 60 (sixty) days prior to the event and contain sufficient information to enable an evaluation of the scientific value of the sessions.
- 10.3.7 Companies sponsoring an HCP to speak at a Company-sponsored educational event or congress shall ensure, as a condition of the sponsorship, that the HCP is familiar with the approved indications for relevant Health Products and is aware of the obligation not to Promote unapproved Company Health Products or indications. This does not apply to independently organised third-party educational events or Company-sponsored educational events, which are non-Promotional, and where an independent scientific faculty has chosen the topics and speakers.



10.3.8 In the case of international congresses held in South Africa, unapproved Health Products or indications shall not be Promoted unless Section 14(3) of the Medicines Act applies.

See guideline following.

Guideline to Section 10.3

Note 1: Entertainment at conference

A Company may not fund attendance at a concert, purchase of entertainment tickets or pay for entertainment (including sport and hunting activities) in any form. However, if there is background music or a local performance at the venue where the event is taking place, which is not paid for by a Company, this may be permitted.

10.4 Transparency Related to Sponsorships

10.4.1 When meetings are sponsored by Companies or any Person on their behalf, the sponsorship shall be disclosed in the papers relating to the meetings and in any published proceedings.

10.4.2 The declaration of sponsorship shall be sufficiently prominent to ensure that readers are aware of it at the outset.

10.5 Hospitality for Administrative Staff during Meetings

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



CHAPTER 11: PROMOTIONAL ITEMS AND GIFTS

11.1 Promotional Aids

11.1.1 Medical and Educational Services/Goods

11.1.1.1 Medical and educational goods and services, which enhance and/or maintain patient care, may be provided to HCPs subject to the provisions of the Code in specific those related to inducements and Promotional Aids. They shall not be provided to HCPs for their personal benefit.

11.1.1.2 Medical and educational goods shall not bear the name of any Health Product, but may bear the name of the Company providing them.

11.1.1.3 The value of medical and educational goods that may be provided shall be determined by the Board from time to time.

Guideline to Section 11.1.1

Note 1: Items of medical utility

1. *Scientific medical reference books, journals, periodicals and anatomical models intended for teaching or patient benefit:*
2. *For scientific medical reference books / journals and periodicals*
 - *individual practicing HCPs or practices, the value should not exceed R 3000 (inclusive of VAT)/year*
 - *training or academic institutions, the value should not exceed R 10 000 (inclusive of VAT)/year*
3. *The value of medical devices should not exceed R300 (inclusive of VAT) / per item with a cap of R3 000 (inclusive of VAT)/ practice or institution per annum.*
4. *Other items of medical utility may be offered or provided if such items are of modest value, do not offset routine business practices and are beneficial to enhancing the provision of medical services and patient care.*
5. *Items might include an anatomical model for use in an examination room, or medical textbooks, as both primarily involve a patient benefit. A DVD or CD player however will not be permissible.*
6. *Items should not be offered on more than an occasional basis, even if each individual item is appropriate.*

Note 2: Medical and educational goods and services

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



2. *The role of Company Representatives in relation to the provision of goods and services supplied in accordance with the Code needs to be in accordance with the principles set out below. In this context Companies should consider using staff other than Health Product representatives.*
3. *If Company Representatives provide, deliver or demonstrate medical and educational goods and services then they must not be linked in any way to the promotion of Health Products.*
4. *In order to comply with this stipulation the Company Representative must not carry out both activities at the same visit.*
5. *Company Representatives may introduce a service by means of a brief description and/or delivering materials, but may not instigate a detailed discussion about the service at the same time as a call at which Health Products are promoted.*
6. *The acceptability of the role of Company Representatives will depend on the nature of the goods and services provided and the method of provision.*
7. *The nature of the service provider, the person associated with the provision of medical and educational goods and services, is important i.e. is the service provider a Health Product Company Representative or is the service provider some other appropriately qualified person, such as a sponsored registered nurse? If the goods and services require patient contact, for example either directly or by identification of patients from patient records and the like, then Health Product representatives must not be involved. Only an appropriately qualified person, for example a sponsored registered nurse, not employed as a Health Product representative, may undertake activities relating to patient contact and/or patient identification. Health Product representatives could provide administrative support in relation to the provision of a screening service, but must not be present during the actual screening and must not discuss or help interpret individual clinical findings.*
8. *Neither the Company nor Company Representatives may be given access to data/records that could identify, or could be linked to, particular patients unless healthcare professional and patient consent is received in writing.*
9. *Companies must ensure that patient confidentiality is maintained at all times and that data protection legislation is complied with.*
10. *Service providers must operate according to detailed written instructions provided by the Company. These should be similar to the briefing material for Company Representatives as referred to in Section 5.18. The written instructions should set out the role of the service provider and should cover patient confidentiality issues. Instructions on how the recipients are to be informed, etc. should be included. The written instructions must not advocate, either directly or indirectly, any course of action which would be likely to lead to a breach of the Code.*
11. *Service providers must abide by the principle set out in Section 5.18 that in an interview, or when seeking an appointment, reasonable steps must be taken to ensure that they do not mislead as to their*



identity or that of the Company they represent.

12. *A recipient of a service must be provided with a written protocol to avoid misunderstandings as to what the recipient has agreed. The identity of the sponsoring Company must be given.*

Note 3: Package deals

Section 11.1.1 does not prevent the offer of package deals for patients in terms of which the purchaser of particular Health Products receives with them other associated benefits, such as apparatus for administration, provided that the transaction as a whole is fair and reasonable and the associated benefits for the patient are relevant to the Health Products involved.

11.1.2 Occasional Items

11.1.2.1 Occasional Promotional items given to HCPs, appropriate administrative staff, sales and other staff shall be acceptable provided that they are:

11.1.2.1.1 inexpensive and of modest intrinsic value i.e. within the cost limits set from time to time by the Board;

11.1.2.1.2 not for personal use e.g., no entertainment CDs/DVDs, electronic items for entertainment, tickets to attend sporting events or other forms of entertainment are permitted,

11.1.2.1.3 educational and/or of scientific value, beneficial to the patient and/or relevant to the HCP's practice; and

11.1.2.1.4 not cash or cash equivalents (e.g. vouchers).

11.1.2.2 It shall be permissible to brand these occasional items. The following information may be included on occasional items:

11.1.2.3 The proprietary name of the Health Product;

11.1.2.4 An indication that the name of the Health Product is a trademark; and

11.1.2.5 The Company name, Company logo and/or Health Product logo.

11.1.2.6 It is not necessary for the minimum information required by the legislation for an Advertisement of a Health Product to be included on the occasional item provided no Promotional claims are made.

11.1.2.7 The value of occasional items that may be provided shall be determined by the Board from time to time.

11.1.2.8 Gifts for the personal benefit (such as sporting or entertainment tickets, electronics items, social courtesy gifts, etc.) of HCPs (either directly or through clinics and institutions) are prohibited. Providing



or offering cash, cash equivalents or personal services is also prohibited. For these purposes, personal services are any type of service unrelated to the HCP's profession and that confer a personal benefit on the HCP.

Guidelines to Section 11.1.2

Note 1: Occasional items

1. *Items of general utility, which have been held to be acceptable items to HCPs as being inexpensive and of relevance to their practices, include but are not limited to pens, pads, diaries, nail brushes, desk trays, calendars, and desk clocks.*
2. *Diaries and desk pads bearing advertisements of Health Products must comply with the provisions of Regulation 42 and 21 (in respect of medical devices and IVDs) and the Code.*

Note 2: Detail on promotional Aids

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

Note 3: Value of occasional items

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

11.1.3 Cultural Courtesy Gifts

A single inexpensive gift per year, not related to the HCP's practice, the maximum value of which shall be determined by the Board from time to time, may be given by a Company to an HCP in recognition of significant national, cultural or religious days.

11.2 Items for Patients and Patient Organisations

- 11.2.1 HCPs may be provided with items, which are part of a formal patient support programme, the details of which have been appropriately documented and approved in advance in accordance with the Code, and which shall be passed to patients.
- 11.2.2 The items shall be inexpensive and benefit patient care directly. In the case of the Health Product being recommended or prescribed for the patient, the item may bear the name and/or logo of the Company and/or the Health Product.
- 11.2.3 Collaboration between one or more Companies in respect of the provision of items that benefit patient care as contemplated in this Section 11.2 is acceptable provided it shall always benefit the patient and be in accordance with the law and the Code.
- 11.2.4 Patient support and/or patient group meetings, patient-related events and patient support materials may be sponsored provided that records are retained as required in terms of the Code and that no Health Product Promotion takes



place. The fact that sponsorship or support has been provided shall be displayed on the materials and/or at the meeting or event.

Guideline to Section 11.2

Note 1: Patient support items

1. *Patient support items may be provided to HCPs by Company Representatives during the course of a promotional call and Company Representatives may deliver such items when they are requested by HCPs, for example on reply paid cards. Examples of items which will be acceptable include a peak flow meter as part of a scheme for patients to regularly record readings or a pedometer as part of a scheme to encourage exercise, perhaps for obese patients subject to the provisions of relevant legislation.*
2. *Patient support items may be made available for use by HCPs even though they may not be passed on to patients for them to keep. Their purpose is to allow patients to gain experience in using their Health Products whilst under the supervision of a HCP. Examples include inhalation devices (with no active ingredient) and devices intended to assist patients to learn how to self-inject. The perceived value to the HCP and the patient must be similar.*

Note 2: Items for patients

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

Note 3: Direct patient contact

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



CHAPTER 12: CONTRACTING AND REIMBURSING HEALTHCARE PROFESSIONALS

12.1 Contracted Services

- 12.1.1 It is permitted to use HCPs and/or patient organisations as consultants and advisers, whether in groups or individually, for services such as speaking at meetings and chairing them, involvement in medical/scientific studies, Clinical Trials or training services, participation in advisory board meetings, and market research, where such participation involves a FFS/Honorarium and/or reimbursement of travel expenses and/or the provision of Hospitality.
- 12.1.2 The arrangements covering these consultancy or other services, which shall be genuine, shall, to the extent relevant to the particular arrangement, fulfil all the following criteria:
- 12.1.2.1 A fee may not be paid in respect of loss of income.
 - 12.1.2.2 A written agreement must be in place prior to the commencement of the services, specifying the nature of the services to be provided and the details of the payment of those services.
- 12.1.3 A Company shall have a documented process for determining the value of the FFS/Honorarium for HCPs, which shall include:
- 12.1.3.1 A written record of the basis on which the FFS/Honorarium was determined;
 - 12.1.3.2 A description of the legitimate need identified for contracting the services prior to requesting them;
 - 12.1.3.3 Documented details of arrangements made with the prospective consultants/advisers;
- 12.1.4 Whenever an HCP consults, advises, prepares written material or speaks on behalf of a Company, a written signed undertaking must be in place confirming that the HCP will declare his/her relationship with the company.
- 12.1.5 Companies that employ an HCP on a part-time basis, who continues to practice his profession, shall require the HCP to sign a declaration to the effect that he is obligated to declare his employment arrangements with the Company whenever he writes or speaks in public about any other issue relating to that Company.
- 12.1.6 The criteria for selecting consultants/advisers for their services shall be directly related to the identified need of the Company and those responsible for selecting them shall have the necessary expertise to evaluate whether or not the particular HCPs meet those criteria. The rationale shall be documented.



