



## THE SOUTH AFRICAN CODE OF MARKETING PRACTICE FOR HEALTH PRODUCTS

Version 12, 25th June 2019

1. **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.**
2. **Companies may have standards which are stricter in which case these standards will be applied by members**
3. **Membership of the MCA is either in collaboration with industry trade associations or as independent, non-association-aligned members.**
4. **Guidelines to the Code assist in the interpretation and application of the Code. They can be obtained from [www.marketingcode.co.za](http://www.marketingcode.co.za).**
5. **The version control history of amendments to the Code is referenced at the end of the Code document. V10 of the Code was ratified at the AGM of the MCA on the 16<sup>th</sup> November 2016 and focused on integrating Complementary Medicines into the Code.**
6. **For further information on the MCA or the Code enforcement provisions, please contact [info@marketingcode.co.za](mailto:info@marketingcode.co.za).**



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## GLOSSARY

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1. In the Code:
  - 1.1 words and phrases that are defined in the Medicines Act have the meanings assigned to them in the Medicines Act unless otherwise stated or inconsistent in the context;
  - 1.2 words and phrases that are defined in the Code have the meanings assigned to them in the Code unless inconsistent in 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 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;
  - 1.9 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.
  - 1.10 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 **Clinical Trial**<sup>1</sup> 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

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<sup>1</sup> Medicines Act, General Regulations, GN 859, 25 August 2017.



- 2.1.1 discover, or verify the clinical, pharmacological or pharmacodynamic effects of the Medicine;
- 2.1.2 identify any adverse events;
- 2.1.3 study the absorption, distribution, metabolism and excretion of the Medicine; or
- 2.1.4 ascertain its safety or efficacy.
- 2.2 **Complementary Medicine**<sup>2</sup> means any substance or mixture of substances that:
  - 2.2.1 Originates from plants, fungi, algae, seaweeds, lichens, minerals, animals or other substance as determined by the Regulatory Authority;
  - 2.2.2 is used or purporting to be suitable for use or manufactured or sold for use
    - 2.2.2.1 in maintaining, complementing, or assisting the physical or mental state; or
    - 2.2.2.2 to diagnose, treat, mitigate, modify, alleviate or prevent disease or illness or the symptoms or signs thereof or abnormal physical or mental state, of a human being or animal and
  - 2.2.3 is used
    - 2.2.3.1 as a **Health Supplement**; or
    - 2.2.3.2 in accordance with those disciplines as determined by the Regulatory Authority.
- 2.3 **Health Supplement**<sup>3</sup> means any substance, extract or mixture of substances as determined by the Regulatory Authority, sold in dosage forms used or purported for use in restoring, correcting or modifying any physical or mental state by:
  - 2.3.1 complementing health;
  - 2.3.2 supplementing the diet; or
  - 2.3.3 a nutritional effect,and excludes injectable preparations, Medicines or substances listed as Schedule 1 or higher in the Medicines Act.
- 2.4 **Instructions for Use** means Instructions for Use of Medical Devices as defined in Regulation 23 of the Regulations relating to Medical Devices and *In Vitro* Diagnostic Medical Devices (IVDs).

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<sup>2</sup> Medicines Act, General Regulations, GN 859, 25 August 2017.

<sup>3</sup> Medicines Act, General Regulations, GN 859, 25 August 2017.



- 2.5 ***In Vitro Diagnostic (IVD)***<sup>4</sup> 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.
- 2.6 ***Medical Device***<sup>5</sup> 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)
- 2.6.1 intended by the manufacturer to be used, alone or in combination, for humans or animals, for one or more of the following:
- 2.6.2 diagnosis, prevention, monitoring, treatment or alleviation of disease;
- 2.6.3 diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- 2.6.4 investigation, replacement, modification or support of the anatomy or of a physiological process;
- 2.6.5 supporting or sustaining life;
- 2.6.6 control of conception;
- 2.6.7 disinfection of Medical Devices; or
- 2.6.8 providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body; and
- 2.6.9 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.
- 2.7 ***Medicine***<sup>6</sup>
- 2.7.1 means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in:
- 2.7.2 the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in humans; or
- 2.7.3 restoring, correcting or modifying any somatic or psychic or organic function in humans; and
- 2.7.4 includes any veterinary Medicine.
- 2.8 ***Patient Information Leaflet*** means the information pertaining to a medicine as provided for in Regulation 12 of the General Regulations, written in a

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<sup>4</sup> Medicines Act.

<sup>5</sup> Medicines Act.

<sup>6</sup> Medicines Act.



manner that is easily understandable to the patient.

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

2.10 **User**<sup>7</sup> 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**<sup>8</sup> 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

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<sup>7</sup> Medicines Act, Regulations Relating to Medical Devices and *In Vitro* Diagnostic Medical Devices (IVDs), GN1515, 9 December 2016.

<sup>8</sup> Medicines Act as amended for purposes of the Code.



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 **Board** means the Board of the MCA.
- 3.5 **Business Day** means any day other than a Saturday, Sunday or public holiday in terms of the laws of the Republic of South Africa.
- 3.6 **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.
- 3.7 **Code** means The South African Code of Marketing Practice for Health Products.
- 3.8 **Constitution** means the Constitution of the MCA.
- 3.9 **Consumer** means a Person:
- 3.9.1 to whom a Health Product is Promoted in the ordinary course of a Company's business;
- 3.9.2 to whom a Health Product is supplied (which includes sold, rented, leased and exchanged); or
- 3.9.3 who uses, in any manner whatsoever, or consumes a Health Product,
- 3.9.4 including a member of the general public and a patient.
- 3.10 **Company** means a manufacturer, importer, wholesaler, distributor or retailer of Health Products.
- 3.11 **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.
- 3.12 **Complainant** means the party lodging a complaint for an alleged breach or contravention of the Code.
- 3.13 **Company Representatives** means all relevant personnel, including representatives and 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.

- 3.14 **Electronic Communication** means any text, voice, sound, audiovisual 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.
- 3.15 **Electronic/Digital Media** includes the Internet, websites, applications, social media, electronic signage and e-commerce.
- 3.16 **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.
- 3.17 **Executive Officer** means the Executive Officer of the MCA
- 3.18 **Fast-Moving Consumer Goods (FMCG)** 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.
- 3.19 **Fee-for-Service (FFS)/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.
- 3.20 **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.



- 3.21 **Health Products** means Medicines, scheduled substances, Complementary Medicines, Medical Devices, and IVDs as regulated by the Medicines Act.
- 3.22 **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.
- 3.23 **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.
- 3.24 **HPCSA** means the Health Professions Council of SA established in terms of section 2 of the Health Professions Act 56 of 1974.
- 3.25 **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.
- 3.26 **Institution** means an organisation, establishment, foundation, society, or the like, devoted to the Promotion of a particular cause. This includes private hospitals and clinics.
- 3.27 **Launch** means the introduction for the first time of a Health Product.
- 3.28 **Marketing Code Authority (MCA)** 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.
- 3.29 **Medicines Act** means the Medicines and Related Substances Act 101 of 1965 and Regulations, guidelines, directives, notices, ordinances, codes or any enforceable document issued by the Regulatory Authority and includes any legislation that amends or repeals and replaces the Medicines Act.
- 3.30 **Member** means a member of the MCA.
- 3.31 **Minimum Requirements** means the legislated requirements for written Advertisements as set out in the General Regulations<sup>9</sup> for Medicines and the

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<sup>9</sup> Regulation 42 of the General Regulations, GN 859, 25 August 2017 (Medicines Act).



