CODE OF PRACTICE FOR THE KENYA PHARMACEUTICAL AND MEDICAL DEVICES INDUSTRY

Version 2

KENYA ASSOCIATION OF PHARMACEUTICAL INDUSTRY

Code of Practice for the Kenya Pharmaceutical and Medical Devices Industry

Kenya Association of Pharmaceutical Industry

2nd Edition, March 2019

This Code of Practice enumerates the principles and standards that the members of KAPI, have committed to follow in order to raise and uphold the bar of ethical standards in their practices. This version supersedes all other previous versions.

Contents

Acknowledgement

In the development of this code, KAPI has consulted widely, incorporated principles and advice from various codes around the world in the Pharmaceutical industry worldwide and its own members for the tireless efforts in piecing this code together.
This code is a collection of principles derived from:

- The IFPMA Code of Practice
- IFPMA Note for Guidance on Sponsorship of Events and Meetings, Nov 2014
- The EFPIA Code on the Promotion of Prescription-only Medicines to, and Interactions with, Healthcare Professionals, 6th June 2014
- EFPIA Code of Practice on Relations Between the Pharmaceutical Industry and Patient Organizations
- Guidelines for Advertisement and Promotion of Medicines and Medical Devices in Kenya, April 2012 (Kenya Pharmacy and Poisons Board)
- The Code of Promotional Practices for Pharmaceutical Representatives in Kenya
- Code of Marketing Practice (Marketing Code Authority, South Africa), 13th Sept 2013
- AIFD Code of Promotional Practice, 1st July 2008 (Association of Research Based Pharmaceutical Companies, Turkey)
- IPHA Code of Practice for the Pharmaceutical Industry, Edition 8.1 (Irish Pharmaceutical Healthcare Association)

KAPI wishes to specially acknowledge the following for their advice and support in the development of this code:

- International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)
- European Federation of Pharmaceutical Industries and Associations (EFPIA)
- The Pharmaceutical and Healthcare Association of the Philippines (PHAP)
- Association of Research Based Pharmaceutical Companies (AFID- Turkey)
- Asociación Mexicana de Industrias de Investigación Farmacéutica, A.C. –

KAPI would like to thank the Executive committee and the Compliance sub-committee of KAPI for their dedication to developing this code.

Foreword

International media focus on promotion practices has resulted in increased scrutiny of the practice world over on the operations of the Pharmaceutical and Medical Devices industry. Enactment of anti-corruption and anti-bribery laws that have a wider jurisdiction of enforcement , in the United states ,United Kingdom amongst other countries have highlighted the need to transparency in operation across many countries. Kenya has also enacted anti-corruption laws that have created the need for more transparency and accountability in interactions with healthcare professionals and the public.

The formation of the East African community and the subsequent harmonization in Regulatory requirements have also highlighted the need for the Industry to develop this code that we believe will go a long way building trust with our key stakeholders, Healthcare professionals and Patients, which are key providing access to our products and the promotion of engagements that will build capacity and increase access to more of markets within the region.

In recent times, corruption and bribery has been become a major area of focus for the government and the public in almost all sectors of the economy. With the market becoming more liberalized and even more competitive due to an increase in players, the focus on corruption and bribery activities increases.

These factors have escalated the need to develop a code of practice, which we believe will provide for KAPI to distinguish itself from other players within the industry and offer competitive advantage to KAPI members. This code is being launched initially as a self-regulation code. For KAPI members but we will be working towards the adoption of the code as a Country code, for implementation across all players within the Pharmaceutical sector and eventually within the East African Region.

Preamble

KAPI and its members are committed to educational and promotional efforts that benefit patients and promotional programs and collaborations that enhance the practice of medicine. KAPI also seeks to preserve the independence of the decisions taken by healthcare professionals in prescribing medicines and using medical technologies for the benefit of patients. Ethical promotion is vital to the industry's mission of helping patients by researching, developing and marketing new products. Ethical promotion helps to ensure that healthcare professionals have access to information they need, that patients have access to the products they need, and that products are prescribed and used in a manner that provides the maximum healthcare benefit to patients.

Industry relationships with Healthcare Professionals (HCP's) must support, and be consistent with, the professional responsibilities healthcare professionals have towards their patients. Companies must maintain high ethical standards when conducting promotional activities and comply with applicable legal, regulatory and professional requirements. Through the promotion of this Code, KAPI seeks to ensure that ethical promotional practices are established in Kenya. KAPI *member companies and anyone acting on their behalf must comply directly with this code*.