- 12.1.7 The number of consultants/advisers retained shall not be greater than the number reasonably necessary to achieve the identified need.
- 12.1.8 The contracting Company shall maintain records concerning the services provided by consultants/advisers and shall make appropriate use of them.
- 12.1.9 The engagement of the consultants/advisers to provide the relevant services shall not be an inducement to recommend, prescribe, purchase, supply, sell or administer any particular Health Product.
- 12.1.10 If an HCP attends an event (an international event or otherwise) in a consulting or advisory capacity, the relevant provisions of the Code apply. Payment of a FFS/Honorarium and reimbursement of out-of-pocket expenses, including travel costs, are permissible provided this is in terms of a written agreement and a written record of such expenses and payments is retained by the Company Code Compliance Officer. Actual costs must be retained by the company.

Guideline to Section 12.1

Note 1: Acceptable consulting services

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

1. *speakers for conferences and congresses;*
2. *presentation and demonstrations at Company sponsored product training;*
3. *advisory boards;*
4. *training services;*
5. *development of educational material/ software or programs;*
6. *development and/or management of patient compliance software/programs.*

12.2 Payment Exclusions

- 12.2.1 No direct or indirect payments may be made to HCPs for any services other than those specified in Chapter 12.
- 12.2.2 Payments may not be made either directly or indirectly to HCPs or groups of HCPs, for the rental of rooms or other services.
- 12.2.3 HCPs involved in bona fide, and, where relevant, peer reviewed research, are not subject to the provisions of Chapter 12.

12.3 Patient Registries

- 12.3.1 When HCPs provide information to Patient Registries, the following requirements apply:



- 12.3.1.1 a FFS/Honorarium may be paid, which is commensurate with the work performed;
- 12.3.1.2 registries may not be disguised as Promotion and shall have scientific and/or healthcare policy merits and relate to a legitimate project to obtain data/information. Proof of such bona fide Registry, shall include scientific protocols, Research Ethics Committee approval and relevant agreements; and
- 12.3.1.3 registries shall comply with all the applicable legislation, including but not limited to the protection of patients' personal information and informed consent for the collection and use of that information.

Guideline to Section 12.3

Note 1: Consent for access to patient data

1. *Neither the Company nor its Company Representatives may be given access to data/records that could identify or could be linked to a particular patient unless with the express written consent of the patient and the HCP. This does not apply to clinical researchers whose activities are controlled under the Good Clinical Practice Guidelines, in line with the best international practice viz.*
 - *patient confidentiality. Companies must ensure that patient confidentiality is maintained at all times.*
 - *approval by Company Code Compliance Officer of materials relating to the provision of medical and educational goods and services, such as internal instructions, external instructions, the written protocol for recipients and printed material etc., must be examined by the Company Code Compliance Officer. Companies are to ensure that the requirements of the Code are met.*
- 2 *A copy of the materials must be made available to the SA Marketing Code Authority on request.*



CHAPTER 13: MEETINGS AND EVENTS INVOLVING PATIENT ORGANISATIONS

Sponsorship

- 13.1.1 Where sponsorship or support has been provided by a Company for a meeting or event involving patient organisations, this shall be displayed on the materials and/or at the meeting or event.
- 13.1.2 When Companies provide financial support and/or significant indirect and/or non-financial support to patient organisations, a written agreement, stating the amount of funding and also its purpose is required.
- 13.1.3 Funding arrangements shall be documented, transparent and publicly acknowledged.
- 13.1.4 Events organised by Companies for patient organisations that are wholly or mainly of an entertainment, leisure, social or sporting nature shall not be permitted.
- 13.1.5 Companies shall not seek to influence the contents of the patient material of the organisation they sponsor in a manner favourable to their own commercial interests. This shall not preclude Companies from correcting factual inaccuracies.
- 13.1.6 The use of a patient organisation's logo and/or company proprietary material shall require written permission from that organisation or Company.

13.2 Contracted Services

- 13.2.1 Contracts between Companies and patient organisations for the provision of services to those Companies shall only be allowed if these services are provided for the purposes of support for healthcare or research.
- 13.2.2 It is permitted to engage patient organisations as experts and advisers for services such as participation in advisory board meetings and speaker engagements where there is a written agreement. An FFS/Honorarium may be paid for such services.



CHAPTER 14: RELATIONS WITH CONSUMERS AND THE MEDIA

14.1 Advertising of Medicines in Schedule 2 & above, Class C & D Devices & IVDs

14.1.1 The advertising of Medicines, medical Devices and IVDs must occur as provided for in the Medicines Act.

14.1.2 This means that only schedules 0 and 1 Medicines and Medical Devices and IVDs in classes A and B may be advertised to consumers.

The advertising of male and female condoms are, however, not subject to this prohibition.

14.2 Advertising of Schedule 0 and 1 Medicines, Class A and B Medical Devices

14.2.1 The Advertising or Promotion of Medicines and Complementary Medicines in Schedules 0 and 1 to Consumers shall be permitted.

14.2.2 The Advertising or Promotion of Medical Devices and IVDs in Classes A and B to Consumers shall be permitted.

Guideline to Section 14.1 and 14.2

Note 1: Classification of Medical Devices and IVDs

Risk	Risk determined by	Example devices	Example IVDs
Low	Intended use (NB), level of risk to patients, users & others, degree of invasiveness, duration of use/ exposure.	Tongue depressor	Reagents
Low-moderate		Suction equipment	Urine self-test strips
Moderate-high		Orthopaedic implants	Malaria rapid test
High		Heart valves	HIV screening test

14.3 Requests from Individual Consumers

Companies shall refuse requests from individual Consumers for information or advice on personal medical matters and the enquirer shall be advised to consult his own HCP.

14.4 Information Available to Consumers

14.4.1 Information made available to Consumers about Health Products, either directly or indirectly, shall be

14.4.1.1 factual; and

14.4.1.2 balanced.



14.4.2 Information that is made available directly or indirectly to Consumers about Health Products shall not:

14.4.2.1 raise unfounded hopes for successful treatment; or

14.4.2.2 be misleading or disparaging with regard to the safety of the Health Product; and

14.4.2.3 refer to a Health Product's safety, quality or efficacy.

14.4.3 The provisions of Section 14.4 shall not prohibit education or information on the substitution of a Health Product or information on the safe usage, and/or storage of Health Products in general.

Guideline to Section 14.4

Note 1: Information to Consumers

1. *This section allows for the provision of non-promotional information about Schedules 2 and above Medicines and Classes C and D to Consumers either in response to a direct inquiry from an individual, including inquiries from journalists, or by dissemination of such information via press conferences, press announcements, television and radio reports, public relations activities and the like. It also includes information provided by means of posters distributed for display in surgery waiting rooms etc.*
2. *This prohibition does not apply to vaccination campaigns or other public health campaigns carried out by Companies and approved by the Department of Health and/or the Regulatory Authority.*
3. *Any information so provided must observe the principles set out in this section, that is, it should be factual, balanced and must not encourage Consumers to ask their HCPs to prescribe a specific Health Product. It must not constitute the Advertising of Health Products to the general public prohibited under the Medicines Act which must be observed if an inquiry is from a Consumer.*
4. *Particular care must be taken in responding to requests from the media to ensure that the provisions of the Code are upheld.*
5. *In the event of a complaint which relates to the provisions of this section, Companies may be asked to provide copies of any information supplied, including copies of any relevant press releases and the like. This information will be assessed to determine whether it fulfils the requirements of this section. Professional Information/Patient Information Leaflets/Instructions for Use may be provided to Consumers on request. Companies may provide HCPs with approved Professional Information/ Patient Information Leaflets /Instructions for Use concerning a Health Product for supply to their patients to whom the Health Product has already been prescribed.*

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

This section prohibits the provision of information or advice on personal medical



matters to individual Consumers requesting it. The intention behind this prohibition is to ensure that Companies, organisations or individuals do not interfere in the patient/HCP relationship by offering advice or information that should be in the domain of the HCP. Answering requests of Consumers as to whether a particular Health Product contains sucrose or some other inactive ingredient, or whether there will be problems associated with drinking alcohol whilst taking a particular Health Product or whether the Health Product should be taken before or after a meal, is acceptable.

14.5 Patient Education

14.5.1 Patient education ('help-seeking Advertisements') directed at Consumers is acceptable, provided that the material:

14.5.2 for Schedule 2 and above Medicines, or Classes C and D Medical Devices and IVDs

14.5.2.1 does not contain the name of the specific Health Product, nor allude to the name of the Health Product;

14.5.2.2 does not make or allude to a medicinal or therapeutic claim;

14.5.2.3 does not provide any risk-related information on a health product;

14.5.2.4 conveys to Consumers that treatment is available for a medical condition; and

14.5.2.5 provides the statement, "For more information, refer to your HCP".

14.5.3 Companies may provide training and education for Consumers and may also sponsor the training provided by other organisations. The relevant training material shall be accurate, the information shall be balanced and include a clear indication of the identity of the Company that has produced the sponsored material. Refer also to Chapter 13.



CHAPTER 15: MATTERS SPECIFIC TO MEDICAL DEVICES AND IVDs

15.1 Demonstrations

- 15.1.1 Medical Devices and IVDs used for demonstration/exhibition purposes are typically unsterilised, Medical Devices intended for single use or mock-ups of Medical Devices and IVDs used for HCP and patient awareness, education and training.
- 15.1.2 Exhibition/demonstration Medical Devices and IVDs shall not be used in patient care.
- 15.1.3 Exhibition/demonstration Medical Devices and IVDs shall be identified as not being intended for patient use through wording such as “Sample,” “Not for Human Use,” or other suitable wording on the Medical Device or IVD, its packaging, and/or in the accompanying documentation.
- 15.1.4 An HCP may use an exhibition/demonstration Medical Device to show a patient the kind of Medical Device that will be implanted in him/her.

