



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

Version 11

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 compliance 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 was focussed 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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Final Draft

## 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 with the context;
  - 1.2 words and phrases that are defined in the Code have the meanings assigned to them in the Code unless inconsistent with the context;
  - 1.3 any word or phrase defined in any section hereunder, shall bear the same meaning throughout the remainder of this Code;
  - 1.4 unless specifically otherwise provided, any number of days prescribed shall be determined by excluding the first and including the last day or, where the last day falls on a day that is not a Business Day, the next succeeding 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 number includes the plural, and vice versa;
  - 1.7 a reference to the one gender shall include the other genders;
  - 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 partly in the form of a data message as defined in the Electronic Communications and Transactions Act 25 of 2002.
  - 1.10 where it is required that a document shall be signed by a person and the document 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
    - 2.1.1 discover, or verify the clinical, pharmacological or pharmacodynamic effects of the Medicine;

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

- 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).
- 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

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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.

<sup>4</sup> Medicines Act.

<sup>5</sup> Medicines Act.

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 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.

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<sup>6</sup> Medicines Act.

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

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 and other vehicle Advertising; light box Advertising as well as any other form of marketing or 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.

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

- 3.6 **Call Up** means Health Products, which have been identified as requiring registration in terms of Section 14(3) of the Medicines Act, which permits its 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 (which includes marketed and advertised) 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 and as such includes a member of the general public and a patient.
- 3.10 **Company** means a company, closed corporation, organisation, firm, vendor, individual or the like who may import, export, manufacture, sell, distribute or market Health Products ( ) and third parties acting on their behalf (e.g. advertisers).
- 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, that interact with HCPs and Consumers with regards to Health Products, or that 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, audio-visual or image message sent over an electronic communications network, which is stored in the network or in the recipient's terminal equipment until it is collected by the recipient and includes telephone, mobile phone, SMS, e-mail, mobile messaging, 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. A 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, 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 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 first-time introduction of a Health Product.
- 3.28 **Marketing Code Authority (MCA)** means the juristic body established as a voluntary association to create a mechanism for self-regulation of Companies, which are subject to the Code, and through which body 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 stated in the General Regulations<sup>9</sup> for Medicines and the Regulations relating to Medical Devices and IVDs<sup>10</sup> for Medical Devices and IVDs.
- 3.32 **Nominated Appellant** means the person contemplated in Section 16.12 who lodges an appeal in a matter where a Nominated Complainant 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 is identified by the Executive Officer.
- 3.34 **Off-label Use** means the use of a 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 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 **Promotional Activity** means any activity associated with Health Product promotion

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

<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).

and excludes a Promotional Event.

- 3.38 **Promotional Aids** means non-monetary items given away free of charge to promote a Company or Health Product.
- 3.39 **Promotional Material** includes Promotional Aids, detail aids, leave-behind pieces, booklets and advertorials, and includes the items listed under the definition of Advertisement, irrespective of the medium used, which includes Electronic/Digital Media.
- 3.40 **Promotional Events** means events organised in association with the promotion of a Health Product. Continuing Professional Development (CPD) or Continuing Medical Education (CME) events, which comply with the requirements of the Code are not considered Promotional Events.
- 3.41 **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 that serves one or more predetermined scientific, clinical, or policy purpose.
- 3.42 **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).
- 3.43 **Respondent** means the party against whom a Complainant has lodged a complaint for an alleged breach or contravention of the Code.
- 3.44 **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 this [Pharmacy] Act and other legislation applicable to services which specially pertain to the scope of practice of a pharmacist, and the legislation applicable to the pharmacy which is under his or her personal supervision.
- 3.45 **Retailer** means a business supplying Health Products directly to Consumers and includes FMCG retailers.
- 3.46 **Right of Sale** refers to the authorisation in terms of Section 14(3) of the Medicines Act to sell a Health Product.
- 3.47 **Sanction Policy Document** means the document which the Board publishes 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 with 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 its real nature. Promotion in the form of financial or material benefits shall not be offered to or sought by healthcare practitioners 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**

2.1.1 The objectives of the MCA shall be to:

- 2.1.1.1 ensure and maintain the ethical promotion and Advertising of Health Products within the scope of the Code by Companies subject to the Medicines Act and the Code;
- 2.1.1.2 ensure that those bound by the Code maintain high ethical and professional standards when conducting Promotional Activities and comply with applicable legal, regulatory and professional requirements;
- 2.1.1.3 adjudicate on complaints in terms of the Code; and
- 2.1.1.4 update and publish, on a regular basis, a code of practice for the marketing of Health Products.

### **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 a 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 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 Health 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 Marketing and Promotion of Health Products**

- 3.2.1 The marketing and 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), as relevant. 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 prior to the Health Product being registered by the Regulatory Authority in terms of Section 15 of the Medicines Act, unless Section 14(3) of the Medicines Act is applicable.
- 3.2.2 All Companies shall comply with applicable legal, regulatory and professional requirements as well as with the letter and the spirit of the Code.

- 3.2.3 Considering the provisions of Section 18C of the Medicines Act regarding Codes of Practice for relevant industries, the MCA intends that this Code be acknowledged as such for the Industry. Various Health Product trade associations and Companies have adopted the Code. This signifies the Industry's commitment towards ensuring that the marketing and promotion of Health Products to HCPs and Consumers are 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, as well as promotional programs and collaboration that enhance the rational use of Health Products and fair competition in the marketing and promotion thereof. 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, contracted events' 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 to the extent that they may influence the demand for Health Products, that agree to be subject to the Code; and
- 3.3.1.3 All Health Products, irrespective of being registered by the Regulatory Authority. Unregistered Complementary Medicines, Medical Devices and IVDs shall be evaluated against relevant legislation and guidelines, where there is not yet approved Professional Information/ /Patient Information Leaflet/Instructions for Use, for purposes of the Code.
- 3.3.2 The following specific activities of Companies, including their licence holders, agents, contractors, third-party distributors/marketers, contracted events' 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 his professional or other activities may prescribe, purchase, supply, administer, loan, rent or lease a Health Product or recommend the use thereof;
- 3.3.2.2 All Advertising and/or Promotional Material, which is directed at Consumers to inform them about the Health Products available for self-medication or use;

- 3.3.2.3 All Advertising and promotion in relation to and all activities directly or indirectly related to the marketing of a Health Product, which may reflect on the marketing 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 contemplated 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 circumvent the Code by engaging or using third parties, such as licence holders, agents, contractors, distributors/marketers and/or events' organisers, including but not limited to dispensing system software or ordering system vendors, shall infringe 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 marketing or promotion of Stock Remedies as defined under the Fertilisers, Farmfeeds, Agricultural Remedies and Stock Remedies Act 36 of 1947;
- 3.3.6.4 Issues relating to pricing, bonusing, sampling and perverse incentives governed by 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 and do not cover all possible situations that are 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 to regularly update 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 in terms of both 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 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 a Consumer or a group of Consumers.
- 3.5.3 Any Person or committee interpreting and applying the Code shall consider the Guidelines for guidance as to 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 adjudication, appeal and ex parte committees, as to amendments that should be considered by the relevant MCA structures in correcting 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 In any review of Advertising and/or Promotional Material or Promotional Events covered by this Code, consideration shall be given 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 at 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 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 self-regulation of the Industry 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.

Final Draft

## **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, 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 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 relevant requirements of the Code, applicable professional and good practice codes and all 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 information about their Health Products, which is issued by themselves and 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 according to detailed written instructions provided by the Company. The written instructions shall set out the role of the Company Representative in providing the service and shall cover patient privacy and confidentiality issues. Where patient contact may be

involved, instructions on how the recipients or patients are to be informed shall be included. The written instructions shall not advocate, either directly or indirectly, any course of action, which is 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 not be linked in any way 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 delivering materials but shall not instigate a detailed discussion about the service at the same time as a call at 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, particular patients unless written informed consent from both the HCP and patient has been received.
- 4.6.5 Companies shall ensure that patient confidentiality is maintained at all times and that data protection legislation is complied with.