Ethos

KAPI member companies engage in medical and biopharmaceutical research in order to benefit patients and support the provision of high-quality patient care. All pharmaceutical companies represented by KAPI promote, sell and distribute their products in an ethical manner and in accordance with all the rules and regulations governing the supply of medicines and healthcare services.

Our Ethos set out the basic standards that inform the Code of Practice for the Kenya Pharmaceutical and Medical Devices Industry. Our core values and principles of fairness, care, respect and honesty form the foundation of the code and must guide all our interactions with our healthcare partners.

Trust

Act with integrity and honesty to improve patient care and build trust with those we serve and to respect the independence of healthcare providers, patients and other stakeholders.

Care

Protect the safety of those who use our products – from the conduct of clinical trials and throughout the product lifecycle.

Innovation

Improve global health through innovative products and services, upholding the highest ethical, scientific, and medical standards.

Quality

Commit to providing high-quality products that have proven clinical efficacy and have a reliable safety profile.

Fairness

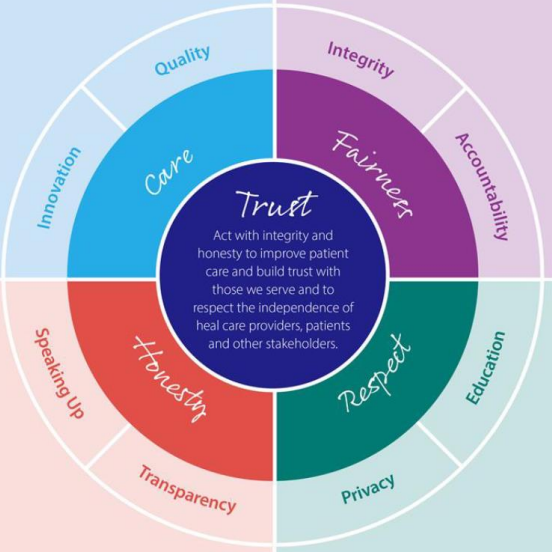
Support and respect fair trade practices and open competition.

Integrity

Act responsibly, ethnically and professionally. Do not offer, promise, provide, or accept anything of value in order to inappropriately influence a decision, gain an unfair advantage.

Accountability

Be accountable for our actions and decisions, including the appropriate oversight or external third parties that act on our behalf.



Honesty

Ensure truthful and balanced communication with governmental authorities, healthcare professionals, patients and other stakeholders.

Speaking Up

Foster a culture in our respective organisations where concerns are shared openly and honestly so that we learn from mistakes and continuously improve.

Transparency

Advance science and patient care by sharing industry-sponsored clinical trial data in a responsible, accurate and appropriate manner.

Respect

Respect all people and embrace a culture of diversity and inclusion. Protect the environment. Treat animals under our care responsibly.

Privacy

Respect privacy rights and appropriately manage and protect personal information.

Education

Support the advancement of the scientific and medical education for the ultimate benefit of patients.

Members Pledge

As a KAPI Member, I acknowledge our company's responsibility to adhere to the Code of Practice for the Pharmaceutical and Medical Devices Industry in Kenya (The Code) in our commitment to operate our businesses ethically and with integrity.

I pledge to uphold the Guiding Principles of The Code such as integrity, transparency, independence, accountability and patient focus to ensure that all our interactions with public and private sectors, healthcare professionals, medical institutions and patient organizations, are at all times ethical, appropriate and professional.

As a member, I recognize my role in leading the promotion of The Code among company employees through information and education and thorough training.

_____

Company Name

_____

Name of company representative

_____

Position

_____

Signature of company representative

_____

Date

Introduction

Kenya Association of the Pharmaceutical Industry (KAPI) is the representative body of the Pharmaceutical Industry in Kenya. KAPI is also a member of IFPMA. Its membership comprises of:

1. Multinational companies operating locally either through legal entity or third party.
2. Local Pharmaceutical companies
3. Medical Devices companies
4. Veterinary Medicine Companies

KAPI encourages fair competition among member companies. The Code of Practice for the Kenya Pharmaceutical and Medical Devices Industry (hereinafter referred to as The Code), is not intended to restrain the promotion of medicinal products or technologies or limit interactions with, healthcare professionals in a manner that is detrimental to fair competition. Instead, it seeks to ensure that member companies conduct such promotion and interaction in a truthful manner, avoiding deceptive practices and potential conflicts of interest and in compliance with applicable laws and regulations.

The Code thereby aims to foster an environment where the general public can be confident that choices regarding their treatment are being made in the best interest of their healthcare needs.

