SINGAPORE ASSOCIATION OF PHARMACEUTICAL INDUSTRIES

SAPI Code of Marketing Practices

2016 Revision

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SAPI Guiding Principles on Ethical Conduct and Promotion

The Singapore Association of Pharmaceutical Industries' member companies engage in medical and biopharmaceutical research in order to benefit patients and support high-quality patient care. Pharmaceutical Companies, represented by SAPI promote, sell and distribute their products in an ethical manner and in accordance with all the rules and regulations for medicines and health care.

The following Guiding Principles set out basic standards that form the 2012 SAPI Code of Practice which applies to the conduct of SAPI Member Companies and their agents, to help ensure that their interactions with stakeholders are appropriate.

1. The health-care and well-being of **patients is the first priority for pharmaceutical companies**.

2. Pharmaceutical companies will conform to high standards of quality, safety and efficacy as determined by regulatory authorities.

3. Pharmaceutical companies' i**nteractions** with stakeholders must at all times be **ethical, appropriate and professional**. **Nothing should be offered or provided** by a company in a manner or on conditions that would have an inappropriate influence.

4. Pharmaceutical companies **are responsible for providing accurate, balanced, and scientifically valid** data on products.

5. **Promotion must be ethical, accurate, balanced** and must not be misleading. Information in promotional materials must support proper assessment of the risks and benefits of the product and its appropriate use.

6. Pharmaceutical Companies will respect the **privacy and personal information of patients**.

7. A**ll clinical trials and scientific research sponsored** or supported by companies will be conducted with the intent to develop knowledge that will **benefit patients and advance science and medicine**. Pharmaceutical companies are committed to the transparency of industry sponsored clinical trials in patients.

8. **Pharmaceutical companies should adhere to SAPI's and other applicable industry codes in both the spirit and the letter**. To achieve this, pharmaceutical companies will ensure that all relevant personnel are appropriately trained.

SAPI Code of Marketing Practices

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Preamble

i. The ethical promotion of prescription medicines is vital to the pharmaceutical industry's mission of helping patients by discovering, developing and promoting new medicines. Ethical promotion helps to ensure that healthcare professionals globally have access to 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.

ii. Whereas the Health Products Act 2007 provides the main framework for the legal control of the importation, manufacture, distribution and advertising of medicinal products, thereby setting the basic statutory requirements necessary for the protection of the public health, there are areas of activities which, although they may not constitute breaches of the law, they may, by virtue of their unethical nature and, if unrestrained, bring about undue harm to the public health and loss of credibility and respectability for the pharmaceutical industry.

iii. The Code of Practice (hereafter refers to as Code) established by the Singapore Association of Pharmaceutical industries (SAPI) with the approval of its members, is to provide guidance for the proper conduct in the marketing and promotion of medicinal products and is to serve as basis for self-discipline within the industry. This would include any activity undertaken by the company or distributors that promote the prescription, supply, sale, or distribution of pharmaceutical products, including vaccines.

iv. The Code includes standards for the ethical promotion of pharmaceutical products to healthcare professionals and helps ensure that member companies' interactions with healthcare professionals and other stakeholders, such as medical institutions and patient organizations, are appropriate and perceived as such.

v. The Code, which is in keeping with the spirit of the revised Code of Practice of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) 2012, is administered by the Marketing Practices Committee appointed by the Board of Directors. Acceptance and active observance of this Code are mandatory for membership with SAPI.

The SAPI Code

1. Scope and Definitions

1.1 Scope

The Code covers interactions with healthcare professionals, medical institutions and patient organizations, and the promotion of pharmaceutical products. Where direct promotion to the public is allowed, this is covered by local laws, regulations and/or relevant codes of practice. Member companies should of course, comply with these local laws, regulations and/or codes.

In all matters of application, interpretation and enforcement of any section of the Code, it is to be understood that compliance with Singapore laws, regulations and regulatory decisions and requirements will take precedence.

1.2 Definitions

For the purposes of the Code:

- "pharmaceutical product" means all pharmaceutical or biological products (irrespective of patent status and/or whether they are branded or not) which are intended to be used on the prescription of, or under the supervision of, a healthcare professional, and which are intended for use in the diagnosis, treatment or prevention of disease in humans, or to affect the structure or any function of the human body.

- "promotion" means any activity undertaken, organized or sponsored by a member company which is directed at healthcare professionals to promote the prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s) through all methods of communications, including the internet. Promotion of OTC products directed to HCPs is within the scope of this Code

- Products for infant nutrition, diagnostic tests, and surgical and medical devices and OTC products directed to consumers are not included in the scope of this Code.

- "health-care professional" means any member of the medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, recommend, purchase, supply, or administer a pharmaceutical product.

- "patient organization" means typically a not-for-profit institution that primarily represent the interests and needs of patients, their families and and/or caregivers.

- "medical institution" means typically an organization that is comprised of healthcare professionals and/or that provides healthcare or conducts healthcare research.

- "member company" means any company that is a member of SAPI

2. Basis of Interactions

2.1 Basis of Interactions

Member companies' relationships with healthcare professionals and other stakeholders are intended to benefit patients and to enhance the practice of medicine. Interactions should be

focused on informing healthcare professionals about medicines, providing scientific and educational information and supporting medical research and education.

2.2 Transparency of Promotion

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. Promotion should not be disguised.

