



**CODE OF PRACTICE
FOR THE
MARKETING OF
PRESCRIPTION MEDICINES
IN SOUTH AFRICA**

December 2006 [amended 4 March 2008]



PIASA Code of Practice for the Marketing of Medicines in South Africa

The Pharmaceutical Industry Association of South Africa (PIASA) represents the pharmaceutical industry operating in South Africa and Southern Africa. Representing 24 pharmaceutical companies PIASA companies have more than 8 000 employees committed to developing, conducting clinical trials and bringing to patients, new medicines that improve health and the quality of life.

The pharmaceutical industry internationally makes a substantial contribution to public health by its research and development, and by making available and optimising the use of pharmaceutical products to prevent, diagnose and treat diseases and disabilities. Besides contributing to social progress and improving public health, the pharmaceutical industry is a major industrial asset to the South African economy, generating economic growth and delivering innovation.

December 2006 [amended 4 March 2008]

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PIASA Code of Practice for the Marketing of Medicines in South Africa

TABLE OF CONTENTS

Introduction

Part I : **PIASA** Code of Practice for the Marketing of Medicines to healthcare professionals

Part II: **Complaints Procedure**
The procedure for handling any complaints under the Code.

NOTE: Guidance Notes to assist with interpretation of the Code is available as a separate document.

Terminology

The terminology used has been simplified to make for easier understanding.

- The "PIASA Code of Practice for the Marketing of Medicines in South Africa" is referred to throughout as "the Code".
- The Medicines and Related Substances Control Act No. 101 of 1965 as amended, is referred to throughout as "the Medicines Act".

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PIASA CODE OF PRACTICE FOR THE MARKETING OF MEDICINES

PART 1 4 March 2008

Part 1 of the PIASA Code of Practice for the Marketing of Medicines has been amended in line with the revised draft SA Marketing Code [Part A] finalised and agreed by the Pharmaceutical Industry Marketing Code Steering Committee on 29 January 2008. This has been endorsed by all members of PIASA and is therefore incorporated into the PIASA Code of Practice as Part 1 in place of the original Part 1 [last version Nov 2006].

Part 11 of the PIASA Code remains unchanged.

That is until the Department of Health accepts and endorses the draft SA Marketing Code in full and publishes this in the Government Gazette as a final document when it will apply to all marketers of medicines in South Africa.

INDEX

1.	PREAMBLE	7
2.	INTRODUCTION TO, APPLICATION AND INTERPRETATION OF THE CODE	7
3.	GLOSSARY.....	10
PART 1 - MARKETING AND PROMOTION OF MEDICINES TO HEALTHCARE PROFESSIONALS		11
4.	REGISTRATION STATUS OF MEDICINES.....	11
5.	ADVERTISING AND PROMOTION MATERIAL	11
6.	JOURNAL ADVERTISING	12
7.	INFORMATION, CLAIMS AND COMPARISONS	12
8.	DISPARAGING REFERENCES	13
9.	HIGH STANDARDS, FORMAT, SUITABILITY AND ENDORSEMENT BY HCP'S	14
10.	DISGUISED PROMOTION	14
11.	PROVISION OF REPRINTS AND THE USE OF QUOTATIONS	15
12.	DISTRIBUTION OF PROMOTIONAL MATERIAL	15
13.	SCIENTIFIC INFORMATION SERVICE	16
14.	CERTIFICATION OF PROMOTIONAL MATERIALS, MEETINGS AND OTHER ACTIVITIES	16
15.	MEDICAL SALES REPRESENTATIVES	17
16.	TRAINING	18
17.	INTERACTIONS WITH HEALTHCARE PROFESSIONALS	18
18.	INDUCEMENTS, GIFTS AND PROMOTIONAL ITEMS, COMPETITIONS	20
19.	RELATIONS WITH THE GENERAL PUBLIC AND THE MEDIA	21
20.	SAMPLES.....	22
21.	THE INTERNET.....	22
22.	COMPLIANCE WITH UNDERTAKINGS	22

1. BACKGROUND

PIASA has been working throughout 2007 with other trade associations in supporting the development of a South African Marketing Code for all marketers of medicines. The draft SA Marketing Code was finalized on 29 January 2008 and has been supplied to the Department of Health for acceptance, endorsement and publication in the government gazette. Formal presentations to government officials and other stakeholders are on-going. The draft SA Code is therefore not a final document. Although endorsed in principle by all participating trade associations it is not an official government document but indicates the intention of all stakeholders to support and comply with the Code.

The supporting trade associations are:

PIASA, IMSA, NAPM, SMASA, PHARMISA and NAPW, IHD and PHD.

PIASA and SMASA as trade associations, already had Codes of Practice and Complaints procedures in place. PIASA members were requested to indicate their support by e-mail for the revised SA Code and this support was received.

Part 1 of the PIASA Code of Practice November 2006 has therefore been replaced by Part A of the SA Marketing Code. However Part 11 of the PIASA Code i.e. the complaints procedure, remains. In future all complaints against a PIASA member will be made and processed in terms of the revised Part 1 of the Code [i.e. the SA Marketing Code]. This will continue until the Department of Health publishes the final version of the SA Marketing Code and the Marketing Code Authority has been established.

Certain relevant parts e.g. the Preamble and Introduction of the Draft South African Marketing Code, have also been included here to give the background and objectives of the SA Marketing Code and identify those parties to whom the Code will apply. Currently these are relevant for PIASA members in complying with Part 1 of the PIASA Code.

