

SA CODE OF PRACTICE FOR THE MARKETING OF MEDICINES

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SA CODE OF PRACTICE FOR THE MARKETING OF MEDICINES

1. PREAMBLE

WHEREAS

- 1.1 Section 18C of the Medicines Act 101 of 1965 (“the Act”) empowers the Minister, after consultation with the pharmaceutical industry and other stake holders, to make regulations relating to the marketing of medicines, including an enforceable Code of Practice;
- 1.2 the companies in the pharmaceutical industry have agreed to subscribe to a code of practice for the marketing of medicines in South Africa based on the principle of self regulation as set out in this Code;
- 1.3 the enforcement of the Code will be entrusted to a MARKETING CODE AUTHORITY (“MCA”) as herein provided.

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

2.1 Introduction

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

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

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

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

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

The pharmaceutical industry is committed to educational and promotional efforts that benefit patients and promotional programs and collaborations that enhance the rational use of medicine and fair competition in the marketing of medicine. The industry seeks to preserve the independence of

the decisions taken by healthcare professionals. The pharmaceutical industry has an obligation and responsibility to provide accurate information and education about its products to healthcare professionals in order to establish a clear understanding of the appropriate use of medicines. Industry relationships with healthcare professionals must support, and be consistent with the professional responsibilities healthcare professionals have towards their patients.

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

2.2 Application of the Code

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

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

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

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

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

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

2.2.2 The Code does not apply to the following situations:

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

2.2.2.2 The following documents are not covered by the Code:

2.2.2.2.1 Trade catalogues to suppliers including price lists.

2.2.2.2.2 Product labels, packaging materials and in-pack leaflets. These are subject to the labelling and package insert requirements in terms of the Regulations to the Medicines Act and the Guidelines pertaining thereto.

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

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

2.2.2.5 The Code is not applicable to wholesalers, distributors and logistics companies except to the extent that they may influence the demand for medicines.

2.3 Interpretation of the Code

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

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

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

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

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

2.4 Status of the guidelines to the Code

2.4.1 Guidance on the interpretation of the Code appears as supplementary information to the text in a separate document, Guidelines to the South African Marketing Code. The examples

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

2.5 Scope of application

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

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

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

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

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

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

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

The provisions in PART B have to be seen in the light of the exemption for Schedule 0 medicines from the provisions of section 18A to the Medicines Act.

2.6 PART C - ENFORCEMENT OF THE CODE

- 2.6.1 The Code is based on the principle of self regulation of the industry through a procedure for handling complaints which is in line with international standards and practice, but made binding through the legislative recognition of the self-regulatory and subsequent processes which may include the medicines regulatory authority.
- 2.6.2 The process of enforcement and the relevant bodies responsible for such enforcement are set out in Part C of this Code.
- 2.6.3 The MCA has the power to refer issues not within the scope and ambit of this Code to the appropriate authorities, councils or bodies with the authority to deal with such issues.
- 2.6.4 The MCA has the power to outsource any of its enforcement functions in terms of the provisions set out in Part C of this Code and/or to align its administration with that of other Codes in force in the healthcare sector at any point in time.

2.7 Glossary

In this Code, words and phrases that are defined in the Medicines Act shall bear the same meanings as they do in the Act and all regulations issued in terms of this Act.

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

- 2.7.1 Advertising and/or promotion and promotional materials or activities, include, but are not limited to advertorials; branded materials relating to product sponsorship; aerial promotions such as on hot air balloons and/or blimps; booklets; cinema commercials; consumer leaflets; consumer broadsheets; direct mail materials; website and other Internet materials, including press releases intended for internet publication; on-pack statements; outdoor advertising; point of sale materials; posters; print advertisements (for use in newspapers, magazines, etc.); promotional aids including those used for direct selling activities; promotional scripts for use by telephone help lines; promotional text messages; consumer promoters; telephone help lines; television and radio/audio commercials; sports, art and other sponsorships; airport, washroom, shopping centre advertising and/or promotion; touch screen advertising; aisle, ceiling, floor advertising and other signs; counter top advertising; window displays; gondola end advertising; bunting; advertising on electronic ordering systems; bus, taxi and other vehicle advertising; and light box advertising.
- 2.7.2 Company means a company, closed corporation, organisation, firm, vendor or individual who may sell or promote medicines.
- 2.7.3 Company Code Compliance Officer means anyone duly authorised by the company, or appointed by the company in writing, to sign documents or give instructions on behalf of the company.
- 2.7.4 Electronic journals mean electronic versions of journals that can be viewed online via any personal computer or other electronic device.

- 2.7.5 Health Care Professional (HCP) means any member of the medical, dental, pharmacy, veterinary or nursing professions and any other persons registered with a professional council or body who in the course of their professional activities may prescribe, recommend, purchase, evaluate, supply or administer a medicine as registered under the Medicines Act and, for the purposes of this Code, includes all persons operating under the HCP.
- 2.7.6 Honorarium means a payment or an award granted in recognition of a special service by a professional person. Honoraria can be paid at fair market value for speeches, articles, appearances or other services rendered in terms of a written agreement, which may be subject to scrutiny by the MCA should such honorarium be the subject of a complaint in terms of the Code.
- 2.7.7 Medicines Act (i.e. Medicines and Related Substances Act No 101 of 1965 as amended) means the body of legislation governing the registration and marketing of medicine, as amended from time to time and includes any future legislation that amends or repeals and replaces the Medicines Act.
- 2.7.8 Promotional item means merchandise given away free of charge in an effort to create awareness of a company or product.
- 2.7.9 Minimum Requirements means the legislated requirements for written advertisements as stated in Regulations to the Medicines Act.

3. OBJECTIVES OF THE MCA

The objectives of the MCA shall be:

- 3.1 to ensure and maintain the ethical promotion and advertising of medicines by all parties and entities, including companies and their employees and agents as described in clause 2.2 and who are or may be subject to the Act (hereinafter referred to as the “Companies” and the company);
 - 3.2 to ensure that those bound by the Code maintain high ethical standards when conducting promotional activities and comply with applicable legal, regulatory and professional requirements.
 - 3.3 to adjudicate on complaints and disputes in terms of the Code.
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PART A --- MARKETING AND PROMOTION OF MEDICINES TO HEALTHCARE PROFESSIONALS

4. REGISTRATION STATUS OF MEDICINES

A medicine must not be advertised or promoted:

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

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

5. ADVERTISING AND PROMOTION MATERIAL

- 5.1 All advertising and/or promotional material must be based on the current approved South African package insert.
- 5.2 The minimum requirements must:
 - 5.2.1 Conform with the applicable regulations in terms of the Medicines Act.
 - 5.2.2 Form part of the promotional material and not be separate.
 - 5.2.3 Be included in all promotional material (except for promotional items - see Clause 18.3).
 - 5.2.4 Be provided in a clear and legible manner.
 - 5.2.5 Be consistent with the most recently approved package insert for the medicine.
- 5.3 In all forms of advertising and/or promotion i.e. written, audio, audio-visual, internet, the statement "For full prescribing information refer to the package insert approved by the medicines regulatory authority" should appear or be stated. This does not apply to promotional items as referred to in Clause 18.3.
- 5.4 In the case of an advertisement included as part of independently produced information on the internet, the statement should be in the form of a direct link between the first page of the advertisement and the minimum information.
- 5.5 In the case of printed promotional material consisting of more than two pages, the minimum information can appear either on the first or last page.
- 5.6 Promotional material other than advertisements appearing in professional publications must include the date or a code number identifying the version on which the promotional material was drawn up or last revised.
- 5.7 Audio-visual or audio material such as films, video recordings, sound bites, interactive data systems and such like:

- 5.7.1 The minimum information must be provided either by way of a document that is made available to all persons to whom the material is shown or sent, or by inclusion on the audio-visual recording or in the interactive data system itself in line with the general provisions in Clause 5.2.
- 5.7.2 When the minimum information is included in an interactive data system, instructions for accessing it must be clearly displayed.
- 5.7.3 If the material consists of sound only, the minimum information may be provided by the way of a document that is made available to all persons to whom the material is played or sent.

6. JOURNAL ADVERTISING

- 6.1 An advertisement which contains two or more pages must not be false or misleading when each page is read in isolation.
- 6.2 An advertisement taking the form of a loose insert in a journal may not be of a size larger than the page size of the journal itself.
- 6.3 Advertisements in journals must not resemble editorial matter unless clearly identified as advertorial or as a sponsored feature.
- 6.4 In the case of a journal advertisement where the prescribing information appears overleaf, a reference to where it can be found must appear in a type size which is legible at either the beginning or the end of the advertisement.