15.2 Performance Evaluations, Appraisals and Training

- 15.2.1 It is common practice for Medical Device and IVD Companies to engage local HCPs to evaluate and appraise a new device. Such evaluations may take place prior to its national launch, or in combination with a launch.
- 15.2.2 Health Product appraisals for the evaluation of a Medical Device or IVD shall comply with the following requirements:
 - 15.2.2.1 the provision of Medical Devices or IVDs for appraisal complies with the applicable legislative provisions; The provision of equipment free of charge must take place in accordance with the provisions of the applicable legislation,
 - 15.2.2.2 a written agreement between the Company and HCP is in place;
 - 15.2.2.3 no payment is made to the HCP who wishes to conduct a product appraisal of a Medical Device or IVD product for his own purposes;
 - 15.2.2.4 reasonable compensation may be paid to the HCP involved in a Medical Device or IVD performance evaluation requested by a Company for justifiable medical or scientific reasons, provided that this relates to the HCP's resources spent on the evaluation (e.g. personnel costs, laboratory infrastructure such as electricity/water, etc.) and is documented in a formal agreement;
 - 15.2.2.5 there an evaluation is conducted, and payments are made as part of a Clinical Trial or investigation or registered/approved research



project, this complies with the relevant provisions of the Medicines Act and other applicable legislation;

15.2.2.6 written results of the evaluation are provided to the Company.

15.2.2.7 all evaluations have a finite period of time or alternatively a finite number of procedures that will be performed;

15.2.2.8 all evaluations have scientific and therapeutically relevant aims;

15.2.2.9 where the evaluation constitutes a research project, before the evaluation commences an equipment evaluation protocol is approved by an accredited Research Ethics Committee;

15.2.2.10 All costs for the duration of the equipment evaluation are borne by the Company. These shall be documented and the Company may be required to provide such documentation as part of a Code enforcement process; and

15.2.2.11 If the evaluation leads to publications, lectures and other presentations, the sponsoring Company's name is disclosed.

Guideline to Section 15.2

Note 1: Technology

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

Note 2: Single use/consumables/disposables

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

Note 3: Multiple use/capital equipment

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



15.3 Loan or Placed Equipment

- 15.3.1 The sale or placement of Medical Devices or IVDs with an HCP where the agreement between the Company and the HCP includes the purchase of consumables/disposables associated with the Medical Device or IVD shall be done in terms of a written agreement, clearly outlining the terms and conditions of the arrangement, including the financial arrangements. The agreement shall not encourage or constitute a perverse incentive to use or prescribe a particular product.
- 15.3.2 The consumables may be used to cross-merchandise the capital equipment in a defensible and fair manner.
- 15.3.3 The funding or leasing of a Medical Device or IVD in lieu of purchasing consumables shall be in line with the provisions of the applicable legislation.

Guideline on Section 15.3

Note 1: Items on long term loan

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

Incidental Notes to supplement the MCA Code for training certification reference purposes.

CTAC 15th August 2021

These notes have been prepared to support company personnel in completing the MCA online certification. The notes give context to the minor differences in the advertising and promotion legislation for medicines and medical devices including in vitro diagnostic devices (IVDs). The notes are not intended to change the content of the Code or Guidelines in any way

Current published legislation should always be consulted.

The term "health products" includes all medicines and complementary medicines, medical devices and IVDs as defined in the Medicines Act. The requirements of the Act are the same for all health products. There are minor differences in the Regulations for devices and IVDs. These are explained below.

MCA assessments will now cover all health products. This is because more and more companies include both medicines and medical devices and IVDs in their portfolios. It is considered to be in the interests of both companies and their representatives to be competent to promote all health products.

Advertising of Medicines vs. Medical Devices and IVDs

Health products may only be advertised or promoted according to the content of the approved "professional information" of medicines or "instructions for the use" of a medical device or IVD. No additional claims may be made for a product. The claims made must be as prescribed in the professional information or instructions for use.

No person shall publish or distribute false and/or misleading advertisement concerning medicines, medical devices or IVDs⁸.



There are restrictions on persons to whom medicines ¹ and medical devices may be advertised².

Advertising of Medicines:

The Act defines a medicine broadly and includes any product where therapeutic claims are made, irrespective of category of the product. Therefore, even if a product does not necessarily have any pharmaceutical activity, if promotional materials make claims the product is subject to the control of the Act, including the controls on promotion and advertising³.

The scheduling status is determined after consideration of the safety, therapeutic index, the potential for abuse and the need for specialised input on the diagnosis needed for the prescribing of a product.

The higher the schedule status of a medicine, the greater the advertising and promotional restrictions.

The Schedules for advertising of medicines go from Schedule 0-Schedule 7 as per the following table:

Medicines schedule status	May be advertised to:
Medicines in Schedules 0 to 1	*May be advertised directly to the public.
Medicines in Schedules 2 to 6	May be advertised only to healthcare professionals and authorised prescribers.
Medicines above Schedule 6	May not be advertised.
Information to the public regarding prices, names, pack sizes, price, and strength of Schedule 2 to Schedule 6 medicines	Not restricted provided the rest of advertisement complies and no claims are made. Pack shots of Schedule 2 – Schedule 6 products should not be included in any advertisement.
No person shall advertise any medicine or scheduled substance for sale unless such advertisement complies with the prescribed requirements.	
No advertisement may go beyond the information contained in the approved professional information for a medicine or instructions for use of a medical device or IVD.	
Misleading advertising of any health products included in the Act is prohibited.	
Where more than one active ingredient is present, reference may only be made to the individual ingredients if a statement to this effect is included in the professional information. If no such statement is included, an advertisement must comply with the professional information or instructions for use.	
When a medicine is advertised verbally for the first time, its printed Professional Information must be offered and must be available on subsequent occasions. If a medicine is advertised electronically for the first time, then the electronic version of the Professional Information must be made available.	

*Can be advertised and promoted to the public/consumers

In addition, Schedules 0 medicine may be displayed in the pharmacy front shop and Schedule 1 and 2 medicines should not be directly accessible to the public. Scheduled 3 and higher medicines should only be accessible by a pharmacist, pharmacist intern or pharmacist's assistant under the direct supervision of a pharmacist in the private sector or in certain instances, indirect supervision of a pharmacist in the public sector.



Advertising Medical Devices and IVDs:

Advertisement for a registered medical device may not contain a statement which deviates from the evidence submitted with regards to its safety, quality, or performance⁷. In the case of an unregistered medical device, the essential principles of safety and performance apply⁷.

Medical devices and IVDs are categorized into one of the four categories or classes (A – D) at the time of licensing depending on the safety of use and the extent to which they are invasive.

Classification	Level of Risk
Class A	*No public health risk or low personal risk
Class B	*Low public health risk or moderate personal risk
Class C	Moderate public health risk or high personal risk
Class D	High public health risk

*Can be advertised and promoted to the public/consumers

The level of risk is explained in a bit more detail with examples (but not limited to):

Risk	Risk determined by	Example devices	Example IVDs
*Low	Intended use (NB), level of risk to patients, users & others, degree of invasiveness, duration of use/ exposure	Tongue depressor	Reagents
*Low-moderate		Suction equipment	Urine self-test strips
Moderate-high		Orthopaedic implants	Malaria rapid test
High		Heart valves	HIV screening test



Medical devices and IVDs in Classes A and B may be advertised to the public/consumers. However, advertising of male and female condoms is not subject to this prohibition. Classes C and D Medical devices may only be advertised to healthcare providers, unless stated otherwise by SAHPRA⁷.

Additional information about advertising:

When advertising Schedule 2 to Schedule 6 medicines or Class C or Class D medical devices for the first time, the product information, or instructions for use in the case of a medical device, must accompany the advertisement.

Advertisements may not make a claim for a health product which goes beyond what is in the approved professional information of medicine¹ or the approved instructions for use in the case of a medical device or IVD⁴.

A written advertisement for a medicine must contain the following information⁵:

the proprietary name;

in the case of a written advertisement;

the approved name and quantity of each active ingredient. Where the medicine only contains one active ingredient, this must be in a font at least half the size of the largest letter of the proprietary name;

the registration number of registered medicines;

in the case of 'old medicines', the reference number allocated to such application followed by the words 'Act 101/1965'; and

a name used, other than the proprietary name, must not exceed half the size of the proprietary name.

Special Requirements:

Advertisements for veterinary medicines must state; "for veterinary use only"⁶.

Advertisements for complementary medicines (which includes health supplements)¹:

a statement identifying the discipline of the medicine where relevant;

an indication that the medicine must be used in accordance with the applicable complementary discipline and principles where relevant; and

if the medicine has not received registration with the Authority, the following disclaimer must be included: 'This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use'.

An advertisement for Medical Devices must contain⁷:

the class of the medical device;

the name of the license holder in terms of Section 22C(1)(b), where applicable;

in the case of a registered medical device or IVD, the name and address of the holder of the certificate of registration and the registration number allocated to the medical



device or IVD; and

in the case of Class C or Class D medical device or IVD, written information including at least the information referred to in regulation 7 or regulation 8 of the Regulations relating to Medical Devices or IVDs must be available, where applicable.

For further information contact Val Beaumont, MCA Executive Officer. val@marketingcode.co.za

¹ Regulation 42 of the General Regulations, GN 859 in GG 41064 of 25 August 2017, issued in terms of the Medicines and Related Substances Act 101 of 1965

² Regulation 21 of the medical device regulations, GN 1515 in GG 40480 of 9 December 2016, issued in terms of the Medicines and Related Substances Act 101 of 1965

³ Advertising and Promotion of Medicines, Medical Devices and IVDs (Health Products) (Updated June 2019)

⁴ Regulations related to medical devices and in vitro diagnostic medical devices (IVDs), Regulation 21(c).

⁵ General Regulations to Act 101/1965 42(5) 5

⁶ General Regulations to Act 101/1965 42 (5)(c)(i) and (ii)

⁷ Regulation 22 of the medical device regulations, of 21 May 2021, draft issued in terms of the Medicines and Related Substances Act 101 of 1965.

⁸ Regulation 20 (1)(a) of the medical device regulations, GN 1515 in GG 40480 of 9 December 2016, issued in terms of the Medicines and Related Substances Act 101 of 1965.



CHAPTER 16: ENFORCEMENT OF THE CODE

16.1 IPASA Members

16.1.1 The MCA has the power to adjudicate complaints about Innovative Pharmaceutical Association of South Africa (IPASA) members in respect of articles 7.5.1.1 and 7.5.1.2 of the IFPMA Code. Chapter 16 also applies to the adjudication of these complaints.