2. EXTRACTS FROM THE DRAFT SA MARKETING CODE 29 January 2008 [modified where applicable for PIASA members]

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 stakeholders, 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;

2. INTRODUCTION, 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 it interacts with.

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 holder, their agents, contractors, third party distributors / marketers. Companies that circumvent the code by engaging or using other companies or agents or dispensing system software vendors or ordering systems will be infringing the Code.

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

2.2.1.3 It also covers advertising 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 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 –PIASA Part 1) 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 veterinary medicines, complementary medicines and medical devices.

- 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, 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 will provide companies with an indication as to how the Code should be applied and adhered to, in practical terms. **The rulings of PIASA** will form precedent on what constitutes acceptable practices in the marketing of medicines.

2.3.2 The Code should not be construed 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.

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 in order to sell, recommend or arrange for the sale or prescription of their products.”

2.3.4 In any review of advertising 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, Guidance Notes on the South African Marketing Code. The examples given are intended to illustrate and clarify the meaning of the Code. They are not exhaustive and do not cover all possible situations to be covered by the provisions of the Code.

2.4.2 These guidelines will be updated regularly, 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 of the South African Marketing Code

2.5.1 PART A [PIASA Part 1] The marketing and promotion of medicines to healthcare professionals

PART A [PIASA Part 1] 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 of medicines in Schedules S0 and S1 to the general public is permitted but advertising of medicines in Schedules S2 to S6 to the general public is not allowed under the Medicines Act and Regulations. Therefore the provisions of PART A [PIASA Part 1] apply to all medicines 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 of medicines in Schedules S0 and S1, to the general public is permitted by law. The main purpose of the Code is to help ensure that advertising 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 (S0 and S1) medicines registered or sold in terms of the Medicines Act. ...
The provisions of PART B of the Code do not apply to advertising aimed at healthcare

professionals.

The provisions in PART B have to be seen in the light of the exemption for S0 medicines from the provisions of section 18A to the Medicines Act.

NOTE: Part B does not form part of the PIASA Code but has been accepted by the Self Medication Association of South Africa [SMASA]. Any complaints about the marketing of any self medication product should be referred to SMASA directly or through the ASA.

3. 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:

Advertising 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; Touch screen advertising; Aisle, ceiling, floor advertising and other signs; Counter top advertising; Window displays; Gondola end advertising; Bunting; Advertising on electronic ordering systems; Bus, taxi and other vehicle advertising; and Light box advertising.

Company: may refer to a company, closed corporation, organisation, vendor or individual who may sell or promote medicines.

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.

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

Health Care Professional (HCP): includes members of the medical, dental, pharmacy 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.

Honorarium: is a payment or an award granted in recognition of a special service by a professional person. Honorariums can be paid at fair market value for speeches, articles, appearances or other services rendered.

Medicines Act (i.e. Medicines and Related Substances Act No 101 of 1965 as amended): refers to the body of legislation governing the registration and marketing of medicine, as amended from time to time.

Promotional item: is merchandise given away free of charge in an effort to create awareness of a company or product.

PIASA CODE OF PRACTICE FOR THE MARKETING OF MEDICINES

PART 1 - MARKETING AND PROMOTION OF MEDICINES TO HEALTHCARE PROFESSIONALS

NOTE: The numbering of the Clauses in the PIASA Code Part 1 has been taken directly from the draft SA Marketing Code and retained for the sake of uniformity with that Code in the future. Please note that the numbering starts at Clause 4.

4. REGISTRATION STATUS OF MEDICINES

- A medicine must not be 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 The approved package insert may be used as a reference in all promotional material and advertising.
- 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 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 bytes, interactive data systems and such like:
 - 5.7.1 The minimum information may 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.

- 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 that 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 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, substantiable and representative features are 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/ tradenames 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 tradename.

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 administration 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 in the case of a dispute. The arbitrator 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 reference to safety must not be stated in such a way as to imply that a product has no side effects, toxic hazards or risks of addiction. The word 'safe' must not be used without scientific 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 must not be disparaged.
- 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 a medicine.
- 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 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 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.
- 10.4 Observation/ Non-interventional studies of registered medicines are studies where the medical 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.
- 10.5 Non-interventional studies 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 Study protocol should be submitted to the 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 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 MRA upon their 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.
- 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 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 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.

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 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, 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

- 14.2.1 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 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 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 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 product launches, no sponsorship or payment of travel and accommodation can be extended to healthcare professionals.
- 17.1.8 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.
- 17.1.9 CPD meetings:
 - 17.1.9.1 No product promotion is allowed in the CPD meeting room. Company-branded items / promotion are permissible.
 - 17.1.9.2 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.
 - 17.1.9.3 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.

- 17.1.10 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. *(If this is not accepted by the HPCSA then we recommend the following be included. Then 17.1.7 would hold. If approved then 17.1.7 deleted)*
- 17.1.11 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 congress, 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.
- 17.3 **Sponsorship of meetings at patient support groups**
- Patient support group meetings and events may be sponsored provided that proper records are kept and that no product promotion takes place.
- 17.4 **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.
- 17.5 **Stand-alone entertainment, leisure, social or cultural events with healthcare professionals**
- 17.5.1 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.
- 17.5.2 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.
- 17.6 **Other interactions with healthcare professionals**
- 17.6.1 Consultancy services
- 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.