3. Pre-Approval Communications and Off-Label Use

3.1 No pharmaceutical product shall be promoted for use in Singapore until the requisite approval for marketing for such use has been given by the Health Sciences Authority, Singapore

3.2 This provision is not intended to prevent the right of the scientific community and the public to be fully informed concerning scientific and medical progress. It is not intended to restrict a full and proper exchange of scientific information concerning a pharmaceutical product, including appropriate dissemination of investigational findings in scientific or lay communications media and at scientific conferences. Nor should it restrict public disclosure of information to stakeholders and others concerning any pharmaceutical product, as may be required or desirable under law, rule or regulation.

3.3 Only Medical Departments of our member companies will respond to unsolicited queries pertaining to pre-approved label use.

3.4 At international scientific meetings held in Singapore, where a significant number of attendees is from outside of Singapore, advertising of locally unapproved products/ indications may be acceptable.

3.5 When such advertising is undertaken, material should clearly indicate that the product is not locally approved.

4. Standards of Promotional Information

4.1 Consistency of Product Information

It is understood that national laws and regulations usually dictate the format and content of the product information communicated on labelling, packaging, leaflets, data sheets and in all promotional material. Promotion should not be inconsistent with locally approved product information.

4.2 In general, the standards of promotion should subscribe to the good practice of ensuring that:

a) Companies are responsible to ensure compliance with the Code
b) Data are substantiated
c) False or misleading claims are not promoted
d) Unapproved products and indications are not promoted
e) The material and data are presented in good taste
f) Unqualified superlatives are not allowed
g) New products are clearly identified
h) Comparative statements must be used carefully
i) Imitation that may give rise to confusion is not allowed

j) Medical ethics is adhered to

k) Distinction of promotional material is clearly defined

4.3 Data from in vitro and animal tests should be clearly marked as such, and not be cited in such a way that it could give an incorrect or misleading impression

4.4 Substantiation

Promotion should be capable of substantiation either by reference to the approved labeling or by scientific evidence. Such evidence should be made available on request to healthcare professionals. Companies should deal objectively with requests for information made in good faith and should provide data which are appropriate to the source of the inquiry.

4.5 Opinions

The medical and scientific opinions of opinion leaders and health professionals, and products, activities or representatives of other pharmaceutical companies must not be disparaged.

5. Printed Promotional Material

Where local regulations are in force, which define requirements, these take precedence.

5.1 Printed promotional material shall be presented in a legible manner. The scientific basis and presentation of the product information must be in conformity with the general principles set out in Section 4 of the Code and where applicable, with the authorised product information.

5.1.1. Promotional material such as mailings and journal advertisements and loose inserts must not be designed to disguise its real nature.

5.1.2. Advertisements in journals should not be designed so as to resemble editorial material.

5.1.3. Promotional material should conform, both in text and illustration, to canons of good taste and should recognise the professional standing of the recipient.

5.1.4. Representation of the nude adult human form or partly clothed figures, should not be used in promotional material in such a way as to arouse a visual or emotional response in order to attract attention to the text. Displays of part of the naked body which are necessary to illustrate pictorially the message of the text are permissible, provided that they conform to the dictates of decency and good taste.

5.1.5. Material and articles from the lay press should not be used as promotional material.

5.1.6. Illustrations must not mislead as to the nature of the claims or comparisons being made, nor as to the purpose for which the product is used.

5.1.7. Artwork and graphics must conform to the letter and the spirit of the Code. Graphs and tables should be presented in such a way so as to give a clear, fair, balanced view of the matters with which they deal, and should only be included if they are relevant to the claims or comparisons being made.

5.1.8. Graphs and tables must not be used in any way which might mislead, for example by the incompleteness or by the use of suppressed zeros or unusual scales.

5.2. Reprints, abstracts and quotations in print or other media.

5.2.1. Such material from medical literature or from personal communications received from doctors, must accurately reflect the meaning of the author and the significance of the study (which should not be distorted by the addition of highlighting or underlining to give prominence to selected portions of the material)

5.2.2. Care must be taken to avoid ascribing claims or views relating to the medical products to authors when such claims or views no longer represent or may not represent the current view of the authors concerned.

5.3. All Advertisements

5.3.1 All advertisements appearing in print must include:

- the name of the product (normally the brand name);
- the active ingredients, using an approved name where one exists (INN);
- the name and address of the company or its agent responsible for marketing the product.

5.3.2. The mailing address of the contact from which further information may be obtained must appear, either in the advertisement itself or be readily accessible from the publication in which the advertisement appears.

5.4. Full Advertisements

Full advertisements are those which include promotional claims for the use of the products. In addition to the requirements of paragraph 5.3., full advertisements must also include prescribing information in the form of:

- Health Sciences Authority approved indication or indications for use together with the dosage and method of use;
- a succinct statement of the contraindications, precautions and side effects.
- any locally obligated warnings relating to the product
- a statement that full prescribing information is available on request;
- the name and address of the local operating unit or the address from which full information can be obtained;
- in cases where journal advertisements and prescribing information are separated, it must be clear where in the journal the prescribing information can be found
- journal advertisements must be of sufficient size to ensure that all wording is legible
- the word "new" should not be used to describe products that have been available in a specific market for more than 12 months.

5.5 Reminder Advertisements

A “reminder” advertisement is defined as a short advertisement containing no more than the name of the product and a simple statement of indications to designate the therapeutic category of the product. For “reminder” advertisements, “abbreviated prescribing information” referred to in 5.4 above may be omitted.