#### **Guideline to Section 4.6**

##### **Note 1: Provision of Services by Company Representatives**

The nature of the service provider, the person associated with the provision of medical and educational goods and services, is important i.e. is the service provider a Health Product representative of the Company or is the service provider some other appropriately qualified person, such as a sponsored registered nurse? If the goods and services require patient contact, for example either directly or by identification of patients from patient records and the like, then Health Product representatives must not be involved. Only an appropriately qualified person, for example a sponsored registered nurse, not employed as a Health Product representative, may undertake activities relating to patient contact and/or patient identification.

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

##### **Note 2: Promotional activities by Company Representatives**

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

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

### **Note 3: Value-added services**

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

### **Note 4: Access to patient records**

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

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

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

### **Note 5: Reimbursement Services**

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

## **4.7 Scientific/Product Queries**

- 4.7.1 Inquiries from HCPs and Consumers regarding 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 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 inquirers 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 inquirers to consult their HCPs.

- 4.7.6 Companies shall ensure that their response to any public inquiry is not promotional.
- 4.7.7 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

#### **Guideline to Section 4.7**

##### **Note 1: Communications of scientific information to HCPs or Consumers**

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

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

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

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

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

#### **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 do not mislead as to 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, together with the manner in which they are made, do not cause inconvenience.
- 4.10.2 The wishes of individuals on whom Company Representatives would like to call and the arrangements in force at any particular organisation or establishment shall be

observed.

#### 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 at a direct request from the surgeon, operating room staff or any other HCP.

#### **Guideline to Section 4.11**

##### **Note 1: Operating Room or Clinical Environment**

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

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

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

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

## 5 CHAPTER 5: PROMOTION AND ADVERTISING

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### 5.1 General Principles

#### 5.1.1 Self-Medication

- 5.1.1.1 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 responsible use of self-medication and shall not encourage individuals to exclusively self-diagnose or self-medicate. 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 exclusion of more serious complaints or where 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, 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.
- 5.1.2 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.

#### Guideline to Section 5.1

##### Note 1: Weight management/slimming/body image

A weight reduction regime in which the intake of energy is lower than its output is the most common self-treatment for achieving weight reduction. Any claims made for the effectiveness of a weight reduction method or product must be backed by appropriate evidence. Testimonials that are not supported by trials do not constitute substantiation.

Marketers must show that weight reduction is achieved by loss of body mass before claims are made for a weight reduction aid or regimen. Combining a diet with an unproven weight reduction method does not justify making weight reduction claims for that that method.

A statement to the effect of: *'Only effective when used in conjunction with a kilojoule controlled balanced diet'* should be included on the label and in the advertisement for a product intended for weight loss/management

- 5.1.3 Advertisements shall not suggest that using a Health Product could enhance normal good health (except for 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 the HCPs can ensure that the Health Products prescribed or recommended will be 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 to diagnose, advise, prescribe or treat Consumers virtually, 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 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.
- 5.1.10 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 of 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 sales person 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 that relates to Health Products, but which is 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 could 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 relevant legislation.

### **Guideline to Section 5.2**

#### **Note 1: Reply paid cards**

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

## 5.3 **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 to such HCP or potential User. On subsequent occasions, such information shall be 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.

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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).

### **Guideline to Section 5.3**

#### **Note 1: High standards, suitability and taste**

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

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

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

#### **Note 2: Public interest criteria**

The following should be taken into account:

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

### **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:
  - 5.5.2.1 form part of the Promotional Material (except for 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 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 Regulatory Authority.*" This applies to all forms of Advertising and/or Promotional Material, including written, audio, audio-visual and Internet Advertisements and Promotional Material relating to Health Products, which is 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 which basis 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 some people.

## 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 mislead as to 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, balanced view of the matters with which they deal, and shall not be included unless they are relevant to the claims or comparisons being made.
- 5.6.4 Depictions of children shall not be used in relation to Health Products not authorised for use in children.
- 5.6.5 All artwork, including illustrations, shall not 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.

#### **Guideline to Section 5.6**

##### **Note 1: Artwork and visual representations**

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

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

Anatomical drawings, graphs and tables must not mislead.

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

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

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

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

### **5.7 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, if:

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 the same 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 made, are harmful or ineffectual.

## **Guideline to Section 5.7.1**

### **Note 1: Hanging comparisons**

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

### **Note 2: Price comparisons**

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

## 5.7.2 Accuracy, Balance and Fairness

- 5.7.2.1 This section applies to information or claims of a medical or scientific nature and also to, amongst others, information or claims relating to price lists and market share.
- 5.7.2.2 Information, claims and comparisons used in Promotional Material and activities, shall be accurate, balanced, fair, objective and unambiguous, shall be based on an up-to-date evaluation of all the evidence, and shall 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 mislead 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 as to 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, except for those limited circumstances where they relate to a clear fact about a Health Product and are substantiated.

## **Guideline to Section 5.7.2**

### **Note 1: Accuracy, balance and fairness of claims**

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

### **Note 2: Superlatives**

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

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

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

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

### **Note 4: Absolute risk and relative risk**

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

### **Note 5: Use of pharmaco-economic data**

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

### **Note 6: Emerging opinions**

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

### **Note 7: Use of statistical data**

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

be used in Promotional Material. Statistical significance must not be used to infer the clinical significance of an outcome or study.

### 5.7.3 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 mislead.

5.7.3.3 Advertising and/or Promotional Material shall not mislead about the novelty of a 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, 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 other pharmacokinetic particulars shall be acceptable if 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 man.

5.7.4.6.2 It shall be misleading to use the term 'natural' to describe ingredients that employ chemicals to change their composition or comprise the products of new technologies, including additives and flavourings that are the product of the chemical industry or extracted by chemical processes.

5.7.4.6.3 Advertising and/or promotional material shall not suggest that the safety, quality or efficacy of a Health Product is due to the fact that 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.

#### **Guideline to Section 5.7.4**

##### **Note 1: Speed of absorption claims (6.7.4.4)**

All speed of absorption and speed of action claims must be in line with the approved Professional Information. For indications such as pain and fever,

- 'fast' is taken to mean that the Health Product works within about 30 minutes,
- 'immediate benefit' as within 10 seconds,
- 'all day relief' if the Health Product works for at least 10 hours, and
- 'all night relief' if the Health Product works for at least 8 hours.

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

5.7.5.1 An Advertisement for a self-medication Health Product must not refer, 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 clearly state if Health Products are suitable for use over extended periods of time or where the Health Product is indicated for disease risk reduction or prevention.

5.7.5.3 Advertising and/or promotion shall not claim guarantees on a Health Product's effects, safety or quality.

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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*

- 5.7.5.4 Advertising and/or promotional material can refer to the prevention of symptoms and use of a Health Product in chronic conditions, if 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.

#### **Guideline to Section 5.7.7**

##### **Note 1: Exaggerated or misleading claims**

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

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

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

##### **Note 3: Sales claims**

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

#### 5.7.6 Use of the word 'Safe'

- 5.7.6.1 The word 'safe' or its grammatical derivatives 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 mislead.

#### 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 forms of those diseases, conditions, ailments or defects which are:

5.7.9.1 generally accepted not to be appropriate to be diagnosed and or treated 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 to 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, substantiation of any product claim shall be in accordance with the requirements of the Medicines Act.

5.8.4 All references shall be listed on 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 If confidential data on file, such as information relating to trade secrets, sensitive commercial information or information of a competitive nature, is involved, the material may be given to an independent arbitrator acceptable to both parties for assessment, in the case of a dispute. The arbitrator shall make an assessment as to whether the unpublished data support the statement(s) made in the Promotional Material. Alternatively, the information may be shared on conditions acceptable to both parties.

**Guideline to Section 5.8.**

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

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

- published data in a peer-reviewed journal
- standard textbooks, such as 'Martindale: The Complete Drug Reference' and 'British National Formulary'

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

**Note 2: Data in support of a claim**

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

**5.9 Endorsements, Testimonials and Quotations**

**5.9.1 Endorsements and Testimonials**

5.9.1.1 Advertising and/or Promotional Material shall not contain a recommendation of a Health Product by scientists, HCPs or community and 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 that is 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 marketing, promotional material, endorsements or testimonials has to 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 communications or opinions shall not be used unless the Company is able to supply written substantiation, based on scientific data, upon request.
- 5.9.2.4 Quotations from any study shall not mislead as to 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, and 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 accurately given 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.