7. INFORMATION, CLAIMS AND COMPARISONS

- 7.1 Accuracy, balance, fairness of claims.

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

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

- 7.2 Exaggerated or misleading claims

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

7.3 Comparisons

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

- 7.3.1 It is not misleading or disparaging.
- 7.3.2 Medicines or services for the same needs or intended for the same purpose are compared.
- 7.3.3 One or more material, relevant and representative features which is capable of substantiation is compared.
- 7.3.4 No confusion is created between the medicine advertised and that of a competitor or between the advertisers' trademarks, proprietary names, other distinguishing marks and those of a competitor.
- 7.3.5 The trademarks, proprietary names, other distinguishing marks, medicines, services, activities or circumstances of a competitor are not discredited or denigrated.
- 7.3.6 Trademarks/trade names or company names of another company may only be mentioned with written permission from the other company.
- 7.3.7 No unfair advantage is taken of the reputation of a brand, trademark, proprietary name or other distinguishing marks of another company.
- 7.3.8 Medicines or services are not presented as imitations or replicas of goods or services bearing another company trademark or trade name.
- 7.3.9 Hanging (open ended) comparisons are not allowed.

7.4 Substantiation

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

7.5 References

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

7.6 Unpublished supporting data

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

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

7.7 Artwork

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

7.8 Use of the word 'safe'

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

7.9 Use of the word 'new'

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

7.10 Other claims

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

8. DISPARAGING REFERENCES

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

8.1.1 safety, quality and efficacy;

8.1.2 the effectiveness of the official registration process by which the product obtained market authorisation;

8.1.3 disparaging references relating in general terms to generic or originator medicines.

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

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

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

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

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

- 9.4 Promotional material must not include any reference to the medicines regulatory authority unless this is specifically required by the medicines regulatory authority, through the applicable legislative and other provisions. This provision does not preclude references to important medicines regulatory authority Guidelines and Policies, such as those on the reporting of adverse events, which serves as important regulatory frameworks for the utilisation of medicines.
- 9.5 Reproductions of official documents must not be used for promotional purposes unless permission has been given in writing by the appropriate body.
- 9.6 The telephone, SMS, e-mail, telex or facsimile machines must not be used for promotional purposes, except where, when first contact is made, the option to opt out is given and the decision is subsequently respected. The option to opt out should also be provided on all subsequent communications, even if the addressee has not opted out after the first contact.
- 9.7 All material relating to medicines and their uses, which is sponsored by a pharmaceutical company, must clearly indicate the details of the company that sponsored it. The only exception to this clause is market research material that need not reveal the name of the company involved but must state that a pharmaceutical company sponsors it.
- 9.8 Postcards, other exposed mailings, envelopes or wrappers must not carry matter which may be regarded as advertising and/or promotion to the general public contrary to relevant legislation.

10. DISGUISED PROMOTION

- 10.1 Promotional material and activities must not be disguised.
- 10.2 Market research activities, post-marketing surveillance studies, post authorisation studies, clinical trials and the like must not be disguised promotion, nor contain or lead to disparaging comments about competitors or their products. Such trials/studies must be conducted with a primarily scientific or educational purpose. Material relating to pharmaceutical products and their uses, whether promotional in nature or not, which is sponsored by a company should clearly indicate by whom it has been sponsored.
- 10.3 Clinical trials should not be undertaken for the purpose of promotion of medicines intended for administration to human beings.
- 10.4 Observational/Non-interventional studies of registered medicines are studies where the medicinal product(s) is(are) prescribed in the usual manner in accordance with the approved medicines regulatory authority package insert. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data. This clause is not applicable to veterinary medicines.

- 10.5 Observational/Non-interventional studies involving medicines that are intended for administration to humans, that are prospective in nature and that involve the collection of patient's data from or on behalf of an individual, or groups of healthcare professionals specifically for the study must comply with all of the following criteria:
- 10.5.1 The study is conducted with a scientific purpose and there must be:
 - 10.5.1.1 a written study plan (protocol) and
 - 10.5.1.2 written contracts between healthcare professionals and/or the institutions at which the study will take place, on the one hand, and the company sponsoring the study on the other hand, which specify the nature of the services to be provided and, subject to what is stated below, the basis for payment of those services.
 - 10.5.2 Remuneration provided must be reasonable and of fair market value to the work performed.
 - 10.5.3 The study protocol must be submitted to the appropriate ethics committee for review.
 - 10.5.4 Personal data privacy including the collection and use of personal data must be respected.
 - 10.5.5 The study must not constitute an inducement to participate, recommend, prescribe, purchase, supply, sell or administer a particular medicinal product.
 - 10.5.6 The study protocol must be approved by the company's scientific/ medical department, who must also supervise the conduct of the study.
 - 10.5.7 The study results must be analysed by or on behalf of the contracting company and summaries thereof must be made available within a reasonable period of time to the company's scientific service, which service shall maintain records of such reports for a reasonable period of time. The company should send the summary report to all healthcare professionals that participated in the study and should make the summary report available to the MCA upon request. If the study shows results that are important for the assessment of benefit-risk, the summary report should be immediately forwarded to the medicine regulatory authority. In addition, companies are encouraged to publicly disclose the summary details and results of non-interventional studies in a manner that is consistent with the parallel obligations with respect to clinical trials.
 - 10.5.8 Medical Sales Representatives may only be involved in an administrative capacity and such involvement must be under the supervision of the company's scientific service that will also ensure that the Medical Sales Representatives are adequately trained. Such involvement must not be linked to the promotion of any medicinal product or used as a pretext to obtain access to the healthcare professional for any purpose.
- 10.6 Material issued by companies that relates to medicines but which is not intended as promotional material for those medicines per se, for example

corporate advertising, press releases, market research material, financial information to inform shareholders, the stock exchange, should be examined to ensure that it does not contravene the Code or the relevant statutory requirements.

11. PROVISION OF REPRINTS AND THE USE OF QUOTATIONS

- 11.1 Reprints of articles in journals must not be provided unsolicited to any healthcare professional unless the articles have been published in a peer reviewed publication in line with good principles of scientific review and publication. When providing a reprint of an article about a medicine, it should be accompanied by prescribing information. If a non-peer-reviewed article is requested by a healthcare professional, a copy may be provided on written request.
- 11.2 Quotations from medical and scientific literature must accurately reflect the intention and meaning of the author(s). If unpublished, "personal communications" shall not be used unless the company, organisation or individual is able to supply written substantiation based on scientific data upon request.
- 11.3 Quotations taken from public broadcasts, for example radio, television or the Internet, and from private occasions, such as medical conferences or symposia relating to medicines, must not be used without the formal permission of the speaker unless there is a published record of the proceedings and this is accurately given as a reference.
- 11.4 Utmost care must be taken to avoid ascribing claims or views to authors when these no longer represent the current views of the authors concerned.
- 11.5 The provision of articles and the use of quotations are also subject to the provisions of Clause 8.

12. DISTRIBUTION OF PROMOTIONAL MATERIAL

- 12.1 Promotional material should only be sent or distributed to those categories of persons whose need for, or interest in, the particular information can reasonably be assumed.
- 12.2 A company that is requested by an addressee to cease or limit the volume of promotional material should respect the wishes of the addressee.
- 12.3 Mailing lists must be kept up-to-date. Requests from healthcare professionals to be removed from promotional mailing lists must be complied with promptly and no name may be restored except at their request or with their permission.

13. SCIENTIFIC INFORMATION SERVICE

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

14. CERTIFICATION OF PROMOTIONAL MATERIALS, MEETINGS AND OTHER ACTIVITIES

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

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

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

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

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

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

14.2 The Certificate

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

14.3 Recertification of promotional material

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

14.4 Retention of documentation

14.4.1 Companies, organisations or individuals shall preserve all certificates and the relevant accompanying information for not less than five years after the final use of the promotional material or the

date of the meeting and produce them on request from the MCA or the medicines regulatory authority.

- 14.4.2 In relation to certificates for promotional material, the material must be preserved in the form certified with information indicating the persons to whom it was addressed, the method of dissemination and the date of first dissemination. It is, however, in the interest of storage space, acceptable to store accurate photographic or other electronic representations of material, information or items.
- 14.4.3 All documents/material relating to marketing and promotion, including the agenda for the event, irrespective of the nature of the campaign or event, have to be retained for the minimum period.

15. MEDICAL SALES REPRESENTATIVES

15.1 Training of Medical Sales Representatives

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

15.2 Compliance with codes and laws by Medical Sales Representatives

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

15.3 Gaining interviews

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

15.4 Organising meetings

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

15.5 Consideration for healthcare professionals and others

Medical Sales Representatives must ensure that the frequency, timing and duration of calls on healthcare professionals, pharmacies, hospitals, other healthcare facilities, medical schemes or funders and the like, together with

the manner in which they are made, do not cause inconvenience. The wishes of individuals on whom Medical Sales Representatives wish to call, and the arrangements in force at any particular establishment, must be observed.