- 17.6.2 No direct payments to healthcare professionals for any other services
 - 17.6.2.1 Payments may not be made to doctors or groups of healthcare professionals, either directly or indirectly, for rental for rooms or other services.
 - 17.6.2.2 Healthcare professionals involved in *bona-fide* and if relevant, peer reviewed research, are not subject to the Code.
- 17.6.3 Certification of Meetings for the purposes of certification envisaged in Clause 14, the following details have to be retained:
 - 17.6.3.1 Details of the programme, both scientific/education and entertainment/ hospitality, if any,
 - 17.6.3.2 Invitations, the choice of venue(s),
 - 17.6.3.3 Documentation as to the rationale for the meeting or sponsorship,
 - 17.6.3.4 Participant selection processes and criteria,
 - 17.6.3.5 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 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, may be given as a maximum of 1 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
Competitions should fulfill the following criteria:
- 18.5.1 The competition is based on medical/ product knowledge or the acquisition of scientific knowledge;
- 18.5.2 The prize is relevant to the practice of medicine, dentistry or pharmacy; and
- 18.5.3 Individual prizes or educational items offered and within the cost limit agreed with PIASA or the professional associations.
- 18.5.4 Entry into a competition must not be dependent upon prescribing, ordering or recommending of a product and no such condition shall be made or implied.
- 18.6 Donations and grants to charities
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 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. 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.
- 19.3 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.
- 19.4 Companies are responsible for information that is issued by their public relations agencies about their products.
- 19.5 Patient education ("help-seeking advertisements") directed at general public is acceptable, provided that it:

- 19.5.1 Does not contain the name of the specific medicine.
- 19.5.2 Does not make or allude to a medicinal claim.
- 19.5.3 Does not provide any risk information.
- 19.5.4 Lets the public know that treatment exists for a medical condition.
- 19.5.5 "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 2 to Schedule 6 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 can 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.

NEW PIASA MARKETING CODE

Part 11

COMPLAINTS PROCEDURE

DECEMBER 2006

VERSION 4

PIASA CODE OF PRACTICE FOR THE MARKETING OF MEDICINES

PART 11

COMPLAINTS PROCEDURE

**A procedure for handling complaints about the marketing
of medicines in South Africa.**

TABLE OF CONTENTS

1. Who will handle complaints
2. Marketing Practices Committee
3. Marketing Practices Appeal Board
4. Funding for administration of the Code
5. Complaints Procedure
6. Action on Complaints
7. Marketing Practice Committee Rulings
8. Referral to the Marketing Practices Appeal Board
9. Sanctions
10. Sanctions that may be applied by the Marketing Practices Committee
11. Marketing Practice Appeal Board Rulings
12. Case reports
13. Possible Breaches identified by Secretariat MPC or MPAB
14. General Provisions
15. Annual report

1. WHO WILL HANDLE COMPLAINTS

- 1.1. Complaints will be handled by
 - a. The Secretariat of the Pharmaceutical Industry Association of South Africa [PIASA].
 - b. A Marketing Practices Committee [MPC];
 - c. A Marketing Practices Appeal Board [MPAB].
- 1.2 The PIASA Secretariat will be responsible for the administration of the Code including the provision of advice, guidance and training on the Code and for arranging for mediation and conciliation between companies when requested to do so,
- 1.3 PIASA will administer the procedure by which complaints made under the Code are evaluated initially by the Secretariat and, where appropriate, are referred to the Marketing Practices Committee [MPC] followed, where required, by referral to the Marketing Practices Appeal Board. [MPAB]
- 1.4 The members of the MPC and the MPAB are appointed by the Executive Council

The MPC [Marketing Practices Committee] consists of

- a Chairman who shall be either a practising lawyer with at least 5 years experience, or a person with at least 10 years experience in the pharmaceutical industry in a management position and
- two members appointed by the Executive Council of the Pharmaceutical Industry Association of South Africa [PIASA].

The term of office of the MPC will be for 12 months or until the next Annual General Meeting when the new Executive Council is appointed.

The MPAB [Marketing Practices Appeal Board] comprises:

- An independent Chairman, who shall be a practising advocate or an attorney. Such a person shall be of at least five years standing in South Africa, provided that he or she shall not have been a member of the Panel, whose decision is the subject matter of the appeal.
- Two members of PIASA as full members of the MPAB and two alternates. Either of these alternates may be called on to serve on the Appeal Committee when required to do so eg. in case the nominated member is unavailable or has to recuse him/herself due to a possible conflict of interest.

The term of office of the MPAB will be for 12 months or until the next Annual General Meeting when the new Executive Council is appointed.

- 1.5 The Secretariat may consult the MPC or the MPAB upon any matter concerning the Code or its administration.

- 1.6 The Secretariat has the authority to request copies of any relevant material from a marketer or supplier of medicines, including copies of the certificates authorising promotional material or activities, standard operating procedures for approval of promotional material and any promotional activities and copies of relevant briefing material for representatives.
- 1.7 Patients and other stakeholders in the health care sector, including the Department of Health, will be notified of the voluntary adoption and endorsement of the PIASA Marketing Code by all PIASA members.
- 1.8 Any company, organisation or individual involved in the promotion and marketing of medicines, who is not a member of PIASA, may voluntarily agree to endorse the Code and to submit themselves to the PIASA Marketing Practices Committee and Appeal Board for the handling of any complaints.