Guiding Principles on Ethical Conduct and Promotion [adapted from IFPMA Page 4]

I. The health and well-being of patients are the first priority for pharmaceutical and medical devices companies.
II. The member companies will conform to high standards of quality, safety and efficacy as determined by regulatory authorities.
III. Member companies' interactions 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.
IV. Member companies are responsible for providing accurate, balanced, and scientifically valid data on products.
V. 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.
VI. Member companies will respect the privacy and personal information of patients and Healthcare professionals.
VII. All 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. Member companies are committed to the transparency of industry sponsored clinical trials in patients.
VIII. Member companies should adhere to both the spirit and the letter of applicable industry codes. To achieve this, Member companies will ensure that all relevant personnel are appropriately trained.

1.1. Scope

The Code covers:

- The promotion to healthcare professionals of prescription-only medicinal products and technologies
- Interactions between healthcare professionals/associations and member companies
- Interactions between patients/patient associations/general public and member companies.

This Code is applicable to all member companies, their subsidiaries, and any companies affiliated with them or their subsidiaries ***("Member Companies").***

The Code covers all interactions including, but not limited to, oral and written promotional activities and communications, journal and direct mailing, the activities of Medical Sales Representatives, the use of internet and other electronic communications, the use of audio-visual systems such as films, video recordings, data storage services and the like, and the provision of informational or educational materials, items of medical utility, hospitality in relation to events and medical samples.

The Code also covers interactions between Member Companies and healthcare professionals including, but not limited to those in the context of research or contractual arrangements such as non-interventional studies, consultancy and advisory board arrangements.

The Code does not cover the following:

a. The labelling of medicinal products and accompanying package leaflets, which are subject to the provisions of the local laws and guidelines.
b. Correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product or technology;
c. Factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general precautions, trade catalogues and price lists, provided they include no product claims;

d. Non-promotional, general information about companies (such as information directed to investors or to current/prospective employees), including financial data, descriptions of research and development programs, and discussion of regulatory developments affecting a company and its products.
e. Studies other than observational, non-interventional studies and market research.

Note: The Code is not intended to inhibit the exchange of medical and scientific information during the development of a product.

1.2. Definitions

Data on File:
Scientific data generated by a company that is unpublished. Data on file used should have been submitted to the regulatory authorities for the purposes of obtaining local registration.

Government Official:
Any officer or employee of a Government Authority or any department, agency or instrumentality thereof, including state-owned and state-controlled entities, or of a public international organization, or any person acting in an official capacity for or on behalf of any such government, department, agency, or instrumentality or on behalf of any such public international organization.

Governmental Authority:
Means any foreign, domestic, federal, territorial, state or local governmental authority of any nature, or body exercising, or entitled to exercise, any administrative, executive, judicial, legislative, police, regulatory, customs, immigration, or taxing authority or power of any nature. Officers and employees of government hospitals, research institutions, universities, and other healthcare institutions or facilities will be deemed to be Government Officials.

Healthcare Professional (HCP):
Any member of the medical, dental, pharmacy or nursing professions, or any other similar person whose professional activities may include the recommendation, purchase, prescription, administration or supply of a pharmaceutical company's products to patients or customers or whose activities involve undertaking any procedures (diagnostic, interventional, surgical) using medical devices on patients in an invasive and non-invasive manner; practicing in either the public or private sector, or both.

Items of Medical Utility:
Items of Medical Utility are items that are:

a. Intended for the direct education of HCPs or patients and
b. Do not have value to HCPs or healthcare organizations outside of the scope of their practice and educational need.

Patient Organizations:
An independent organization which has the goal of providing direct support to people affected by an illness or advocating for, among other things, patients' rights, disease awareness and patient information in one or more therapeutic areas. Such organizations are often established by patients, their family members and caregivers but may also include Health Care Professionals (HCPs), volunteers and policy makers among their membership or leadership.

Patient Organizations/association:
Not-for-profit organizations that represent the interests and views of consumers of health care. They may range from small volunteer groups to large organizations or umbrella organizations, and generally they promote views that are independent of government, the pharmaceutical industry and Health Care Professionals.

Pharmaceutical Products or Medicines:
Products marketed, promoted, sold or distributed by a pharmaceutical company, including products that are co-marketed or co-promoted, to the extent that the pharmaceutical company controls the promotion of such products that are being co-marketed or co-promoted. Products in this code will include both pharmaceutical products and medical devices.

Promotion:
Any activity undertaken, organized or sponsored by a Pharmaceutical Company that is intended to promote the prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s) through all methods of communication, including the internet and social media.

Local Market Authorization:
The granting of permission or license to market a product in Kenya.