Regulations relating to Medical Devices and IVDs<sup>10</sup> for Medical Devices and IVDs.

- 3.32 **Nominated** 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.
- 3.33 **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.
- 3.34 **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** has the opposite meaning.
- 3.35 **Panels of Experts** means those persons appointed by the Board by virtue of their expertise to serve on adjudicating, appeal or ex parte committees.
- 3.36 **Person** includes a body corporate, partnership, association, organisation, entity or trust.
- 3.37 **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.
- 3.38 **Promotional Activity** means any activity associated with Health Product Promotion and excludes a Promotional Event.
- 3.39 **Promotional Aids** means non-monetary items given away free of charge to Promote a Company or Health Product.
- 3.40 **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.
- 3.41 **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.
- 3.42 **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

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<sup>10</sup> Regulation 21 of the Regulations Relating to Medical Devices and *In Vitro* Diagnostic Medical Devices (IVDs); GN1515, 9 December 2016 (Medicines Act).



serving one or more predetermined scientific, clinical, or policy purpose.

- 3.43 **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).
- 3.44 **Respondent** means the party against whom a Complainant has lodged a complaint for an alleged breach or contravention of the Code.
- 3.45 **Responsible Pharmacist**<sup>11</sup> 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.
- 3.46 **Retailer** means a business supplying Health Products directly to Consumers and includes FMCG retailers.
- 3.47 **Right of Sale** refers to the authorisation given in terms of Section 14(3) of the Medicines Act to sell a Health Product.
- 3.48 **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.

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<sup>11</sup> Pharmacy Act 53 of 1974.



## **1 CHAPTER 1: PREAMBLE**

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### **1.1 Preamble**

- 1.1.1 Whereas the National Drug Policy<sup>12</sup> (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
- 1.1.2 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
- 1.1.3 Whereas Regulation 21 of the Regulations relating to Medical Devices and IVDs provides requirements for the Advertising of Medical Devices and IVDs; and
- 1.1.4 Whereas Regulation 42 of the General Regulations to the Medicines Act provides requirements for the Advertising of Medicines;
- 1.1.5 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.
- 1.1.6 The Executive Officer acts as the custodian of the Code.

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<sup>12</sup> The South African National Drug Policy, Department of Health, 1996.



## **2**      **CHAPTER 2: OBJECTIVES OF THE MCA**

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### **2.1**      **Objectives**

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



### **3 CHAPTER 3: SPIRIT, APPLICATION, INTERPRETATION AND SCOPE OF CODE**

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#### **3.1 The Spirit of the Code**

- 3.1.1 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.
- 3.1.2 The ethical Promotion of Health Products is vital in ensuring that 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.
- 3.1.3 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.
- 3.1.4 All Companies shall maintain high ethical standards when conducting Promotional Activities.

#### **3.2 The Promotion of Health Products**

- 3.2.1 The Promotion of a Health Product shall:
- 3.2.1.1 be in accordance with the Medicines Act;
  - 3.2.1.2 comply with the terms of its registration, where relevant;
  - 3.2.1.3 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
  - 3.2.1.4 not occur before to the Health Product is registered by the Regulatory Authority in terms of Section 15 of the Medicines Act, unless Section 14(3) of the Medicines Act applies.
- 3.2.2 All Companies shall comply with the applicable legal, regulatory and professional requirements and with the letter and the spirit of the Code.



- 3.2.3 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.
- 3.2.4 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 the their Promotion. The Industry seeks to preserve the independence of the decisions taken by HCPs.
- 3.2.5 The MCA takes cognisance of other professional and industry codes applicable to the Health Products sector and professions with which this sector interacts.
- 3.2.6 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.
- 3.3 Application of the Code**
- 3.3.1 The Code applies to the following:
- 3.3.1.1 All Companies that are Members of the MCA, including their licence holders, agents, contractors, third party distributors/marketers, contractual event organisers and/or any third party acting on their behalf;
- 3.3.1.2 All non-members of the MCA, including Retailers, wholesalers and distributors that agree to be subject to the Code; to the extent that they may influence the demand for Health Products; and
- 3.3.1.3 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 does not yet exist, for purposes of the Code.
- 3.3.2 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 also subject to the Code:
- 3.3.2.1 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;



- 3.3.2.2 All Advertising and/or Promotional Material directed at Consumers to provide information about the Health Products available for self-medication or use;
- 3.3.2.3 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
- 3.3.2.4 Interactions between the Industry and HCPs and the Industry and Consumers as envisaged in the Medicines Act.
- 3.3.3 The principles underpinning the interactions with HCPs and Consumers as well as Advertising and Promotion in the Code apply equally to all Health Products.
- 3.3.4 Section 15 of the Code deals with specific activities related to Medical Devices and IVDs only.
- 3.3.5 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, including but not limited to dispensing system software or ordering system vendors, shall be regarded as infringing the Code.
- 3.3.6 The Code does not apply to:
  - 3.3.6.1 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;
  - 3.3.6.2 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;
  - 3.3.6.3 The Promotion of Stock Remedies as defined under the Fertilisers, Farm Feeds, Agricultural Remedies and Stock Remedies Act 36 of 1947;
  - 3.3.6.4 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;
  - 3.3.6.5 Company sales incentives; and
  - 3.3.6.6 Clinical Trials of Health Products.
- 3.4 **Status of the Guidelines to the Code**
  - 3.4.1 The Guidelines are supplementary information, which shall be used in the interpretation of the Code. The examples contained in the Guidelines are intended to illustrate and clarify the meaning of the provisions of the Code.



They are not exhaustive in that they do not cover all possible situations covered by the provisions of the Code. The Guidelines are secondary to Code requirements.

- 3.4.2 The Guidelines shall be updated regularly by the MCA, as part of its mandate to ensure education, application and enforcement of the Code. These Guidelines shall also be used regularly to update the applicable monetary values and examples of conduct that constitute violations of the Code.

### 3.5 **Interpretation of the Code**

- 3.5.1 The provisions of the Code shall be interpreted both in terms of the letter and spirit of the Code.

- 3.5.2 The following principle shall guide the interpretation of this Code:

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:

- 3.5.2.1 illegal; and/or
- 3.5.2.2 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
- 3.5.2.3 which in the opinion of the MCA may adversely affect the interests of any Consumer or group of Consumers.

- 3.5.3 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.

- 3.5.4 The Code shall not be construed to be in conflict with any existing law applicable to Health Products, including but not limited to the Medicines Act, the Patents Act 57 of 1978, the Copyright Act 98 of 1978, the Trade Marks Act 194 of 1993, the Pharmacy Act 53 of 1974, the Consumer Protection Act 68 of 2008 and the National Health Act 61 of 2003.

- 3.5.5 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.

- 3.5.6 The rulings of the structures of the MCA as provided for in the Code establish the precedent on what constitutes acceptable practices in the marketing and Promotion of Health Products.

### 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.



## **4 CHAPTER 4: COMPANY REPRESENTATIVES**

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### **4.1 Professionalism**

- 4.1.1 Company Representatives shall conduct the Promotion of Health Products in a professional manner.
- 4.1.2 Companies 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 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.
- 4.2.3 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. It is recommended that MSL personnel should not report into marketing and sales departments.

### **4.4 Compliance**

- 4.4.1 All Company Representatives, including MSL personnel, shall comply with all the relevant requirements of the Code, the applicable professional and good practice codes and all the applicable laws and regulations, including the Protection of Personal Information Act 4 of 2013 (POPI Act).

### **4.5 Responsibility for Product Information**

- 4.5.1 Companies are responsible for the information about their Health Products, issued by themselves or their third-party service providers.