#### **Guideline to Section 5.9**

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

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

##### **Note 3: Testimonials**

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

#### **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 as a 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 type size, which is legible on either the first or the last page.

## **Guideline to Section 5.10**

### **Note 1: Journals with an international distribution**

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

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

### **Note 2: Professional Information and Patient Information Leaflet**

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

## **5.11 Disparaging Claims**

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

5.11.1.1 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 originator 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, which is used in market research, whether promotional in nature or not, and which is 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, if 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 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 unsolicited to any HCP 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 prescribing information.
- 5.15.4 If a non-peer-reviewed article is requested by an HCP, a copy may be provided on written request or in accordance with the provisions 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 that is 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 their request or with their permission.
- 5.16.4 These provisions are subject to the provisions of applicable legislation such as the Consumer Protection Act 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 Health Product details of each Health Product that they will promote and instructions as to 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.

### **Guideline to Section 5.16**

#### **Note 1: Electronic detailing**

The principles embodied in the Code apply equally to electronic detailing (“eDetailing” or “e-Detail aid”) using such devices as iPads, tablets, etc. Care should be taken to ensure that all text complies with the requirements of the legislation and the Code and is easily legible from a comfortable distance.

Care should be taken when each page is viewed separately that the information is not false or misleading when read in isolation.

Placement of mandatory requirements such as, generic names, p-values, statements of significance, etc. should follow the same principles of the Code and should be clearly visible on the screen – they cannot only be visible within an animated feature such as a pop-up, etc.

The reference “refer to approved Professional Information for full prescribing information” is no longer mandatory if the full Professional Information is directly accessible from within the eDetail aid.

It is possible to give emphasis to a specific part of the content/area of a tablet screen through the use of light boxes, stretching/enlarging graphs etc.

Content must not be constructed in such a way that there is loss of context by obscuring critical elements, for instance, a claim remains visible, but a related qualifier statement, or other descriptive text that provides context, is hidden by a pop-up screen.

Qualifying statements should follow the same principles embodied in the Code. They should be linked to the relevant claim with a readily identifiable asterisk or similar device.

Qualifying statements must appear directly below or adjacent to the claim, and must be in prominent text such that the text size for the qualifying statement is larger than the other minimum text size on the screen. A qualifying statement should always be visible when its corresponding claim is on the screen.

The qualifying statement must not be hidden by pop-ups, if a section of the screen is enlarged, or positioned such that a person has to scroll further down the page to see it.

Other mandatory information should all be no more than 2 clicks away from any one screen (i.e. could access via a menu bar) or appear as part of the e-detailer e.g. at the end of each 'chapter/section' of information where an e-detailer is so designed.

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

- 5.18.1 Promotion of Health Products by way of any form of Electronic Communication or by using 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 where, when first contact is made with the relevant Person, the option to opt out is provided to that Person and the Person's decision is subsequently respected by the Company.
- 5.18.3 The option to opt out shall also be provided with 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 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 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 within the body of the Advertisement a reference to refer, before prescribing, to the approved Professional Information/Patient information leaflet/Instructions for Use, or
  - 5.18.5.2 a direct hyperlink to the Professional Information/Patient information leaflet/Instructions for Use outside of 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 the reader 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 must be a secure site, designed to allow access only to HCPs.
- 5.18.7.2 In the case of an Advertisement on the Internet, 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 legislation.
- 5.18.7.3 It shall be clear when the reader is leaving the site or when the reader is being directed to a site that the Company has not developed or is not responsible for.
- 5.18.7.4 Any references or linkages to other reputable information sources shall be to sources, which provide valuable educational material that will 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 Audio-visual material

- 5.18.8.1 Audio-visual 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 that is made available to all Persons to whom the material is shown or distributed, or by inclusion on the audio-visual recording or in the interactive data system itself.
- 5.18.8.3 When the minimum information is included in an interactive data system, 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 that is made available to all Persons to whom the material is played or sent.

#### **Guideline to Section 5.17**

##### **Note 1: Electronic journals**

The first part of an advertisement in an electronic journal, such as the banner, is often the only part of the Advertisement that is seen by readers. It must therefore

include a clear, prominent statement as to where the minimum information can be found. This should be in the form of a direct link.

The first part is often linked to other parts and in such circumstances, the linked parts will be considered as one advertisement. If the first part mentions the Health Product name, then this is the most prominent display of the brand name and the non-proprietary name of the Health Product or a list of the active ingredients using approved names where such exist, must appear immediately adjacent to the most prominent display of the brand name. The size must be such that the information is easily readable.

The requirement that Promotional Material and activities should not be disguised should also be borne in mind.

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

A Company may wish to provide promotional and educational material to HCPs via an application downloaded on mobile media platforms (electronic devices). If the application contains Promotional Material it must be a secure application that is designed to allow access only to HCPs. Examples of acceptable Smartphone Apps include, but are not limited to medical dictionaries, access to clinical papers, conference proceedings or planners, and dose calculators.

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

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

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

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

### **Note 3: QR Codes/2D Codes**

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

#### **Note 4: Social Media**

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

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

whether discussion boards need to be monitored and how regularly;

how to manage inappropriate conversation;

establishing rules for participants joining a discussion forum that:

- outline what is inappropriate conversation (e.g. offensive language, racist comments, promotion of a product) and that conversations may be monitored;
- describe whether any content would be excluded from the media, and the process for excluding it;
- provision for discussion boards to be shut down at any time;
- responsibilities for reporting of monitoring and reporting of Adverse Events reported via this media.

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

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

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

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

#### **Note 5: Company-controlled websites for HCPs**

A mechanism such as a password protected site or other entry system will comply with the requirements of this section. An entry system such as a provider number will also be acceptable. The password to gain access to a restricted access site should not be a word that will be easily identifiable, such as the product name.

### **Note 6: Minimum information on audio-visual material**

Where details of the requirement for inclusion of “minimum information” is shown in the audio-visual material as part of the recording, it must be of sufficient clarity and duration to be heard or seen by the listener/viewer. The minimum information must be an integral part of the Advertisement. It is not acceptable for the Advertisement and the minimum information to be separated by any other material.

Publications and Advertisements may be affixed to the side of the audio-visual device or included on the box containing the audio-visual material. The minimum information must, however, be made available for any Advertisement for a Health Product appearing on audio-visual material or in an interactive data system or on the Internet, including journals on the Internet.

### **Note 7: Webinars**

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

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

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

## **5.19 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 regarding Off-label Use, shall comply with 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) to 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 about an unapproved Health Product or indication with the HCP shall be with the Company's medical department personnel and not a member of a commercial function or team.

#### **Guideline to Section 5.18**

##### **Note 1: Provision of information during medicine development**

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

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

Medical schemes require advance information about the introduction of new medicines or changes to the existing medicines in order to review the reimbursement status before approval for reimbursement. Information that may be provided includes:

- Health Product that contains a new active substance, or active substances prepared in a new way (e.g. biotechnology)
- Health Product that has a new registered indication
- Health Product that has a novel and innovative means of administration

Information may be directed to policy-makers in which case the registration status of the product, must be clearly indicated

Only factual information and Company logos instead of product promotional logos should be used.

**Note 3: Promotion at international conferences**

The display and provision of Promotional Material for unregistered medicine and/or indications is permitted at international meetings in South Africa provided the following conditions are met:

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

Final Draft

## **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 either be the responsible pharmacist and/or a natural person responsible for the enforcement of and compliance by the Company 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 he 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 include:
- 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, parts 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, if required.
- 6.1.7 The Executive Officer may, either in response to a formal complaint or for any other reason, monitor and review 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 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 to the MCA for scrutiny.
- 6.1.8 The purpose of 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, which records 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 and truthful 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, as may be 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 Criteria; for selection
  - 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 be 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 form approved with information indicating the Persons to whom it was addressed, the method of dissemination and the date of first dissemination.

### **Guideline to Section 6.2**

#### **Note 1: Certification of travel arrangements**

When certifying meetings that involve travel inside or outside South Africa, the Company Code Compliance Officer must ensure that all the arrangements are examined, including the programme, the venue, the reasons for using that venue, the intended audience, the anticipated cost and the nature of the hospitality and the like.