1.3. Applicability of the Code

The Code sets out the minimum standards which KAPI considers must apply. In the event of a conflict between the provisions of the Applicable Codes set forth within and the local laws and guidelines, the more restrictive of the conflicting provisions shall apply.

The spirit, as well as the letter of the provisions of the Code must be complied with. KAPI also encourages compliance with the letter and spirit of the provisions of the "IFPMA" Code of Pharmaceutical Marketing Practices, where applicable.

Marketing Authorization and Off-Label Promotion 2

Companies shall not promote a product until all necessary approvals have been received.

Products must only be promoted for use in indications as approved by the Regulatory Authority.

Promotional content must be consistent with the Approved prescribing information and other conditions as set out by the Regulatory Authority.

These restrictions also apply to unapproved indications for registered products.

Notes:
When the local authority provides a special license for a particular medication for a patient, this shall not imply permission to promote the product locally.

Medical information and promotional claims 3

KAPI is committed to the rational use of products and central to this goal is the provision of relevant information to healthcare professionals. Such information should include knowledge gained from the research and development of products as well as from their clinical use.

3.1. Responsibility

It is the responsibility of each member company to ensure that methods of promotion must:

a. Not bring discredit upon or reduce confidence in the industry.
b. Be of a nature which recognizes the special nature of the products and the professional standing of the recipient(s).
c. Not be likely to cause offence.
d. Be for the best interest of the patient.

Promotion should only be directed the HCP's specialty, practice area or need.

Mailing lists must be kept up-to-date. Requests by healthcare professionals to be removed from promotional mailing lists must be complied with.

Data privacy considerations should be adhered to and personal information handled with discretion.

Activities of company representatives and any third party paid by or acting on behalf of the company shall comply with the Code, local laws and guidelines at all times.

3.2. Product Information

3.2.1. Full Disclosure of Product Information

Full disclosure of updated Product Information must be made available upon request. Exceptions to the full disclosure rule are items and materials that serve only as reminders of the product's existence without making promotional claims. This full disclosure rule shall apply also to reformulated products as approved by the Regulator. Where the material only indicates the brand name, generic name and preparation, no full disclosure of product information shall be required.

The Product Information should include:

a. The Brand name of the product and the generic name (INN) of each active substance;
b. Pharmacological data–a brief description of pharmacologic effects and mechanism of action;
c. Clinical information, including indications, dosage regimen and relevant pharmacokinetic data, contraindications, precautions and warnings, adverse effects, drug interactions, and over dosage precautions.
d. Pharmaceutical information, including: dosage forms, strength of dosage forms, storage conditions and description of the product and the name and address of manufacturer(s) and importer(s).

3.2.2. Abridged Disclosure Product Information

a. Brand name of the product and the generic name (INN) of each active substance;
b. Composition;
c. Approved indications for use;
d. Contraindications;
e. Precautions for use;
f. Adverse effects and drug interactions;
g. Available dosage forms and dosage regimens;
h. Routes of administration; and
I. Reference to special groups of patients.

3.3. Promotional Information

3.3.1. Accurate Scientific Claims

Promotion must be accurate, balanced, fair, objective and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicinal product concerned. It should be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It must not mislead by distortion, exaggeration, undue emphasis, omission or in any other way.

All information, claims and graphical representations provided to healthcare professionals and members of the general public must be current, accurate, balanced and must not be misleading either directly, by implication or by omission. Every effort must be made to avoid ambiguity.

Claims must be referenced where there is a possibility that a reader may be misled if the source of the reference is not disclosed. Data on file may be used as reference and made available upon request.

3.3.2. Substantiation

Promotional claims must be capable of substantiation and must be referenced. In particular, promotional claims about side-effects must reflect available evidence or be capable of substantiation by clinical experience.

The substantiation of any claims must be promptly provided in response to requests from healthcare professionals.

Substantiation need not be provided, however, in relation to the validity of elements approved in the marketing authorization.

When promotion refers to published studies, clear references should be given.

3.3.3. Use of Quotations in promotion

Quotations from medical and scientific literature or from personal communications must be faithfully reproduced (except where adaptation or modification is required in order to comply with any Applicable Code(s), in which case it must be clearly stated that the quotation has been adapted and/or modified) and the precise sources identified.

All artwork, including graphs, illustrations, photographs and tables taken from published studies included in promotional material should:

a. Clearly indicate the precise source(s) of the artwork;
b. Be faithfully reproduced, except where adaptation or modification is required in order to comply with any Applicable Code(s), in which case it must be clearly stated that the artwork has been adapted and/or modified.