### **4.6 Provision of Services by Company Representatives**



- 4.6.1 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.
- 4.6.2 The provision, delivery or demonstration of medical and educational goods and/or services shall in no way be linked to the Promotion of products and shall not be combined with Promotional visits. Company Representatives may introduce a service by means of a brief description and/or the delivery of materials but shall not instigate a detailed discussion about the service at the same time as a call during which products are Promoted.
- 4.6.3 Company Representatives shall not offer reimbursement services to facilitate product changes.
- 4.6.4 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.
- 4.6.5 Companies shall ensure that patient confidentiality is maintained at all times as well as compliance with the data protection legislation.
- 4.7 **Scientific/Product Queries**
- 4.7.1 Inquiries from HCPs and Consumers with regard to the use of Health Products shall be handled by appropriately qualified personnel.
- 4.7.2 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).
- 4.7.3 Unsolicited queries from Consumers on any Off-label Use shall be referred to their treating HCPs.
- 4.7.4 Requests from individual Consumers for information or advice on the diagnosis of a disease or choice of therapy shall always be refused and the enquirers advised to consult their HCPs.
- 4.7.5 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.
- 4.7.6 Companies shall ensure that their response to any public enquiry is not



Promotional.

4.7.7 The company shall keep a record of unsolicited requests for literature from HCPs. This information should not be conveyed by the Marketing or Sales Department or the medical representative.

4.8 **Adverse Events/Product Technical Complaints/Usability Issues Reporting**

4.8.1 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.

4.9 **Gaining Interviews with HCPs**

4.9.1 Company Representatives shall not employ any inducement or subterfuge to gain an interview with an HCP.

4.9.2 No compensation, payment, reward or benefit shall be paid or offered for the granting of an interview by an HCP.

4.9.3 Donations to charities in return for Company Representatives gaining interviews are prohibited.

4.9.4 Company Representatives shall take reasonable steps to ensure that they are not misleading in respect of their identity or the Company that they represent.

4.10 **Respect for HCPs and Others**

4.10.1 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.

4.10.2 Company Representatives shall respect the wishes of any individuals on whom they would like to call and observe the arrangements in force at any particular organisation or establishment.

4.11 **Operating Room or Clinical Environment**

4.11.1 Company Representatives who visit operating rooms or clinical environments shall be appropriately trained on operating room/clinical environment protocol(s).

4.11.2 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.



## **5 CHAPTER 5: PROMOTION AND ADVERTISING**

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### **5.1 General Principles**

#### **5.1.1 Self-Medication**

5.1.1.1 The Advertising and/or Promotion of self-medication (i.e. a Medicine, Complementary Medicine or Health Supplement) should not encourage Consumers to discontinue the use of prescribed Medicines, Complementary Medicines or Health Supplements.

5.1.1.2 Advertising and/or Promotion of self-medication shall not suggest that the relevant Health Product is a foodstuff, cosmetic or other non-medicinal product.

5.1.1.3 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.

5.1.1.4 Advertising and/or Promotion shall encourage the responsible 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.

5.1.1.5 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.

5.1.2 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.

5.1.3 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).

5.1.4 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.

5.1.5 Advertising and/or Promotion shall not be aimed principally or exclusively at children under 12 years of age.

5.1.6 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.

- 5.1.7 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.
- 5.1.8 Advertising and/or Promotion shall not offer the virtual diagnosis, advice, prescription or treatment of Consumers, including by correspondence.
- 5.1.9 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.
- 5.1.10 Advertising and/or Promotion shall not encourage, either directly or indirectly, the indiscriminate, unnecessary or excessive use of any Health Product.
- 5.1.11 Advertising shall not contain improper, alarming or misleading claims about a recovery.
- 5.1.12 An Advertisement and/or Promotion shall not offer any personal incentive to a pharmacy assistant, or other non-healthcare professional salesperson at retail level, to recommend or supply Health Products.
- 5.1.13 Statements, representations or tie-off lines shall not be made for the purpose of encouraging Consumers to ask their HCPs to prescribe/recommend a specific Health Product.
- 5.1.14 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.
- 5.1.15 **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 **Advertising and Promotional Material**

5.2.1 Companies shall not be involved in Promotional schemes, which are hazardous to Consumers or which bring or may bring the Industry into disrepute.

5.2.2 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.

## 5.3 **Information to be Provided to HCPs**

5.3.1 When Company Representatives Introduce a Medicine<sup>13</sup> or a class C or D Medical Device or IVD<sup>14</sup> to an HCP or potential User for the first time, they should provide a copy of the latest Regulatory Authority-approved Professional Information/Patient Information Leaflet/Instructions for Use for the HCP or potential User. On subsequent occasions, such information shall be made available on request.

5.3.2 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.

## 5.4 **Professional Information/Patient Information Leaflet and Instructions for Use**

5.4.1 All Advertising and/or Promotional Material shall be based on the current Regulatory Authority-approved Professional Information/Patient Information Leaflet/Instructions for Use.

5.4.2 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.

## 5.5 **Minimum Requirements for Advertisements and Promotional Material**

5.5.1 Advertisements shall comply with the Minimum Requirements.

5.5.2 In addition, Advertisements shall:

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<sup>13</sup> Regulation 42 of the General Regulations, GN 859, 25 August 2017 (Medicines Act).

<sup>14</sup> Regulation 21 of the Regulations relating to Medical Devices and IVDs, GN1515, 9 December 2016 (Medicines Act).



- 5.5.2.1 form part of the Promotional Material (with the exception of Promotional Aids, which do not contain Promotional claims) and shall not be supplied separately;
- 5.5.2.2 be provided in a clear and legible manner;
- 5.5.2.3 not be flippant;
- 5.5.2.4 be consistent with
  - 5.5.2.4.1 **the most recent Regulatory Authority approved Professional Information/ /Patient Information Leaflet/Instructions for Use; or**
  - 5.5.2.4.2 **the Medicines Act, where the Health Product is not registered, but enjoys the Right of Sale and no Professional Information/Patient Information Leaflet/Instructions for Use is available.**
- 5.5.2.5 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;
- 5.5.2.6 not be false or misleading when each page is read in isolation in the event of an Advertisement containing two or more pages;
- 5.5.2.7 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, audiovisuals 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.
- 5.5.3 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.
- 5.5.4 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.
- 5.5.5 Advertisers are encouraged to convey the message that Health Products should be treated with respect and may not be suitable for everybody.
- 5.6 **Artwork and Visual Representations**
  - 5.6.1 All artwork, including illustrations, graphs, tables, logos, and trade dress, shall comply with the letter and spirit of the Code.
  - 5.6.2 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.

- 5.6.3 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.
- 5.6.4 Children shall not be depicted in conjunction with Health Products not authorised for use in children.
- 5.6.5 No artwork, including illustrations, shall show children under the age of 12 using or within reach of Health Products without adult supervision.
- 5.6.6 Advertising shall not use misleading, alarming or improper visuals to represent changes in the human body.
- 5.6.7 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.
- 5.6.8 Advertisements shall not use inappropriate imagery or use imagery out of context.
- 5.6.9 Pictograms shall not be used to depict opinions or interpretations.

## 5.7 **Information, Claims and Comparisons**

### 5.7.1 Comparisons

5.7.1.1 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:

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

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

5.7.1.1.3 **they are not misleading or disparaging;**

5.7.1.1.4 **they are substantiated and not left open to interpretation.**

5.7.1.1.5 **they are intended for the same needs or purpose;**

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

5.7.1.1.7 **no confusion is created.**

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

5.7.1.3 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.