6. Electronic Materials, including Audio Visuals

The same requirements shall apply to electronic promotional materials as apply to printed materials. Specifically, in the case of pharmaceutical product related websites:

- the identity of the pharmaceutical company and of the intended audience should be readily apparent;

- the content should be appropriate for the intended audience;

- the presentation (content, links, etc.) should be appropriate and apparent to the intended audience; and

- country-specific information should comply with local laws and regulations.

7. Interactions with Healthcare Professionals

7.1 Events and Meetings

7.1.1 Scientific and Educational Objectives

The purpose and focus of all symposia, congresses and other promotional, scientific or professional meetings (an "Event") for healthcare professionals organized or sponsored by a company should be to provide scientific or educational information and/or inform healthcare professionals about products.

7.1.2 Events Involving Foreign Travel

No company may organize or sponsor an Event for healthcare professionals (including sponsoring individuals to attend such an Event as described in Article 7.2) that takes place outside of their home country unless it is appropriate and justified to do so from the logistical or security point of view. International scientific congresses and symposia that derive participants from many countries are therefore justified and permitted.

7.1.3 Promotional Information At Events

Promotional information which appears on exhibition stands or is distributed to participants at international scientific congresses and symposia may refer to pharmaceutical products which are not registered in the country where the Event takes place, or which are registered under different conditions, provided that the following conditions are observed:

- Host country regulations should permit such an arrangement;
- The meeting should be a truly international, scientific Event with a significant proportion of the speakers and attendees from countries other than the country where the Event takes place;

- Promotional material (excluding promotional aids as described in Article 7.5.2) for a pharmaceutical product not registered in the country of the Event should be accompanied by a suitable statement indicating the countries in which the product is registered and make clear that such product is not available locally;

- Promotional material which refers to the prescribing information (indications, warnings, etc.) authorized in a country or countries other than that in which the Event takes place but where the product is also registered, should be accompanied by an explanatory statement indicating that registration conditions differ internationally; and

- An explanatory statement should identify the countries in which the product is registered and make it clear that it is not available locally.

7.1.4 Appropriate Venue

Pharmaceutical companies may initiate, hold, organize or sponsor a wide range of meetings. All events must be held in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the event or meeting.

With any meeting, certain basic principles shall apply:-

7.1.4.1 The primary objective of the meeting must serve to enhance medical knowledge and improve the quality use of medicine in Singapore.

7.1.4.2. The meeting must have a clear educational and/or scientific content. Objective evidence of the educational value of the event is required (e.g. agenda or scientific program) that clearly states the educational purposes, content, meeting start and finish times and duration of the educational sessions. Companies should undertake to review the educational value and venue, prior to agreeing to organize or sponsor an event

7.1.4.3. Any venue must be appropriate and conducive to the scientific or educational purpose of the meeting. Lavish or extravagant venues must not be used; and companies must avoid venues that are renowned for their leisure and entertainment facilities. The choice of venue must also be able to withstand public and professional scrutiny and comply with professional and community standards of ethics and compliance

7.1.4.4 In determining whether such a meeting is acceptable or not, consideration must also be given to the overall cost, facilities offered by the venue, nature of the audience, associated activities e.g. hospitality, subsistence provided and the like. As with any meeting, it should be the program that attracts delegates and not the associated hospitality or venue.

7.1.5 Limits

Refreshments and/or meals incidental to the main purpose of the Event can only be provided:

- exclusively to participants of the Event; and
- if they are moderate and reasonable as judged by local standards.

Providing hospitality in relation to food and drinks as per social/cultural norms in a local setting to members of the medical and allied professions should be limited to <S$120 per person per meal. This is applicable to Singapore only and excludes GST and Service Charge. However, this should be accompanied with dissemination of scientific or educational information.

7.1.6 No stand-alone entertainment or other leisure or social activities may be provided or paid for by member companies. However, entertainment of modest nature which is secondary to refreshments and/or meals is allowed during meetings.

7.2 Sponsorship

Member companies may sponsor healthcare professionals to attend Events provided such sponsorship is in accordance with the following requirements:

- The Event complies with the requirements in this Code as described in 7.1;

- The event is primarily dedicated, in both time and effort, to objective scientific and educational activities

- When a Congress/Symposium is organised, a minimum of 75 per cent of time should be spent on core activities of the Congress/Symposium and a maximum of 25 per cent of time devoted to hospitality, entertainment activities in relation to food and drinks limited to entertainment of modest nature which is secondary to refreshments and/or meals
- Sponsorship to healthcare professionals is limited to the payment of travel, meals, accommodation and registration fees.

- No payments are made to compensate healthcare professionals for time spent in attending the Event

- Any sponsorship provided to individual healthcare professionals must not be conditional upon an obligation to prescribe, recommend, purchase, supply, administer or promote any pharmaceutical product.

- All SAPI Members/Associates and their affiliates and members should only provide Economy Class tickets for air travel of less than 6 hours. This should apply to all faculty members e.g. speakers, members of Advisory Boards as well as attendees.

- When a Congress/Symposium sponsored by a pharmaceutical company based in Singapore is to be held in an overseas location, majority of the attendees should be from the country in which the Congress/Symposium is held.

- Any activities that have an element of chance should not be part of Symposia/Exhibitions.

7.3 Guests

Companies should not pay any costs associated with individuals accompanying invited healthcare professionals.