This would include travel arrangements for speakers. It would also include any arrangements to sponsor travel or accommodation for delegates to a local conference where the money is paid to the professional body organising the conference, or sponsorship of travel or accommodation for delegates to an international conference.

#### **Note 2: Joint ventures and co-promotion**

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

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

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

### **6.3 Re-Approval of Promotional Material**

6.3.1 Promotional Material that is still in use shall be re-approved at intervals of 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 the minimum period of 5 (five) years.

6.4.2 Companies shall preserve all proof of approvals 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 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
  - 7.2.2.4 That such donations are not made for Health Product promotional purposes
- 7.2.3 Donations may only be made to organisations subject to applicable legislation.
- 7.2.4 The donation shall be made directly to the relevant organisation and must not be paid directly to Healthcare Professionals or to 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 of interest or potential conflict of interest between the Company and the organisation supported.
- 7.2.7 A donation shall not constitute a payment that will 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 allowed
- 7.2.9 Companies are encouraged to make available publicly, information about donations, grants or benefits in kind made by them as covered in this section.

## Guideline to Section 7.2

### Note 1: Donations to charities

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

## 7.3 Sponsorship

7.3.1 Companies may sponsor medical education or training, or similar services provided by other organisations. Sponsorship material shall be accurate, contain balanced information on the subject and include a clear indication of which Company has produced the sponsored material.

7.3.2 Nothing shall be offered or provided in a manner or on conditions that will 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 proper and effective use of Health Products through financial support of HCP activities.

7.4.2 A Company may provide a grant or financial support provided that the grant or financial support is 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 Improvement of patient outcomes.
- 7.4.4 A grant or financial support shall not be conditional on an HCP, institution or health related organisation recommending, prescribing, dispensing or administering a Company's Health Product(s).
- 7.4.5 Clear guidelines, which can be publicly disclosed, if required, shall be developed in relation to the awarding of grants and financial support.
- 7.4.6 There shall be a written agreement in place outlining the nature of the grant or financial support provided.

#### **Guideline to Section 7.4**

##### **Note 1: Faculty expenses for HCPs visiting South Africa**

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

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

## **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.

#### **Guideline to Section 8**

##### **Note 1: Banded pack for Schedule 0 products**

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

It is not permissible to band together different dosage forms or products e.g. Product X syrup and Product X lozenges or Product X and Product Y.

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

## 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 completion of a survey, or as a prize for a competition; and
  - 9.1.1.6 the competition complies with relevant legislation such as the Consumer Protection Act, if applicable.

#### Guideline to Section 9.1

##### Note 1: Competitions and quizzes for HCPs

- The use of competitions, quizzes and such like for the purposes of sales promotion is an acceptable form of promotion.
- Any competition must be in good taste and must not involve any subject matter that is inappropriate for the promotion of a health product as required under Clause 9.1.
- Participation in competitions and quizzes related to the promotion of Schedule 2-6 Health Products is limited to HCPs only.
- A competition is acceptable if its subject-matter as well as the prize(s) offered are clearly related to the HCP's practice.
- Entrance into the competition should not be linked to the sale, recommendation or prescription of the Health Product in any manner or form.
- The maximum value per prize in a promotional competition for HCPs is R 2 000 (inclusive of VAT) per event or Promotional Activity.
- The total value of all prizes for a competition for HCPs must not exceed R40 000 (inclusive of VAT).

- If the prize is congress sponsorship, it may cover bona fide conference fees, accommodation and travel for the winner only and will be subject to the Code requirements for sponsorship

## 9.2 **Consumer Competitions**

9.2.1 Competitions for Consumers shall be permissible provided that:

- 9.2.1.1 entry into consumer competitions is 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 only relates to Schedules 0 and 1 Medicines or Classes A and B Medical Devices and
- 9.2.1.4 the competition complies with relevant legislation such as the Consumer Protection Act, if applicable.

### **Guideline to Section 9.2**

#### **Note 1: Value of competition prizes**

The total value of the prizes for a consumer competition must not exceed R100 000 (inclusive of VAT); and each individual prize may not exceed R5 000 (inclusive of VAT).

A donation of any nature linked to the competition needs to be included in the total prize money.

Competitions to wholesalers, the FMCG trade, spaza store owners, retailers, forecourt owners and the like are to be treated in the same manner as a competition to a HCP with the same criteria applying.

#### **Note 2: Competitions open to Consumers**

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

## 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 Programs 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 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 benefit 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.

#### Guideline to Section 10.1

##### Note 1

The following is a tabulated summary of what would be regarded as acceptable or not acceptable when interacting with HCPs. Please note that the table provides a set of examples only and is not intended as an exhaustive list.

	Medical Education content	Company branded event-related pens, notepads, lanyards, token bags	Promotional product content	Product branded promo aids, brand reminders
Company educational event	√	√	X	X
Third-party educational event (dependent on 3 <sup>rd</sup> party agreement)	√	√	X	X
Advisory Board meeting	√	√	X	X
Clinical Investigator meeting	√	√	X	X
Trade display	√	√	√	√
Medical representative detailing healthcare professional	√	√	√	√

**Note 2: Venues**

Programmes requiring 'hands on' training in medical procedures should be held at training facilities, medical institutions, laboratories, or other appropriate facilities.

It is inappropriate to host HCPs at venues that would be considered holiday destinations and which are distant from their normal place of practice, unless it is a bona fide educational meeting, conference or congress, endorsed by a Professional Healthcare Association

**Note 3: The reasonableness of hospitality**

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

**Note 4: International travel**

Companies may sponsor business class travel for HCPs only for:

- Faculty members presenting at a congress irrespective of day of arrival.
- HCPs attending advisory boards and clinical investigations irrespective of day of arrival.

Business class airfares may not be exchanged for two Economy tickets so that a companion/spouse may accompany the HCP.

It is not appropriate to pay for travel expenses for guests or spouses/partners of HCPs or for any other person who does not form part of the trainees or invited attendees at such a meeting.

Travel should be arranged by the sponsoring company (or their designated travel agent), and should be restricted to the designated meeting dates (dependent on the travelling time involved, which may include arriving 48 hours before the meeting, and departing soon thereafter).

An official agenda should be prepared for the meeting.

**Note 5: Local travel**

Where there are objective reasons to support the need for out-of-town travel to facilitate the exchange of information, reasonable travel costs, including economy class airfares for the attending HCPs who reside outside of the main centre or centres where such training takes place, may be reimbursed. The only exception for economy class travel locally will be a documented medical condition that necessitates business class travel.

It is not appropriate to pay for travel expenses for guests or spouses/partners of HCPs or for any other person who does not form part of the trainees or invited attendees at such a meeting.

**Note 6: Any other travel**

For any other travel, economy class travel is the standard class travel that companies may offer HCPs to attend both local and international events, including congress attendance and site visits.

**Note 7: Conference programme**

International events:

- An event is 'international' when participants are practicing in different countries. A national meeting with international speakers will still be considered national if all the participants are practicing in the same country.

The schedule of the scientific conference programme:

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

The availability of the programme in advance:

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

The relevance of the programme:

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

#### **Note 8: Geographic location**

No Company may organise or sponsor an event that takes place outside its home country unless:

- most of the invitees are from outside of its home country and, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the event in another country, or;
- given the location of the relevant resource or expertise that is the object or subject-matter of the event, it makes greater logistical sense to hold the event in another country.

The time of the year should be taken into account in determining if a geographic location is appropriate.

The geographic location should not be the main attraction of the conference. The image of the location among Consumers, media and authorities may not be perceived as a purely luxury, touristic/holiday and/or entertainment venue.

#### **Note 9: Meals**

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

- The meal should be incidental to the bona fide presentation of scientific, educational, or business information and provided in a manner conducive to the presentation of such information. The meal should not be part of an entertainment or recreational event.
- Meals may occur at the HCPs' place of business. However, in some cases the place of business may be a patient care setting that is not available for, or conducive to, such scientific, educational, or business discussions.

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

- where the medical technology cannot easily be transported to the HCPs' location,
- when it is necessary to discuss confidential product development or improvement information, or
- where a private space cannot be obtained on-site.

Meals may only be provided to HCPs who actually attend the meeting. Meals for guests of HCPs or for any other person who does not have a bona fide professional interest in the information being shared at the meeting is not allowed.