- 5.7.1.4 Hanging (open-ended) comparisons shall not be allowed.
- 5.7.1.5 Points of comparison shall be factual and reflect the body of scientific evidence.
- 5.7.1.6 Comparisons shall not imply that the Health Products with which comparisons are being made are harmful or ineffectual.

#### 5.7.2 **Accuracy, Balance and Fairness**

- 5.7.2.1 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.
- 5.7.2.2 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.
- 5.7.2.3 All claims in Promotional Material shall be capable of standing alone and shall not be qualified by the use of footnotes and the like.
- 5.7.2.4 Information, claims and comparisons or the manner, in which they are portrayed, shall not be misleading directly or by implication, distortion or undue emphasis.
- 5.7.2.5 Material shall be sufficiently comprehensive to enable the recipients/readers to form their own opinion of the therapeutic value of the Health Product.
- 5.7.2.6 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.
- 5.7.2.7 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.

#### 5.7.3 **Claims of Novelty and Uniqueness**

- 5.7.3.1 A Health Product, or any of its attributes, shall not claim to be unique unless the claim is substantiated.
- 5.7.3.2 Use of the word "unique" shall not be misleading.
- 5.7.3.3 Advertising and/or Promotional Material shall not be misleading about the novelty of the preparation of the Health Product.



#### 5.7.4 Claims relating to formulation

##### 5.7.4.1 Non-content claims

5.7.4.1.1 **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.**

##### 5.7.4.2 Reference to specific properties of ingredients

5.7.4.2.1 **Claims shall not imply that an active ingredient or Health Product has some special merit, quality or property unless this can be substantiated.**

5.7.4.2.2 **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.**

##### 5.7.4.3 Unknown active ingredient

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

##### 5.7.4.4 Pharmacokinetic properties

5.7.4.4.1 **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.**

##### 5.7.4.5 Herbal products

5.7.4.5.1 **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.**

##### 5.7.4.6 Natural Ingredients

5.7.4.6.1 "Natural" used in the context of "Natural Ingredient"<sup>15</sup> means, essentially, ingredients provided by nature, not the work of man or interfered with by

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<sup>15</sup> UK Food Standards Agency, Jul 2008. *Criteria for the Use of the Terms Fresh, Pure, Natural etc. in Food Labelling*



man.

5.7.4.6.2 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 .

5.7.4.6.3 Advertising and/or Promotional material shall not suggest that the safety, quality or efficacy of a Health Product is because it is natural.

5.7.4.6.4 **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.**

5.7.5 **Claims relating to Efficacy, Effectiveness and Performance**

5.7.5.1 An Advertisement for a self-medication Health Product 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.

5.7.5.2 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.

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

5.7.5.4 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.

5.7.6 **Use of the word “Safe”**

5.7.6.1 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.

5.7.6.2 The word “safe” shall not be used without scientific qualification and substantiation.

5.7.7 **Use of the words “The” and “Ultimate”**

5.7.7.1 Use of the words “the” and “ultimate” shall not be misleading.

5.7.8 **Use of the word “New”**

**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.

#### 5.7.9 **Use of the word “Serious”**

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

- 5.7.9.1 generally accepted not to be appropriate for diagnosis and/or treatment without consulting a suitably qualified HCP, and/or
- 5.7.9.2 generally accepted to be beyond the ability of the average Consumer to evaluate accurately and treat safely without regular supervision by a qualified HCP.

#### 5.8 **Substantiation**

- 5.8.1 All information, claims or comparisons shall be capable of substantiation.
- 5.8.2 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.
- 5.8.3 For Complementary Medicines, the substantiation of any product claim shall be in accordance with the requirements of the Medicines Act.
- 5.8.4 All references shall be listed in the Advertisement or Promotional Material.
- 5.8.5 Referencing shall be of a standard recognised by scientific journals.
- 5.8.6 Upon any request, a Company shall, without delay, provide the reference material related to the Promotional Material.
- 5.8.7 When Promotional Material refers to data, including unpublished data on file, the relevant part of this data shall be provided on request without delay.
- 5.8.8 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.

#### 5.9 **Endorsements, Testimonials and Quotations**

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



- 5.9.1.2 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.
- 5.9.1.3 The name, photograph, film, video, television or radio Advertisement, or any other reproduction of an HCP shall not be used in any way contrary to the applicable professional code for the relevant profession and all endorsements, where permitted by professional codes, shall be done within the scope of such codes.
- 5.9.1.4 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.
- 5.9.1.5 Testimonials shall be current and the genuine views of the relevant person.
- 5.9.2 Quotations
  - 5.9.2.1 Any quotation chosen by a Company for use in Promotional Material shall comply with the requirements of the Code.
  - 5.9.2.2 Quotations from medical and scientific literature shall accurately reflect the intention and meaning of the author(s).
  - 5.9.2.3 Unpublished, personal communication or opinions shall not be used unless the Company is able, on request to supply written substantiation, based on scientific data.
  - 5.9.2.4 Quotations from any study shall not be misleading about the study's overall significance to the reported outcomes.
  - 5.9.2.5 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.
  - 5.9.2.6 Reference to use by HCPs: 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 **Journal Advertising**
  - 5.10.1 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.
  - 5.10.2 Advertorial: Advertisements in journals shall not resemble editorial matter



unless clearly identified as an advertorial or sponsored feature.

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

#### 5.11 **Disparaging Claims**

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

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

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

5.11.1.3 generic or original Health Products in general;

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

5.11.1.5 an ingredient or treatment type.

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

#### 5.12 **Disguised Promotion**

5.12.1 Promotional Material and activities shall not be disguised.

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

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

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

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

#### 5.13 **Market Research**



- 5.13.1 Market research shall be conducted with the objective of gaining legitimate insights.
- 5.13.2 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.
- 5.13.3 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.
  
- 5.14 **Clinical Trials**
- 5.14.1 All Clinical Trials must have a legitimate scientific purpose and be conducted in accordance with the legislation. Clinical Trials are not subject to the Code. However, post-marketing surveillance studies, post-authorisation studies, observational/non-interventional studies and the like must not be disguised Promotion.
  
- 5.15 **Provision of Reprints of Journal Articles**
- 5.15.1 Reprints of articles in journals shall not be provided to any HCP if they are unsolicited unless the articles are "On-label" and have been published in a peer reviewed publication in line with good principles of scientific review and publication.
- 5.15.2 Unsolicited articles shall be considered as Promotion and shall comply with the Code.
- 5.15.3 When providing a reprint of an article about a Health Product, it shall be accompanied by the prescribing information.
- 5.15.4 If a non-peer-reviewed article is requested by an HCP, a copy may be provided by written request or in accordance with the provisions for issuing scientific or medical information.
  
- 5.16 **Distribution of Advertisements and Promotional Material**
- 5.16.1 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.
- 5.16.2 A Company requested by an addressee to cease or limit the volume of Promotional Material shall respect the wishes of the addressee.
- 5.16.3 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.

- 5.16.4 These provisions are subject to the provisions of the applicable legislation such as the Consumer Protection Act 68 of 2009 and the Protection of Personal Information Act 4 of 2013.

5.17 **Detailed Briefing Material**

- 5.17.1 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.

- 5.17.2 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.

5.18 **Electronic Communication and Electronic/Digital Media**

- 5.18.1 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.

- 5.18.2 Electronic Communication and Electronic/Digital Media shall not be used for Promotional purposes, except in the case where first contact is made with the relevant Person, the option to opt out is provided for that person and his/her decision is subsequently respected by the Company.

- 5.18.3 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.