16.2 General Principles

16.2.1 The MCA is recognised as the self-regulatory authority for the ethical Promotion of Health Products.

16.2.2 The MCA has the power to create the required enforcement mechanisms and sanctions as provided for in this Code and the Constitution and has all the powers necessary to ensure the efficiency and effectiveness of the self-regulatory mechanism.

16.2.3 The Executive Officer acts as the custodian of the enforcement processes described in this Code and the Constitution.

16.2.4 Non-members of the MCA may agree, in terms of the Constitution, to be subjected to the enforcement mechanisms created by the Code and the Constitution unless they are required by law to abide by them.

16.2.5 The version of the Code applicable at the time that conduct takes place, which is alleged to constitute a transgression of the Code, shall be used for purposes of enforcement of the relevant provisions of the Code during the complaints, adjudication and appeals processes.

16.3 Referral of Complaints

16.3.1 The MCA has the power to refer a complaint to any appropriate body or Regulatory Authority, where it is of the opinion that the complaint relates to any non-compliance with the Medicines Act or if it is unable to resolve the complaint and/or a Company does not comply with the ruling of any of the MCA's enforcement structures.

16.4 External Remedies

16.4.1 Any aggrieved party may, after exhausting all the internal remedies provided for in this Code, approach the appropriate body or Regulatory Authority or a court of law to resolve a matter, which it considers not to have been satisfactorily resolved.

16.4.2 A Person is not deprived of the right to obtain any interim relief in an appropriate court of law while pursuing the internal remedies.



16.5 Repeat Complaints Received by the MCA

- 16.5.1 The MCA shall not accept a complaint in respect of a particular section in relation to the same activity or the same material relating to the same Company, which has been the subject of previous complaints irrespective of the outcome of the previous complaint.
- 16.5.2 This prohibition shall not preclude an appeal against a ruling of an Adjudicating Committee.

16.6 Enforcement Structures

- 16.6.1 Panels of Experts are appointed by the Board in terms of the Constitution. These Panels serve as resources of expertise for the appointment of adjudicating, appeal and Ex Parte Committees in accordance with the Constitution.
- 16.6.2 Adjudicating Committees act as the enforcement structures of the first instance of the Code. An Adjudicating Committee is appointed from Panels of Experts by the Executive Officer when a complaint is lodged. The mandate of each Adjudicating Committee so appointed shall relate only to a single hearing of a specific complaint. Adjudicating Committees shall have the powers set out in Section 16.7.
- 16.6.3 Appeal Committees deal with appeals of rulings made by the Adjudicating Committees, and the non-compliance of Companies with rulings or undertakings in line with the Code. An Appeal Committee is appointed from Panels of Experts by the Executive Officer when an appeal is lodged. The mandate of each Appeal Committee so appointed shall relate only to a single appeal or hearing of a specific matter. Appeal Committees shall have the powers set out in terms of Section 16.8.
- 16.6.4 Ex Parte committees deal with the interpretation of questions relating to the application of the Code and/or the Guidelines in specific circumstances. An Ex Parte committee is appointed from the Panels of Experts by the Executive Officer when required. Disputes between Companies shall be explicitly excluded from the jurisdiction of Ex Parte committees.

16.7 Powers of an Adjudicating Committee

- 16.7.1 The Adjudicating Committee shall be entitled to adopt such procedures and formalities in respect of the adjudication of a complaint as it may determine in its sole discretion from time to time. This shall include the use of electronic mechanisms (e.g. teleconferencing, video-conferencing, etc.).
- 16.7.2 The Adjudicating Committee shall be entitled, in its sole discretion, to determine whether the adjudication of the complaint shall be paper-based or in the form of a face-to-face hearing where the relevant parties shall be entitled to appear in person and make oral submissions, depending on the complexity of the matter and/or the clarity of the information provided by the parties concerned.



- 16.7.3 The Adjudicating Committee may in its sole discretion and without hearing any party, postpone or adjourn any proceedings for such periods as it deems fit. Should this occur, the Executive Officer shall inform the parties accordingly.
- 16.7.4 The Adjudicating Committee shall be entitled to obtain independent expert opinion, or, request an independent person with the necessary expertise to appear before the committee to provide his opinion on a matter relevant to the case before it. The Adjudicating Committee shall share such independent opinion obtained with both the Complainant and the Respondent.
- 16.7.5 The Adjudicating Committee may resolve to take no action in respect of a complaint and shall make such a decision supported by written reasons, i.e. the Adjudication Ruling, where one or more of the following circumstances are applicable:
- 16.7.5.1 the Complaint does not fall within the mandate of the MCA, i.e. the conduct which is complained of cannot be resolved in terms of the Code;
 - 16.7.5.2 the length of time elapsing between the date of the occurrence of the conduct complained about and the date when the complaint was made is such that an adjudication is no longer practicable or desirable;
 - 16.7.5.3 the subject-matter of the complaint is trivial;
 - 16.7.5.4 the complaint is frivolous, vexatious, or not made in good faith;
 - 16.7.5.5 the Complainant no longer wishes to pursue the complaint.
 - 16.7.5.6 the complaint does not allege any facts which may constitute grounds for a remedy under the Code;
 - 16.7.5.7 the complaint relates to an activity or material of the Respondent, which has already been considered by the MCA;
 - 16.7.5.8 more than 3 (three) years has elapsed after the act or omission which is the cause for the complaint; or
 - 16.7.5.9 in the case of a course of conduct or continuing practice, more than 3 (three) years has elapsed after the date on which that conduct or practice ceased.
- 16.7.6 In matters where the Code has been contravened, the Adjudicating Committee shall have the power to impose on the Respondent any one or more of the sanctions outlined in the Sanction Policy Document as determined by the Board from time to time, with due consideration of the principles and guidelines in and the limits imposed by the Sanction Policy Document, including the factors



outlined in Section 16.7.6.1 for contraventions in respect of Advertising and/or Promotional Activities.

16.7.6.1 Without constraining the discretion of the Committee, in circumstances where the Respondent has been found to have contravened the Code in respect of Advertising and/or Promotional Activities, the Committee shall have consider to the following factors amongst others in deciding on a suitable sanction:

16.7.6.2 whether the publication or Promotional Activity has ceased;

16.7.6.3 how widely the offending material was distributed;

16.7.6.4 what steps have been taken to withdraw the published/issued material;

16.7.6.5 whether corrective statements have been issued;

16.7.6.6 whether the breach was deliberate, negligent or inadvertent;

16.7.6.7 whether there were/are safety implications;

16.7.6.8 whether the material or publication was/is misleading and the extent of this;

16.7.6.9 the manner in which the perceptions of HCPs or Consumers have been/will be affected;

16.7.6.10 whether commercial damage or harm has been caused, and the extent of this damage; and

16.7.6.11 whether the Respondent has previously breached the Code.

16.7.7 Should the Adjudicating Committee find the complaint to be trivial, vexatious, frivolous or not made in good faith, shall have the power to order the Complainant to pay such costs and expenses incurred by the MCA in respect of the complaints and/or adjudication process as it considers just and equitable in the circumstances. The Adjudicating Committee shall not have the power to make an order in respect of the payment by any party of the legal costs incurred by either the Complainant or the Respondent in respect of the complaints and/or adjudication processes.

Guideline to 16.7.7

Note 1:

The Committee can also order the Complainant to pay a fine as per guidance in the MCA Sanctions Policy document related to trivial, frivolous or vexatious complaints. An Adjudicating Committee shall have the power to adjudicate a complaint de novo in accordance with a ruling of an Appeal Committee.



16.8 Powers of an Appeal Committee

- 16.8.1 An Appeal Committee shall be entitled to adopt such procedures and formalities in respect of the determination of an appeal as it in its sole discretion may determine from time to time, which shall include the use of electronic mechanisms (e.g. teleconferencing, video-conferencing, etc.) as may be appropriate.
- 16.8.2 The Appeal Committee shall be entitled to determine in its sole discretion and, depending on the complexity of the matter, and/or clarity of information provided by the parties, whether the appeal shall take place in the form of either a paper-based determination of the appeal or a face-to-face hearing where the relevant parties shall be entitled to appear in person and make oral submissions.
- 16.8.3 The Appeal Committee may in its sole discretion and without hearing any party, postpone or adjourn any proceedings for such periods as it deems fit. Should this occur, the Executive Officer shall inform the parties accordingly.
- 16.8.4 The Appeal Committee shall be entitled to obtain independent expert opinion, or, request an independent person with expertise to appear before it and provide his opinion on a matter relevant to the matter before it. The Appeal Committee shall share such independent opinion obtained with both the Appellant and Appellee.
- 16.8.5 An Appeal Committee shall have the power to make one or more of the following decisions in respect of an appeal heard by it:
- 16.8.5.1 dismiss the appeal;
 - 16.8.5.2 uphold the appeal;
 - 16.8.5.3 impose any one or more appropriate sanctions as outlined in the Sanction Policy Document as determined by the Board from time to time, with due consideration of the principles and guidelines stipulated and any limits imposed by the Sanction Policy Document, as well as the factors outlined in Section 16.7.6.1 of the Code for contraventions in respect of Advertising and/or Promotional Activities;
 - 16.8.5.4 refer the matter back to the Adjudicating Committee for hearing of the matter de novo if the Adjudicating Committee has not taken any action in respect of a complaint as contemplated in Section 0 and the Appeal Committee has over turned the ruling of the Adjudicating Committee;
 - 16.8.5.5 order a party to pay all or a portion of the costs incurred by the MCA in connection with the appeal or any postponement thereof;



16.8.5.6 order that the prescribed appeal fee, or any portion of it, be forfeited, or refunded, having regard to the outcome of the appeal; and/or

16.8.5.7 direct that the matter be reported to an appropriate body or Regulatory Authority.

16.8.5.8 for purposes of clarity, it is specifically stated that the Appeal Committee shall not have the power to order the payment by any party of the legal costs incurred by either of the parties to the appeal in respect of the complaint, adjudication and/or appeal process.

16.8.5.9 Should the Appeal Committee find the complaint, the subject of the appeal, to be trivial, vexatious, frivolous or not made in good faith, the Appeal Committee shall have the power to order the party that lodged the complaint to pay such costs and expenses incurred by the MCA in respect of the complaints, adjudication and/or appeals process as the Appeal Committee considers just and equitable in the circumstances.

16.9 Company-to-Company Complaints Process

16.9.1 As a first course of action, Companies shall attempt to resolve an alleged transgression of the Code directly between themselves.