7.4 Fees for Services

Health care professionals may be engaged as consultants and advisors for services such as speaking at and/or chairing meetings and events, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration. The arrangements which cover these genuine consultancies or other services must, to the extent relevant to the particular arrangement, fulfill all the following criteria:

- a written contract or agreement must be agreed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis for payment of those services;

- a legitimate need for the services must be clearly identified and documented in advance;

- the criteria for selecting consultants must be directly related to the identified need and the consultants must have the expertise necessary to provide the service;
- the number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need;

- the hiring of the consultant to provide the relevant service must not be an inducement to prescribe, recommend, purchase, supply, and/or administer any medicine; and

- the compensation for the services must be reasonable and reflect the fair market value of the services provided.

7.5 Gifts and Other Items

7.5.1 Prohibition of Cash & Personal Gifts

Payments in cash or cash equivalents (such as gift certificate) must not be provided or offered to healthcare professionals. Gifts for the personal benefit of healthcare professionals (such as sporting or entertainment tickets, electronics items, etc.) must not be provided or offered.

7.5.2 Gifts

i) Promotional items valued at no more than $20 may be provided to HCPs as long as the items are related to the HCP's work and/or entail a benefit to patient care. Items provided to HCPs as a token of appreciation for services rendered by HCPs should be limited to $50 or less.

ii) Inexpensive food items and drinks as per social/cultural norm may be provided to HCPs during the course of day to day promotional activities only and should be limited to less than $20 per HCP.

iii) Congratulatory flowers limited to job promotions, Conferment of Awards or Clinic Opening should be limited to $150 per occasion; congratulatory messages in any form of media on behalf of a HCP or a Centre are strictly prohibited.

iv) Exceptional gifts during various festive seasons should be symbolic and modest, with a value of up to $50, such as cakes, cookies and mandarin oranges. Each HCP should only be offered a maximum of two such gifts per year.

7.5.3 Educational Material & Items of Medical Utility

Text or reference books/information, subscription to on-line journals and other educational materials may be given to health care providers if they serve a genuine educational function as follows:

i) Private Specialists/General Practitioners/Public Hospital Doctors – less than $1000 per HCP per year.

ii) Public/Restructured Hospital Clinical Departments e.g. NUH Cardiology, SGH Endocrinology, etc. and Private Medical centres/Hospitals – less than $1,000 per Clinical Department/Private Medical Centre/Hospital per year. However, this is limited to "Healthcare" or "Biomedical" Journals only

iii) Items of medical utility may be loaned or provided free of charge provided such items are of modest value and are beneficial to the provision of medical services and for patient care; value of such items should be limited to less than $200.

7.5.4 Donations & Grants

Companies may provide donations to requests, strictly for charitable purposes and charitable organisations. In addition, companies can provide grants towards financial support strictly for educational programmes, (including but not limited to requests to fund accredited CME programmes, non-accredited educational programmes, fellowships, advocacy organisations, societies, medical conferences, congresses or independent meetings) if they are:

- ***unsolicited***
- ***from an institution or organization, not an individual healthcare practitioner***
- ***unrelated to the prescribing, purchasing, registration of any products***
- ***substantiated by written documentation of details of programme***
- ***able to withstand public scrutiny***

8. Samples

8.1 Giving away of 'samples' as an inducement to purchase is prohibited. Reasonable quantities of samples (including patient starter packs), clearly identified as such, may be supplied to the prescribing professions to familiarise them with the products, to enable them to gain experience with the product in their practice, or upon request. Samples should not be sold.

8.2 Samples must not be used for clinical studies

8.3 Where samples of products restricted by law to supply on prescription are distributed by a representative, the sample must be handed directly to the doctor or given to a person authorised to receive the sample on his behalf.

8.4 Companies should have adequate systems of control and accountability for samples provided to healthcare professionals including how to look after such samples whilst they are in possession of medical representatives.

9. Clinical Research and Transparency

9.1 Transparency

Companies are committed to the transparency of clinical trials which they sponsor. It is recognized that there are important public health benefits associated with making clinical trial information more publicly available to healthcare practitioners, patients, and others. Such disclosure, however, must maintain protections for individual privacy, intellectual property and contract rights, as well as conform to legislation and current national practices in patent law.

9.2 Distinct from Promotion

All human subject research must have a legitimate scientific purpose. Human subject research, including clinical trials and observational studies, must not be disguised promotion.

10. Support for Continuing Medical Education

Continuing medical education (CME) helps ensure that healthcare professionals obtain the latest and most accurate information and insights on therapeutic areas and related interventions that are critical to the improvement of patient care and overall enhancement of the healthcare system. The primary purpose of an educational meeting must be the enhancement of medical knowledge and therefore financial support from companies is appropriate.

When companies provide content to CME activities and programs, such material must be fair, balanced and objective, and designed to allow the expression of diverse theories and recognized opinions. Content must consist of medical, scientific or other information that can contribute to enhancing patient care.

Companies must follow Article 7 of the Code where applicable.

11. Interactions with Patient Organizations

11.1 Scope

The pharmaceutical industry has many common interests with patient organizations. All interactions with patient organizations must be ethical. The independence of patient organizations must be respected.

11.2 Declaration of Involvement

When working with patient organizations, companies must ensure that the involvement of the company and the nature of that involvement are clear from the outset. No company may require that it be the sole funder of the patient organization or any of its programs.

11.3 Written Documentation

Companies that provide financial support or in-kind contribution to patient organizations must have in place written documentation setting out the nature of support, including the purpose of any activity and its funding.