- 5.18.4 These provisions are subject to the provisions if the applicable legislation such as the Consumer Protection Act and the Protection of Personal Information Act.

- 5.18.5 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 material is Promotional it must include:



- 5.18.5.1 a reference to refer to the approved Professional Information/Patient Information Leaflet/Instructions for Use, before prescribing, and within the body of the Advertisement.
- 5.18.5.2 a direct hyperlink to the Professional Information/Patient information leaflet/Instructions for Use outside the application, or
- 5.18.5.3 provide access to it via a hyperlink within the application.
- 5.18.6 When linking to a PDF of one or more of these documents on a third party site, where the reader cannot navigate away from the page displaying the document, a pop-up box warning them that they are leaving the Company-controlled site is not required.
- 5.18.7 **Internet**
  - 5.18.7.1 All material contained on a website directed to HCPs must also comply with the provisions of the Code and be a secure site, designed to allow access to HCPs only.
  - 5.18.7.2 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 the minimum information required by the legislation.
  - 5.18.7.3 When the reader is leaving the site or being directed to a site that the Company has not developed or is not responsible for this should be clear.
  - 5.18.7.4 Any references or linkages to other reputable information sources shall be to those sources, which provide valuable educational material to enhance the quality use of 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 Africa 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."*
  - 5.18.7.5 References and links should not be made to any non-compliant sites
- 5.18.8 **Audiovisual material**
  - 5.18.8.1 Audiovisual material includes audio material, and refers to, for example, films, video recordings, sound bites and interactive data systems.
  - 5.18.8.2 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 audiovisual recording or in the



interactive data system itself.

- 5.18.8.3 When the minimum information is included in an interactive data system, the instructions for accessing it shall be clearly displayed.
- 5.18.8.4 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.

5.19 **Unapproved Indications**

- 5.19.1 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.
- 5.19.2 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.
- 5.19.3 Information provided with regard to the Off-label Use, shall comply with the relevant legislation and the Code.
- 5.19.4 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 ...*".
- 5.19.5 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.



## **6 CHAPTER 6: APPROVAL OF PROMOTIONAL MATERIALS AND ACTIVITIES**

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### **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 the enforcement of the Code 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 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 standard operating procedure (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 SOP and related documentation shall be available for auditing by the MCA or the Regulatory Authority, where required.
- 6.1.7 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 their Company Representatives. The Executive Officer may therefore request a Company to submit to the MCA for scrutiny 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 Representatives.



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 Invitations;

6.2.3.3 Choice of venue(s);

6.2.3.4 the rationale for the meeting or sponsorship;

6.2.3.5 Speaker and participant selection processes;

6.2.3.6 The selection criteria

6.2.3.7 FFS/Honoraria paid; and

6.2.3.8 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.

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**

6.4.1 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 for a minimum period of 5 (five) years.

6.4.2 Companies shall preserve all proofs of approval pertaining to Code compliance and the relevant accompanying information for not less than 5 (five) years 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.

6.4.3 In the interest of storage space, it shall be acceptable to store accurate photographic or other electronic representations of material, information or items.



## **7 CHAPTER 7: INDUCEMENTS, DONATIONS AND SPONSORSHIP**

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### **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, or Consumers as an inducement to prescribe, lease, borrow, supply, stock, dispense, administer, use or buy any Health Product.

### **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:
  - 7.2.2.1 They are made for the purpose of supporting healthcare or research;
  - 7.2.2.2 They are documented and kept on record by the donor/grantor; and
  - 7.2.2.3 They do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific Health Products?
  - 7.2.2.4 That such donations 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 Healthcare Professional or healthcare 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 there is no conflict/potential conflict of interest between the Company and the organisation it is supporting.
- 7.2.7 A donation shall not constitute a payment that would otherwise be unacceptable under the Code. Companies shall have an agreement with the relevant organisation in terms of which disclosure of the donation is incumbent on both parties.



- 7.2.8 Donations in lieu of FFS/Honoraria are not permitted
- 7.2.9 Companies are encouraged to make publicly available any information about donations, grants or benefits in kind made by them as covered in this section.
- 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 with the proviso that the grant or financial support is provided 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 Company's Health Product(s).
- 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.



## **8 CHAPTER 8: SAMPLES**

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8.1 Health Products

8.1.1 The supply of Health Product(s) as samples shall comply with relevant legislation.

8.2 Personal Care Products

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



## **9 CHAPTER 9: COMPETITIONS**

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### **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;
- 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.

### **9.2 Consumer Competitions**

9.2.1 Competitions for Consumers shall be permissible provided that:

- 9.2.1.1 entry into consumer competitions is neither dependent on the conditional purchase of a Health Product nor is a Health Product offered as a prize;
- 9.2.1.2 the value of the prize does not exceed the limits set by the MCA Board from time to time;
- 9.2.1.3 the competition relates only to Schedules 0 and 1 Medicines or Classes A and B Medical Devices and
- 9.2.1.4 the competition complies with the relevant legislation such as the Consumer Protection Act, where applicable.



## **10 CHAPTER 10: MEETINGS AND EVENTS WITH HCPs**

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### **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 clear 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 or otherwise, 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.

### **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/Promotions 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;
- 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.

### 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 approval 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 must 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.

10.4 **Transparency Related to Sponsorship**

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

10.5.1 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.



## 11 CHAPTER 11: PROMOTIONAL ITEMS AND GIFTS

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### 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.

#### 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:

11.1.2.2.1 **The proprietary name of the Health Product;**

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

11.1.2.2.3 **The Company name, Company logo and/or Health Product logo.**

11.1.2.3 It is not necessary for the minimum information<sup>16</sup> required by the legislation for an Advertisement of a Health Product to be included on the occasional item provided no Promotional claims are made.

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

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<sup>16</sup> Regulation 42 of the General Regulations, GN 859, 25 August 2017 and Regulation 21 of the Regulations pertaining to Medical Devices and IVDs GN1515, 9 December 2016 (Medicines Act).



### 11.1.3 **Cultural Courtesy Gifts**

11.1.3.1 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, to be passed on to patients and 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.

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.



## **12 CHAPTER 12: CONTRACTING AND REIMBURSING HEALTHCARE PROFESSIONALS**

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### **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 must 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;
  - 12.1.3.4 A written signed undertaking by the consultant/adviser that he will declare that he is a consultant/adviser to the Company whenever he writes or speaks in public about a matter that is the subject of the agreement or any other issue relating to that Company.
- 12.1.4 Companies that employ an HCP on a part-time basis, who continues to practise 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.
- 12.1.5 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.
- 12.1.6 The number of consultants/advisers retained shall not be greater than the



number reasonably necessary to achieve the identified need.

- 12.1.7 The contracting Company shall maintain records concerning the services provided by consultants/advisers and shall make appropriate use of them.
- 12.1.8 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.
- 12.1.9 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.

## 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.
  - 12.3.1.3 Registries shall comply with all the applicable legislation, including but not limited to the protection of patient privacy and obtaining informed consent from the relevant person in respect of the collection and use of the patient information.



## **13 CHAPTER 13: MEETINGS AND EVENTS INVOLVING PATIENT ORGANISATIONS**

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### **13.1 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, significant indirect support and/or significant 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.

### **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.



## **14 CHAPTER 14: RELATIONS WITH CONSUMERS AND THE MEDIA**

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### **14.1 Advertising of Schedule 2 and Above Medicines, Class C and D Medical Devices and IVDs**

14.1.1 Medicines shall not be Advertised to Consumers if they are in Schedule 2 or higher.<sup>17</sup>

14.1.2 Medical Devices and IVDs shall not be Advertised to Consumers if they are in Class C and Class D. Male and Female condoms are excluded from this requirement.<sup>18</sup>

### **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.

### **14.3 Requests from Individual Consumers**

14.3.1 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.