**Note 10: Hospitality and accommodation at congresses**

The level of accommodation offered must be appropriate, modest in nature, and the costs involved must not exceed that level that the recipients would normally accept when paying for themselves.

The appropriateness of accommodation: Companies may not pay for or reimburse HCP lodging expenses at top category or luxury hotels.

The accommodation must be limited to the duration of the conference – accommodation and/or other services provided to HCP delegates should not cover a period of stay beyond the official duration of the conference.

The registration fee: The registration fee should cover only the scientific programme and authorised activities and hospitality.

**Note 11: HCPs unconnected to any congress**

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

**10.2 CPD Meetings**

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

10.2.1.1 No Health Product promotion is allowed in the meeting room. Company-branded

items/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 Health Product Promotional Material displayed outside of the meeting room is not visible to Consumers if it is not permissible to market such Health Product directly to Consumers;
- 10.2.1.4 For local CPD events and Health Product launches, which are held in major cities, reasonable travel arrangements or reimbursement of actual travel expenses may be made to ensure that the HCPs who do not reside/practise in major cities are able to access the applicable information;
- 10.2.1.5 The criteria for selection of attendees/invitees are transparent and available to the MCA on request for scrutiny.
- 10.2.2 Companies shall not pay HCPs for their time whilst attending 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 to provide medical education that will 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 of 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 is directly related 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 as to which HCP is sponsored shall be made by the Company's Code Compliance Officer.
- 10.3.5 The decision to sponsor an HCP must be able to withstand public and professional scrutiny.

- 10.3.6 For medical or scientific congresses, conferences and seminars held in South Africa or internationally, whether 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, Hospitality provided and the like;
  - 10.3.6.3 As with any meeting, it shall be the program 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.

### **Guideline to Section 10.3**

#### **Note 1: Entertainment at conference**

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

#### **10.4 Transparency Related to 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 it 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 especially those related to inducements and Promotional Aids. They shall not be provided to HCPs for their personal benefit.

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

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

#### **Guideline to Section 11.1.1**

##### **Note 1: Items of medical utility**

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

For scientific medical reference books / journals and periodicals

- individual practicing HCPs or practices, the value should not exceed R 2 500 (inclusive of VAT)/year
- training or academic institutions, the value should not exceed R 10 000 (inclusive of VAT)/year

The value of medical devices should not exceed R300 (inclusive of VAT) / per item with a cap of R 2500 (inclusive of VAT)/ practice or institution per annum.

Other items of medical utility may be offered or provided if such items are of modest value, do not offset routine business practices and are beneficial to enhancing the provision of medical services and patient care.

Items might include an anatomical model for use in an examination room, or medical textbooks, as both primarily involve a patient benefit. A DVD or CD player however will not be permissible.

Items should not be offered on more than an occasional basis, even if each individual item is appropriate.

##### **Note 2: Medical and educational goods and services**

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

- The role of Company Representatives in relation to the provision of goods and services supplied in accordance with the Code needs to be in

accordance with the principles set out below. In this context Companies should consider using staff other than Health Product representatives.

- If Company Representatives provide, deliver or demonstrate medical and educational goods and services then they must not be linked in any way to the promotion of Health Products.
- In order to comply with this stipulation the Company Representative must not carry out both activities at the same visit.
- Company Representatives may introduce a service by means of a brief description and/or delivering materials, but may not instigate a detailed discussion about the service at the same time as a call at which Health Products are promoted.
- The acceptability of the role of Company Representatives will depend on the nature of the goods and services provided and the method of provision.
- The nature of the service provider, the person associated with the provision of medical and educational goods and services, is important i.e. is the service provider a Health Product Company Representative or is the service provider some other appropriately qualified person, such as a sponsored registered nurse? If the goods and services require patient contact, for example either directly or by identification of patients from patient records and the like, then Health Product representatives must not be involved. Only an appropriately qualified person, for example a sponsored registered nurse, not employed as a Health Product representative, may undertake activities relating to patient contact and/or patient identification. Health Product representatives could provide administrative support in relation to the provision of a screening service, but must not be present during the actual screening and must not discuss or help interpret individual clinical findings.
- Neither the Company nor Company Representatives may be given access to data/records that could identify, or could be linked to, particular patients unless healthcare professional and patient consent is received in writing.
- Companies must ensure that patient confidentiality is maintained at all times and that data protection legislation is complied with.
- Service providers must operate according to detailed written instructions provided by the Company. These should be similar to the briefing material for Company Representatives as referred to in Clause 15. The written instructions should set out the role of the service provider and should cover patient confidentiality issues. Instructions on how the recipients are to be informed, etc. should be included. The written instructions must not advocate, either directly or indirectly, any course of action which would be likely to lead to a breach of the Code.

- Service providers must abide by the principle set out in Clause 15 that in an interview, or when seeking an appointment, reasonable steps must be taken to ensure that they do not mislead as to their identity or that of the Company they represent.
- A recipient of a service must be provided with a written protocol to avoid misunderstandings as to what the recipient has agreed. The identity of the sponsoring Company must be given.

## 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 limit 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;

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 The minimum information<sup>16</sup> required by the legislation for an Advertisement of a Health Product does not have to be included on the occasional item provided that 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).

## **Guideline to Section 11.1.2**

### **Note 1: Occasional items**

Items of general utility, which have been held to be acceptable items to HCPs as being inexpensive and of relevance to their practices, include but are not limited to pens, pads, diaries, nail brushes, desk trays, calendars, and desk clocks.

Diaries and desk pads bearing advertisements of Health Products must comply with the provisions of Regulation 42 and 21 (in respect of medical devices and IVDs) and the Code.

### **Note 2: Detail on promotional Aids**

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

### **Note 3: Value of occasional items**

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

### **Note 4: Package deals**

Clause 12.1.2 does not prevent the offer of package deals for patients in terms of which the purchaser of particular Health Products receives with them other associated benefits, such as apparatus for administration, provided that the transaction as a whole is fair and reasonable and the associated benefits for the patient are relevant to the Health Products involved.

#### 11.1.3 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, which are to be passed on to patients and which are part of a formal patient support program, the details of which have been appropriately documented and approved in advance as per the Code.
- 11.2.2 The items shall be inexpensive and directly benefit patient care. 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 that it shall always benefit patients and be in accordance with the law and the Code.

- 11.2.4 Patient support and/or patient group meetings, patient-related events and patient support materials may be sponsored provided that records are retained as required in terms of the Code and that no Health Product promotion takes place. The fact that sponsorship or support has been provided shall be displayed on the materials and/or at the meeting or event.

### **Guideline to Section 11.2**

#### **Note 1: Patient support items**

Patient support items may be provided to HCPs by Company Representatives during the course of a promotional call and Company Representatives may deliver such items when they are requested by HCPs, for example on reply paid cards. Examples of items which will be acceptable include a peak flow meter as part of a scheme for patients to regularly record readings or a pedometer as part of a scheme to encourage exercise, perhaps for obese patients subject to the provisions of relevant legislation.

Patient support items may be made available for use by HCPs even though they may not be passed on to patients for them to keep. Their purpose is to allow patients to gain experience in using their Health Products whilst under the supervision of a HCP. Examples include inhalation devices (with no active ingredient) and devices intended to assist patients to learn how to self-inject. The perceived value to the HCP and the patient must be similar.

#### **Note 2: Items for patients**

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

#### **Note 3: Direct patient contact**

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

## 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 and chairing of meetings, involvement in medical/scientific studies, Clinical Trials or training services, participation at advisory board meetings, and participation in market research, where such participation involves a FFS/Honorarium and/or reimbursement of travel expenses and/or the provision of Hospitality.
- 12.1.2 The arrangements that cover 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, which specifies 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 HCP's, 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 the services;
- 12.1.3.3 Documented details of arrangements entered into 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 on a part-time basis an HCP, who is still practising his profession, shall require such HCP to sign a declaration to the effect that he shall have an obligation 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 shall be directly related to the identified need of the Company for their services and the persons responsible for selecting the consultants/advisers shall have the expertise necessary to evaluate whether 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, and makes appropriate use of, the services provided by consultants/advisers.
- 12.1.8 The hiring of the consultants/advisers to provide the relevant services shall not be an inducement to recommend, prescribe, purchase, supply, sell or administer a 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 it is in terms of a written agreement and a written record of such expenses and payments is retained by the Company Code Compliance Officer. Actual costs must be retained by the Company.