15.6 Information to scientific service of company

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

15.7 Information to be provided to healthcare professionals

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

15.8 Follow up on requests for information

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

15.9 Detailed briefing materials

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

15.10 Company responsibility for Medical Sales Representatives

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

16. TRAINING

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

17. INTERACTIONS WITH HEALTHCARE PROFESSIONALS

17.1 Hospitality/Venues of meetings and events

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

- 17.1.1 The merit and focus of the meeting should be clearly scientific and/or educational.
- 17.1.2 The venue and hospitality should be secondary to the meeting both in time allocation and focus.
- 17.1.3 The venue should be appropriate and conducive to the scientific or educational objectives and the purpose of the event or meeting.
- 17.1.4 Hospitality, meals and entertainment should be modest. As a general rule, hospitality must not exceed what the healthcare professionals would normally be prepared to pay for themselves.
- 17.1.5 Invitations should not be extended to spouses or other guests except if they are healthcare professionals or administrative staff i.e. any costs incurred by spouses or other guests cannot be reimbursed or paid for by the company.
- 17.1.6 Inappropriate financial benefit or material benefits including excessive hospitality cannot be offered and/or extended to healthcare professionals.
- 17.1.7 For speakers, payment of reasonable honoraria and reimbursement of out of pocket expenses, including travel are permissible provided it is in terms of a written contract.
- 17.1.8 CPD meetings:
 - 17.1.8.1 No product promotion is allowed in the CPD meeting room. Company-branded items/promotion are permissible.
 - 17.1.8.2 Speakers should use the INN names of products during CPD events. Companies must make it known to speakers that the use of trade names is not permitted.
 - 17.1.8.3 Product promotional material displayed outside of the CPD meeting room should not be accessible to the general public, if it is not permissible to market such product directly to the public.
- 17.1.9 For local CPD events and product launches which are held in major cities, reasonable travel arrangements or travel reimbursement can be made to ensure that the healthcare professionals that do not reside/practice in major cities are able to access the applicable information.
The criteria for selection of attendees/invitees must be transparent and available to the MCA on request for scrutiny.
- 17.2 For medical or scientific congresses, conferences or seminars held in South Africa, internationally or international meetings organised overseas and held in South Africa.
 - 17.2.1 Meetings organised by pharmaceutical companies, other organisations or individuals at venues outside South Africa, that are educational and scientific in nature and involve South African healthcare professionals are acceptable.
 - 17.2.2 The rationale for any meeting, or sponsorship to attend a meeting, is to be transparent, valid and cogent.

- 17.2.3 Consideration must be given to the educational programme, overall cost, facilities offered by the venue, nature of the audience, hospitality provided and the like.
- 17.2.4 As with any meeting, it should be the programme that attracts delegates and not the associated hospitality or venue and all entertainment and events have to be subordinate in time and nature to the sponsored meeting, congress, conference or seminar.
- 17.2.5 Payment of registration fees, travel and accommodation must be made to the professional associations/organisers and not directly to the healthcare professional or appropriate administrative staff, unless proof is received that the amounts spent are in the name of the sponsored person and which corresponds to each and every line item as per the agreed sponsorship. No payment may be made to the professional/staff for time spent at the event.
- 17.2.6 Sponsored speakers may receive reasonable honoraria.
- 17.2.7 Advertisement and promotion are subject to domestic legislation, i.e. if a product is not registered in South Africa, it cannot be promoted, even if the congress is international in nature, unless exemption has been granted in terms of applicable legislation.

(Note: Sponsorship of patient support groups removed here and moved to clause 19)

17.3 Transparency

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

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

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

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

17.5 Other interactions with healthcare professionals

17.5.1 Consultancy services

17.5.1.1 The engagement of a healthcare professional to provide genuine consultancy or other genuine services to a company is permitted. Healthcare professionals that provide consulting services to a company and are still practicing their profession must declare their employment arrangement with the company whenever they write or speak in public about a matter that is the subject of the employment or any other issue relating

to that company. Such arrangement must be formalised in a written agreement, which may be subject to scrutiny by the MCA if such interaction forms part of a complaint lodged in terms of this Code.

17.5.2 No direct payments to healthcare professionals for any other services

17.5.2.1 Payments may not be made to doctors or groups of healthcare professionals, either directly or indirectly, for rental for rooms or other services.

17.5.2.2 Healthcare professionals involved in *bona-fide* and if relevant, peer reviewed research, are not subject to the Code.

17.5.3 Certification of Meetings

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

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

17.5.3.2 Invitations, the choice of venue(s).

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

17.5.3.4 Participant selection processes and criteria.

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

18. INDUCEMENTS, GIFTS AND PROMOTIONAL ITEMS, COMPETITIONS

18.1 Inducements

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

18.2 Gifts and promotional items

Occasional gifts and promotional items to healthcare professionals and appropriate administrative staff are acceptable provided that they are:

18.2.1 Inexpensive and of minimal intrinsic value i.e. within the cost limit set from time to time **per annum** by the MCA.

18.2.2 Not for personal use e.g. no entertainment CD's/DVD's, electronic items for entertainment, tickets to attend sporting events or other forms of entertainment.

18.2.3 Educational and/or scientific value, benefit the patient and/or be relevant to the practice.

18.3 Promotional items

It is permissible to brand promotional items. The minimum information for a medicine as required under Clause 5 does not have to be included on a promotional aid provided that no promotional claims are made. The following information may be included on such items:

18.3.1 The name of the medicine.

18.3.2 An indication that the name of the medicine is a trademark.

18.3.3 Relevant company name, company logo and/or product logo.

18.4 Cultural courtesy gifts

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

18.5 Competitions

18.5.1 Competitions should fulfill the following criteria:

18.5.2 the competition is based on medical/product knowledge or the acquisition of scientific knowledge;

18.5.3 the prize is relevant to the practice of medicine, dentistry or pharmacy; and

18.5.4 individual prizes or educational items offered and within the cost limit set from time to time by the MCA;

18.5.5 entry into a competition must not be dependent upon prescribing, ordering or recommending of a product and no such condition shall be made or implied.

18.6 Donations and grants to charities

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

18.6.1.1 They are made for the purpose of supporting healthcare or research;

18.6.1.2 They are documented and kept on record by the donor/grantor; and

18.6.1.3 They do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

- 18.6.2 Donations must not be paid directly to healthcare professionals.
- 18.6.3 Companies are encouraged to make available publicly, information about donations, grants or benefits in kind made by them as covered in this section.
- 18.7 Corporate Social Investment
 - 18.7.1 Donations to meet identified corporate social responsibility projects may also be made if judged on its merits, approved by the responsible person(s) in each company or organisation and documented.
 - 18.7.2 Corporate social investment is excluded from the operation of the Code in so far as such donations do not induce the overall over or under utilisation of a medicine.

19. RELATIONS WITH THE GENERAL PUBLIC AND THE MEDIA

- 19.1 Medicines must not be advertised to the general public if they are prescription only medicines.
- 19.2 Patient support group meetings, events and patient support materials may be sponsored provided that proper records are kept and that no product promotion takes place. The fact that sponsorship or support has been provided should be displayed on the materials and/or at the meeting or event.
- 19.3 Information that is made available to the general public either directly or indirectly about medicines must be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or be misleading or disparaging with respect to the safety of the product and may not refer to a medicine's safety, quality or efficacy. Statements, representations or tie-off lines must not be made for the purpose of encouraging members of the public to ask their doctors to prescribe a specific medicine. Clause 19.1 does not prohibit education or information relating to substitution of a medicine or information on safe use, storage of a medicine in general.
- 19.4 Requests from individual members of the public for information or advice on personal medical matters must be refused and the enquirer should be recommended to consult with his or her own healthcare professional.
- 19.5 Companies are responsible for information that is issued by their public relations agencies about their products.
- 19.6 Patient education ("help-seeking advertisements") directed at general public is acceptable, provided that it:
 - 19.6.1 Does not contain the name of the specific medicine.
 - 19.6.2 Does not make or allude to a medicinal claim.
 - 19.6.3 Does not provide any risk information.
 - 19.6.4 Lets the public know that treatment exists for a medical condition.
 - 19.6.5 "For more information, refer to your doctor or pharmacist (or healthcare professional)" is mentioned.