Particular care must be taken to ensure that artwork included in promotion does not mislead about the nature of a medicine (for example whether it is appropriate for use in children) or mislead about a claim or comparison (for example by using incomplete or statistically irrelevant information or unusual scales).

Graphs and tables shall be faithfully reproduced and the full source clearly indicated. Further, they must be presented in such a way as to give a clear, fair, balanced view of the matters with which they deal.

Quotations from medical and scientific literature or personal communication must faithfully reflect the meaning of the author.

Utmost care should be exercised to avoid ascribing claims or views to authors when these no longer represent the current views of the authors concerned.

3.3.4. Unqualified Superlatives

Promotion must encourage the rational use of medicinal products by presenting them objectively and without exaggerating their properties. Claims must not imply that a medicinal product, or an active ingredient, is "unique" or has some special merit, quality or property unless the claim(s) can be substantiated.

The word "safe," for example, must not be used without qualification. It must not be stated that a product has no side-effects, toxic hazards or risks of addiction or dependency.

Information and claims about side-effects must reflect current available evidence.

3.3.5. New Products

The word "new" must not be used to describe any product, presentation, or therapeutic indication that has been available and generally promoted for more than 12 months in Kenya.

3.3.6. Comparative Statements

Comparison of products must not be disparaging, but must be factual, fair and capable of substantiation and referenced to its source. Care must be taken to ensure that it does not mislead by distortion, by undue emphasis or by any other way. Clinical terminology, rather than mere claims that a product is better, stronger or more widely prescribed, should be used to describe improved benefits.

"Data on file", when used to substantiate comparative statements, must comply with the requirements of Section 2.0.

Any comparison made between different medicinal products must be based on up to date data, relevant and comparable aspects of the products. Comparative promotion must not be misleading or disparaging.

Brand names of products of other companies must not be used in comparison.

3.3.7. Imitation

Promotional information should not imitate the devices, copy slogans or general layout adopted by other manufacturers in a way that is likely to mislead orconfuse.

3.3.8. Disparaging References

Members should not either directly or by implication disparage other companies, their products, services, activities or promotions.

The clinical and/or scientific opinions of members of healthcare professionals must not be disparaged either directly or by implication.

3.3.9. Use of HCP Personal Information

Healthcare professionals' personal information such as names, contacts or photographs must not be used without their written consent.

3.3.10. Transparency of Promotion

Promotion must not be disguised.

Clinical assessments, post-marketing surveillance and experience programs and post-authorization studies (including those that are retrospective in nature) must not be disguised promotion. Such assessments, programs and studies must be conducted with a primarily scientific or educational purpose.

Where a company pays for or otherwise secures or arranges the publication of promotional material in journals, such promotional material must not resemble independent editorial matter.

Material relating to medicines, medical devices and their uses, whether promotional in nature or not, which is sponsored by a company must clearly indicate that it has been sponsored by that company.

3.3.11. Provision of Additional Information during code enforcement

Upon written request, the member company will provide additional accurate and relevant information about products being marketed to healthcare professionals. This information will be provided to the Ethics Committee for the purposes of substantiation during the adjudication/code enforcement process.

All data cited in promotional materials in support of a claim must be provided within 15 working days upon request. This includes all data classified as "Data on file". The company must have it available upon request.

3.3.12. Provision of Substantiating Data to HCPs

In addition to the information supplied or generally available, a company will, upon reasonable request, provide healthcare professionals with additional accurate and relevant information about the products which it markets and about the company itself.

Data in support of a claim, including "data on file" or "in press," MUST BE MADE AVAILABLE without delay upon reasonable request even though the material is not generally available to the medical community.

Requests by HCPs may be made either verbally or through written requests. However where a request is written, the information must be provided within 10 working days. two (2) weeks.

3.3.13. Level of Substantiating Data

Any information used to support a medical or promotional claim must include sufficient detail and be of adequate quality to allow evaluation of the validity of results and hence the claim.

Such substantiating information must not rely solely on "data on file".

3.4. Electronic Materials, including Audiovisuals

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

a. The identity of the company and of the intended audience should be readily apparent;
b. The content should be appropriate for the intended audience; and
c. The presentation (content, links, etc.) should be appropriate and apparent to the intended audience.

Interactions with Healthcare Professionals 4

4.1. Independence of HCPs

No financial benefit or benefit in kind (including grants, scholarships, subsidies, support, consulting contracts or educational or practice-related items) may be provided or offered to a healthcare professional as an inducement for prescribing, recommending, purchasing, supplying or administering products or for a commitment to continue to do so. Nothing may be offered or provided in a manner or on conditions that would inappropriately influence a healthcare professional's prescribing practices.