2. MARKETING PRACTICES COMMITTEE

- 2.1 The MPC [Marketing Practices Committee] consists of
 - a Chairman who shall be either a practising lawyer with at least 5 years experience, or a person with at least 10 years experience in the pharmaceutical industry in a management position and
 - two members appointed by the Executive Council of the Pharmaceutical Industry Association of South Africa [PIASA].
- 2.2 The term of office of the MPC will be for 12 months or until the next Annual General Meeting when the new Executive Council is appointed.
- 2.3 The MPC meets as business requires in order to consider complaints made under the Code. As a condition of appointment, nominated members of the MPC and alternates enter into a confidentiality agreement regarding the deliberations of the Committee in the form determined by PIASA and must recuse themselves from any meetings or hearings where there could be a conflict of interest.
- 2.4 The MPC may request the Secretariat to obtain expert assistance in any field. Expert advisers who are consulted may be invited to attend a meeting of the Committee but have no voting rights.

3 MARKETING PRACTICES APPEAL BOARD

3.1 Composition

- 3.1.1 The MPAB [Marketing Practices Appeal Board] comprises:
 - An independent Chairman, who shall be a practising advocate or an attorney. Such a person shall be of at least five years standing in South Africa, provided that he or she shall not have been a member of the Panel, whose decision is the subject matter of the appeal.
 - Two members of PIASA as full members of the MPAB and two alternates. Either of these alternates may be called on to serve on the

Appeal Committee when required to do so eg. in case the nominated member is unavailable or has to recuse him/herself due to a possible conflict of interest.

3.1.2 The term of office of the MPAB will be for 12 months or until the next Annual General Meeting when the new Executive Council is appointed.

3.1.3 As a condition of appointment, members of the Marketing Practices Appeal Board [MPAB] must enter into a confidentiality agreement regarding the deliberations of the MPAB in the form determined by PIASA and must recuse themselves from any meetings or hearings where there could be a conflict of interest.

3.1.4 The Secretariat attends meetings of the Appeal Board as an observer and provides administrative support to the MPAB as appropriate.

3.2 MPAB Procedure for Meetings

3.2.1 The Marketing Practices Appeal Board [MPAB] meets as business requires to consider appeals under the Code and any other matter that relates to the Code. The MPAB receives reports on all complaints that have been submitted under the Code and details of the action taken on them.

3.2.2 The Chairman and two members of the MPAB constitute a quorum.
NOTE: It would be preferable if at least one of the members were a qualified health care professional.

3.2.3 Decisions are made by consensus. If however consensus cannot be reached, majority voting shall apply. The Chairman has both an original and a casting vote.

3.2.4 If a member of the MPAB is involved in a case either as complainant or respondent, that member does not receive copies of the papers circulated in connection with the case and is required to withdraw from the MPAB during its consideration. Members of the MPAB are also required to declare any other interest in a case prior to its consideration. The Chairman determines whether it is appropriate for that member to remain for the consideration of the case.

3.2.5 The Chairman may obtain expert assistance in any field. Expert advisers may be invited to attend a meeting of the MPAB but have no voting rights.

3.2.6 When appeals are considered by the MPAB, both the complainant and the respondent are entitled to appear or be represented.

3.2.7 Where an appeal is brought which is concerned with an issue of fact between a complainant and the respondent concerned that cannot be properly resolved without the oral evidence of the persons directly involved, the Chairman may invite such persons to attend and give evidence.

4. FUNDING FOR THE ADMINISTRATION OF THE CODE

Initial administrative costs for handling complaints will be absorbed by PIASA but the costs of any hearing or other costs will be recovered from the complainant and /or respondent as determined by the MPC or the MPAB.

There will be no charge for handling complaints from consumers or individual health care professionals. These expenses will be absorbed by PIASA or the respondent as determined by the MPC or the MPAB.

5. COMPLAINTS PROCEDURE

All complaint procedures will be administered in accordance with general principles of fairness. Complaints may be lodged by a member company, or any other company, organisation or individual including individual health care professionals.

5.1.1 Complainants are encouraged to contact the company, organisation or individual concerned prior to lodging a complaint, as a satisfactory solution may be immediately available.

5.1.2 Companies and/or organisations are encouraged to seek resolution of their differences informally before invoking the formal procedures described, possibly through mediation of the PIASA Secretariat. No informal communications will be acted upon by the Secretariat.

5.1.3 Where a complaint is made by a consumer or other person outside the industry, the complainant may simply state the nature of the conduct to which objection is taken and give the reason(s) for the objection. Where the complaint is based on scientific issues, supporting literature is desirable to ensure a balanced review.

5.1.4 Industry-generated complaints must be initiated by a letter signed or authorised in writing by the company's or organisation's chief executive to the PIASA Secretariat, and must state those clauses of the Code that are alleged to have been breached.