20. SAMPLES

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

21. THE INTERNET

- 21.1 Access to promotional material directed at the South African public provided on the Internet in relation to Schedule 02 to Schedule 06 should be limited through a password protection scheme to healthcare professional and appropriate administrative staff only.
- 21.2 Information or promotional material covered by Clause 21.1 about medicines which is placed on the Internet outside South Africa will be regarded as within the scope of the Code if it was placed there by a South African company, or an affiliate of a South African company, or at the instigation or with the authority of such a company and it makes specific reference to the availability or use of the medicine in South Africa.
- 21.3 Medicines covered by Clause 21.1 may be advertised in a relevant, independently produced electronic journal intended for healthcare professionals or appropriate administrative staff which cannot be accessed by non-healthcare professionals.
- 21.4 Package inserts for medicines covered by Clause 21.1 above may be included on the Internet and be accessible by members of the public provided that they are not presented in such a way as to be promotional in nature.
- 21.5 It should be made clear to an internet user when he/she is leaving any of the company sites, or sites sponsored by the company, or is being directed to a site, which is not that of the company.

22. COMPLIANCE WITH UNDERTAKINGS

When an undertaking has been given in relation to a ruling under the Code, the company concerned must ensure that it complies with that undertaking.

PART B: --- MARKETING AND PROMOTION OF MEDICINES DIRECTLY TO THE CONSUMER

23. REGISTRATION STATUS OF MEDICINES

A medicine must not be promoted:

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

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

24. ADVERTISING AND/OR PROMOTION

- 24.1 Advertisements must be consistent with the requirements of the Medicines Act.
- 24.2 Advertisements shall not mislead or disparage either directly or by implication. Information, claims and comparisons must be accurate, balanced, fair, objective, unambiguous and supportable and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly. The use of medical terminology is acceptable provided that this does not confuse or mislead the consumer.
- 24.3 Advertising and/or promotion shall not be misleading as to the nature of the product, its ingredients or indication(s).
- 24.4 Advertisements must not contain any other express or implied exaggerated claims as to the benefits that can be obtained from use of the medicine.
- 24.5 Efficacy claims should clearly state if medicines are intended to be used over extended periods of time or where the medicine is indicated for disease risk reduction or prevention.
- 24.6 Advertising and/or promotion can refer to the prevention of symptoms and use of a product in chronic conditions, if in line with the registered indication. The advertisement shall make it clear under what circumstances use of the product is appropriate. This is particularly important in therapeutic areas where individuals may be asymptomatic.
- 24.7 Advertising and/or promotion shall not cause consumers unwarranted anxiety with regard to any condition. Nor should it suggest that suffering might arise if a consumer fails to respond to the advertisement's claim. Advertising and/or promotion must not suggest that the condition will deteriorate or that it will become more severe if the individual does not use the medicine featured. Language which causes fear or distress should not be used.
- 24.8 Advertisements should not suggest that using a medicine could enhance normal good health or be a substitute for a healthy diet and lifestyle.

- 24.9 Advertising and/or promotion shall not be aimed principally or exclusively at children (under the age of twelve years).
- 24.10 Advertising and/or promotion shall not show children using, or within reach of, medicine without adult supervision.
- 24.11 Advertising and/or promotion shall encourage responsible self-medication and should not encourage individuals to exclusively self-diagnose. Nor should it encourage self-diagnosis where medical intervention is required. Particular care should be taken where symptoms are generalised and a diagnosis is made by exclusions of more serious complaints or where use of the medicine could mask the symptoms of a more serious condition. Advertisements should encourage individuals to share information with the pharmacist or healthcare practitioner so that they can ensure the medicine will be suitable for the intended user.
- 24.12 Advertising and/or promotion shall not suggest that a medical consultation or surgical operation is unnecessary nor shall it discourage consumers from seeking medical or pharmaceutical advice. Consideration should be given to the inclusion of information concerning the availability of professional advice.
- 24.13 Advertising and/or promotion shall not offer to diagnose, advise, prescribe or treat personally by correspondence.
- 24.14 Advertising and/or promotion shall not claim guarantees on a product's effects, safety or quality.
- 24.15 Advertising and/or promotion shall not encourage, either directly or indirectly, the indiscriminate, unnecessary or excessive use of any medicine.
- 24.16 Advertisements should not be flippant or use inappropriate imagery or imagery out of context. Advertisers are encouraged to convey the message that medicines should be treated with respect and may not be suitable for some people.
- 24.17 Sponsored advertorials shall be appropriately identified as such in the particular publication at the place where it appears, in order to be distinguished from editorials.
- 24.18 Advertising and/or promotion should not encourage consumers to discontinue the use of prescribed medicines.
- 24.19 Advertising and/or promotion shall not contain recommendation of a product by scientists or health professionals unless substantiated.
- 24.20 Advertising and/or promotion shall not include recommendation by a person who, because of their celebrity status, may encourage consumers to take a particular medicine.

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

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

- medicines regulatory authority and incorporated in the approved package insert.
- 25.2 In the case of an advertisement for a medicine which contains more than one active ingredient, no specific reference shall be made to the specific properties of any individual active ingredient unless a reference of this nature has been approved by the medicines regulatory authority for inclusion in the package insert of the medicine.
- 25.3 A written advertisement for a medicine shall comply with Regulation 45 of the Medicines Act.
- 25.4 Advertising and/or promotion shall not unfairly denigrate or discredit, either directly or by implication, a competitor product, ingredient or treatment type.
- 25.5 Advertising and/or promotion should not suggest that a product's effects are better than or equal to another identifiable product or treatment.
- 25.6 Advertising and/or promotion shall not state that a product does not contain an active ingredient or ingredients used in competitor products other than as permitted by the medicines regulatory authority.
- 25.7 Trade names of products of other companies shall not be used without permissions of the owner.
- 25.8 Hanging (open ended) comparisons are not allowed.
- 25.9 Comparisons are only permitted in advertising and/or promotion or promotional material if:
- 25.9.1 they are not misleading or disparaging;
 - 25.9.2 medicines or services for the same needs or intended for the same purpose are compared;
 - 25.9.3 one or more materials, relevant and representative features, capable of substantiation, are compared;
 - 25.9.4 no confusion is created between the medicine advertised and that of a competitor or between the advertiser's trademarks, proprietary names, other distinguishing marks and those of a competitor;
 - 25.9.5 the trademarks, proprietary names, other distinguishing marks, medicine, services, activities or circumstances of a competitor are not discredited or denigrated. Trademarks/proprietary name of a competitor may only be mentioned with written permission from the competitor;
 - 25.9.6 no unfair advantage is taken of the reputation of a trademark, proprietary name or other distinguishing marks of a competitor;
 - 25.9.7 medicines or services are not presented as imitations or replicas of goods or services bearing a competitor's trademark or trade name.
- 25.10 Substantiation for any information, claim or comparison must be provided at the request of the marketing code authority. It need not be provided, however, in relation to the validity of indications approved in the product registration.
- 25.11 When a written advertisement refers to the medicines regulatory authority approved package insert as well as scientific, published studies, clear and complete references must be listed on the advertisement.

- 25.12 When a written advertisement refers to unpublished data on file, the relevant part of this data must be provided at the request of the MCA.
- 25.13 All artwork including illustrations, graphs, tables, logos and trade dress must conform to the letter and spirit of the Code.
- 25.14 Graphs and tables must be presented in such a way as to give a clear, fair, balanced view of the matters with which they deal, and must not be included unless they are relevant to the claims or comparisons being made.
- 25.15 Information and claims about side effects must reflect available evidence or be capable of substantiation by clinical experience. It must not be stated that a product has no side effects, toxic hazards or risks of addiction. It is acceptable to highlight the absence of a specific side effect, e.g. 'no drowsiness'. The word 'safe' or phrases containing reference to safety must not be used without adequate scientific substantiation.
- 25.16 Exaggerated, all-embracing claims or superiority claims must not be made and superlatives must not be used except for those limited circumstances where they relate to a clear fact about a medicine. Claims should not imply that a medicine or an active ingredient has some special merit, quality or property unless this can be substantiated.
- 25.17 The word 'new' must not be used to describe any product or presentation, which has been generally available or any therapeutic indication, which has been available on the market for more than twelve months in South Africa.
- 25.18 Advertising and/or promotion of a self-medication medicine shall not suggest that a product is a foodstuff, cosmetic or other non-medicinal product.
- 25.19 Although it is acceptable to indicate that a self-medication medicine is palatable, advertising and/or promotion shall make clear that it is a medicine.
- 25.20 Advertising and/or promotion shall not suggest, directly or indirectly, that a product contains an unknown active ingredient.
- 25.21 A product, or any of its attributes, shall not claim to be unique unless substantiated.
- 25.22 Advertising and/or promotion shall not mislead about the novelty of a preparation.
- 25.23 Advertising and/or promotion claims relating to speed of absorption, dissolution, distribution or other pharmacokinetic particulars are acceptable if supported evidence and if in line with the product's registration dossier. However, such evidence may not be extrapolated to claims that a product offers improved efficacy or speed of efficacy, without supporting evidence to substantiate such claims.
- 25.24 Advertising and/or promotion shall not suggest that the safety, quality or efficacy of a product is due to the fact that it is natural. Advertising and/or promotion shall not claim that a product is 'natural'.
- 25.25 Advertising and/or promotion shall not suggest that a product is herbal, unless all the active ingredients are plants or extracts of plants. 'Herbal' can only be used to describe those elements that are of plant origin e.g. 'herbal ingredient'.
- 25.26 Claims for weight management, meaning weight loss, measurement reduction, clothing size reduction and weight control/maintenance, can only

be made in conjunction with reference to sensible lifestyle factors including a diet and exercise.