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<sup>17</sup> Regulation 42 of the General Regulations, GN 859, 25 August 2017 (Medicines Act).

<sup>18</sup> Regulation 21 of the Regulations relating to Medical Devices and IVDs, GN1515, 9 December 2016 (Medicines Act).



## 14.5 **Patient Education**

- 14.5.1 Patient education ('help-seeking Advertisements') directed at Consumers is acceptable, provided that the material:
  - 14.5.1.1 for Schedule 2 and above Medicines, or Classes C and D Medical Devices and IVDs, does not contain the name of the specific Health Product, nor allude to the name of the Health Product;
  - 14.5.1.2 does not make or allude to a medicinal or therapeutic claim;
  - 14.5.1.3 does not provide any risk-related information on a health product;
  - 14.5.1.4 conveys to Consumers that treatment is available for a medical condition; and
  - 14.5.1.5 provides the statement, "*For more information, refer to your HCP*".
- 14.5.2 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 to Chapter 13 in this regard also.



## **15 CHAPTER 15: MATTERS PERTAINING TO MEDICAL DEVICES AND IVDs SPECIFICALLY**

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### **15.1 Demonstrations**

- 15.1.1 Medical Devices and IVDs used for demonstration/exhibition purposes are typically unsterilised, Medical Devices intended for single use and IVDs or mock-ups of such 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 Where 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.

### 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.



## **16 CHAPTER 16: ENFORCEMENT OF THE CODE**

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### **16.1 General Principles**

- 16.1.1 The MCA is recognised as the self-regulatory authority for the ethical Promotion of Health Products.
- 16.1.2 The MCA shall have the power to create the required enforcement mechanisms and sanctions as provided for in this Code and the Constitution and shall have all the powers necessary to ensure the efficiency and effectiveness of the self-regulatory mechanism.
- 16.1.3 The Executive Officer acts as the custodian of the enforcement processes described in this Code and the Constitution.
- 16.1.4 Non-members of the MCA may agree, in terms of the Constitution, to be subject to the enforcement mechanisms created by the Code and the Constitution or required by law to abide by them.

### **16.2 Referral of Complaints**

- 16.2.1 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.

### **16.3 External Remedies**

- 16.3.1 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.
- 16.3.2 A Person is not deprived of the right to obtain any interim relief in an appropriate court of law while pursuing the internal remedies.

### **16.4 Repeat Complaints Received by the MCA**

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

### **16.5 Enforcement Structures**

- 16.5.1 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.

- 16.5.2 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 16.6.
- 16.5.3 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 submitted. 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 16.7.
- 16.5.4 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.

#### 16.6 **Powers of an Adjudicating Committee**

- 16.6.1 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.).
- 16.6.2 In its sole discretion, the Adjudicating Committee shall be entitled 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.
- 16.6.3 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.
- 16.6.4 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.

- 16.6.5 The Adjudicating Committee may resolve to take no action in respect of a complaint and shall take such a decision motivated in writing, i.e. the Adjudication Ruling, where one or more of the following circumstances are applicable:
  - 16.6.5.1 The Complaint is not within the mandate of the MCA, i.e. the conduct the subject of the complaint cannot be resolved in terms of the Code;
  - 16.6.5.2 The length of time elapsing between the date of the occurrence of the reason for the complaint and the date when the complaint was made is such that an adjudication is no longer practicable or desirable;
  - 16.6.5.3 The subject-matter of the complaint is trivial;
  - 16.6.5.4 The complaint is frivolous, vexatious, or not made in good faith;
  - 16.6.5.5 The Complainant no longer wishes to pursue the complaint.
  - 16.6.5.6 The complaint does not allege any facts which may constitute grounds for a remedy under the Code;
  - 16.6.5.7 The complaint relates to an activity or material of the Respondent, which has already been considered by the MCA;
  - 16.6.5.8 More than three years has elapsed after the act or omission which is the cause for the complaint;
  - 16.6.5.9 In the case of a course of conduct or continuing practice, more than three years has elapsed after the date on which that conduct or practice ceased.
- 16.6.6 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, the stipulated guidelines and the limits imposed in the Sanction Policy Document, including the factors outlined in Section 16.6.7 of the Code for contraventions in respect of Advertising and/or Promotional Activities.
- 16.6.7 Without constraining the discretion of the Adjudicating Committee, in circumstances where the Respondent has been found to have contravened the Code in respect of Advertising and/or Promotional Activities, the Adjudicating Committee shall have consider to the following factors amongst others in deciding on a suitable sanction:
  - 16.6.7.1 Whether the publication or Promotional Activity has ceased;
  - 16.6.7.2 How widely the offending material was distributed;
  - 16.6.7.3 What steps have been taken to withdraw the published/issued material;



- 16.6.7.4 Whether corrective statements have been issued;
  - 16.6.7.5 Whether the breach was deliberate, negligent or inadvertent;
  - 16.6.7.6 Whether there were/are safety implications;
  - 16.6.7.7 Whether the material or publication was/is misleading and the extent of this;
  - 16.6.7.8 The manner in which the perceptions of HCPs or Consumers have been/will be affected;
  - 16.6.7.9 Whether commercial damage or harm has been caused, and the extent of this damage; and
  - 16.6.7.10 Whether the Respondent has previously breached the Code.
- 16.6.8 For purposes of clarity, it is specifically stated that 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 process.
- 16.6.9 Should the Adjudicating Committee find the complaint to be trivial, vexatious, frivolous or not made in good faith, the Adjudicating Committee 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.
- 16.6.10 An Adjudicating Committee shall have the power to adjudicate a complaint de novo in accordance with a ruling of an Appeal Committee.
- 16.7 **Powers of an Appeal Committee**
- 16.7.1 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.
- 16.7.2 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.
- 16.7.3 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.
- 16.7.4 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.

16.7.5 An Appeal Committee shall have the power to make one or more of the following decisions in respect of an appeal heard by it:

16.7.5.1 Dismiss the appeal;

16.7.5.2 Uphold the appeal;

16.7.5.3 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 in the Sanction Policy Document, as well as the factors outlined in Section 16.6.7 of the Code for contraventions in respect of Advertising and/or Promotional Activities;

16.7.5.4 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 16.6.5 and the Appeal Committee has over turned the ruling of the Adjudicating Committee;

16.7.5.5 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;

16.7.5.6 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

16.7.5.7 Direct that the matter be reported to an appropriate body or Regulatory Authority.

16.7.6 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.

16.7.7 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 first 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.

## 16.8 **Company-to-Company Complaints Process**

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

16.8.2 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.

16.8.3 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.

16.8.4 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.

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 section or sections in the Code. This information shall be kept confidential by the Executive Officer 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) in the Code or amendments to it, as may be necessary.

16.8.5 Where a response is not received as envisaged in Section 16.8.2 or the complaint is not resolved to the satisfaction of any party, a formal complaint may be lodged with the MCA in line with Section 16.11.

16.8.6 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 16.8 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).

16.8.7 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 16.8 and may lodge a complaint directly with the MCA as provided for in Section 16.11.

#### 16.9 **General Rules Pertaining to Complaint and Appeal Documentation**

16.9.1 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.

16.9.2 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.