16.9.2 The complaint shall be submitted in writing by the Complainant to the Company Code Compliance Officer or another suitable senior person on the Respondent's side, describing the nature of the complaint and the section or sections of the Code alleged to have been contravened. A written response to the complaint shall be requested within 7 (seven) business days.

16.9.3 Where a response has been received and the complaint resolved, the matter shall be considered closed. The parties shall keep all documentation relevant to the complaint on record for a period of 5 (five) years.

16.9.4 The MCA considers a reasonable time to resolve the matter to be 15 (fifteen) Business days, but the timelines shall be determined by the parties.

16.9.5 Where the matter has been resolved between the parties, the Executive Officer may be provided with the names of the Companies involved and the alleged infringement with reference to the specific sections in the Code. This information shall be kept confidential and shall not be published. It shall be used solely for record purposes by the Executive Officer and to inform the Guidelines in respect of the specific section(s) of the Code or amendments required to the Code, as may be necessary.

16.9.6 Where a response is not received as envisaged in Section 16.9.2 or the complaint is not resolved to the satisfaction of any party, a formal complaint may be lodged with the MCA in accordance with Section 16.12.



16.9.7 A Company may justify the need for the process to be anonymous to the Executive Officer. Upon written approval by the Executive Officer, such Company may undertake the process described in Section 16.13 through a representative of its choice, who may raise any alleged contravention of the Code with the relevant Company (i.e. the Respondent), without divulging the name of the first-mentioned Company (i.e. the Complainant).

16.9.8 Where the alleged contravention is of such magnitude that issues of patient safety, are raised, a Company shall not be obliged to follow the process stipulated in Section 16.9 and may lodge a complaint directly with the MCA as provided for in Section 16.12.

16.10 General Rules Pertaining to Complaint and Appeal Documentation

16.10.1 All information and documents in respect of a complaint or appeal shall be clearly legible, in the format prescribed by the MCA from time to time, signed by the Company Code Compliance Officer or another authorised person, numbered and indexed and submitted to the MCA within the prescribed time periods.

16.10.2 It shall be the responsibility of the Complainant and Appellant to ensure that the prescribed forms are correctly completed and accompanied by all the necessary supporting documentation.

16.10.3 Where audio/audio-visual material is submitted this shall be clearly indicated in the documentation.

16.10.4 A complaint shall clearly set out the details of the Complainant, the Respondent, the complaint and the sections of the Code, allegedly contravened and shall be accompanied by the following:

16.10.4.1 proof that the parties have made all reasonable attempts to resolve the matter between themselves subject to Section 16.9;

16.10.4.2 supporting literature and any studies relied upon, where the complaint is based on scientific issues;

16.10.4.3 copies of any Advertising and/or Promotional Material and/or any other relevant material (such as invitations, agreements, correspondence, etc); and

16.10.4.4 any other information the Complainant considers relevant for the assessment of the complaint.

16.10.5 The Complainant shall provide the MCA with (4) four numbered and indexed copies of the complaint and the required documents as well as an exact electronic copy of the full submission.



16.10.6 Any submission or communication, other than the initial complaint and/or the initial lodging of an Appeal, may be done electronically by the relevant person, party or Committee.

16.10.7 The Executive Director shall submit all documents and communications related to a complaint, an appeal or another matter before an Appeal Committee or for the purposes of enforcement to the Company Code Compliance Officers of the various parties subject to Section 16.14. The Executive Officer may in his discretion submit all documents and communications in electronic format. Any submission or communication made electronically shall be deemed to have been received by the Company Code Compliance Officer of the receiving party on the date of dispatch unless otherwise proved by the receiving party.

16.11 Powers of the Executive Officer

16.11.1 The Executive Officer shall, on receipt of the complaint or appeal, determine whether:

16.11.1.1 the complaint or appeal is in the prescribed format and complete;

16.11.1.2 any of the grounds stipulated in Section 16.11.3 are present; and

16.11.1.3 the Respondent/Appellee is a member of the MCA or, if the Respondent/Appellee is not a member of the MCA, he has agreed to be subject to or is required by law to be subject to the Code enforcement processes.

16.11.2 Where the complaint or appeal is not in the prescribed format, is incomplete or deficient in any respect, the Executive Officer shall request the Complainant or Appellant to resubmit the complaint or appeal in the prescribed format and/or submit any outstanding information and documentation.

16.11.3 The Executive Officer may, after due consideration of the complaint, issue a notice of non-referral to the Complainant, where:

16.11.3.1 the complaint appears to be trivial, frivolous, vexatious or not made in good faith;

Guideline to Section 16.11.3.1

Note 1:

(a) The Complainant may refer / challenge the decision of the Executive Officer to not accept the complaint on trivial, frivolous or vexatious grounds. (16.11.6). The Executive Officer must then refer such referral / challenge to an Adjudicating Committee, which would follow the usual dispute resolution processes.

(b) The point about the trivial, frivolous, vexatious nature of the complaint must



then be raised as a preliminary point (Point in Limine) for the Adjudication Committee to rule on, before such committee proceeds with the merits of the complaint.

(c) Should the Complainant take the Adjudication Committee decision on appeal, the ordinary appeal procedures shall be followed as per Section 16.16.

16.11.3.2 the complaint does not allege any facts which may constitute grounds for a remedy under the Code;

16.11.3.3 the complaint is not within the mandate of the MCA;

16.11.3.4 the complaint relates to an activity or material of the Respondent, which has already been considered by the MCA;

16.11.3.5 more than 3 (three) years has elapsed after the act or omission which gave rise to the complaint; or

16.11.3.6 in the case of a continuing conduct or practice, if more than 3 (three) years has elapsed after the date on which this conduct or practice ceased.

16.11.4 In any case where the Executive Officer decides to take no action, or no further action on a complaint, the Executive Officer shall inform the Complainant of that decision in writing and the reasons for it.

16.11.5 Where a complaint is received in relation to an activity or material of the Respondent, which has already been considered by the MCA, the Executive Officer shall refer the Complainant and Respondent to the outcome of the previous complaint.

16.11.6 An appeal (referral / challenge) may be lodged against a decision of the Executive Officer in terms of Section 16.11.3 as set out in Section 16.16.

16.11.7 Where the Executive Officer or another enforcement structure of the MCA has found a complaint to be trivial, frivolous, vexatious or not made in good faith, then no structure within the MCA shall hear a complaint from that Complainant for a period of 12 (twelve) months from the date of such finding unless the decision of the Executive Officer was overturned by an Appeal Committee.

Guideline to Section 16.11.7

Note 1:

For the sake of clarity, either the Executive Officer or an Adjudication Committee can find that a complaint was trivial, frivolous or vexatious.

16.11.8 The Executive Officer may in his sole discretion and on written application by a party, on good cause shown, and on such terms and conditions as he may



determine, including the need to ensure the expeditious resolution of Code matters, and in the interests of justice and fairness, extend or shorten the time periods referred to in the Code, including condoning the submission of documents outside of the prescribed time periods, after considering the impact on both parties of such extension/shortening of the said time periods.

16.11.9 The Executive Officer may waive any complaint or appeal fees of any party in accordance with the policy determined by the Board from time to time.

16.12 Lodging of a Formal Complaint with the MCA

16.12.1 Any Person may lodge a complaint in the prescribed format with the MCA against a Company, which has allegedly contravened a section(s) of the Code provided that where the Company is not a member of the MCA, it has agreed to be subjected to the Code enforcement mechanisms or is by law required to subject itself to these mechanisms.

16.12.2 A complaint shall be considered valid if it is within the MCA mandate and meets all the requirements stipulated in Chapter 16 and subject to Section 16.11.3.

16.12.3 A complaint fee shall be payable at the time of submission. The Executive Officer shall advise the Complainant of the prescribed fee applicable at the time.

16.12.4 The date on which a valid complaint is received by the Executive Officer or the date of receipt of the complaint fee, whichever occurs last, shall be the date of commencement of the enforcement process, i.e. the Complaint Log Date.

16.12.5 A Complainant may at any time withdraw the complaint by written notice to the Executive Officer. In this case, the complaint fee shall be forfeited.

16.13 Nominated Complainant

16.13.1 Where the Executive Officer is of the opinion that there has been a contravention of the Code, he shall immediately bring this to the attention of the Board which shall appoint from among the members of the MCA/Panels of Experts, an individual, who is not conflicted, as the Nominated Complainant in the matter.

16.13.2 The Nominated Complainant shall act as Complainant and the provisions of the Code shall apply mutatis mutandis to the Nominated Complainant, but no complaint fee shall be payable by him and the Adjudicating Committee shall not be entitled to order the payment of MCA costs by the Nominated Complainant.

16.13.3 The Nominated Complainant or another person so appointed by the Board from amongst the members of the MCA or the Panels of Experts shall act as Appellant (i.e. the Nominated Appellant) upon the instruction of the Board



where it decides that a ruling by an Adjudicating Committee in respect of a complaint made by a Nominated Complainant shall be appealed. The provisions of the Code shall apply mutatis mutandis to the Nominated Appellant, but no appeal fee shall be payable by him and the Appeal Committee shall not be entitled to order the payment of the MCA's costs by the Nominated Complainant.

16.14 Exchange of Complaint-Related Documentation between the Parties

- 16.14.1 The Executive Officer shall, within 2 (two) Business Days of the Complaint Log Date, send a copy of the complaint to the Respondent's Company Code Compliance Officer and request a response within 7 (seven) Business Days.
- 16.14.2 The Executive Officer shall send the Respondent's reply, if any, including copies of all supporting documents, unless these documents are confidential in terms of Section 5.9.8 of the Code, to the Complainant, requesting a reply within 7 (seven) Business Days.
- 16.14.3 The Executive Officer shall send a copy of the Complainant's reply, if any, to the Respondent.
- 16.14.4 The exchange of documents shall then be closed subject to the provisions of Section 16.15.6 and the complaint shall proceed to adjudication.
- 16.14.5 The Executive Officer shall compile a Complaint Pack, comprising the complaint with all the supporting documentation and other documents exchanged between the parties, for the Adjudicating Committee.

16.15 Adjudication Process

- 16.15.1 In line with the Constitution, the Executive Officer shall appoint an Adjudicating Committee, to adjudicate the complaint. The appointment of the committee shall be made within 2 (two) business days of the closure of the exchange of documents.
- 16.15.2 Once the Adjudicating Committee has been appointed, an opportunity shall be provided to both parties to raise concerns over any potential conflicts of interest of relating to any committee member with the matter at hand. Only matters, which may impact on the impartiality or objectivity of the Committee, shall be considered when finalising the appointment of the committee. Both parties shall have 2 (two) Business Days from the receipt of the details of the committee members to raise concerns over any potential conflicts of interest in such committee members.
- 16.15.3 The Adjudicating Committee shall be independent and impartial and shall perform its functions in good faith and without fear, favour, bias or prejudice.
- 16.15.4 Within 2 (two) Business Days of the finalisation of the Adjudicating Committee, the Executive Officer shall provide the Complaint Pack, in either



hard copy or digital format. The document must be assembled in an appropriate order with an index to consecutively numbered pages, to the members of the Adjudicating Committee.