NB:

1. Everything on which the complainant proposes to rely should be included because generally there will be no opportunity to add anything later. Therefore the formal complaint should:
 - include a copy of the advertisement or promotional material in question;
 - include copies of any studies relied on;
 - explain why it is claimed that the Code has been contravened;

- specify the section or sections of the Code said to have been contravened;
 - identify the category of breach. This will be confirmed or amended after review by the Secretariat.
- 5.1.5 Industry-generated complaints should not be used simply as a competitive tool.
- 5.1.6 If the complaint has been resolved by agreement between the companies [or the complainant and respondent] after the initiation of the formal complaint process and before final determination of the complaint, the complainant (or, in the case of an appeal, the appellant) must inform the Secretariat immediately and the complaint [or appeal] will be treated as withdrawn. However the complainant [or the appellant] shall be responsible for meeting the costs of the complaint up to that point [except in the case of a private individual].
- 5.1.7 The company, organisation or individual whose conduct is the subject of the complaint must be given full details of the complaint. The chief executive of the company or organisation or the individual concerned **[the respondent] is requested to comment on the matter of the complaint within seven [7] working days.**
- 5.1.8 The Secretariat will provide to the complainant a copy of the respondent's response. The **complainant may deliver to the Secretariat within five [5] working days,** any reply it wishes to make. The Secretariat will send a copy of the complainant's reply [if any] to the respondent.
- 5.1.9 **Complaints must be lodged** with the PIASA Secretariat **within 30 days** of discovery of the offending promotional material.

6. ACTION ON COMPLAINTS

- 6.1 When PIASA receives information which indicates that a company, organisation or individual may have contravened the Code, the Chief Executive of the company or organisation or the individual concerned must be given full details of the complaint and is requested to comment on the matters of complaint **within seven [7] working days.**
- 6.2 In complaints where it is clear that there has been, or has not been, an infringement of the Code, the PIASA Secretariat may make a decision immediately based on legal requirements.

Alternatively, the Secretariat may use its discretion to refer the matter to the MPC or the Medicines Control Council [for legal infringements] for resolution. Should the decision result in an appeal, the matter will be referred directly to the MPAB.

- 6.3 If a complainant does not accept a decision of the PIASA Secretariat or the MPC then the matter is referred to the Marketing Practices Appeal Committee for a decision, which is final.

- 6.4 Upon receipt of the comments from the respondent, the Committee must determine whether there is a *prima facie* case to answer under the Code. If, in the view of the Director, no *prima facie* case has been established the complainant and the respondent are so advised. If the complainant does not accept that view, the matter is referred to the Marketing Practice Committee for a decision, which is final.
- 6.5 The Marketing Practices Committee may decide to hold a hearing at which both representatives of the complainant and the respondent [who must be employees of the respective companies] may appear and may be asked to state their case and to answer questions put by members of the Committee. However a hearing is not obligatory. No lawyers who are not company employees may represent the companies involved at such a hearing.

The respondent will be required to bring the following items to such a hearing:

- The company Standard Operating Procedure for approval of promotional material or activities
- The Certification related to approval of the promotional material or activity which is the subject of the complaint.

Note:

Where the respondent is not a PIASA member, and has not agreed voluntarily to submit to the PIASA Marketing Practices Committee, complaints against that respondent will be referred to the Department of Health / MCC Inspectorate for evaluation and appropriate action.

7 MARKETING PRACTICE COMMITTEE RULINGS

- 7.1 Where the Marketing Practice Committee rules that **there is a breach of the Code**, the company, organisation or individual concerned is so advised and is given the reasons for the decision. The **respondent has seven [7] working days** to provide a written undertaking that the promotional activity or use of the material in question (if not already discontinued or no longer in use) will cease forthwith and that all possible steps will be taken to avoid a similar breach of the Code in the future.

This undertaking must be signed by the chief executive of the respondent or by the individual respondent or with his or her authority and must be accompanied by details of the actions taken by the respondent to implement the undertaking, including the date on which the promotional material was finally used or appeared and/or the last date on which the promotional activity took place, and confirmation that the corrective steps, if any, as determined by the Committee have been taken publicly to undo the damage caused by the breach of the Code. The **respondent must also pay within twenty working days** an administrative charge based on the number of matters ruled in breach of the Code by the MPC.

- 7.2 Where the Committee rules that there is **no breach of the Code**, the complainant and respondent are so advised. Where the complaint is from a pharmaceutical company, or other business organisation **the**

complainant must pay within twenty working days an administrative charge based on the number of matters alleged and ruled by the MPC not to be in breach of the Code. When advised of the outcome, the complainant will be sent a copy of the comments and enclosures submitted by the respondent in relation to the complaint.

- 7.3** The complainant or the respondent may appeal against rulings of the Director or Committee to the Code of Practice Appeal Board. **Appeals must be lodged within ten working days** of the notification of the ruling of the Director or Committee and must be accompanied by reasons as to why the Director's or Committee's ruling is not accepted. These reasons will be circulated to the Appeal Board.
- 7.4** Where an appeal is lodged by the complainant, **the respondent has ten working days to comment on the reasons given by the complainant for the appeal** and these comments will be circulated to the Appeal Board. The complainant has five working days to comment on the respondent's comments upon the reasons given by the complainant for the appeal and these comments also will be circulated to the Appeal Board.