26. DISPARAGING REFERENCES

- 26.1 The medicine, products and activities of other companies must not be disparaged.
- 26.2 The health professions and the clinical and scientific opinions of their members must not be disparaged.

27. SUITABILITY AND TASTE

- 27.1 All material and activities must recognize the special considerations relating to the promotion of the medicine and must not be likely to cause offence.
- 27.2 The name or photograph or film of a member of a health profession must not be used in any way that is contrary to the conventions of that profession.
- 27.3 Promotional material must not imitate the devices, copy, slogans or general layout adopted by other companies, organisations or individuals, in a way that is likely to mislead or confuse.
- 27.4 Promotional material must not include any reference to the medicines regulatory authority unless this is specially required by the medicines regulatory authority.
- 27.5 Reproductions of official documents must not be used for promotional purposes unless permission has been given in writing by the appropriate body.
- 27.6 All material relating to medicines and their uses, which is sponsored by a company, must clearly indicate that the company, organisation or individual had sponsored it. Market research material need not reveal the name of the company, organisation or individual involved but must state that a company, organisation or individual sponsors it.

28. PROHIBITIONS OR RESTRICTED REPRESENTATIONS

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

29. QUOTATIONS

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

30. TESTIMONIALS

- 30.1 Testimonials shall comply with the approved package insert and with the other principles of this Code.
- 30.2 Testimonials should be less than three years old and be the genuine views of the user.
- 30.3 The use of healthcare professionals for marketing, promotion, endorsements or testimonial has to take place within the scope set by the professional codes applicable to such professionals.

31. HEALTHCARE PROFESSIONALS

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

32. VIEWS OF AUTHORS

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

33. SCIENTIFIC INFORMATION SERVICES

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

34. CERTIFICATION OF PROMOTIONAL MATERIAL

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

35. RELATIONS WITH THE GENERAL PUBLIC AND THE MEDIA

- 35.1 Requests from individual members of the public for information or advice on personal medical matters must be refused and the enquirer advised to consult his or her own health professional.
- 35.2 Companies are responsible for information about their products that is issued by their public relations agencies.

36. PROMOTIONS, GIFTS, PRIZES AND INDUCEMENTS

- 36.1 No company shall be involved in promotional schemes which are hazardous to the public or which bring the industry into disrepute.
- 36.2 Entry into consumer competitions shall not be dependent on the conditional purchase of a medicine nor shall a medicine be offered as a prize. The value of the prize shall not exceed the limits set by the Marketing Code Authority from time to time.

37. HOSPITALITY AND MEETINGS

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

38. TRAINING AND EDUCATION

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

39. MEDICAL SALES REPRESENTATIVES / CONSUMER PROMOTERS

- 39.1 Companies should ensure that Medical Sales Representatives/consumer promoters have adequate training to ensure sufficient scientific knowledge of the medicines which they promote to enable the provision of precise and complete information about such medicines.
- 39.2 All materials including slides and handouts shall comply with the requirements of the Code.
- 39.3 Product training must be consistent with the package insert of a medicine.
- 39.4 Medical Sales Representatives/consumer promoters must notify their company regarding any information received in relation to the use of medicines which they promote, particularly any information relating to adverse event reporting.
- 39.5 Medical Sales Representatives/consumer promoters are to conduct the promotion of product in a professional manner, and are not permitted to disparage any opposition products.

40. COMPLIANCE WITH UNDERTAKINGS

When an undertaking has been given in relation to a ruling under the Code, the company concerned must ensure compliance with that undertaking.

PART C --- ENFORCEMENT OF THE CODE

41. POWER OF THE MCA TO CARRY OUT OBJECTIVES

The MCA shall have all powers necessary to achieve its objectives including, without limitation, the powers:

- 41.1 to appoint an Executive Board, in the manner provided herein, in which shall vest the authority and responsibility to achieve the objectives and exercise the powers of the MCA;
- 41.2 appoint and remunerate an Executive Director to fulfil such administrative functions as are provided for in this Code and as may be determined by the Executive Board from time to time;
- 41.3 to contract any of its functions, including the right to administer this Code and its enforcement, to any entity it finds competent and suitable to fulfil such functions, subject to the oversight of the Executive Board and in terms of an agreement setting out the scope and nature of such functions;
- 41.4 to enter into co-operation and other agreements with any other trade association, with any group and/or institution/organisation, in order to further the objectives of the Code and health sector-wide adherence to Codes of Marketing Practice;
- 41.5 to appoint and remunerate such other employees as may be required from time to time;
- 41.6 to constitute and appoint Adjudicating Boards and Appeal Boards;
- 41.7 to appoint persons to the Legal Panel;
- 41.8 to ensure compliance with the provisions of the Code;
- 41.9 to impose penalties for any breach or contravention of this Code by a Company;
- 41.10 to print, publish and circulate whether electronically or otherwise, or to assist and subsidise, at its discretion, the printing, publishing and circulation of an official publication and newspapers and periodicals devoted to the pharmaceutical industry;
- 41.11 to develop, refine and publish a set of Code Guidelines and ensure that they remain relevant and up to date.
- 41.12 to provide advice, guidance and training on the Code;
- 41.13 to monitor all advertising and/or promotion of medicines, in whatever form, including but not limited to journal advertising, internet advertising and electronic advertising by Companies;
- 41.14 to request a Company to submit copies of any advertising and/or promotional material, including copies of the certificates authorising such material as well as copies of briefing instructions furnished to Medical Sales Representatives of such Companies;
- 41.15 to indemnify the Executive Director, any Directors, Boards, and members of any Boards against all losses, costs and damages which they or any of them

may be put to in the *bona fide* exercise and discharge by them of the powers and duties conferred and imposed upon them;

- 41.16 to open banking accounts in the name of the MCA, to draw, accept and endorse cheques, bills of exchange and promissory notes in connection with the business of the MCA;
- 41.17 to purchase, hire or otherwise acquire such land, houses, buildings, furniture, fixtures and fittings, equipment or any other property, and to improve, lease, sell or otherwise deal with them;
- 41.18 to invest any moneys of the MCA on deposit in a bank or building society, or in a savings account in a bank or building society, or on first mortgage on immovable property, provided the amount lent on mortgage shall be limited to two-thirds of the sworn valuation of the property, with power from time to time to vary any of the investments and re-invest the proceeds of any sale thereof in the manner aforesaid;
- 41.19 generally, without limitation, to do anything it may consider necessary or proper for the attainment of its objectives;
- 41.20 remunerate employees, consultants, advisors, investigators and the like.

42. MEMBERSHIP OF THE MCA

- 42.1 All members of the Associations as identified in clause 43 shall be members of the MCA ("the Members"). All Members shall be bound by the provisions of this Code.
- 42.2 In terms of Section 18C of the Medicines Act, all companies shall be bound by the provisions of this Code.
- 42.3 Clause 2.2 deals with the application of the Code to parties other than "companies".
- 42.4 Members shall be obliged to pay an annual membership fee to the MCA, either directly or via the relevant Association to which a Member belongs. The manner of payment and the annual amount will be determined by the Executive Board from time to time.