Gifts of any kind for the personal benefit of healthcare professionals are not allowed, irrespective of value, kind or occasion. The only exceptions are as follows:

a. Equipment, tools, devices, computers and educational materials may be donated or loaned to medical training institutions and hospitals, but not to individuals. Clinics belonging to doctors are not considered institutions. Items for donation must have direct use in medical care and diagnosis. Examples of these are ECG machines, stethoscopes, x-ray machines/films, scanners, and other diagnostic equipment. Business machines and appliances, communications equipment (such as fax machines, pagers and cellular phones), furniture, and air conditioners are not allowed as donations.
b. Items of medical utility may be offered for free provided that such items are of modest value and are beneficial to the provision of the medical services and for patient care. They should not be offered on more than an occasional basis, even if each individual item is appropriate. Items of medical utility can include the company name, but must not be product branded, unless the product's name is essential for the correct use of the item by the patient (see article 4.5).
c. Medical books as well as subscriptions to medical journals may also be offered free of charge. Medical books must be given directly to the healthcare professional, and subscriptions to journals must be in the name of the healthcare professional.

4.2. Events and Meetings

Companies are constantly engaged in activities that are geared towards ensuring healthcare professionals are kept constantly in touch with continuing developments in the pharmaceutical and medical field.

With this in mind, the practice has arisen of meetings and events being organized between the industry and the professions for the further exchange of ideas and information. In addition, the custom has grown of the industry supporting independent meetings of healthcare professionals intended to update and expand the continuing education of the professions themselves.

Many of these meetings could not take place without the support and assistance of the pharmaceutical industry. Companies may legitimately provide assistance that is directly related to the bona fide continuing education of the healthcare professionals and which genuinely facilitates attendance of the healthcare professional for the duration of the educational aspect of the event. Such support and assistance must however, always be such as to leave healthcare professionals' independence of judgement manifestly unimpaired.

4.2.1. 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.

The scientific content of any scientific meeting should at minimum 2/3 of the entire program. Hospitality should be secondary to the meeting program.

4.2.2. Events organized outside Kenya

No company may organize or sponsor an Event for healthcare professionals that take place outside the HCP's country of practice unless it is appropriate and justified to do so as per the conditions below:

a. Most of the invitees are from outside Kenya and, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the event in another country; or
b. Given the location of the relevant resource or expertise that is the object or subject matter of the event, it makes greater logistical sense to hold the event in another country (an "international event").
c. There is a significant and obvious security risk of holding such an event in Kenya; or

d. There is a significant epidemic outbreak that justifies restricted travel to Kenya.

International scientific congresses and symposia that derive participants from many countries are therefore justified and permitted.

4.2.3. Promotional Information at International Events hosted in Kenya

At international congresses or symposia held in Kenya, promotional material which appears on exhibition stands or is distributed to participants may refer to a medicinal product or indication for a medicinal product which is not the subject of an authorization in Kenya provided that each of the following conditions are observed:

a. The meeting must be an international, scientific event with a significant proportion (60% or more) of the speakers and delegates from other countries where this product is registered;
b. An explanatory statement should identify the countries in which the product is registered and make it clear that it is not locally approved.
c. To ensure that the promotional material does not promote the prescription, supply, sale or consumption of the medicinal product in Kenya, a clearly visible and legible statement must be included to the effect that the medicinal product is not authorized or that it is authorized for different indications locally;
d. Promotional material which refers to the prescribing information (indications, warnings, formulations etc.) authorized in other countries must include an explanatory statement indicating that licensing conditions differ internationally.

Scientific papers on such products may, however, be provided in accordance with the ***"Note"*** under Clause 1.1; Scope of the Code.

4.2.4. Exhibit Booths

Exhibit booths must be directed only to healthcare professionals. The display must clearly identify the exhibitor and must comply with the requirements of this code.

Contests, raffles, and other similar activities should not be conducted in the booths.

Video presentations must be relevant. For instance they should either be educational or scientific or related to the products promoted.

4.2.5. Appropriate Venue

All promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (including, for example, advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies) (each, an "event") organized or sponsored by or on behalf of a company must be held at an appropriate venue that is conducive to the main purpose of the event.