8. REFERRAL TO THE MARKETING PRACTICES APPEAL BOARD

- 8.1** Failure or refusal of a company or organisation or individual to comply with the procedures set out in Clause 7 above, shall be reported to the Marketing Practices Appeal Board for consideration.
- 8.2** The Marketing Practices Committee may also report to the MPAB any company, organisation or individual whose conduct in relation to the Code, or in relation to a particular case before it, warrants consideration by the Appeal Board for possible further sanctions against the company organisation or individual. Such a report to the Appeal Board may be made notwithstanding the fact that a company organisation or individual has provided an undertaking requested by the Committee.
- 8.3** Where the MPC reports a company, organisation or individual to the MPAB the company, the organisation or individual concerned is provided with a copy of the report prior to its consideration and is entitled to have a representative or representatives appear before the Appeal Board to state the company's organisation's or individual's case.
In this case the Chief Executive Officer of the companies involved will be invited to attend the hearing.

9. SANCTIONS

9.1 Breaches

Where a breach of the Code has been established, the PIASA Secretariat or the MPC must classify what kind of breach has occurred, in accordance with the classification set out below:

Class 1 Breach: a breach of the Code that has no safety implications and will have no effect on how consumers or healthcare professionals view the product or its competitors.

Class 2 Breach: a breach of the Code with no safety implications but which will impact on the perceptions of the consumer or healthcare professionals regarding the product or competitor products.

Class 3 Breach: a breach of the Code that has safety implications or will have a major impact on how consumers or healthcare professionals view the product or competitor products or the pharmaceutical industry.

Repeat Breach: when the same or a similar breach is repeated in the promotion of either a particular product, or any product or practice of a company organisation or individual which had been found to be in breach of the Code within the preceding 24 months.

9.2 The PIASA Secretariat or MPC must consider whether or not any sanctions will be imposed although there is no obligation to impose a sanction where breaches of the Code have been established.

In determining whether or not to impose a sanction and, if so, what that sanction should be, the PIASA Secretariat or MPC or MPAB will consider all the circumstances of the case, including whether:

- publication has ceased;
- steps have been taken to withdraw the material published;
- corrective statements have been made;
- the breach was deliberate or inadvertent;
- the company, organisation or individual that is the subject of the complaint has previously breached the Code;
- there were or are safety implications;
- the perceptions of healthcare professionals or consumers have been or will be affected.

10. SANCTIONS THAT MAY BE APPLIED BY THE MARKETING PRACTICES COMMITTEE

10.1 Undertaking to stop offending behaviour

The MPC may require the company, organisation or individual to give an undertaking in writing to discontinue any advertising or promotional practice which has been determined to constitute a breach of the Code on or before a date determined by the MPC, such date being determined in line with the severity of the breach of this Code.

The MPC may require the company, organisation or individual to give an undertaking to **cease publication** in any media (until they can be supported) of an advertisement or of a particular claim or claims which, in the advertisement or other promotional materials before the Committee, have been determined to constitute a breach of the Code.

Where a breach involving failure to provide substantiation is found, the Committee may direct the company to **provide substantiation** within such time as the MPC may specify.

10.2 Publication of Reprimand and Warning

The MPC may decide to recommend to the PIASA Secretariat that a company, organisation or individual found to have breached the Code, should be reprimanded and warned and the details of that reprimand and warning should be published on the PIASA website or any other publication as determined by the MPC.

10.3 Retraction and/or corrective statements

The MPC may require the company, organisation or individual to **issue retraction** statements or letters and/or corrective statements, letters or advertisements and/or to use its best endeavours to retrieve advertisements found to be in breach on such conditions as the MPC specifies, as appropriate. The format, size, wording, mode of publication and method of distribution of such statements/ advertisements shall be specified by the MPC in its determination and will in general conform to the original statement/advertisement. It shall be approved by the PIASA Secretariat before publication. This does not preclude the party that is the subject of the complaint from suggesting minor amendments to the retraction or corrective statements. However, the MPC through its Chair may set a time limit on any such suggestions and is under no obligation to accept the amendments. The time for lodging an appeal is unaffected.

Subject to the appeal process set out in the Code, the decision of the MPC is final.

Failure of the offending company to comply with any of the above sanctions shall entitle the MPC to direct the Secretariat to publish in national newspapers or appropriate publications, details of the breach of the Code and the PIASA's Executive Council's consequent requirements for remedial action, at the expense of the company, organisation or

individual involved and to inform the appropriate organisations of the complaint and the finding

10.4 Abuse of the Code

If, in the course of hearing a complaint lodged by an industry member, the MPC considers that the complaint has been submitted as a competitive tool and for vexatious reasons, the MPC may request the complainant to show cause why the MPC should not impose a sanction and an order for costs for vexatious use of the Code.

11. MARKETING PRACTICES APPEAL BOARD RULINGS

11.1 Where a complainant appeals and the MPAB upholds the ruling that there was no breach of the Code, the complainant and the respondent are so advised, and the **complainant must pay within twenty working days** an administrative charge based on the number of matters taken to appeal on which no breach is ruled.

Where a respondent appeals and the MPAB rules that there was no breach of the Code, the **respondent must pay within twenty working days** an administrative charge based on the number of matters taken to appeal on which no breach is ruled.

11.2 Where the MPAB rules that there is a breach of the Code, the respondent is so advised in writing and is given the reasons for the decision. **The respondent then has five [5] working days to provide a written undertaking** providing the information specified in Paragraph 10.1 above.

The company, organisation or individual promoting or marketing the medicine must also pay within twenty working days an administrative charge based on the number of matters ruled in breach of the Code.

11.3 A company, organisation or individual ruled in breach of the Code may also be required by the MPAB to take steps to recover items given in connection with the promotion of a medicine. Details of the action taken must be provided in writing to the MPAB.