43. EXECUTIVE BOARD MEMBERS – COMPOSITION AND NUMBER

- 43.1 There shall be an Executive Board of Directors constituted as follows:
 - 43.1.1 One Director shall be nominated by each of the following trade associations ("the Associations"):
 - 43.1.1.1 The Pharmaceutical Industry Association of South Africa (PIASA);
 - 43.1.1.2 The National Association of Pharmaceutical Manufacturers (NAPM);
 - 43.1.1.3 Innovative Medicines South Africa (IMSA);
 - 43.1.1.4 The Self-Medication Association of South Africa (SMASA);

- 43.1.1.5 Pharmaceuticals made in South Africa (PHARMISA);
 - 43.1.1.6 The South African Animal Health Association (SAAHA);
 - 43.1.1.7 The South African Medical Device Industry Association.
- 43.1.2 One Director appointed by public nomination from amongst organisations not belonging to any trade association.
- 43.2 The Executive Board may, as its sole discretion, co-opt non-voting Directors to inform its work.
- 43.3 Should further associations be established, which in the opinion of the then representatives of the MCA should become part of MCA, such associations will become eligible to nominate Directors to the Executive Board as provided for in Clause 43.1 and the provisions of Clause 43.1 will be interpreted accordingly.
- 43.4 Each of the Executive Board Directors appointed in terms of Clause 43.1 shall have the power to appoint any person approved for that purpose by the Executive Board Directors, to act as an alternate Director in his place and at his discretion to terminate such appointment. On any such appointment being made, the alternate Director shall (except as to remuneration and power to appoint an alternate) be subject in all respects to the terms and conditions existing with reference to the other Directors. Each alternate Director, while so acting, shall exercise the same powers and discharge all the duties of the Director he represents. An alternate Director shall be entitled to receive notices of meetings of the Directors and to attend and vote as a Director but only at any such meeting at which the Director appointing him is not personally present and to count towards a quorum at such meeting and generally at such meeting to perform all the functions of his appointer as a Director.
- 43.5 After the first year of operation of the MCA, three Directors (including one from each of the Associations referred to in Clause 43.1.1, shall resign and replacement Directors shall be nominated by each of the Associations or relevant bodies. The same process will be followed at the end of each two yearly interval.
- 43.6 If the independent Directors referred to in Clause 43.1.2 are unable to agree which one of the staff resigns, the Executive Director shall by lot make that decision.

44. MEETINGS AND PROCEEDINGS

- 44.1 A quorum for meetings of the Executive Board shall be five Executive Board Directors, provided that in the event of further associations becoming eligible to nominate Directors, the number needed for a quorum shall be increased by one for each new joining association.
- 44.2 The Executive Board shall meet for the regular despatch of business, adjourn or otherwise regulate its meetings as it deems fit. The Executive Board may act notwithstanding any vacancy providing the number of Executive Board Directors does not fall below the number required for a quorum.

- 44.3 A resolution in writing signed by a majority of the Executive Board Directors for the time being shall be as valid and effectual as if it had been passed at a meeting of the Executive Board.
- 44.4 The Directors of the Executive Board shall annually elect one of the Executive Board Directors to be Chairman of the Executive Board.

45. POWERS OF THE EXECUTIVE BOARD

- 45.1 The Executive Board shall:
 - 45.1.1 exercise all the powers provided for in Clauses 41.2 to 44.18;
 - 45.1.2 manage and conduct all the affairs of the MCA;
 - 45.1.3 exercise and execute all the disciplinary powers of the MCA;
 - 45.1.4 administer and conduct all the financial affairs of the MCA;
 - 45.1.5 determine, from time to time, the fees in respect of complaints and appeals;
 - 45.1.6 determine, from time to time, the levies and charges in respect of other services, such as training and general advice, which may be provided by the MCA to Companies, Associations and Members.
- 45.2 The Executive Board shall:
 - 45.2.1 biennially review the principles embodied in the Code and review the enforcement and governance provisions and make recommendations to the medicines regulatory authority;
 - 45.2.2 compile and publish six monthly reports on complaints received by the MCA and submit these reports to the Department of Health;
 - 45.2.3 interpret the meaning, effect and intent of any of the provisions and clauses of this Code.
- 45.3 The Executive Board shall have the power to delegate any of its powers or functions to any person or persons (with or without the power of sub-delegation and/or with or without conditions as it may in its discretion deem fit) and to vary or withdraw or increase or decrease the powers or functions delegated at any time.
- 45.4 The Executive Board shall publish or cause to be published an annual report to the Members setting out details of the tasks which had been undertaken by the Executive Board, the Adjudicating Board and Appeal Board in the preceding year.

46. CHIEF EXECUTIVE OFFICER

- 46.1 Acting in terms of Clause 45.3 the Executive Board shall delegate to the Executive Director all such powers as are necessary to enable the Executive Director to conduct and perform the functions and duties which are provided for in this Code.
- 46.2 Notwithstanding anything to the contrary contained in this Code, the Executive Director shall not attend or be part of any hearings before an

Adjudicating Board or Appeal Board, save and except as an observer and then only in open sessions when the particular Board is not in deliberation.

47. ADJUDICATING, APPEAL AND LEGAL PANELS

- 47.1 The Executive Director shall at such times as he may consider appropriate approach the Associations to call for nominations of persons considered by the Associations to be eligible to be included as members of the Adjudicating, Appeal and Legal Panels. On receipt of such nominations the Executive Director will decide upon the names of the persons which he deems appropriate to appoint as members of the Adjudicating Panel, as members of the Appeal Panel and as members of the Legal Panel.
- 47.2 The Adjudicating Panel will consist of a minimum of twelve individuals who shall include persons with medical, regulatory and marketing expertise, skills and qualifications, who shall be eligible to serve for a maximum period of 5 years.
- 47.3 The Appeal Panel will consist of a minimum of twelve individuals comprised of persons with medical and regulatory expertise, skills and qualifications who shall be eligible to serve for a maximum period of 5 years.
- 47.4 The Legal Panel will consist of attorneys and/or advocates of at least 5 years standing in South Africa and with substantial experience in pharmaceutical industry matters.
- 47.5 When a person has been appointed to the Adjudicating or Appeal Panels and the period of the appointment (or re-appointment) is completed or due to be completed, such person may, in the sole discretion of the Executive Board, be re-appointed to the Adjudicating or Appeal Panels for such period as it may determine.
- 47.6 A person may not simultaneously serve as a member on the Adjudicating and Appeal panels.
- 47.7 All persons appointed to any of the panels, will sign an agreement in terms of which they agree:
- 47.7.1 that when they sit as members of any Board, to keep all deliberations of such Board confidential;
- 47.7.2 that when they are nominated to sit as a member of any Board, to immediately indicate any direct or indirect interest they may have in the matter to be considered by such Board which may cause a conflict of interest and to recuse themselves from sitting.

48. LODGING OF COMPLAINTS

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

- 48.1.1 proof that the company and complainant have made all reasonable attempts to resolve the matter between themselves;
 - 48.1.2 if the complaint is based on scientific issues, supporting literature and any studies relied on;
 - 48.1.3 copies of any advertisements and/or promotional material which may be relevant;
 - 48.1.4 any other information the Complainant considers relevant to the determination of the complaint.
- 48.2 If the Complainant is a Member of the MCA, the complaint shall make reference to the sections of the Code which may have been contravened and shall in addition be accompanied by:
- 48.2.1 the prescribed complaint fee applicable at the time;
 - 48.2.2 proof that the Complainant had, as soon as the reason for the complaint became known to him, approached the Respondent with the view of resolving the dispute amicably between them without the need of intervention by the MCA and that such approach proved unsuccessful;
 - 48.2.3 if the complaint is based on scientific issues, supporting literature and any studies relied on;
 - 48.2.4 copies of any advertisements and/or promotional material which may be relevant;
 - 48.2.5 any other information the Complainant considers relevant to the determination of the complaint.
- 48.3 The Executive Director shall within seven working days from receipt of the complaint, send a copy of the complaint to the Respondent and request a formal response within seven working days from the date upon which the Respondent receives the complaint.
- 48.4 The Executive Director shall within seven working days from receipt of the response, send a copy of the response to the Complainant and invite a reply within five working days from the date upon which the Complainant receives the response. The reply, if any, will on receipt be sent to the Respondent.
- 48.5 After receipt of the reply, if any, the Executive Director will forward the documents to the Chairman of the Adjudicating Board for investigation and adjudication as provided for in this Code.
- 48.6 A complaint may be withdrawn by the Complainant at any time before the complaint is referred to the Adjudicating Board by the Executive Director, in which case the complaint fee will be forfeited. Once the complaint has been referred to the Adjudicating Board the complaint cannot be withdrawn and will be adjudicated on.
- 48.7 The Executive Director may, on good cause shown and subject to such conditions as he/she may impose, extend the time periods referred to in Clause 48.3, 48.4, 49.2 provided that all offending promotional material is immediately withdrawn and/or offending conduct ceased.

49. NOMINATED COMPLAINANT

- 49.1 The Executive Director shall scrutinise promotional material and advertisements issued by companies on an ongoing basis to ensure that the advertisements do not contravene the provisions of the Code. The Executive Director shall also monitor such further conduct by Companies as s/he deems fit to ensure compliance with the Code.
- 49.2 Should the Executive Director be of the opinion that there has been a breach s/he will immediately bring this to the attention of the Executive Board, who will appoint from amongst the members an individual, not conflicted, who will become the nominated complainant in the matter.
- 49.3 The nominated complainant will act as complainant and in accordance with the processes outlined in this Code and no objection fees will be payable.