It should be the program that attracts delegates and not the associated venue or hospitality. Companies must not organize meetings to coincide with sporting, entertainment or other leisure events or activities at the location. Venues that are renowned for their entertainment or leisure facilities or are extravagant must not be used. The following considerations should be in place when selecting venues:

a. Events should be conducted in clinical, educational, conference, or other settings, including hotel or other commercially available meeting facilities conducive to the effective transmission of knowledge.
b. Programs requiring "hands on" training in medical procedures should be held at training facilities, medical institutions, laboratories, or other appropriate facilities.
c. Venue must be truly business in nature or commercial centre providing conference facilities conducive to the exchange of scientific and medical information.
d. The meeting facilities should only be accessible to the intended audience.
e. The venue should not be the main attraction of the conference.
f. The image of the venue/location in the eye of public opinion/media/authorities, must not be deemed extravagant/ luxurious/ exclusively touristic/holiday in nature and/or entertainment venue.
g. The venue must not be one that predominantly markets itself as exclusive and high end.
h. The venue must not be lavish even if the cost is low compared to other venues.
i. Venue must not, be a golf club or have a golf course or other leisure activities that may be associated with opulence.
j. Venue must not be holding a sporting event, a musical concert, and significant cultural event etc., at the same time as the scientific event.

The star rating of a hotel or use of the term "resort" will not apply in Kenya as this may not be indicative of the real public perception and status of the hotel. It is also recognized locally that a number of business/conference hotels are either beachside or lakeside hotels. These hotels are typically used for meetings in Kenya and member companies can use these hotels with careful considerations of other amenities and activities that are ongoing at the time of meeting to ensure it's appropriate to use them.

Companies organizing events locally on behalf of their branches in other countries must use the local knowledge and experience to evaluate the appropriateness of venues.

In deciding whether to support an event organized by a third party, companies shall be guided by the provisions of Appendix 1 (see section 10.1, extracted from The IFPMA Note for Guidance on Sponsorship of Events and Meetings, Nov 2014).

4.2.6. Smaller Meetings

The sponsorship of local medical meetings e.g. monthly meetings, initiated by an organizing body of the healthcare professions, is frequently sought from companies. In such instances, companies must respond only to formal written requests for support from the organizing committee. Any request for support should indicate the exact anticipated items of expenditure for which the support is sought. Support must not extend beyond:

a. Cost of room/venue hire
b. Cost of equipment hire and meeting materials
c. Actual travel expenses of speaker(s)
d. Honorarium to speaker(s) if appropriate
e. Modest meals and/or light refreshments

Promotional input from companies at an appropriate stage of the meeting must be with the agreement of the organizer or through a printed acknowledgement.

In any series of such meetings, as for example monthly hospital meetings, no one company should undertake the sponsorship of such a series of meetings to the exclusion of other available and willing sponsors. No payment must be made by a company in order to be included on a shortlist of possible sponsors.

No company should make a payment to maintain business or obtain a business advantage where such payment or advantage would constitute a violation of any applicable anti-bribery legislation (e.g. The Anti-Corruption and Economics Crime's Act, 2003), regulations and/or codes

4.2.7. Larger Meetings

For larger meetings initiated by the healthcare professions, such as annual association meetings, support usually involves the rental of a stand or space for the purposes of exhibiting the company's product range. This form of exhibition by companies is acceptable. The exhibition however must be clearly separated from the scientific session of the meeting to distinguish between the promotional activity and the non-promotional/scientific activity. A visit to the exhibition stand must also not be made a mandatory part of the program.

Other support for such meetings must not extend beyond a contribution to the general expenses of the meeting. An acknowledgment of this support, by way of a list of sponsors on the program (if any) and/or by way of a similar list displayed on a notice board, is acceptable.

Sponsorship of major annual or bi-annual meetings of any discipline within the healthcare professions should not be undertaken by any one company to the exclusion of other available and willing sponsors. No payment must be made by a company in order to be included on a shortlist of possible sponsors.

No company should make a payment to maintain business or obtain a business advantage where such payment or advantage would constitute a violation of any applicable anti-bribery legislation (e.g. The Anti-Corruption and Economics Crime's Act, 2003), regulations and/or codes.

4.2.8. Hospitality

Hospitality in the form of refreshments and/or meals incidental to the main purpose of the event may be provided. Refreshments and/or meals may only be provided:

a. Exclusively to participants of the event; and
b. If they are moderate and reasonable. As a general rule, the value of hospitality should not exceed what the HCPs would be prepared to pay for personal purposes.

No entertainment or other leisure or social activities should be provided or paid for by a member company. It is not permitted to fund social activities, the attendance to a concert, purchase of entertainment tickets or pay for entertainment in any form. Any entertainment, even if secondary to the meal is prohibited.

Requirements in this code in regards to venues shall apply in connection to hospitality.

Companies must maintain a log of all attendees and the identity of the venue.