11.4 Events

Companies may provide financial support for patient organization meetings provided that the primary purpose of the meeting is professional, educational, and scientific in nature, or otherwise supports the mission of the patient organization. When companies hold meetings for patient organizations, companies must ensure that the venue and location is appropriate and conducive to informational communication. In addition, any meals or refreshments provided by a company must be modest as judged by local standards.

12 Communications to the Public

12.1 Where it is permitted by law to communicate directly with patients regarding their prescription medicines, all such information should be accurate, fair and not misleading.

12.2 Communications to the public may include the provision of patient package inserts and other leaflets and booklets, etc., made available to inform patients about products prescribed by health professionals.

12.3 Where companies assist in the conduct of public/patient disease awareness programs providing information on, signs and symptoms of medical conditions, illnesses, and available treatments, such activities should comply with the Disease Awareness Guidelines of the Health Promotion Board.

12.4 Request from individual members of the public for information or advice on personal medical matters, including about the product which has been prescribed, should be redirected his or her own doctor.

13. MEDICAL RERESENTATIVES

13.1. Training and Responsibilities

13.1.1. Medical representatives must be adequately trained and possess sufficient medical and technical knowledge to present information on their company's products in an accurate, responsible and ethical manner. They must also feed back to their company, from contacts in the medical and allied professions, information which they receive on the use of products and particularly reports of side effects.

13.1.2. The training given to medical representative should be an on-going process and should include familiarity with SAPI and IFPMA Codes of practices. The Certified Medical Representative (CMR) awarded by SAPI is one of the qualifications for Medical Representatives in Singapore.

13.1.3. It is the onus of the company to familiarise all employees of the sales, marketing, regulatory, medical or such areas related to the principles of the code of conduct and practices of SAPI and of local legislation.

13.1.4. Medical representatives should ensure that the frequency, timing and duration of calls, together with the manner in which they are made, are such as not to cause inconvenience to the health care professional. The wishes of an individual health care professional, or the arrangements in force at any particular establishment, must be observed by medical representatives.

13.2. Company Responsibility

A company will assume the responsibility, under the SAPI Code, for correcting breaches of the Code resulting from misconduct or misrepresentation of facts by any representative.

13.3. Remuneration

The system of remuneration of representatives should not be such as to adversely influence the proper prescribing of pharmaceutical products by the physician. The provision relating to remuneration is intended to ensure that no incentives are provided that would lead to unethical behaviour of representatives, and not whether a fixed salary or bonus system is used for compensation.

14. Company Procedures and Responsibilities

14.1 Procedures

Companies should establish and maintain appropriate procedures to ensure compliance with relevant codes and applicable laws and to review and monitor all of their activities and materials in that regard.

14.2 Training

Companies should also ensure that relevant employees receive training appropriate to their role.

14.3 Responsibilities for Approving Promotional Communications

i) A designated company employee with sufficient knowledge and appropriate qualifications should be responsible for approving all promotional communications. In the alternative, a senior company employee(s) could be made responsible provided that he or she receives scientific advice on such communications from adequately qualified scientific personnel.

ii) Date of first use of all promotional materials circulated to the market shall not be more than TWO years from the date of approval. Any materials used beyond this point must be re-approved. Henceforth, all published promotional materials shall be dated and updated regularly. Thus, date of print must be defined on document.

iii) A register, the approval folder and a sample of each approved item must be maintained locally for a minimum of 2 years.

15. ADMINISTRATION OF THE CODE.

15.1 Submission of Complaint.

Members that are involved in any dispute should treat that any complaint to the Marketing Practices Committee is a last resort action to resolve the issue after they have exhausted all reasonable avenues, including contacts between the CEOs of both companies, to resolve it amicably. All complaints on breach of SAPI Marketing Code of Practice, must be made in writing and submitted by the CEO of the complainant company (in order that the CEO of that company is aware that a complaint has been submitted) together with a processing fee of $1,500.00 to SAPI. It will first be validated to ensure that:

- It appears to be a genuine matter, submitted in good faith. A documentation to show that there has been a communication between the CEOs of the involved parties, to show that all parties have tried to resolve the issue amicably.
- There is sufficient evidence to enable the complaint to be processed.
- It is not a duplication of a case, which has already been resolved under the Code.

The minimum information required is:

Source of the complaint

- The complaint letter must come with company letterhead.

Company

- For each case in the complaint, the identity of company which is alleged to be in breach of the Code, and the name of any product(s)/ marketing activities which are specifically involved.

Reference material

- For each case, a specific reference to the source of the advertisement/activity which is the subject of the complaint of printed material or other evidence.

Date

- The date of the alleged breach of the Code.

Summary

- For each case, brief description of the complaint with a specific reference to the part of the Code under which the complaint is being made (section & paragraph numbers)

15.1.1 All complaints of breaches of the Code against member companies must be sent directly to SAPI instead of through third parties, e.g. Health Sciences Authority, Ministry of Health.

If a complaint against a member company is referred or re-directed to SAPI by any third party, the complaining member company must pay the applicable processing fee to SAPI to review the complaint.

15.1.2 Externally generated complaints from doctors, pharmacists or members of the public against any member company will be dealt with in the same manner as if they came from a member company, except that no processing fee will be levied on the complainant.

15.2. Marketing Practices Committee Members.

15.2.1. The Marketing Practices Review Committee (MPC) for the review of any complaint shall consist of at least 50% of the MPC voting members, subject to a minimum of 5 members and 1 secretariat staff. The MPC members are unique for each case, to prevent any lack of quorum if there is a conflict of interest.