50. COMPOSITION OF ADJUDICATING BOARDS

- 50.1 Once the process set out in Clauses 48 and 49, if applicable, has been completed, the Executive Director will appoint an Adjudicating Board consisting of at least three members from the persons listed on the Adjudicating Panel and shall document the substantiation for their selection. Pending the hearing, the Executive Director shall keep the identity of the appointed members confidential.
 - 50.1.1 The quorum for an Adjudicating Board shall be three, one of which shall be appointed as Chairman by the Board. The Chairman shall not have a casting vote.
 - 50.1.2 The Adjudicating Board shall have the power, in its sole discretion, to co-opt at the commencement of any hearing or at any other time, any person or persons to sit on such Adjudicating Board where it considers that such person or persons will be able to assist in the hearing. Any member who has absented himself from any part of the hearing shall not take any further part in those proceedings.
- 50.2 The absence of a member of an Adjudicating Board on any occasion during the hearing shall not affect the validity of such Adjudicating proceedings, provided the number of remaining members meets the quorum requirement.

51. ADJUDICATING HEARINGS

- 51.1 The Adjudicating Board shall consider the documents placed before it by the Executive Director.
 - 51.1.1 Where documents are subject to amongst others Clause 7.6 (arbitration of confidential information), Clause 17 (evaluation of agreement between company and healthcare professional, including that of an honorarium) or Clause 18 (donation or support agreements) the Executive Director will nominate an independent member of the Adjudication Panel as arbitrator in the matter of the specific document or agreement and such agreement may be subject to confidentiality protections and may, in such cases, not be disclosed to the other party in the matter or any other third party

and only the finding of the independent arbitrator will be made known to the Board.

- 51.2 An Adjudicating Board will request the Executive Director to advise the Complainant and Respondent of the date of the hearing of the complaint and invite them to appear before the Adjudicating Board to make such further submissions as may be allowed by the Adjudicating Board.
- 51.3 Although an Adjudicating Board shall be entitled to adopt such procedures and formalities as it in its sole discretion, may from time to time determine, it shall adhere to the principles of natural justice and shall:
 - 51.3.1 allow a party to state its case in writing;
 - 51.3.2 ensure that no member of the Adjudicating Board has any direct or indirect interest in the matter which is being adjudicated upon.
- 51.4 No Party shall have legal representation at Adjudicating proceedings unless the Adjudicating Board, having regard to, *inter alia*, the complexity of the evidence and the legal issues likely to be involved, the serious nature of the matter enquired into and the penalty which may be imposed, in its sole discretion determines otherwise. In such case a Party shall be entitled to legal representation by only a practising attorney or practising advocate or both.
- 51.5 Adjudicating proceedings shall be recorded either manually or by means of recording equipment. The Chairman of the Adjudicating Board shall ensure that the proceedings are transcribed as soon as possible after the conclusion of the hearing and shall thereafter certify the transcript as an accurate record of the proceedings.

52. POWERS OF AN ADJUDICATING BOARD

- 52.1 Should an Adjudicating Board determine that there has been a breach or contravention of the Code, it shall make such a finding and furnish reasons therefore. The finding and reasons shall be communicated to the Parties.
- 52.2 Without fettering the discretion of the Adjudicating Board, in circumstances where it has found that the Respondent had committed a breach of the Code in respect of advertising and/or promotional activities, the Adjudicating Board will have regard to *inter alia* the following factors in deciding on a suitable penalty: whether the publications have ceased; how widely the offending material had been distributed; what steps have been taken to withdraw the published material; whether corrective statements have been issued; whether the breach was deliberate, negligent or inadvertent; whether there were or are safety implications; whether the material or publication was or is misleading and the extent thereof; the manner in which the perception of health care professionals or consumers have been or will be effected; whether commercial damage or harm, and the extent thereof, has been caused; whether the Respondent had previously breached the Code.
- 52.3 An Adjudicating Board shall, in cases of a breach or contravention of the Code, have the power to impose on a Party any one or more of the following penalties:
 - 52.3.1 a reprimand; caution or warning;

- 52.3.2 a fine;
 - 52.3.3 issue a directive that the Respondent's internal procedures be audited by a representative of the MCA and that a report be furnished to the Executive Director after the conclusion of such audit;
 - 52.3.4 issue a directive that any offending promotional activity or material or advertisement be ceased and/or withdrawn forthwith and that satisfactory proof be provided, within a stipulated time period, to the Executive Director that this has been done;
 - 52.3.5 that the Respondent, as represented by himself, or in the case of a company by its Chief Executive Officer, Country Manager, Company Code Compliance Officer or other senior member of management, furnish a written undertaking within a stipulated time period that the Respondent will avoid similar breaches of the Code in the future;
 - 52.3.6 that such action be taken by the Respondent to publicly undo the damage or potential damage caused by or as a result of the breach of the Code;
 - 52.3.7 that the Respondent pay such costs and expenses as the Adjudicating Board considers just and equitable in the circumstances including an order that the Respondent refund the Complainant the amount of the complaint fee;
 - 52.3.8 that the finding of the Adjudicating Board be published to the Members;
 - 52.3.9 such other order as may be considered appropriate to the Adjudicating Board in the circumstances.
- 52.4 Should the Adjudicating Board find that there is no merit in the complaint, or that the complaint was vexatious, frivolous or malicious, the Adjudicating Board may order the Complainant to pay such costs and expenses as the Adjudicating Board considers just and equitable in the circumstances including an order that the Complainant pay the costs, or portion of the costs and expenses incurred by the Respondent.

53. LODGING AN APPEAL

- 53.1 An appeal against a decision by the Adjudicating Board shall lie to an Appeal Board and to no other body. All decisions, penalties, rulings, determinations or findings of an Appeal Board shall be final and binding on the Party or Parties concerned.
- 53.2 Should either the Complainant or the Respondent wish to appeal the finding, decision or penalty imposed by the Adjudicating Board ("the Appellant"), the Appellant shall give notice in writing of his intention to appeal ("Notice of Intention to Appeal") within seven working days from the date on which the finding, decision penalty to be appealed against has been communicated to him. The Notice of Intention to Appeal shall be addressed to the Executive Director and shall be delivered within the prescribed time limit to the Executive Director.

- 53.3 Every Notice of Intention to Appeal shall be accompanied by the prescribed appeal fee.
- 53.4 Once an Appeal has been lodged, the Executive Director shall:
- 53.4.1 as soon as possible thereafter make a copy of the record of the Adjudicating proceedings to which the appeal relates available to the Appellant;
- 53.4.2 advise the other party (hereinafter referred to as the Respondent) that an appeal has been lodged and also furnish the Respondent with the copy of the record.
- 53.5 The Appellant shall lodge, in writing, a Notice of Appeal ("Notice of Appeal") within 10 working days, from the date on which he is notified that the transcript of the Adjudicating proceedings is available. The Notice of Appeal shall set out the penalty, decision or finding appealed against and the grounds of such appeal.
- 53.6 The Notice of Appeal shall be lodged with the Executive Director. On good cause shown, the period for lodging a Notice of Appeal may be extended by the Executive Director, on receipt of a written application from the Appellant, which application shall be lodged within the time period allowed for the lodging of the Notice of Appeal.
- 53.7 Should a Notice of Intention to Appeal or Notice of Appeal not be lodged within the prescribed time periods, the right of appeal or the appeal as the case may be shall lapse; provided that the Executive Director may, on written application to him, in his sole discretion and on such terms and conditions as he may determine, condone the late lodging and reinstate any appeal which has lapsed.
- 53.8 Where an appeal has been lodged, the Respondent may within 10 working days after being provided with a copy of the Appellant's Notice of Appeal, lodge a written response with the Executive Director. On good cause shown, the period for lodging a response may be extended by the Executive Director, on receipt of a written application from the Respondent, which application shall be lodged within the time period allowed for lodging the response. A copy of such response by the Respondent, if any, shall be furnished to the Appellant who shall be entitled to reply thereto within five working days.
- 53.9 An appeal may be withdrawn by the Appellant at any time before the appeal is referred to the Appeal Board by the Executive Director, in which case the appeal fee will be forfeited. Once the appeal has been referred to the Appeal Board the appeal cannot be withdrawn and will be adjudicated on.
- 53.10 In the event of the Executive Director being the nominal complainant, the discretion to extend the time periods as provided for in Clauses 53.6 and 53.7 will be delegated to the Chairman of the Adjudicating Board which made the ruling forming the subject matter of the appeal.