11.4 Where a company, organisation or individual is ruled in breach of the Code the MPAB may require an audit of the company's, organisation's or individual's procedures in relation to the Code to be carried out by the MPC.

12 CASE REPORTS

12.1 At the conclusion of any case under the Code, the complainant is advised of the outcome and a report is published summarising the details of the case.

- 12.2** The respondent company, organisation or individual and the medicine concerned are named in the report. In a case where the complaint was initiated by a company or by an organisation or official body, that company or organisation or official body is named in the report. The information given must not, however, be such as to identify any individual person.
- 12.3** A copy of the report on a case is made available to both the complainant and the respondent prior to publication. Any amendments to the report suggested by these parties are considered by the PIASA Secretariat consulting with the other party where appropriate. If either party does not accept the decision as to whether or not a report should be amended, the matter is referred to the Chairman of the MPC/ MPAB for a decision.
- 12.4** Copies of all case reports are submitted to the MPC and MPAB prior to publication. Copies of the reports are then placed on the PIASA website and are accessible to the public.

13. GENERAL PROVISIONS

13.1 Compliance

Compliance with the Code is mandatory for all PIASA member companies as suppliers and marketers of medicines in South Africa. Non-member companies, organisations or individuals may voluntarily agree to endorse the Marketing Code and to encourage their members to adopt it proactively

13.2 Time Periods for Responding to Matters under the Code

The number of working days within which respondents or complainants must respond to enquiries as referred to in the above procedures, are counted from the date of receipt of the notification in question. An extension of time to respond to such notifications may be granted at the discretion of the PIASA Secretariat.

13.3 Withdrawal of Complaints

A complaint may be withdrawn by a complainant with the consent of the respondent up until such time as the respondent's comments on the complaint have been received by the PIASA Secretariat but not thereafter.

13.4 Notices of Appeal – Withdrawal by a complainant

Notice of appeal may be withdrawn by a complainant with the consent of the respondent up until such time as the respondent's comments on the reasons for the appeal have been received by the, PIASA Secretariat but not thereafter.

13.5 Notices of Appeal – Withdrawal by a respondent

Notice of appeal may be withdrawn by a respondent at any time but if notice is given after the papers relating to its appeal have been circulated to the Marketing Practices Appeal Committee, then a higher administrative charge will be payable.

13.6 Administrative charges for processing complaints

Administrative charges for processing complaints are payable only by marketers and suppliers of medicines who are bound by this Code.

The PIASA Secretariat will inform the MPC or MPAB of the administration and other costs incurred in handling the complaint and of the number of administrative charges that apply in a particular case. If a company, organisation, or individual does not agree with the decision of the PIASA Secretariat, the matter is referred to the Chairman of the MPC or MPAB for a decision.

The MPC, or MPAB if the matter proceeds to appeal, will give a ruling regarding the apportionment of the costs between the complainant and respondent.

13.7 Co-promotion

Where two or more companies, organisations, or individuals are ruled in breach of the Code in relation to a matter involving co-promotion, each company, organisation or individual shall be separately liable to pay an administrative charge.

13.8 No charges by members of the public or non-commercial individuals or organisations

Members of the public, individual health professionals and consumer organizations will not be required to pay administrative charges.

14. POSSIBLE BREACHES IDENTIFIED BY SECRETARIAT, MPC OR MPAB

14.1 Where the Secretariat, MPC or MPAB identifies a possible breach of the Code which has not been addressed by the complainant in a case, the respondent company is invited to comment. The company has seven [7] working days to respond in writing.

14.2 If the company accepts there is a breach of the Code, the company is requested to provide an undertaking to fulfil the requirements specified in Paragraph 10.1 above. No administrative charge shall be payable in these circumstances and there shall be no case report on the matter in question.

14.3 If the company does not accept that there is a breach of the Code, the procedures under Paragraph 8 above onwards shall be followed. The Authority shall act as the complainant in this case.

15. ANNUAL REPORT

The Marketing Committee and PIASA Secretariat will collect data on complaints and queries, provide training on the Marketing Code and publish information about complaints on the Code in the PIASA Annual Report.

GUIDANCE NOTES TO THE PIASA CODE OF MARKETING PRACTICE

Guidelines to operation of the Code.

1) Certification of Promotional Material

Procedures must ensure that:

- promotional material is not issued until its final form has been certified to be in accordance with Clause 10 of the Code
- the names of signatories in each company are listed in the Company SOP for approval of promotional material and activities.
- the form of certificate encompasses at least the requirements of Clause 10.3 material still in use is re-certified at intervals of no more than two years
- the certificates, together with the material in the form certified and information as to whom it was addressed, the method of dissemination and the date of first dissemination are preserved for at least three years after final use (Clause 10.5).

Each certificate should bear a reference number with the same reference number appearing on the promotional material in question so that there can be no doubt as to what has been certified. A particular reference number should relate to only one item of promotional material. Different sizes and different layouts of a piece of promotional material should be separately certified and each should have its own unique reference number.

2) Representatives' Briefing and Training Materials

The certification requirements of Clause 10 of the Code that are covered above apply also to briefing material prepared for representatives in accordance with Clause 11.9. Briefing material includes the training material used to instruct medical representatives about a medicine and the instructions given to them as to how the product should be promoted.

Procedures must ensure that no such material is used or issued prior to certification.