### **Guideline to Section 12.1**

#### **Note 1: Acceptable consulting services**

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

- speakers for conferences and congresses
- presentation and demonstrations at Company sponsored product training
- advisory boards
- training services
- development of educational material / software or programmes
- development and/or management of patient compliance software/programs

### **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 to HCPs or groups of HCPs, either directly or indirectly, for rental of rooms or other services.
- 12.2.3 HCPs involved in bona fide, and, if 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 merit 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 applicable laws, including but not limited to the protection of patient privacy and the obtaining of informed consent from the relevant person in respect of the collection and use of the patient information.

### **Guideline to Section 12.3**

#### **Note 1: Consent for access to patient data**

Neither the Company nor its Company Representatives may be given access to data/records that could identify or could be linked to a particular patient unless with the express written consent of the patient and the HCP. This does not apply to clinical researchers whose activities are controlled under the Good Clinical Practice Guidelines, in line with the best international practice viz.

patient confidentiality. Companies must ensure that patient confidentiality is maintained at all times.

approval by Company Code Compliance Officer of materials relating to the provision of medical and educational goods and services, such as internal instructions, external instructions, the written protocol for recipients and printed material etc., must be examined by the Company Code Compliance Officer. Companies are to ensure that the requirements of the Code are met.

A copy of the materials must be made available to the SA Marketing Code Authority on request.

## **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, there shall be a written agreement, which states the amount of funding and also the purpose thereof.
- 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 text of patient organisation material 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 proprietary material by a Company shall require written permission from that organisation.

### **13.2 Contracted Services**

- 13.2.1 Contracts between Companies and patient organisations in terms of which such organisations provide services to those Companies shall only be allowed if such services are provided for the purpose of supporting healthcare or research.
- 13.2.2 It is permitted to engage patient organisations as experts and advisers for services such as participation at advisory board meetings and speaker services in terms of 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 Requests from individual Consumers for information or advice on personal medical matters shall be refused by Companies and the enquirer shall be advised to consult his own HCP.

### **14.4 Information Available to Consumers**

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

14.4.1.1 factual; and

14.4.1.2 presented in a balanced way.

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

14.4.2.1 raise unfounded hopes of successful treatment; or

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

14.4.2.3 not 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 relating to substitution of a Health Product or information on safe use, 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).

## **Guideline to Section 15.4**

### **Note 1: Information to Consumers**

This section allows for the provision of non-promotional information about Schedules 2 and above Medicines and Classes C and D to Consumers either in response to a direct inquiry from an individual, including inquiries from journalists, or by dissemination of such information via press conferences, press announcements, television and radio reports, public relations activities and the like. It also includes information provided by means of posters distributed for display in surgery waiting rooms etc.

This prohibition does not apply to vaccination campaigns or other public health campaigns carried out by Companies and approved by the Department of Health and/or the Regulatory Authority.

Any information so provided must observe the principles set out in this section, that is, it should be factual, balanced and must not encourage Consumers to ask their HCPs to prescribe a specific Health Product. It must not constitute the Advertising of Health Products to the general public prohibited under the Medicines Act which must be observed if an inquiry is from a Consumer.

Particular care must be taken in responding to requests from the media to ensure that the provisions of the Code are upheld.

In the event of a complaint which relates to the provisions of this section, Companies may be asked to provide copies of any information supplied, including copies of any relevant press releases and the like. This information will be assessed to determine whether it fulfills the requirements of this section. Professional Information/Patient Information Leaflets/Instructions for Use may be provided to Consumers on request. Companies may provide HCPs with approved Professional Information/ Patient Information Leaflets /Instructions for Use concerning a Health Product for supply to their patients to whom the Health Product has already been prescribed.

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

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

14.5 **Patient Education**

- 14.5.1 Patient education ('help-seeking Advertisements') directed at Consumers is acceptable, provided that the material:
- 14.5.1.1 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 health product risk-related information;
  - 14.5.1.4 conveys to Consumers that treatment exists 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 to Consumers and may also sponsor training provided by other organisations. The relevant training material shall be accurate, contain balanced information on the subject and include a clear indication of which Company has produced the sponsored material. Refer also to Chapter 13 in this regard.

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

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### 15.1 Demonstrations

- 15.1.1 Medical Devices and IVDs used for exhibition purposes are typically unsterilised single use Medical Devices and IVDs or mock-ups of such Medical Devices and IVDs that are used for HCP and patient awareness, education and training.
- 15.1.2 Exhibition Medical Devices and IVDs shall not be used in patient care.
- 15.1.3 Exhibition Medical Devices and IVDs shall be identified as not intended for patient use by designations such as “*Sample,*” “*Not for Human Use,*” or another suitable designation on the Medical Device or IVD, its packaging, and/or documentation that accompanies it.
- 15.1.4 An HCP may use an exhibition Medical Device to show a patient the type of Medical Device that will be implanted in the patient.

### 15.2 Performance Evaluations, Appraisals and Training

- 15.2.1 It is common practice for Medical Device and IVD Companies to have local HCPs evaluate and appraise a new device. Such evaluations may take place prior to its launch nationally, 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 for free has to take place within the applicable legislative provisions.
  - 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 wishing to conduct a Medical Device or IVD product appraisal 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 that has been requested by a Company for justifiable medical or scientific reasons, provided that it 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 made as part of a Clinical Trial or investigation or registered/approved research project, it complies with the relevant provisions of the Medicines Act and other applicable legislation;
  - 15.2.2.6 Written evaluation results are provided to the Company.
  - 15.2.2.7 All evaluations have a finite time period or alternatively a finite number of procedures to 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, an equipment evaluation

protocol is approved by an accredited Research Ethics Committee before the evaluation commences;

- 15.2.2.10 All costs for the duration of the equipment evaluation are borne by the Company. This shall be documented. The Company may be required to provide such documentation as part of a Code enforcement process; and
- 15.2.2.11 If the evaluation leads to publications, lectures and other presentations, the sponsoring Company's name is disclosed.

## **Guideline to Section 15.2**

### **Note 1: Technology**

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

### **Note 2: Single use/consumables/disposables**

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

### **Note 3: Multiple use/capital equipment**

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

## **15.3 Loan or Placed Equipment**

- 15.3.1 The sale or placement of Medical Devices or IVDs with an HCP where the agreement between the Company and the HCP includes the purchase of consumables/disposables associated with the Medical Device or IVD shall be done in terms of a written agreement, which clearly outlines the terms and conditions of the arrangement, including the financial arrangements. The agreement shall not encourage perversity.

- 15.3.2 The consumables may be used to cross-merchandise the capital equipment in a manner, which is defensible and fair.
- 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 applicable legislation.

**Guideline on Section 15.3**

**Note 1: Items on long term loan**

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

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

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### **16.1 General Principles**

- 16.1.1 The MCA is recognised as a 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 an efficient and effective 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, or be required by law to abide by, the enforcement mechanisms created by the Code and the Constitution.