- 16.9.3 Where audio/audiovisual material is submitted this shall be clearly indicated in the documentation.
- 16.9.4 A complaint shall clearly set out the details of the Complainant, the Respondent, the complaint and the section or sections of the Code, allegedly contravened and shall be accompanied by the following:
  - 16.9.4.1 Proof that the parties have made all reasonable attempts to resolve the matter between themselves subject to Section 16.8;
  - 16.9.4.2 Supporting literature and any studies relied upon, where the complaint is based on scientific issues;
  - 16.9.4.3 Copies of any Advertising and/or Promotional Material and/or any other relevant material (such as invitations, agreements, correspondence, etc); and
  - 16.9.4.4 Any other information the Complainant considers relevant for the assessment of the complaint.
- 16.9.5 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.
- 16.9.6 Any submission or communication, other than the initial complaint and the initial lodging of an Appeal, which is required to be made in terms of the Code for purposes of enforcement, may be done electronically by the relevant person, party or committee.
- 16.9.7 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 16.13.2. The Executive Officer may in his discretion submit the various 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 substantiated by the receiving party.
- 16.10 Powers of the Executive Officer
  - 16.10.1 The Executive Officer shall, on receipt of the complaint or appeal, determine whether:
    - 16.10.2 the complaint or appeal is in the prescribed format and complete;
    - 16.10.3 any of the grounds stipulated in Section 16.10.6 are present; and
    - 16.10.4 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.

- 16.10.5 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.
- 16.10.6 The Executive Officer may, after due consideration of the complaint, issue a notice of non-referral to the Complainant, where:
  - 16.10.6.1 the complaint appears to be trivial, frivolous, vexatious or not made in good faith;
  - 16.10.6.2 the complaint does not allege any facts which may constitute grounds for a remedy under the Code;
  - 16.10.6.3 the complaint is not within the mandate of the MCA;
  - 16.10.6.4 the complaint relates to an activity or material of the Respondent, which has already been considered by the MCA;
  - 16.10.6.5 more than three years has elapsed after the act or omission which gave rise to the complaint; or
  - 16.10.6.6 in the case of a continuing conduct or practice, if more than three years has elapsed after the date on which this conduct or practice ceased.
- 16.10.7 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 and the reasons for it.
- 16.10.8 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.
- 16.10.9 An appeal may be lodged against a decision of the Executive Officer in terms of Section 16.10.6 as set out in Section 16.15.
- 16.10.10 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, unless this decision was overturned by an Appeal Committee, 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.
- 16.10.11 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.

16.10.12 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.

#### 16.11 **Lodging of a Formal Complaint with the MCA**

16.11.1 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 with the proviso that where the Company is not a member of the MCA, it has agreed to be subject to the Code enforcement mechanisms or is by law required to subject itself to these mechanisms.

16.11.2 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 16.10.6.

16.11.3 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.

16.11.4 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.

16.11.5 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.

#### 16.12 **Nominated Complainant**

16.12.1 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.

16.12.2 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.

16.12.3 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 h and the Appeal Committee shall not be entitled to order the payment of MCA costs by the Nominated Complainant.

**16.13 Exchange of Complaint-Related Documentation between the Parties**

16.13.1 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.

16.13.2 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 5.8.8 of the Code, to the Complainant, requesting a reply within 7 (seven) Business Days.

16.13.3 The Executive Officer shall send a copy of the Complainant's reply, if any, to the Respondent.

16.13.4 The exchange of documents shall then be closed subject to the provisions of Section 16.14.6 and the complaint shall proceed to adjudication.

16.13.5 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.

**16.14 Adjudication Process**

16.14.1 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.

16.14.2 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.

16.14.3 The Adjudicating Committee shall be independent and impartial and shall perform its functions in good faith and without fear, favour, bias or prejudice.

16.14.4 Once the appointment of the Adjudicating Committee has been finalised, as soon as is reasonably possible, but at least within 2 (two) Business Days of



finalising this, the Executive Officer shall provide the Complaint Pack, at least in hard copy, to the members of the Adjudicating Committee.

- 16.14.5 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 to 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 his position with respect to such a request.
- 16.14.6 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 5.8.8 and this party may respond to such information or documents within the timeframes stipulated by the chairperson of the Adjudicating Committee.
- 16.14.7 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.
- 16.14.8 As provided for in the Constitution, the Executive Officer shall not be involved in the hearing, deliberations and/or discussions of the Adjudicating Committee.
- 16.14.9 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.
- 16.14.10 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.
- 16.14.11 The Adjudicating Committee shall adhere to the principles of natural and administrative justice, which shall include:



- 16.14.11.1 affording all parties the opportunity to be heard; and
- 16.14.11.2 ensuring that the members of the Adjudicating Committee are not conflicted with regard to the matter before it.
- 16.14.12 The Adjudicating Committee shall interpret and apply the Code in accordance with the principles of interpretation outlined in the Code.
- 16.14.13 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 or sanctions, 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.
- 16.14.14 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.
- 16.14.15 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.
- 16.14.16 The Adjudicating Committee shall take a decision, including the imposition of a sanction(s) where appropriate and supported by a motivation for this ruling, 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.
- 16.14.17 The Executive Officer shall communicate the Adjudication Ruling to both parties.
- 16.14.18 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.
- 16.14.19 An appeal against an Adjudication Ruling shall be made with the Appeal Committee of the MCA and with no other body.
- 16.15 **Lodging an Appeal**
- 16.15.1 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.
- 16.15.2 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.

16.15.3 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.

16.15.4 The operation of any Adjudication Ruling, which is the subject of an appeal under Section 16.15 shall be suspended pending the decision of the Appeal Committee or the withdrawal of the appeal by the Appellant.

16.16 **Exchange of Appeal-Related Documentation between the Parties**

16.16.1 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 .

16.16.2 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 5.8.8, to the Appellant, requesting a reply within 7 (seven) Business Days.

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

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

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

16.16.5.1 All documents, considered by the Adjudicating Committee; including audio/audiovisual material, pertaining to the original complaint;

16.16.5.2 The Adjudication Ruling; and

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

16.16.6 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.

16.17 **Appeal Hearings**

16.17.1 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.

- 16.17.2 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.
- 16.17.3 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.
- 16.17.4 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.
- 16.17.5 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.
- 16.17.6 As provided for in the Constitution, the Executive Officer shall not be involved in the hearing, deliberations and/or discussions of the Appeal Committee.
- 16.17.7 The Appeal Committee shall be independent and impartial and shall perform its functions in good faith and without fear, favour, bias or prejudice.
- 16.17.8 The Appeal Committee shall adhere to the principles of natural and administrative justice, which shall include:
  - 16.17.8.1 Affording all parties, the opportunity to be heard; and
  - 16.17.8.2 Ensuring that members of the Appeal Committee are not conflicted with regard to the matter before it.
- 16.17.9 The Appeal Committee shall interpret and apply the Code in accordance with the interpretation principles outlined in the Code.
- 16.17.10 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

- 16.17.11 The Appeal Committee may, in its sole discretion, hear further evidence or receive any documents on such terms and conditions as it may decide.
- 16.17.12 The Appeal Committee shall take a decision, including the imposition of a sanction(s) where applicable and supported by a written motivation 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.
- 16.17.13 The Executive Officer shall communicate the Appeal Ruling to both parties.
- 16.17.14 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.
- 16.18 **Validity of Proceedings**
- 16.18.1 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.
- 16.18.2 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.
- 16.18.3 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.
- 16.18.4 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.



**16.19 Publication of Outcomes**

16.19.1 The Executive Officer shall be entitled to publish a summary of any matter heard by an Adjudicating or Appeal Committee on the MCA website.. Where a breach of the Code or Constitution is ruled to have occurred, the identity of the Companies/parties (but not the individuals or panellists) may be published,. This shall be done in consultation with the chairperson of the relevant committee and in his absence by another member of that committee, with the proviso that a matter heard by an Adjudicating Committee shall be published only where no appeal has been lodged within the prescribed time period or after an appeal in respect of the matter has been concluded.