15.2.2. If there is a lack of quorum due to the members being the affected parties in the complaint, the MPC can call upon any member that the MPC deems suitable, to serve under the MPC for a particular case.

15.2.3. The secretariat staff is the Executive Director of SAPI and will not have the voting rights.

15.3. Review Procedures

Any complaint against a breach of SAPI Code of Marketing Practice should be addressed to the Marketing Practices Committee c/o SAPI.

See Appendix A for the summary of the procedures.

15.3.1 A single complaint may cover more than one 'case', i.e. the complaint may refer to several advertisements from different companies and/or for different products. Each 'case' is handled separately by the Marketing Practices Committee (MPC) under the main complaint reference. Complainant's processing fee of $1,500 (Singapore Dollars One Thousand Five Hundred Only) is deposited payable to SAPI upon submission of complaint.

15.3.2. The MPC shall table the complaint at a meeting within 6 weeks of receipt of the complaint from the Secretariat to decide if there is a case for the subject company to address. Whenever necessary, the member against whom the complaint is lodged shall be requested by the MPC to give rebuttal to the allegations.

15.3.3. If, after due consideration, the MPC concludes that there has been a breach of the Code, the offender shall be asked to give an undertaking in writing to stop the activity which is in breach of the Code with immediate effect and not to commit a similar offence in future. The respective company should respond to the decision of the MPC within 14 working days starting from the receipt of MPC decision. The processing fee of $1,500 will be refunded to the complainant within 14 working days and the offending company will pay to SAPI the $1,500 processing fee instead. If the MPC concludes there has not been a breach of the Code, then the complainant's processing fee will be forfeited.

The MPC may impose an administration fee of up to $10,000 over and above the processing fee of $1,500 on member companies found guilty of infringements of the Code. The additional administration fee levied will be pegged to the severity of the infringement and the time and resources required to deliberate on the case

15.3.4. The offending company can appeal the MPC decision within 14 working days and submit the appeal in writing together with a processing fee of $5,000. The MPC will convene an Appeal Committee (AC) within 6 weeks of the receipt of the letter. Please refer to section 10.4 for the make-up of the Appeal Committee. The AC decision will take effect after the approval and endorsement by Board of Directors. The affected parties will comply immediately. If the AC upholds the MPC decision, then the processing fee of $1,500 will be refunded to complainant within 14 working days and the appellant's processing fee of $5,000 will be forfeited. If the AC overturns the MPC decision, then the appellant's processing fee of $5,000 will be refunded within 14 working days and the complainant's processing fee will be forfeited.

15.3.5. The complainant can appeal the MPC decision within 14 working days of the receipt of the decision and submit the appeal in writing together with the additional fee of $3,500 for a total processing fee of $5,000. The MPC will convene an Appeal Committee (AC) within 6 weeks of the receipt of the letter.

Please refer to section 15.4 for the make-up of the Appeal Committee.

The AC decision will take effect after the approval and endorsement by Board of Directors. The affected parties will comply immediately. If the AC upholds the MPC decision, then the appellant's processing fee of $5,000 will be forfeited. If the AC overturns the MPC decision, then the appellant's processing fee of $5,000 will be refunded within 14 working days and the offending company will pay to SAPI the $1,500 processing fee instead.

15.3.6. In the event of the member being unwilling to comply with the decision of MPC and/or AC, and/or that the breach of the Code is perpetuated, the Marketing Practices Committee shall report its finding to the Board of Directors who may then decide whether to refer the matter to the member's parent company or Head Office or publish the matter in the MPC's Quarterly Report.

15.4. Appeal Committee

15.4.1. The appeal committee shall consist of a Chairman, 4 committee members and 2 members of the expert group and a secretariat staff. Please see Appendix B for the summary.

15.4.2. The Chairman nominated by the Board of Directors (BOD) of SAPI must be a member of the Board of Directors of SAPI.

15.4.3. The 4 committee members must be made up of the Chairman of MPC, one member nominated by the offending company, one member nominated by the appealing company and one member nominated by the BOD of SAPI. If the Chairman of the MPC is a party in the complaint, then the Chairman of the Appeal Committee will appoint one of the MPC members to replace the Chairman of the MPC. The nominees must be either medical doctors or pharmacists who are working with any member of SAPI, excluding the affected members involved in the dispute (see Appendix B).

15.4.4. The 2 members of the expert group shall consist of any member from either the Singapore Medical Association or Pharmaceutical Society of Singapore.

15.4.5. The secretariat staff is the Executive Director of SAPI.

15.4.6. All appeal committee members will have voting rights except the secretariat staff.

15.5. Sanctions.

15.5.1. In addition to the sections 15.3.3 – 15.3.6, the BOD may apply the following sanctions;

15.5.1.1. In the case of international companies, the matter will be referred to the Head Office of the Company, informing it of the case and the Board of Director's decision and appealing to the Head Office to persuade their subsidiary to comply, by withdrawing the offending material, or discontinuing the practice not later than 4 weeks from the date of the communication.

15.5.1.2. In the interim, the BOD can invoke SAPI constitution paragraph 16 (b) to suspend subject company up to the date of an Extraordinary General Meeting being convened under SAPI Constitution paragraph 9 (e).