54. APPEAL HEARINGS

- 54.1 Once the process set out in Clause 53 has been completed, the Executive Director will forthwith appoint an Appeal Board consisting of at least two members from the persons listed on the Appeal Panel and a further person

listed on the Legal Panel, which latter person shall act as the Chairman of the Appeal Board. The Executive Director shall document the substantiation for their selection. Pending the appeal hearing, the Executive Director shall keep the identity of the appointed members confidential.

- 54.2 The quorum for an Appeal Board shall be three. The Chairman shall not have a casting vote.
- 54.3 Should the number of members of an Appeal Board fall below the quorum stipulated in the Code then the proceedings before that board shall be a nullity and another Appeal Board may be constituted to hear the appeal *de novo*.
- 54.4 Save where otherwise provided in the Code, an Appeal Board, when hearing an appeal, shall adopt such procedures as it, in its sole discretion, may determine.
- 54.5 An Appeal Board shall determine the place, date and time for the hearing of any appeal and shall notify all interested parties accordingly.
- 54.6 The Appellant shall have the right to appear before an Appeal Board to argue his appeal but shall not be entitled to have legal representation unless the Appeal Board, having regard to, *inter alia*, the complexity of the matter, the legal issues involved, the serious nature of the matter and the penalty which had been imposed, in its sole discretion determines otherwise. In such case the Appellant shall be entitled to legal representation by only a practising attorney or advocate or both. Should the Appellant be allowed legal representation, the Respondent shall also be entitled to be represented by a practising attorney and/or practising advocate. Should the Appellant or Respondent not appear at the hearing of an appeal, such appeal may be proceeded with in his absence.
- 54.7 The Appellant and the Respondent (and their respective legal representatives, if any) shall be bound by and confined to the record of the Adjudicating proceedings and shall not be entitled to introduce new evidence save with the permission of the Appeal Board, which may determine such matter in its sole discretion and on such terms and conditions as it may deem fit.
- 54.8 The operation of the finding, penalty or decision of the Adjudicating concerned shall be suspended:-
- 54.8.1 during the seven day period referred to in Clause 53.2; and/or
- 54.8.2 when a Notice of Intention to Appeal has been lodged, pending the final determination of such appeal by an Appeal Board, or the lapsing of the appeal or the withdrawal thereof.
- 54.9 The Appeal Board may, in its sole discretion, without hearing any Party or individual and without giving any reasons, postpone or adjourn any appeal for such periods as it deems fit.

55. POWERS OF AN APPEAL BOARD

- 55.1 An Appeal Board, on hearing an appeal, shall have the powers:
- 55.1.1 to allow the appeal;

- 55.1.2 to dismiss the appeal;
 - 55.1.3 to substitute any finding or decision as it deems fit or substitute such sanction as it deems fit, including any amended penalty;
 - 55.1.4 to make such order as in its opinion the circumstances may require including an order to remit the matter for the hearing of further evidence or an order for the hearing *de novo*;
 - 55.1.5 to hear further evidence or receive any documents on such terms and conditions as it in its discretion may decide;
 - 55.1.6 at any time to order a Party to pay all or a portion of the actual costs and other expenses reasonably incurred by the MCA in connection with an appeal or any postponement thereof, in addition to any other sanction, if it is of the opinion that such order is warranted and to determine the amount of such costs and other expenses;
 - 55.1.7 to order that the prescribed appeal fee, or any portion thereof, be forfeited or be refunded as it may determine having regard to the outcome of the appeal;
 - 55.1.8 an order that the matter be reported to the appropriate authorities including, but not limited to any appropriate statutory regulatory authority and/or the Advertising Standards Authority, with a request or recommendation that further action be taken against the Respondent;
 - 55.1.9 Should the Appeal Board be mindful to make an order as contemplated in Clause 55.1.8, it shall advise the Respondent of its intention to do so and afford the Respondent an opportunity to make submissions to the Appeal Board before a final decision is taken by the Appeal Board in this regard;
 - 55.1.10 to make such rulings as it in its sole discretion shall determine.
- 55.2 An Appeal Board, in addition to any of the powers set out above, shall be entitled to order that the outcome of the appeal hearing be published in such publications, including newspapers, as it may determine in its sole discretion.

TRADE ASSOCIATIONS AND COMPANIES INVOLVED IN DEVELOPMENT OF THE SOUTH AFRICAN MARKETING CODE

Innovative Medicines SA (IMSA)

CONTACT DETAILS:

Physical Address:

52 Glenhove Road, Melrose, 2196.
Telephone Number: 011 880-4644
Fax Number: 011 880-4644
E-mail Address: admin@imsa.org.za
Website: www.imsa.org.za

List of IMSA members

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

National Association of Pharmaceutical Manufacturers (NAPM)

CONTACT DETAILS:

Pharmacy House,
P.O. Box 57031, Arcadia, 0007
6 De Veer Lane, Arcadia, 0083
Pretoria, Tel: (012) 323-7529
Fax: (012) 323-7529
E-mail: napm@mweb.co.za
Website:

List of NAPM members

Abex Pharmaceutica (Pty) Ltd
Austell Laboratories (Pty) Ltd
Be – Tabs Pharmaceuticals (Pty) Ltd
Biodene (Pty) Ltd
Biovac S.A. (Pty) Ltd
Columbia Pharmaceuticals
Dr Reddy's Laboratories (Pty) Ltd
Enaleni/Cipla-Medpro (Pty) Ltd
Ferring Pharmaceuticals (Pty) Ltd
Medreich S.A
Merck Generics SA (Pty) Ltd
OmniMed (Pty) Ltd
Pharma Dynamics (Pty) Ltd
Pharmafrica (Pty) Ltd
Ranbaxy (SA) (Pty) Ltd
Sandoz SA (Pty) Ltd
Sekpharma (Pty) Ltd
Thebe Medicare (Pty) Ltd

Pharmaceuticals made in SA (PHARMISA)

CONTACT DETAILS

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

List of PHARMISA members:

Sekpharma (Pty) Ltd
Specpharm Holdings (Pty) Ltd
The Biovac Institute
Bodene (Pty) Ltd
National Bioproducts Institute
Phambili Hospital Products (Pty) Ltd
Pharmacare Limited trading as Aspen Pharmacare
Bioclones (Pty) Ltd

Pharmaceutical Industry Association of SA (PIASA)

CONTACT DETAILS:

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94 Bekker Street
Vorna Valley
1686
Telephone Number: 011 805-5100
Fax Number: 011 805-5105 / 9
E-mail Address: info@piasa.co.za
Website: www.piasa.co.za

Postal Address:
P O Box 12123
Vorna Valley
1686

List of PIASA Members:

Abbott Laboratories SA (Pty) Ltd
Adcock Ingram Healthcare (Pty) Ltd
Alcon Laboratories (Pty) Ltd
AHN Pharma (Pty) Ltd
AstraZeneca Pharmaceuticals (Pty) Ltd
Bayer-Schering Pharma (Pty) Ltd
Bioclones (Pty) Ltd
Bristol-Myers Squibb (Pty) Ltd
Covidien (Pty) Ltd
Galderma Laboratories (Pty) Ltd
GlaxoSmithKline SA (Pty) Ltd
iNova Pharmaceuticals (Pty) Ltd
Janssen-Cilag (Pty) Ltd
Key Oncologics (Pty) Ltd
Merck (Pty) Ltd
Novo-Nordisk (Pty) Ltd
Schering-Plough (Pty) Ltd
Servier Laboratories (Pty) Ltd
Solvay Pharma (Pty) Ltd
Stiefel Laboratories SA (Pty) Ltd

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List of SMASA members

Adcock Health Ingram
Nycomed
Bausch & Lomb
Bayer Consumer Care
Boehringer-Ingelheim
Cipla Medpro
GlaxoSmithKline
Johnson & Johnson

Merck (Pty) Ltd
Norgine
Novartis Consumer Health
Pharma Dynamics
Pharmafrica
Proctor & Gamble
Reckitt Benckiser
Smith & Nephew
Thebe Medicare
Winthrop Pharmaceuticals (Sanofi-Aventis)
Wyeth Consumer Healthcare

Wholesalers and Distributors

NAPW members
IHD
PHD
UPD

The South African Animal Health Association

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List of SAAHA members

Bayer (Pty) Ltd Animal Health division
Boehringer-Ingelheim Vet Medica
Cipla Vet (Pty) Ltd
Intervet SA (Pty) Ltd
Merial SA (Pty) Ltd
Norbrook Laboratories (SA) (Pty) Ltd
Novartis SA (Pty) Ltd Animal Health
Pfizer Animal Health
Virbac RSA (Pty) Ltd