- 16.15.5 Any party may submit a written request through the Executive Officer to the chairperson of the Adjudicating Committee to supplement any of the information or documents submitted by the MCA in connection with the complaint stating the reasons for such request and the value that such information or documents would add to the adjudication of the complaint. The other party shall be given an opportunity to state its position with respect to such a request.
- 16.15.6 Supplementary information and documents shall only be permitted in exceptional circumstances and on the terms and conditions stipulated by the chairperson of the Adjudicating Committee through the Executive Officer. The decision of the chairperson of the Adjudicating Committee shall be final and binding on all parties. Any supplementary information or documents, which may be submitted, shall be provided to the other party subject to the provisions of Section 5.9.8 and this party may respond to such information or documents within the timeframes stipulated by the chairperson of the Adjudicating Committee.
- 16.15.7 The chairperson of the Adjudicating Committee may request the Respondent to submit copies of the proof of approval authorising the material/event, which is the subject of the complaint, as well as copies of briefing instructions furnished to Company Representatives of the Respondent, within a specified time, where this is relevant to the complaint.
- 16.15.8 As provided for in the Constitution, the Executive Officer shall not be involved in the hearing, deliberations and/or discussions of the Adjudicating Committee.
- 16.15.9 The Executive Officer shall set a date for the hearing of the complaint, as soon as reasonably possible, but within 14 (fourteen) business days of the finalisation of appointment of the Adjudicating Committee or the final date for the submission of supplementary information/documents, whichever occurs last.
- 16.15.10 Where the parties are required to appear in person before the Adjudicating Committee, the date, time and place for the hearing of a complaint shall be determined by the Executive Officer, in consultation with the Adjudicating Committee, and shall be made known in writing to the parties concerned by the Executive Officer not less than 12 (twelve) business days before such hearing.
- 16.15.11 The Adjudicating Committee shall adhere to the principles of natural and administrative justice, which shall include:
- 16.15.12 affording all parties the opportunity to be heard, which may be paper-based or in person at the discretion of the Adjudicating Committee as provided for in this Chapter 16; and



- 16.15.13 ensuring that the members of the Adjudicating Committee are not conflicted with regard to the matter before it.
- 16.15.14 The Adjudicating Committee shall interpret and apply the Code in accordance with the interpretation principles outlined in the Code.
- 16.15.15 No party shall be entitled to legal representation at the adjudication proceedings unless the Adjudicating Committee, in its sole discretion and having regard to the complexity and seriousness of the matter and/or the sanction, which may be imposed, determines that legal representation is desirable. In this case a party shall be entitled to legal representation by one legally qualified person only.
- 16.15.16 At adjudication proceedings, in the case of face-to-face hearings, the parties shall be entitled to call witnesses with the permission of the chairperson in his sole discretion, where this is deemed necessary.
- 16.15.17 The parties shall not be allowed to cross-examine one another, or the witnesses called by the other party, but shall be allowed to challenge any facts presented by any party or witness.
- 16.15.18 The Adjudicating Committee shall make a decision, including the imposition of a sanction(s) where appropriate and supported by written reasons, within 7 (seven) Business Days of the date of the conclusion of the hearing, or the date upon which the adjudication was finalised in the case of a paper-based adjudication. The Adjudication Ruling shall be in the format prescribed by the Board and all committee members shall be required to sign it.
- 16.15.19 The Executive Officer shall communicate the Adjudication Ruling to both parties.
- 16.15.20 The Adjudication Ruling shall be final and binding and no further clarification may be sought from and/or correspondence entered into with the Adjudicating Committee or any member of it by any party.

16.16 Lodging an Appeal

- 16.16.1 Any party aggrieved by an Adjudication Ruling may appeal against such Ruling by giving written notice of the appeal (Notice of Appeal) in the prescribed format to the Executive Officer within 7 (seven) Business Days from the date on which the Adjudication Ruling was made.
- 16.16.2 The Notice of Appeal shall specify the portion of the Adjudication Ruling, including the sanction, which is the subject of the appeal, and set out the full grounds for the appeal. This shall be accompanied by the prescribed appeal fee and all the necessary supporting documents.
- 16.16.3 The Appellant and the Appellee shall be bound by the Adjudication Ruling and confined by it and shall not be entitled to introduce new evidence save with



the permission of the Appeal Committee, which in its sole discretion shall determine such matter and on such terms and conditions as it may deem fit.

16.16.4 The operation of any Adjudication Ruling, which is the subject of an appeal under Section 16.16 shall be suspended pending the decision of the Appeal Committee or the withdrawal of the appeal by the Appellant.

16.17 Exchange of Appeal-Related Documentation between the Parties

16.17.1 The Executive Officer shall within 2 (two) Business Days from receipt of a complete Notice of Appeal or payment of the appeal fee, whichever occurs last, send a copy of the Notice of Appeal to the Appellee's Company Code Compliance Officer and request a response to it within 7 (seven) Business Days.

16.17.2 The Executive Officer shall send the Appellee's reply, where applicable, including copies of all supporting documents, unless these documents are confidential in terms of Section 5.9.8 to the Appellant, requesting a reply within 7 (seven) Business Days.

16.17.3 The Executive Officer shall send a copy of the Appellant's reply, where applicable, to the Appellee.

16.17.4 The exchange of documents shall then be closed and the matter shall proceed to appeal.

16.17.5 The Executive Officer shall compile an Appeal Pack comprising the following documents for the Appeal Committee:

16.17.5.1 All documents, considered by the Adjudicating Committee; including audio/audio-visual material, pertaining to the original complaint;

16.17.5.2 The Adjudication Ruling; and

16.17.5.3 The Notice of Appeal, the Appellee's response and Appellant's reply, where applicable.

16.17.6 An appeal may be withdrawn by the Appellant at any time by written notice to the Executive Officer in which case the appeal fee shall be forfeited.

16.18 Appeal Hearings

16.18.1 The Executive Officer shall appoint an Appeal Committee in terms of the Constitution within 2 (two) Business Days of the closure of the exchange of documents.

16.18.2 Once the Appeal Committee has been appointed, both parties shall be given the opportunity to raise concerns over any potential conflicts of interest relating to any committee member dealing with the matter at hand. Only matters, which may impact the impartiality or objectivity of the committee, shall



be considered in finalising the appointment of the committee. Both parties shall have 2 (two) Business Days from receiving the details of the committee members to raise concerns over potential conflicts of interest of such committee members.

- 16.18.3 The Executive Officer shall submit a hard copy at least of the Appeal Pack to all the members of the Appeal Committee once the appointment of the committee has been finalised.
- 16.18.4 The Executive Officer shall set a date for the hearing of the appeal, as soon as reasonably possible, and within 14 (fourteen) Business Days of the finalisation of the appointment of the Appeal Committee.
- 16.18.5 Where the parties are required to appear in person before the Appeal Committee, the date, time and place for the appeal hearing shall be determined by the Executive Officer, in consultation with the Appeal Committee, and shall be made known in writing to the parties concerned by the Executive Officer no less than 12 (twelve) Business Days before such hearing.
- 16.18.6 As provided for in the Constitution, the Executive Officer shall not be involved in the hearing, deliberations and/or discussions of the Appeal Committee.
- 16.18.7 The Appeal Committee shall be independent and impartial and shall perform its functions in good faith and without fear, favour, bias or prejudice.
- 16.18.8 The Appeal Committee shall adhere to the principles of natural and administrative justice, which shall include:
- 16.18.8.1 Affording all parties, the opportunity to be heard which may be paper-based or in person at the discretion of the Appeal Committee as provided for in this Chapter 16; and
 - 16.18.8.2 Ensuring that members of the Appeal Committee are not conflicted with regard to the matter before it.
- 16.18.9 The Appeal Committee shall interpret and apply the Code in accordance with the interpretation principles outlined in the Code.
- 16.18.10 No Party shall have legal representation at an appeal hearing unless the Appeal Committee, in its sole discretion and having regard to the complexity and/or seriousness of the matter amongst others and the sanction(s) which could be imposed, determines that legal representation is desirable in light of the above and other relevant factors. In such case a party shall be entitled to legal representation by one legally qualified person only
- 16.18.11 The Appeal Committee may, in its sole discretion, hear further evidence or receive any documents on such terms and conditions as it may decide.
- 16.18.12 The Appeal Committee shall make a decision, including the imposition of a sanction(s) where applicable and supported by written reasons i.e. the Appeal



Ruling, within 7 (seven) Business Days of the date of the conclusion of an appeal hearing or the date upon which the appeal was decided in the case of a paper-based appeal. The Appeal Ruling shall be in the format prescribed by the Board and all committee members are required to sign it.

16.18.13 The Executive Officer shall communicate the Appeal Ruling to both parties.

16.18.14 The Appeal Ruling shall be final and binding subject to the provisions of Section 16.3 and no further clarification may be sought from and/or correspondence entered into with the Appeal Committee or any member of it by any party.

16.19 Validity of Proceedings

16.19.1 The failure by any party, without good cause shown, to reply to a request to respond to a complaint, provide further evidence of an alleged contravention of the Code, make any submission or presentation and/or attend a meeting or hearing as envisaged by this Chapter of the Code, shall not invalidate any proceedings undertaken in terms of the Code.

16.19.2 Should a party not abide by the prescribed timeframes where no extension has been granted, and/or no condoning of late submissions has occurred as provided for in the Code, and/or should a party not appear before a relevant Committee as may be required, a ruling may be made by the relevant Committee on the evidence before it, including a ruling against the party who is in default, where this is appropriate and applicable.

16.19.3 Should any member of an Adjudicating or Appeal Committee be absent at any time when the committee meets to deliberate on the matter at hand or during the adjudication or appeals process, the Executive Officer shall in his sole discretion be entitled to appoint another person from the Panels of Experts as a member of the relevant committee, with all the rights and responsibilities relevant to the position, until the conclusion of the adjudicating or appeals proceedings. The parties shall be given an opportunity to object to the replacement committee member on grounds of potential conflict of interest.