15.5.1.3. If no indication of the withdrawal of the material or discontinuance of the practice is received by the set deadline, then the Board of Directors will inform the IFPMA of the matter and take action under Constitution's paragraph 9 (d) and 16 (b) for the termination of the subject company from the Association.

15.5.1.4. In the case of other companies, the BOD can invoke SAPI Constitution paragraph 16 (b) to suspend the company for a period up to the date of an Extraordinary General Meeting being convened under SAPI Constitution in paragraph 9 (e) and take action under Constitution's paragraph 9 (d) and 16 (b) for the termination of the subject company from the Association.

15.5.2. The decision of the Board of Directors in the matter shall be final and information on above sanctions may be made known to the Health Sciences Authority, as well as Script, Market Letter and any other relevant publication, and included in the regular reports of the Marketing Practices Committee and the Annual Report of the Board of Directors to members.

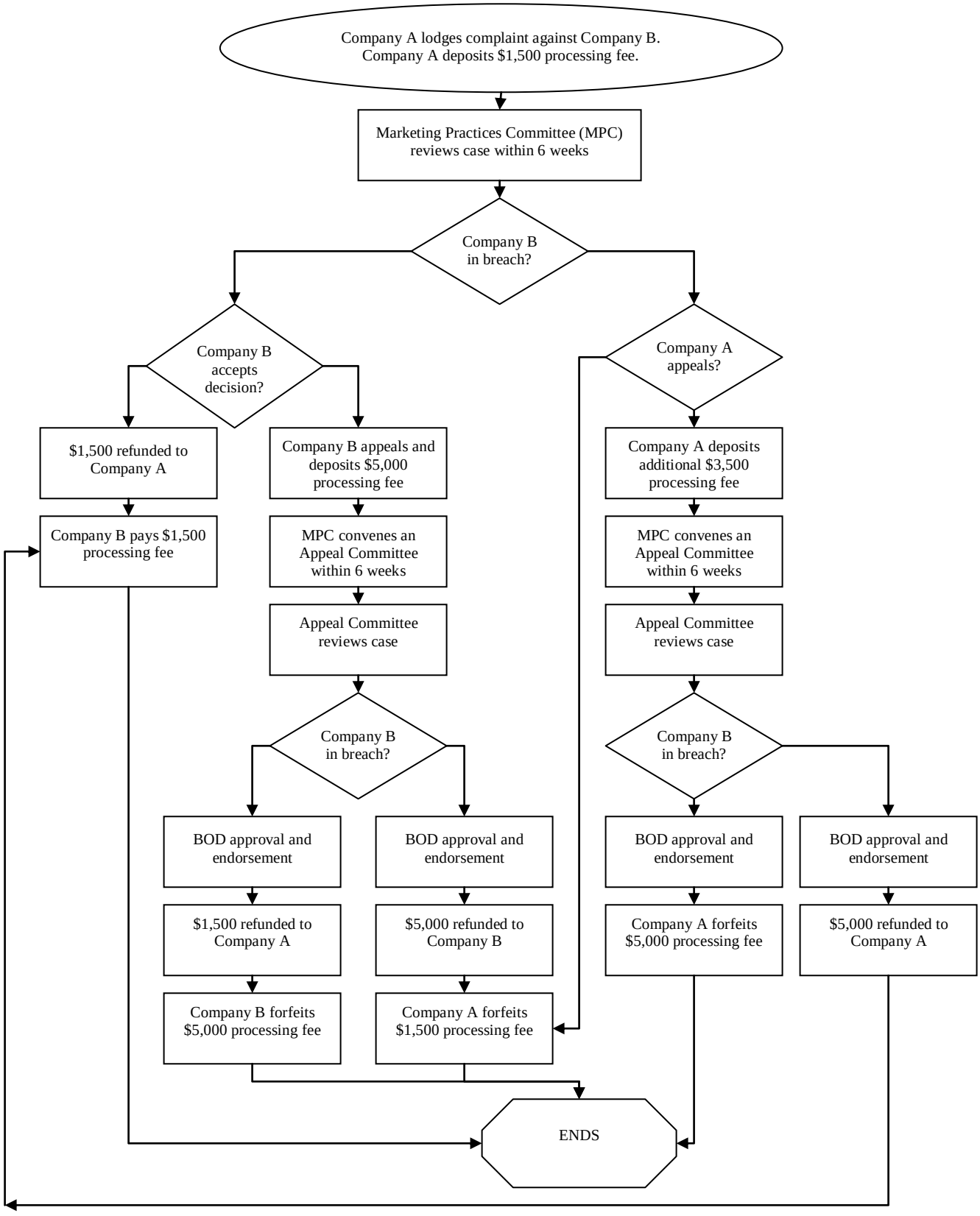
15.5.3. Any details of complaints on alleged breaches of the Code, the decisions of the Marketing Practices Committee and the Appeal Committee and subsequent actions taken by all parties in the matter may not be used by the complainant or the subject company for any publicity or promotional purposes.

15.5.4. The Marketing Practices Committee, the Appeal Committee, the Board of Directors, SAPI and its staff, including individuals serving in any capacity in these committees, shall not be subject to any legal action by any party on decisions taken relating to the complaint.