**16.20 Non-Compliance with Rulings or Undertakings**

16.20.1 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.

16.20.2 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.

16.20.3 Any fine given on a party by an Adjudicating or Appeal Committee shall be paid to the MCA as custodian of the enforcement processes within 30 (thirty) Business Days of the relevant ruling.

16.20.4 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.

16.20.5 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.

16.20.6 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.

- 16.20.7 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.
- 16.20.8 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.
- 16.20.9 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.
- 16.20.10 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.
- 16.20.11 Within 7 (seven) business days of receipt of the relevant documentation, the Appeal Committee shall take a decision, supported by a written motivation, whether there has been a failure to comply with an adjudication or appeal ruling.
- 16.20.12 The Appeal Committee may:
- 16.20.12.1 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
- 16.20.12.2 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 stipulated principles and guidelines and any limits imposed in the Sanction Policy Document; and
- 16.20.12.3 direct the Executive Officer to publish a summary of its decision on the MCA website, including the rationale for such a decision.
- 16.20.13 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.
- 16.21 **Ex Parte Opinions**
- 16.21.1 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 or circumstances upon payment of the prescribed fee and in the prescribed format.

- 16.21.2 The Executive Officer shall appoint an Ex Parte Committee as envisaged by the Constitution to provide the opinion.
- 16.21.3 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.
- 16.21.4 Ex parte matters shall be undertaken in writing, with the proviso that the Ex Parte Committee may request further information and/or clarity from the Applicant as deemed necessary.
- 16.21.5 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.
- 16.21.6 In its consideration of the ex parte request, the Ex Parte Committee shall:
  - 16.21.6.1 consider rulings previously made by Adjudicating and Appeal Committees (where applicable) in respect of the matter under consideration;
  - 16.21.6.2 confine itself to the question or 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
  - 16.21.6.3 provide a written analysis and application of the Code and/or Guidelines to the facts, a conclusion and the rationale for the conclusion.
- 16.21.7 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.



## **17 CHAPTER 17: TRADE ASSOCIATION AFFILIATION**

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### **17.1 Trade Associations involved in development of the Code**

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

### **17.2 Trade Associations and Companies represented by the MCA 2017**

- 17.2.1 Health Products Association (HPA)
- 17.2.2 Independent non-aligned members (Indep)
- 17.2.3 Innovative Pharmaceutical Association of South Africa (IPASA)
- 17.2.4 Pharmaceuticals Made in SA (PHARMISA)
- 17.2.5 Self-medication Manufacturers Association of SA (SMASA)
- 17.2.6 Southern African Laboratory Diagnostics Association (SALDA)



## 18 RECORD OF UPDATES TO THE CODE

### Version Control Form

First version for implementation	<b>2010</b>
Date for implementation	<b>October 2010</b>
<b>Version 1:</b> Updates proposed by SMASA, PIASA, SAMED, SALDA, Update according to ABPI, and EFPIA, IFPMA, EUCOMED	<b>July 2012</b>
<b>Version 2:</b> Changed Health Products to Medicines, IVD, Medical Devices; moved definitions to end of document, definition for Promotional aid and material, Update to ABPI code (Clause 7); added MSL for Pharma; patient support groups added; added icons for application	<b>February 2013</b>
<b>Version 3:</b> Application of Code Clause 24.20 Enforcement: Clause 54 Lodging a complaint; 55 Nominated complaints; 56 Adjudication closed process, not a hearing hence no representation including legal; Clause 59 – closed meeting	<b>4 March 2013</b>
<b>Version 4:</b> Added proxy complaint process	<b>14 March 2013</b>
<b>Version 5:</b> Part D changed in line with the Constitution;	<b>28 March 2013</b>
<b>Version 6:</b> Added definition of business day	<b>2 April 2013</b>
<b>Version 7:</b> New association IPASA (Innovative Pharmaceutical Association of South Africa (merger of PIASA and IMSA) and contact details of associations deleted. Minor typographical changes	<b>16 April 2013</b>
<b>Version 8:</b> Renumbered Part C. Part D updated to align with Constitution	<b>28 May 2013</b>
<b>Version 9:</b>	<b>November 2014</b>



<p>Updated to align with updated international codes.</p> <p>Part A: clauses 5.1; 7.1; 7.13; 18.5; 18.6; 18.8 (Patient registries), 19.4.2; 20; 22.2</p> <p>Part B: 25.2; 25.5; 25.9; 25.11; 25.15, 25.22; 25.23;</p> <p>Part C: Deleted Clauses 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>Clause 4.1.4; 48; 49.2 (deleted entity); 49.4; 49.6-8; 50.2-3; 51.2-4; 51.6; 52.4; 52.7; 53.2; 53.4; 54.2.4; 56 (Title change); 56.3-4; Deleted 59.5 (old no); 54.4; Added 57 Ex Parte Rulings; 57.6; 58.1;58.2; 58.4; 59.5; 57 (Title change); 57.3-4; 60.1.4</p>	
<p><b>Version 10:</b></p> <p>Updated to accommodate complementary and alternative Medicines (CAMS) and the Health Products Association (HPA). Minor typographical changes as well as changes summarised in the change summary.</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><b>November 2016</b></p>



<p>Definition of Faculty added; Faculty means active participants/HCPs who speak, present or serve another specific function at a 3<sup>rd</sup>-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, <i>individuals (clinical or non-clinical) including physicians, nurses, technicians and research coordinators</i>.</p> <p>Definition for Council of Clinical Engineers; Definition has changed the wording institutions, to <i>healthcare facilities</i>.</p> <p>Definition of Honorarium; Additional alternate wording included, or <i>alternatively Fee for Service</i>, and removes the limitations on payment to a <i>professional</i>.</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>	
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Addition:

Sampling

2.5 Scope of Application to include complementary and alternative Medicines;

The word *shareholders* in the industry has been included,

The marketing and Promotion of self-medication products to HCPs now includes *complementary and alternative Medicines (CAMS)*

The marketing and Promotion of self-medication products to the public now includes *complementary and alternative Medicines (CAMS)*.

This change is pulled through into Part A and B of the Code.

Part C Medical Devices

A more concise statement on Part C binds the marketing and Promotion Medical Devices and IVDs to Parts A and B of the Code except where otherwise indicated in Part C.

Part A of the Code

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

7.6 Substantiation

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

7.11 Use of the word "new"

This clause has been changed to read as follows; The word "new" may be used to describe any product, presentation or therapeutic indication, which has not been available in the market for more than 12 months in South Africa. (Wording



merely changes negative to a positive statement – no change in substance).

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

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

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

18.7 Other interactions with 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 1<sup>st</sup> 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 clause has been amended to include complementary and alternative Medicines (CAMS.)

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

40.2 has been amended to include *digital detailers*.

48 lodging of complaints has been amended to make the Company to Company process compulsory

48.7 has been amended by the addition of the following; Either party sending documents to the MCA bears the responsibility 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,



<p>and the Medicines Regulatory Authority at the discretion of the committee.</p> <p>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.</p> <p>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 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><b>Version 11: June 2018</b></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><b>2017</b></p>
<p><b>Version 12: 25<sup>th</sup> June 2019</b></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><b>2019</b></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>Clause 5.5.2.7: “Regulatory Authority” has been replaced with “the Medicines Regulatory Authority”.</p>	
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