16.19.4 In line with the provisions of the Constitution, the MCA shall have the power to outsource any part or all of the enforcement processes provided for in the Code to any competent body. The process undertaken, or outcome facilitated or achieved by such an outsourced body shall be valid and enforceable in all respects.

16.20 Publication of Outcomes

16.20.1 The Executive Officer shall be entitled to publish a summary of any matter heard by an Adjudicating or Appeal Committee on the MCA website. This shall be done in consultation with the chairperson of the relevant Committee and in his absence by another member of the Committee provided that a matter heard by an Adjudication Committee shall be published only no appeal has been



lodged within the prescribed time period or after an appeal in respect of the matter has been concluded.

16.20.2 Where a breach of the Code occurred, the identity of the Companies involved (but not the individuals or panellists) will be published.

16.21 Non-Compliance with Rulings or Undertakings

16.21.1 When an undertaking has been given by a Company in relation to a ruling under the Code or when a ruling is made under the Code, the Company concerned shall ensure compliance with that undertaking and/or ruling.

16.21.2 The party against whom a ruling was made by an Adjudicating or Appeal Committee shall notify the MCA in writing of measures implemented while also providing copies of any supporting documentation requested by the MCA. This communication shall be submitted to the MCA within 14 (fourteen) days of the date by which the party has complied with all aspects of the ruling, including compliance with any sanction imposed. Failure to comply with this requirement shall constitute a failure to comply with the ruling.

16.21.3 Any fine imposed on a party by an Adjudicating or Appeal Committee shall be paid to the MCA within 30 (thirty) Business Days of the relevant ruling.

16.21.4 The Executive Officer shall have the right to refer any alleged non-compliance with an undertaking or a ruling by a Company to an Appeal Committee for adjudication after allowing the alleged offender the opportunity to respond to the alleged non-compliance.

16.21.5 A complaint against any alleged non-compliance with a ruling, i.e. the Non-Compliance Complaint, may be lodged with the Executive Officer by any Person, including a Nominated Complainant, based on an alleged non-compliance with an undertaking/ruling by an Adjudicating or Appeal Committee. The Non-Compliance Complaint shall indicate which part of the relevant ruling has not been complied with and be fully substantiated, providing full details about the nature of the non-compliance.

16.21.6 The Executive Officer shall provide a copy of the Non-Compliance Complaint to the alleged offender who shall within 7 (seven) Business Days provide a written response to the Executive Officer.

16.21.7 The Executive Officer shall convene an Appeal Committee, to decide on the Non-Compliance Complaint, which may not comprise the same members who adjudicated the complaint or heard the appeal on the matter, where applicable.

16.21.8 Without delay upon the expiry of the 7 (seven) business day period during which the alleged offender may submit a response to the Non-Compliance Complaint, the Executive Officer shall provide the Appeal Committee with



copies of the Non-Compliance Complaint, the response by the alleged offender where applicable, as well as the relevant ruling or undertaking.

16.21.9 Neither the Complainant nor the alleged offender shall have the right of appearance before the Appeal Committee, unless permitted by the Appeal Committee in its sole discretion and in exceptional circumstances.

16.21.10 The Appeal Committee shall accept the relevant ruling or undertaking as valid and shall not reopen the matter, consider the matter de novo and/or hear any evidence or argument relating to the validity or accuracy of the ruling or undertaking previously made.

16.21.11 Within 7 (seven) Business Days of receipt of the relevant documentation, the Appeal Committee shall take a decision, supported by written reasons, whether there has been a failure to comply with an adjudication or appeal ruling.

16.21.12 The Appeal Committee may:

16.21.12.1 refer the matter to any appropriate body or regulatory authority for consideration, including a recommendation that legal action be considered by the Complainant or the MCA against the alleged offender; and/or

16.21.12.2 impose any further appropriate sanction or sanctions, on the alleged offender; as outlined in the Sanction Policy Document and determined by the Board from time to time, with due consideration of the principles and guidelines and in any limits imposed in the Sanction Policy Document; and

16.21.12.3 direct the Executive Officer to publish a summary of its decision on the MCA website, including the reasons for such a decision.

16.21.13 For the purposes of clarity, it is specifically stated that an Appeal Committee does not have the power to order the payment of the legal costs by any party incurred by the other party in respect of the matter before it.

16.22 Ex Parte Opinions

16.22.1 A member or a non-member of the MCA or a trade association representing members of the MCA (Applicant) may make an Ex Parte application to the MCA for an advisory opinion in relation to the application of the Code and/or Guidelines in a specific circumstance upon payment of the prescribed fee and in the prescribed format.

16.22.2 The Executive Officer shall appoint an Ex Parte Committee to provide the opinion.

16.22.3 It is specifically stated that should a complaint be lodged in respect of the matter, which is the subject of the advisory opinion, no member of the Ex Parte



Committee which provided the advisory opinion shall sit on the Adjudicating or Appeal Committee to deliberate on the matter.

- 16.22.4 Ex Parte matters shall be undertaken in writing, provided that the Ex Parte Committee may request further information and/or clarity from the Applicant as deemed necessary.
- 16.22.5 An Ex Parte Committee may refuse to accept a request for an advisory opinion on the basis that the Applicant is attempting to address a dispute with another Company and/or on the basis that it is using the Ex Parte process to avoid lodging a complaint or an appeal.
- 16.22.6 In its consideration of the Ex Parte request, the Ex Parte Committee shall:
 - 16.22.7 consider rulings previously made by Adjudicating and Appeal Committees (where applicable) in respect of the matter under consideration;
 - 16.22.8 confine itself to the questions posed by the Applicant, i.e. whether a particular activity is permitted in terms of the Code and/or Guidelines, within the circumstances as outlined by the Applicant; and
 - 16.22.9 provide a written analysis and application of the Code and/or Guidelines to the facts, a conclusion and the reasons for the conclusion.
- 16.22.10 It is specifically provided that when the Ex Parte Committee issues an advisory opinion, such an opinion shall be for guidance purposes only and shall not be binding on any Adjudication or Appeal Committee when adjudicating a complaint or hearing an appeal on that or a similar matter. The Executive Officer may, however, use advisory opinions to inform the Guidelines and may publish the opinions on the MCA's website without giving details of the parties or Ex Parte Committee members involved.



CHAPTER 17: TRADE ASSOCIATION AFFILIATION

17.1 Trade Associations involved in development of the Code

Innovative Pharmaceutical Association of South Africa (IPASA)
Pharmaceuticals Made in SA (PHARMISA)
Self-medication Manufacturers Association of SA (SMASA)
Southern African Laboratory Diagnostics Association (SALDA)
The South African Animal Health Association (SAAHA)
South African Medical Device Industry Association (SAMEDI)

17.2 Trade Associations and Companies represented by the MCA since 2021

Independent non-aligned members (Independents)
Innovative Pharmaceutical Association of South Africa (IPASA)
Pharmaceuticals Made in SA (PHARMISA)
Self-Care Association of South Africa (previously SMASA)



CHAPTER 18: RECORD OF UPDATES TO THE CODE

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: Changed Health Products to Medicines, IVD, Medical Devices; moved definitions to end of document, definition for Promotional aid and material, Update to ABPI code (Section 7); added MSL for Pharma; patient support groups added; added icons for application	February 2013
Version 3: Application of Code Section 24.20 Enforcement: Section 54 Lodging a complaint; 55 Nominated complaints; 56 Adjudication closed process, not a hearing hence no representation including legal; Section 59 – closed meeting	4 March 2013
Version 4: Added proxy complaint process	14 March 2013
Version 5: Part D changed in line with the Constitution;	28 March 2013
Version 6: Added definition of business 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 align with Constitution	28 May 2013
Version 9: Updated to align with updated international codes. Part A: sections 5.1; 7.1; 7.13; 18.5; 18.6; 18.8 (Patient registries), 19.4.2; 20; 22.2	November 2014



<p>Part B: 25.2; 25.5; 25.9; 25.11; 25.15, 25.22; 25.23;</p> <p>Part C: Deleted Sections 42; 44; 45; 46; 47 – refer to Part A and B</p> <p>Part D: Note: timelines in multiples of 7; business days changed to working days;</p> <p>Section 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</p>	
<p>Version 10:</p> <p>Updated to accommodate complementary and alternative Medicines (CAMs) and the Health Products Association (HPA).</p> <p>Minor typographical changes as well as changes summarised in the change summary.</p> <p>The 2016 Code Changes include the following:</p> <p>Date: The new dates to be reflected on the Code will be November 2016 as per the AGM</p> <p>Introductory paragraph: 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.</p> <p>Glossary: Definition of Company Code Compliance Officer amended to limit the authorisation to matters of Code compliance.</p> <p>Definition of Complementary Medicines included; Complementary Medicines means Complementary Medicines as defined in the Medicines and Related Substances Act 101 of 1965 as amended, and Regulations.</p> <p>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.</p> <p>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.</p> <p>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</p> <p>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).</p> <p>Definition for Council of Clinical Engineers; Definition has changed the wording institutions, to healthcare facilities.</p>	<p>November 2016</p>



<p>Definition of Honorarium; Additional alternate wording included, or alternatively Fee for Service, and removes the limitations on payment to a professional.</p> <p>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.</p> <p>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.</p> <p>Application and interpretation</p> <p>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.</p> <p>Addition and deletion of contents listing products not covered by the Code;</p> <p>Deletions:</p> <p>Trade catalogues to suppliers including price lists</p> <p>Complementary Medicines</p> <p>Addition:</p> <p>Sampling</p> <p>2.5 Scope of Application to include complementary and alternative Medicines;</p> <p>The word shareholders in the industry has been included,</p> <p>The marketing and Promotion of self-medication products to HCPs now includes complementary and alternative Medicines (CAMS)</p> <p>The marketing and Promotion of self-medication products to the public now includes complementary and alternative Medicines (CAMS).</p> <p>This change is pulled through into Part A and B of the Code.</p> <p>Part C Medical Devices</p> <p>A more concise statement on Part C binds the marketing and Promotion Medical Devices and IVDs to Parts A and B of the Code except where otherwise indicated in Part C.</p> <p>Part A of the Code</p> <p>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</p>	
--	--



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
Professional Information.