### **16.2 Referral of Complaints**

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

### **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 for resolution of a matter, which it deems not to have been resolved satisfactorily.
- 16.3.2 A Person is not deprived of the right to obtain any interim relief in an appropriate court of law whilst 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 of the same Company that was previously complained about 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 as provided for in 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 adjudicating committees, and non-compliance of Companies with rulings or undertakings as provided for in the Code. An appeal committee is appointed from Panels of Experts by the Executive Officer when an appeal is filed. 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 in its sole discretion may determine from time to time, which shall include the use of electronic mechanisms (e.g. teleconferencing, video-conferencing, etc.).
- 16.6.2 The adjudicating 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 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.
- 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. The Executive Officer shall inform the parties accordingly should this occur.
- 16.6.4 The adjudicating committee shall be entitled to obtain independent expert opinion, or, request an independent person with expertise to appear before the committee and provide his opinion on a matter relevant to the matter before it. The adjudicating committee shall share such independent opinion obtained with both the Complainant and Respondent.
- 16.6.5 The adjudicating committee may resolve to take no action in respect of a complaint and shall make such a decision supported by written reasons, i.e. the Adjudication Ruling, if 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 complained about cannot be resolved in terms of the Code;
  - 16.6.5.2 The length of time that has elapsed between the date when the subject-matter of the complaint arose and the date when the complaint was made is such that an

adjudication of the complaint 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 wants to pursue the complaint.
- 16.6.5.6 The complaint does not allege any facts which, if true, will 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 elapsed after the act or omission that is the cause of 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 that the 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 and guidelines stipulated and 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.
- 16.6.7 Without fettering the discretion of the adjudicating committee, in circumstances where it has found that the Respondent has contravened the Code in respect of Advertising and/or Promotional Activities, the adjudicating committee shall amongst others have regard to the following factors 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 or are safety implications;
  - 16.6.7.7 Whether the material or publication was or is misleading and the extent thereof;
  - 16.6.7.8 The manner in which the perceptions of HCPs or Consumers have been or will be affected;
  - 16.6.7.9 Whether commercial damage or harm has been caused, and the extent thereof; 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 the adjudicating committee 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. The Executive Officer shall inform the parties accordingly should this occur.
- 16.7.4 The appeal committee shall be entitled to obtain independent expert opinion, or, request an independent person with expertise to appear before the committee 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 Upheld the appeal;
- 16.7.5.3 Impose any one or more appropriate sanctions 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 overturned 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 thereof, be forfeited, or, be 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 make an order in respect of 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, which is 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 originally 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 the first course of action, Companies shall attempt to resolve an alleged transgression of the Code directly between them.
- 16.8.2 The complaint shall be submitted in writing by the Complainant to the Company Code Compliance Officer or another suitable senior person at the Respondent, describing the nature of the complaint and the section or sections of the Code alleged to have been contravened. A written response shall be requested within 7 (seven) Business Days from the Respondent.
- 16.8.3 If a response is received and the complaint is resolved, the complaint shall be considered to be closed. The parties shall keep all documentation relevant to the complaint on record for a period of 5 (five) years.
- 16.8.4 A reasonable resolution time of the matter is considered by the MCA to be 15 (fifteen) Business Days, but the timelines shall be determined by the parties.
- 16.8.5 If the matter is 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 solely used for record purposes by the Executive Officer and to inform Guidelines in respect of the specific section or sections in or amendments to the Code, as may be necessary.
- 16.8.6 If a response is not received as contemplated in Section 16.8.2 or the complaint is

not resolved to the satisfaction of any party, a formal complaint may be lodged to the MCA as provided for in Section 16.11.

16.8.7 A Company may justify the need for an anonymous process 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).

16.8.8 If the alleged contravention is of such importance that it raises issues of patient safety, 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 an appeal shall be clearly legible, in the format as may be 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 necessary supporting documentation.

16.9.3 Where audio/audio-visual material is submitted it 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, which have allegedly been 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, if the complaint is based on scientific issues;

16.9.4.3 Copies of any Advertising and/or Promotional Material and/or any other material (such as invitations, agreements, correspondence, etc.), which may be relevant; and

16.9.4.4 Any other information the Complainant considers relevant to the assessment of the complaint.

16.9.5 The Complainant shall provide the MCA with (4) four paginated and indexed copies of the complaint and 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, 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 All documents and communications related to a complaint, an appeal or another matter before an appeal committee or for purposes of enforcement shall be submitted by the Executive Director 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 proved 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 by law required to be subject to the Code enforcement processes.

16.10.5 If the complaint or appeal is not in the prescribed format, 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 to submit any outstanding information and documentation.

16.10.6 The Executive Officer may, after considering the complaint, issue a notice of non-referral to the Complainant, if

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, if true, will 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 elapsed after the act or omission that is the cause of the complaint; or

16.10.6.6 in the case of a course of conduct or continuing practice, if more than three years elapsed after the date that the 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 If 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 A decision of the Executive Officer in terms of this Section 16.10.6 may be appealed as set out in Section 16.15.
- 16.10.10 If a complaint has been found by the Executive Officer or another enforcement structure of the MCA to be trivial, frivolous, vexatious or not made in good faith, unless the 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, on written application by a party, in his sole discretion and on good cause shown and on such terms and conditions as he may determine, extend or shorten the time periods referred to in the Code, including the condonation of the submission of documents outside of the prescribed time periods, after considering the impact of such extension or shortening of time periods on both parties, including the need to ensure the expeditious resolution of Code matters, and in the interest of justice and fairness.
- 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 form with the MCA against a Company, which has allegedly contravened a section(s) of the Code provided that if the Company is not a member of the MCA, it has agreed to be subject to or is by law required to subject itself to the Code enforcement mechanisms.
- 16.11.2 A complaint shall be 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 complaint fee has been received, 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 which case the complaint fee shall be forfeited.
- 16.12 Nominated Complainant**
- 16.12.1 If 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 and the Board shall appoint from amongst the members of the MCA or the 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 the Nominated Complainant and the adjudicating committee shall not be entitled to make an order in respect of the payment of the costs of the MCA against 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 if the Board 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 the Nominated Appellant and the appeal committee shall not be entitled to make an order in respect of the payment of the costs of the MCA against the Nominated Appellant.

#### 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 to the complaint 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 its supporting documentation and other documents exchanged between the parties, for the adjudicating committee.

#### 16.14 **Adjudication Process**

16.14.1 The Executive Officer shall appoint an adjudicating committee, as provided for in the Constitution, 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 potential conflicts of interest of any committee member 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.

- 16.14.3 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, the Executive Officer shall provide the Complaint Pack, at least in hard copy, to the members of the adjudicating committee as soon as is reasonably possible, but at least within 2 (two) Business Days of finalising the appointment of the 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 will add to the adjudication of the complaint. The other party shall be given an opportunity to state his position with respect to such 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 such 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 complained about, as well as copies of briefing instructions furnished to Company Representatives of the Respondent, within a specified time, if 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, and 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 The date, time and place for the hearing of a complaint, if the parties are required to appear in person before the adjudicating committee, shall be determined by the Executive Officer, in consultation with the adjudicating committee, and shall be made known in writing by the Executive Officer to the parties concerned shall not be 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 members of the adjudicating committee are not conflicted in 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 adjudication proceedings unless the adjudicating committee, having regard to, amongst others, the complexity of the matter, the serious nature of the matter and/or the sanction or sanctions, which may be imposed, in its sole discretion determine that legal representation is desirable. In such case a party shall be entitled to legal representation by only one legally qualified person.
- 16.14.14 In the case of face-to-face hearings, parties shall be entitled to call witnesses at adjudication proceedings with the permission of the chairperson, if deemed necessary by the chairperson in his sole discretion.
- 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 such party and witnesses.
- 16.14.16 The adjudicating committee shall make a decision, which includes the imposition of a sanction or sanctions, if appropriate, supported by written reasons on the complaint, i.e. the Adjudication 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 on the form prescribed by the Board. All committee members shall be required to sign the Adjudication Ruling.
- 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 lie with an 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 form 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, which includes the sanction, appealed against and set out the full grounds of appeal. The appeal 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 and confined to the Adjudication Ruling and shall not be entitled to introduce new evidence save with

the permission of the appeal committee, which shall determine such matter in its sole discretion 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 the Notice of Appeal within 7 (seven) Business Days .