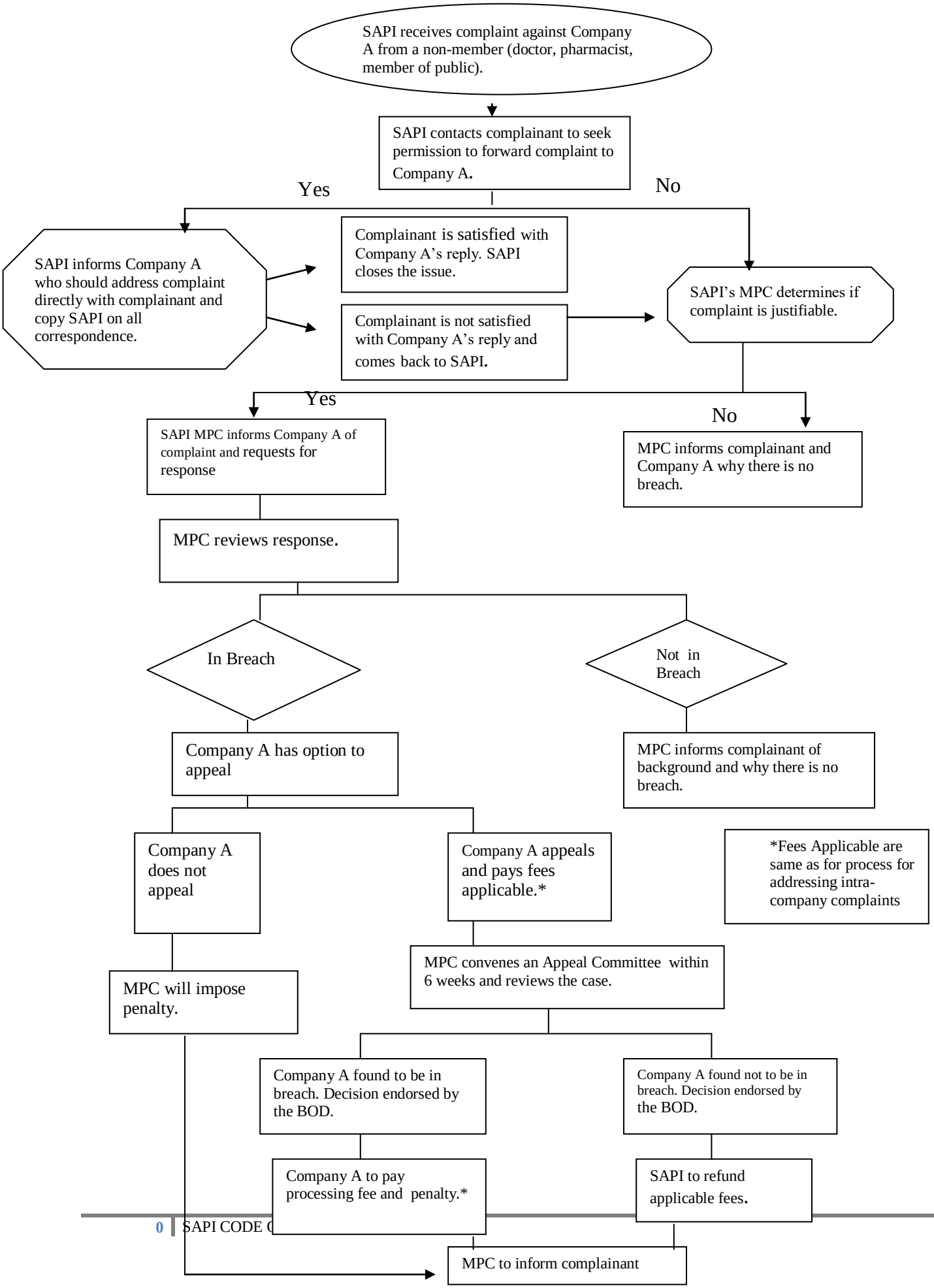
DATE OF APPROVAL: 12 January 2016

DATE OF IMPLEMENTATION: 13 January 2016

Appendix A: Summary of Marketing Practices Review Procedures.



APPENDIX A.1


SAPI receives complaint against Company A from a non-member (doctor, pharmacist, member of public).
SAPI contacts complainant to seek permission to forward complaint to Company A.
Yes
No
SAPI informs Company A who should address complaint directly with complainant and copy SAPI on all correspondence.
Complainant is satisfied with Company A's reply. SAPI closes the issue.
Complainant is not satisfied with Company A's reply and comes back to SAPI.
SAPI's MPC determines if complaint is justifiable.
Yes
No
SAPI MPC informs Company A of complaint and requests for response
MPC informs complainant and Company A why there is no breach.
MPC reviews response.
In Breach
Not in Breach
Company A has option to appeal
MPC informs complainant of background and why there is no breach.
Company A does not appeal
Company A appeals and pays fees applicable.*
*Fees Applicable are same as for process for addressing intra-company complaints
MPC will impose penalty.
MPC convenes an Appeal Committee within 6 weeks and reviews the case.
Company A found to be in breach. Decision endorsed by the BOD.
Company A found not to be in breach. Decision endorsed by the BOD.
Company A to pay processing fee and penalty.*
SAPI to refund applicable fees.
MPC to inform complainant

Appendix B: Marketing Practices Committee and Appeal Committee

APPEAL COMMITTEE		
Position	**Membership**	**Number**
Chairman	Director of BOD	1
Committee members	Chairman of Marketing Practices Committee or Appointed MPC member	1
Committee members	Medical doctors or pharmacists from member companies nominated by the parties involved in the disputes	2
Committee members	Medical doctor or pharmacist from member companies nominated by the BOD	1
Expert group	Members of SMA and/or PSS	2
Secretariat staff	Executive Director of SAPI	1