7.11 Use of the word “new”

This section 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 HCPs

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 cash or a cash equivalent
(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 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 their 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 section 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 for ensuring timeous 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 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



<p>Executive Officer shall in his/her unconstrained 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.</p>	
<p>Version 11: June 2018</p> <p>Complete rewrite of the Code to improve flow, removing ambiguity, contradictions and duplication of content.</p> <p>Alignment of the Code Guidelines to the new format.</p> <p>This has resulted in a Code that integrates common principles pertaining to Promotion of health products to the public and to HCPs into a single flowing document.</p> <p>Greater detail has been added to the section on enforcement to align with the Constitution and facilitate adherence to procedures.</p> <p>Policy changes introduced:</p> <p>The prohibition against the use of celebrities has been removed.</p> <p>A maximum total value for HCP competitions has been introduced (R40 000 per competition)</p>	<p>June 2018</p>
<p>Version 12: 25 June 2019</p> <p>Clarity given to the relationship between the words advertising, marketing and promotion, and a definition for "Promotion" has been added.</p> <p>General editorial corrections.</p> <p>Definition of consumer edited to remove "which includes marketed and advertised" to align with new definition of Promotion.</p> <p>Definition of "Company" was updated.</p> <p>The words "Scheduled substances" have been included in the definition of Health Products.</p> <p>Chapter 2: The Objectives of the MCA have been removed from the Code and are now described in the MCA Constitution.</p> <p>Section 5.5.2.7: "Regulatory Authority" has been replaced with "the Medicines Regulatory Authority".</p>	<p>June 2019</p>
<p>Code & Guideline Version 13: 2020 Revision approved at MCA AGM 23 July, 2020</p> <p>Alignment of definitions with the National Health Act 61 of 2003 2.8 of glossary, 5.2.12</p> <p>Insertion of definition of Health Establishment from the NHI 3.23 and section 5.2.12</p> <p>Insertion of definitions for Social Media and Social Media Influencer 3.49. 3.50.</p> <p>Insertion of guidelines; "Principle-based decision-making" policy in the Code 3.1 – 3.2</p> <p>Insertion of guidance; Determination of FMV 3.3 – 3.4</p>	<p>July 2020</p>



<p>Addition of requirement; Board, CTAC and Panellists to be Code certified 4.2.2</p> <p>Insertion of policy and Guidelines on Influencer marketing 5.10.3</p> <p>Addition of Section 7.1.3 on sponsorship in HCPs facilities</p> <p>Chapter 10; updated table Guideline note 1; 10.1</p> <p>Chapter 11; moved note 4 in 11.1.2 to 11.1.1 note 3</p> <p>Guideline to S14.1 and 2 (table)</p> <p>Addition of 16.1.5 to provide for MCA to adjudicate IPASA-specific complaints.</p> <p>Combine Code & Guidelines into a single document.</p>	
<p>Code & Guideline Version 14</p> <p>Addition of acronyms</p> <p>Amendments in respect of entire Code to align with Legislation (POPI Act)</p> <p>Reordering Chapter 3 to improve meaning and give context</p> <p>3.7 consolidating record keeping requirements in one place</p> <p>Editorial to improve clarity</p>	<p>June 2021</p>
<p>Code & Guideline Version 15</p> <p>Proposed changes</p> <p>3.47 Addition of Definition for Reimbursement Service</p> <p>3.5.4 Addition of "Social Media" to list of third parties for which companies are responsible in respect of product information disseminated.</p> <p>4.5.3 Addition of cross reference</p> <p>5.10.7.3.2 Addition of cross reference</p> <p>5.10.3.8 Addition of cross-reference</p> <p>5.19.8 Addition of cross-reference</p> <p>Guideline to 11.1.1, note 2, line 11 correction to reference</p> <p>Delete Note 4 of 11.2 – duplication</p> <p>Chapter 15 Insertion of CTAC approved incidental notes to support learning and Code certification assessment for Medical Device representative.</p> <p>16.6.2 and 16.6.3 corrections</p>	<p>July 2022</p>
<p>Code V 16 Changes</p> <p>2.1 Glossary:</p> <p>Draft definitions relating to Category D medicines, Discipline specific medicines and health products: Provision is made for accommodating anticipated changes to the regulation of complementary medicines. Exact</p>	<p>2023</p>



changes to be confirmed when regulations are promulgated. (Category D, Discipline Specific, Health Supplements)

Added to give clarity:

3.4.2.1

The Code provides for the contracting of social media influencers at FMV. All promotion done by the social media influencer shall comply with the Medicines and Related Substances Act. The paid partnership and company involvement shall also be transparent.

3.4.2.3

An HCP can be contracted as a social media influencer. The HCP cannot however promote a specific Health Product (thus no mention of a Health Product can be made by the HCP to the consumer). They are only allowed to promote disease awareness and educate the public.

3.4.2.4

If an HCP is contracted as a social media influencer, the paid partnership should be transparent and should not be misleading.

5.6.2.1

form part of the Promotional Material (with the exception of Promotional Aids-and/or elements-which do not contain Promotional claims) and shall not be supplied separately;

5.10.1.3

The name, photograph, film, video, television or radio Advertisement, or any other reproduction of an HCP shall not be used in any way intended to infer recommendation by any doctor, pharmacist or other HCP of a specific Health Product.

5.10.1.4 The use of HCPs for Promotion, Promotional material, endorsements or testimonials should take place within the scope set by the professional codes applicable to such HCPs. Refer to Note 3 below.

Note 3 to 5.10.1

Note 3: Representations from HCPs

(The following extracts from the HPCSA guidelines are included for information and guidance in applying the MCA Code.

The HPCSA ethical rules give guidance on registered practitioners advocating or promoting the use of any medicines or medical devices in terms of ethical rule 23 of the Ethical Rules document.

Rule 23 states:

23(1) A practitioner shall not participate in the manufacture for commercial purposes, or in the sale, advertising or promotion of any medicine or medical device or in any other activity that amounts to selling medicine or medical devices to the public or keeping an open shop or pharmacy,



23(2) "A practitioner shall not engage in or advocate the preferential use or prescription of any medicine or medical device which, save for the valuable consideration he or she may derive from such preferential use or prescription, would not be clinically appropriate or the most cost-effective option."

Note 4: Reporting unprofessional behaviour of persons registered with the HCP:

Any unprofessional conduct by HPCSA registered practitioners should be reported to the HPCSA for investigation, please follow the link:

<https://hpcsaonline.custhelp.com/app/home> to formally lay a complaint against the registered practitioner/s on the HPCSA's online portal in order for the matter to be considered and a determination be made by the relevant Professional Board.

7.1.2 with the addition of "unless excluded from s18A of the Medicines Act in terms of s36 of the Medicines Act." This change is intended to add clarity.

Note 1 and 2 to 8.2.1

Note 1: Banded pack for Schedule 0 products

Banded packs are permissible.

- 1. The products banded together must be Schedule 0 products but may be different dosage forms or different products.*
- 2. The products must also be available for sale as single items so as not to exclusively force purchase of the banded products.*
- 3. Banded packs must comply with legal requirements e.g. Banding packs of paracetamol may result in the combined packs exceeding the maximum paracetamol limit in a pack for a Schedule 0 and as such will not be permissible.*

Note 2: Basketing promotions for Schedule 0 products

Basket promotions are permissible (products are not banded together but sold separately).

- 1. The products promoted together must be Schedule 0 products, but may be different dosage forms or different products.*
- 2. As S0 medicines are exempted from bonusing, discounting and rebating (S18A), it is permissible to have promotions such as "buy two products and pay a discounted price" or "buy three for the price of two".*

Guideline to Section 9.2 Note 1: to Section 9.2;

Until such time as the legislation around the control of Complementary /Category D Medicines (Discipline-specific medicines and Health Supplements) is finalised and implemented by SAHPRA, the MCA Code sections 9.2.1.1 and 9.2.1.3 on Consumer Competitions will not apply to Category D medicines.



<p>10.1 Note 4. Re-insertion of the following phrase at the beginning of the section:</p> <p>Companies may sponsor business class travel for HCP's only for: [this clause had fallen out of the Code erroneously at v12 and is needed in order to make sense of the note].</p> <p>10.1.1 Note 6 Insertion of</p> <p><i>Business class travel may however be provided for flights with flying time longer than 6 hours</i></p> <p>10.1 Note 9 Insert at end:</p> <hr/> <p>No hospitality can be provided to Health Care Professionals attending individually a virtual third-party organised event or a company organized event. Hospitality can be provided to a group of HCPs attending a virtual event together, organised by a member company because this can be considered a face-to-face meeting</p>	
<p>Principle Code changes 2024 Version 17 (Minor & editorial changes not showing here)</p> <p>3.4 Insertion of definition for Artificial intelligence: Artificial Intelligence (AI), means the ability of a digital computer or computer-controlled robot to perform tasks commonly associated with intelligent beings. (Brittanica)</p> <p>5.2.13 Clarity provided for direct-to-consumer promotions: Statements, representations or tie-off lines for direct to consumer promotions shall not be made for the purpose of encouraging Consumers to ask their HCPs to prescribe/recommend a specific Health Product. It is recommended that consumers be encouraged to seek advice from their HCPs.</p> <p>5.2.15 Principles to be applied in respect of Artificial Intelligence. Artificial Intelligence: (AI) means the use of artificial intelligence per se in the marketing and promotion of health products is not prohibited by the Code. It is important for company compliance officers to ensure that the Law and the Code's ethical principles are complied with when applied to AI generated content.</p> <p>Guidelines to new point no 5.2.15.</p> <p>Principles to be applied in making compliance decisions related to AI-generated content.</p> <ol style="list-style-type: none">1. Accountability means taking responsibility for the use of AI systems used by the company. This includes proper governance, the use of safeguards/controls that address potential problems and having plans in place to deal with unexpected problems.2. Human control means that there should be an appropriate level of human supervision and influence based on the assessed risk to individuals. AI should not be given total freedom in making decisions.3. Fairness and minimisation of bias4. Privacy, security, and safety by design	<p>2024</p>



<p>5. Transparency in and how AI is used by the company</p> <p>6. Ethical use of data</p> <p>7. Substantiation of statements and referencing</p> <p>Recommendation: individual company standards should be articulated in a specific policy document (SOP) in order to provide guidance on the minimisation of corporate risk.</p> <p>5.6.7 Promotion of SAHPRA online medicines information data base: Advertisers are encouraged to use and to promote the use of the SAHPRA online medicines information database at https://.medsinfo.sahpra.org.za. <i>SAHPRA has published a toolkit to provide support for use of this directory.</i></p>	
<p>Amendment to Guidelines to achieve alignment with Sanctions Policy V3 Guidelines added to facilitate the implementation of the revised Sanctions Policy Document v3 241112.</p> <p>Guideline to 16.7.7; Note 1</p> <p>Guideline to 16.11.3.1; Note 1</p> <p>Guideline to 16.11.7; Note 1</p>	

For further Information contact:

info@marketingcode.co.za /val@marketingcode.co.za

www.marketingcode.co.za

Executive Officer: Val Beaumont