16.16.2 The Executive Officer shall send the Appellee's reply, if any, 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, if any, 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, including audio/audio-visual material, pertaining to the original complaint, which were considered by the adjudicating committee;

16.16.5.2 The Adjudication Ruling; and

16.16.5.3 The Notice of Appeal, Appellee's response and Appellant's reply, as may be 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, an opportunity shall be provided to both parties to raise concerns over potential conflicts of interest of any committee member 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 at least a hard copy 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 The date, time and place for the hearing of an appeal, if the parties are required to appear in person before the appeal committee, shall be determined by the Executive Officer, in consultation with the appeal committee, and shall be made known in writing by the Executive Officer to the parties concerned and shall not be 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 in the matter before it.
- 16.17.9 The appeal committee shall interpret and apply the Code in accordance with the principles of interpretation outlined in the Code.
- 16.17.10 No Party shall have legal representation at an appeal hearing unless the appeal committee, having regard to, amongst others, the complexity of the matter and/or the serious nature of the matter and the sanction or sanctions, which may be imposed, in its sole discretion 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 only one legally qualified person.
- 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 make a decision, which includes the imposition of a sanction or sanctions, if applicable, supported by written reasons, i.e. the Appeal Ruling, within 7 (seven) Business Days of the date of the conclusion of an appeal hearing or the date upon which the appeal was decided in the case of a paper-based appeal. The Appeal Ruling shall be on the form prescribed by the Board. All committee members are required to sign the Appeal Ruling.
- 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 provided for in 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 and no extension of timeframes has been granted, and/or no condonation 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, if appropriate and applicable.
- 16.18.3 Should any member of an adjudicating or an appeal committee be absent at any time when a meeting of the committee is convened 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 The MCA shall have the power to outsource any part or all the enforcement processes provided for in the Code to any competent body in line with the provisions of the Constitution. 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 on the MCA website, a summary of any matter heard by an adjudicating or appeal committee. Where a breach is ruled to have occurred, the identity of the Companies/parties (but not individuals or panellists) maybe published,. This shall be done in consultation with the chairperson of the relevant committee and in the absence of the chairperson, another member of that committee, provided that a matter heard by an adjudicating committee shall only be published if no appeal is 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 including providing copies of any supporting documentation requested by the MCA. This communication shall be submitted to the MCA within 14 (fourteen) days of when it 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 imposed 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 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 or a 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 and the alleged offender shall within 7 (seven) Business Days provide a written response to the Executive Officer.
- 16.20.7 The Executive Officer shall constitute an appeal committee, which may not comprise the same members who adjudicated the complaint or heard the appeal on the matter, if applicable, to decide on the Non-Compliance Complaint.
- 16.20.8 The Executive Officer shall provide the appeal committee with copies of the Non-Compliance Complaint, response by the alleged offender, if applicable, as well as the relevant ruling or undertaking 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.
- 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 re-open 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 The appeal committee shall make a decision, supported by written reasons, within

7 (seven) Business Days of receipt of the relevant documentation as to 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, as outlined in the Sanction Policy Document as determined by the Board from time to time, with consideration of the principles and guidelines stipulated and any limits imposed in the Sanction Policy Document, on the alleged offender; and

16.20.12.3 direct the publication of a summary of its decision, including the reasons for such a decision, on the MCA website by the Executive Officer.

16.20.13 For purposes of clarity, it is specifically stated that an appeal committee does not have the power to make an order in respect of the payment by any party of the legal costs 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, upon payment of the prescribed fee and in the prescribed form, for an advisory opinion in relation to the application of the Code and/or Guidelines in a specific circumstance or circumstances.

16.21.2 The Executive Officer shall appoint an ex parte committee as provided for in 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 that provided the advisory opinion shall sit on the adjudicating or appeal committee deliberating on the matter.

16.21.4 Ex parte matters shall be undertaken on paper, provided 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 a Company 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 (if any) in respect of the matter under consideration;

16.21.6.2 be confined 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 reasons 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 on 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 website of the MCA without details of the parties or ex parte committee members involved.

Final Draft

## **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 (SAMED)

### **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> Change Health Products to Medicines, IVD, Medical Devices; moved definitions to end of document, definition for promotional aid and material, Updated to ABPI code (Clause 7); added MSL for pharma; patient support groups added; added icons for application	<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 changes as per 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 be aligned with Constitution	<b>28 May 2013</b>
<b>Version 9:</b> Updated to align with updated international codes.	<b>November 2014</b>

<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).</p> <p>Minor Typographical changes. As well as changes summarised in the change summary.</p> <p>The 2016 Code Changes include the following:</p> <p>Date: The new dates to be reflected on the Code will be November 2016 as per the AGM</p> <p>Introductory paragraph: Amended to remove the names of trade associations. The reason for this is because the role of independent members is taking on increasing importance in the MCA due to decisions by trade associations to be involved or otherwise in the MCA.</p> <p>Glossary: Definition of Company Code Compliance Officer amended to limit the authorisation to matters of Code compliance.</p> <p>Definition of Complimentary Medicines included; Complementary Medicines means Complementary Medicines as defined in the Medicines and Related Substances Act 101 of 1965 as amended, and Regulations.</p> <p>Definition of Health Product added; for the purpose of this code, the term Health Products includes Medicines, Complementary Medicines including health supplements(CAMS), Medical Devices and IVDs.</p> <p>Definition of Faculty added; Faculty means active participants/HCPs who speak, present or serve another specific function at a 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</p>	<p><b>November 2016</b></p>

<p>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>Complimentary Medicines</p> <p>Addition:</p> <p>sampling</p> <p>2.5 Scope of Application to include complementary and alternative Medicines;</p> <p>The word <i>shareholders</i> in the industry has been included,</p> <p>The marketing and promotion of self-medication products to HCPs now includes <i>complementary and alternative Medicines (CAMS)</i></p>	
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<p>The marketing and promotion of self-medication products to the public now includes <i>complementary and alternative Medicines (CAMS)</i>.</p> <p>This change is pulled through into part A and B of the code.</p> <p>Part C Medical Devices</p> <p>A more concise statement on Part C binds the marketing and promotion Medical Devices and IVDs to part A and B of the code except where otherwise indicated in Part C.</p> <p>Part A of the Code</p> <p>7.5.6 has been amended with the addition of; unless doing so is permitted by intellectual property law and/or common law, as amended and developed from time to time</p> <p>7.6 Substantiation</p> <p>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.</p> <p>7.11 Use of the word new</p> <p>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).</p> <p>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...</p> <p>Also added here; This provision shall be subject to all national legislation in force from time to time, to the extent applicable.</p> <p>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 <i>their brands</i> as these are unrelated to the promotion of scientific or educational objectives.</p>	
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<p>18.7 Other interactions with HCPs</p> <p>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.</p> <p>19.4 Competitions</p> <p>19.4.3 added; The prize cannot comprise of cash or a cash equivalents (e.g. vouchers) and, ...</p> <p>20 Items for patients and patient organisations</p> <p>20.3 amended by the addition of 'and be in accordance with competition law'.</p> <p>20.9, 20.10, 20.11, 20.12, 20.13, 20.14; deleted</p> <p>21 Samples</p> <p>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 <i>any relevant health legislation or any exemption/s thereto</i>.</p> <p>CAMS and personal care products may not be provided together with any scheduled Medicines</p> <p>23 Compliance with undertakings and rulings</p> <p>The wording has been amended to provide that undertakings must be <i>complied with within the specified timeframe</i>. The words <i>without delay</i> have been deleted.</p> <p>Part B of the Code</p> <p>24 Registration status of Medicines</p> <p>The 1<sup>st</sup> paragraph now reads; The promotion of a registered self-medication <i>and complementary and alternative Medicines(CAM)</i> product must be in accordance with the terms of its registration and must not be inconsistent with the particulars listed in the package insert or approved text.</p> <p>25.12 has been amended to include <i>clinic sisters</i>.</p> <p>26.13.5 has been amended to include complementary and alternative Medicines (CAMS).</p> <p>26.13.6 has been amended to include complementary and alternative Medicines (CAMS).</p> <p>26.13.11 has been amended to provide that it may be stated where applicable that a product contains <i>natural ingredients</i></p> <p>29 Prepared prohibitions or restricted presentations</p>	
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<p>this clause has been amended to include complementary and alternative Medicines (CAMS.)</p> <p>36.3-36.8 has been moved from Part A to Part B</p> <p>40.2 has been amended to include <i>digital detailers</i>.</p> <p>48 lodging of complaints has been amended to make the Company to Company process, compulsory</p> <p>48.7 has been amended by the addition of the following; Either party sending documents to the MCA bears the responsibility of ensuring time is delivery of the requisite documents in hard copy.</p> <p>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.</p> <p>49 has been amended so that the heading reads, Nominated/<i>Pro-Forma</i> Complainant.</p> <p>51.7.5 has been amended to include <i>General Manager</i>.</p> <p>51.7.8 has been amended to read as follows; That the finding of the Adjudicating Committee be published to the members, and the Medicines Regulatory Authority at the discretion of the committee.</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 unfettered discretion appoint a substitute committee member who shall have full rights and responsibilities and shall exercise all such powers as if this person had been a member of the original committee.</p>	
<p><b>Version 11:</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><b>2017</b></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 (R40000 per competition)</p>	
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