3) Representatives' Expenses

There should be a clearly laid down procedure for approval and payment of representatives' expenses and expenditure on meetings and hospitality and the like. A system should be in place for an audit on a systematic or random basis which will check the nature of the expenditure that has been incurred and assess whether that expenditure was in accordance with the requirements of the Code.

4) Representatives' Training

Company procedures must ensure that:

- representatives are adequately trained in relation to every product that they are to promote (Clause 11.1)
- representatives are required to complete a training course in line with the SAQA requirements for medical sales representatives within an agreed period after accepting employment in the pharmaceutical industry whether with their current employer or not. Contract representatives are only used if they have also undergone such training.

Representatives should be provided with written instructions on the application of the Code to their work even if they are also provided with an actual copy of it. Their instructions should cover such matters as the company's policies on meetings and hospitality, and the associated allowable expenditure, and the specific requirements for representatives in Clause 11 of the Code. It should be made clear how reporting to the 'scientific service' of the company is to be carried out in relation to information about the medicines that they promote which comes to their notice, particularly reports of side-effects (Clauses 9 and 11.6).

It should be made clear to representatives if and when and in what circumstances, they can themselves write letters (or prepare other written materials) which mention particular products and are thus almost certain to be considered promotional material.

Such items must be certified, either in advance by way of pro-forma letters or by certifying each individual letter or other item, and must bear prescribing information in accordance with Clause 2.1.

5) Training of other staff

It should be ensured that all relevant 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 or to
- appropriate administrative staff or
- information to be provided to the public,

are fully conversant with the requirements of the Code (Clause 12.1).

Appropriate arrangements should be in place for training on the requirements of the Code. These may be internal arrangements for the appropriate staff members but key personnel should attend one of the seminars or Workshops organised by PIASA.

Adequate arrangements should be in place to ensure that any information as to changes to the Code etc, including reports of decided cases, provided by PIASA on the website or in hard copy, are circulated to relevant personnel.

6) Samples

In terms of Section 18B of the Medicines Act, no sampling for promotional purposes is permitted except that samples may be used for exhibition purposes. *[Reference will be made to the Regulation relating to exhibition samples once this is in place]* Act 101 of 1965 as amended by Acts 90 of 1997 and 59 of 2003 specifies the only conditions for the supply of samples eg.

- for clinical trial purposes,
- for purposes of donations to the State;
- for tender purposes or
- for analysis for quality control purposes [including for registration purposes],

7) Gifts and Inducements

Procedures should ensure that the company complies with Clause 14 relating to gifts and inducements and that promotional gifts or prizes comply with Clauses 14.2 and 14.3. Promotional gifts and prizes must be certified in accordance with Clause 10.

8) Hospitality and Meetings

Procedures should be in place to ensure that all meetings that are planned are checked to see that they comply in all respects with the Code (Clause 13).

These procedures should cover a company's own meetings, those which it sponsors and any sponsorship of attendance at meetings.

9) Breaches of the Code

In the event of a company being found in breach of the Code, procedures should ensure that adequate steps are taken to ensure that relevant information about it is communicated internally to appropriate members of staff. Procedures must be in place to ensure that promotional material found to be in breach of the Code is entirely withdrawn from use. They should include checks that claims etc found to be in breach in one promotional price, do not also appear in other formats, such as exhibition stands, which might otherwise be overlooked.

10) Co-Promotion

Adequate provision should be made in co-promotion agreements and the like to ensure compliance with the Code. Where companies jointly market the same products and the promotional material bears both company names, each company must certify the promotional material involved as the companies concerned will be held jointly responsible for it under the Code (supplementary information to Clause 10.1).

11) Non-Promotional Items

Procedures in place in the company should ensure that any item or activity regarded as non-promotional in nature is vetted by an appropriate member of staff familiar with the Code with a view to determining whether it is indeed non-promotional (supplementary information to Clause 10.1). Account should be taken of the fact that a non-promotional item can be used for a promotional purpose and therefore come within the scope of the Code.

List of PIASA Members:

1. Abbott Laboratories SA (Pty) Ltd
2. Adcock Ingram Healthcare (Pty) Ltd
3. Alcon Laboratories (Pty) Ltd
4. Altana Madaus (Pty) Ltd
5. Aspen Pharmacare Ltd
6. AstraZeneca Pharmaceuticals (Pty) Ltd
7. Bayer (Pty) Ltd Healthcare Division
8. Boehringer Ingelheim (Pty) Ltd
9. Bristol-Myers Squibb (Pty) Ltd
10. Galderma Laboratories (Pty) Ltd
11. GE Healthcare (Pty) Ltd
12. Genop Healthcare (Pty) Ltd
13. GlaxoSmithKline SA (Pty) Ltd
14. Janssen-Cilag
15. Key Oncologics
16. Merck (Pty) Ltd
17. iNova Pharmaceuticals (Pty) Ltd
18. Novo-Nordisk (Pty) Ltd
19. Perry Hill Pharmaceuticals
20. Schering-Plough (Pty) Ltd
21. Sekpharma (Pty) Ltd
22. Servier Laboratories (Pty) Ltd
23. Solvay Pharma (Pty) Ltd
24. Stiefel Laboratories SA (Pty) Ltd
25. Tyco Healthcare (Pty) Ltd
26. UCB Pharma
27. Wyeth South Africa (Pty) Ltd