4.2.9. HCP Sponsorships

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

a. The Event complies with the requirements in this Code as described in 4.1 and that the scientific agenda is the primary basis for the company's sponsorship of or participation in the event;
b. Sponsorship to healthcare professionals is limited to the payment of travel to and from the venue, meals, accommodation only for the duration of the scientific event and genuine registration fees;
c. No payments are made to compensate healthcare professionals for time spent in attending the Event;
d. 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.
e. Cash assistance or check vouchers are not acceptable under any circumstances. Neither is payment of expenses for spouses, family members or guests.
f. Per-diems shall not be offered to HCPs attending meetings and training by companies.

Member companies are expected to act responsibly in terms of numbers of healthcare professionals sponsored to meetings overseas. Sponsored HCP's should be working in a specialty related to the event. Recognition of specialty is based on the healthcare professionals' qualifications and/or current practice.

When supporting healthcare professionals to attend meetings, congresses or conferences, non-refundable and non-endorsable return tickets must be booked. These tickets may be booked to arrive at the meeting and depart from the meeting within 24 hours of the start and end of the meeting.

4.2.10. Guests

Companies must not pay any costs associated with individuals accompanying invited healthcare professionals except in cases of medical necessity.

4.2.11. Fees for Service

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 and/or travel. The arrangements that cover these genuine consultancies or other services must, to the extent relevant to the particular arrangement, fulfill all the following criteria:

a. 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;
b. A legitimate need for the services must be clearly identified and documented in advance of requesting the service and entering into arrangements with the prospective consultant;
c. 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;
d. The number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need;
e. 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
f. The compensation for the services must be reasonable and reflect the fair market value of the services provided. In this regard, token consultancy arrangements should not be used to justify compensating healthcare professionals. The compensation arrangement may include reimbursement of reasonable expenses including travel, meals and accommodation

No honorarium or compensation will be given to the healthcare professional for attending the convention, symposium or CME event. This provision does not apply to healthcare professionals sponsored as speakers in these events.

Member companies should take into consideration other local regulations e.g. withholding tax requirements, when paying fees for service to HCP's, in order to safeguard the reputation of the industry.

4.3. Samples

4.3.1. Samples

Free samples of medicinal products shall not be supplied to any person who is not qualified or authorized (licensed) to prescribe such product.

Where samples of products are distributed by a medical representative, the sample must be handed directly to a person qualified and authorized to prescribe such a product or to a person authorized to receive the sample on their behalf.

The following conditions shall be observed in the provision of samples to a person qualified and authorized to prescribe such a product:

a. Such samples are provided on an exceptional basis only and for the purpose of acquiring experience in dealing with such a product; such a sample must be specific to the HCP who needs to be familiar with the product.
b. Any supply of such samples or any extra samples, should ideally be in response to a signed and dated request from the recipient;
c. Each sample shall be no larger than the smallest commercial presentation or pack size on the market;
d. Each sample shall be appropriately marked as recommended by the health authority;
e. Each sample shall be accompanied by a copy of the most up-to-date approved version of the full prescribing information to that product.
f. Prescription product samples must not be given to healthcare professionals attending congresses or symposia.

A person shall not supply a sample of a medicinal product which is a controlled drug under the Narcotic and Psychotropic substances act (Cap 245).

Samples sent by post must be packed so as to be reasonably secure against the package being opened by children. They also should be shipped and supplied in the appropriate storage conditions to maintain the integrity of the product.

4.3.2. Control and Accountability

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.

This system shall also clearly establish, for each person supplied, the number of samples provided in application of the provision in Clause 4.3.1 b (above).

4.3.3. Items of Medical Utility

See definition under ***"Definitions"*** section.

Un-branded Items of Medical Utility may be provided to a HCP provided by member companies provided the items:

a. Do not offset the operating or routine business expenses that a HCP might otherwise incur;
b. Are offered only on an occasional basis to a HCP, even if each individual item is appropriate; and
c. Modest in value, as judged by local standards, but never to exceed a locally or regionally defined cap that cannot exceed the equivalent of 25 USD per item.
d. Item of medical utility of a value greater than USD 25, may not be given directly to an individual HCP but through the Donations process (see section 6.2 of this code)

Items of Medical Utility may include the company name or product name, logo or contact information ONLY if:

a. It is required by local law or the health authority; or
b. The product's name is essential for the correct use of the item by the patient.

4.4. Gifts and Other Items

No company may offer or give a gift, provide hospitality, benefits in kind, rebates, discounts, kickbacks or any free sample to any HCP or government official in exchange for an explicit or implicit agreement that the pharmaceutical company's products will be used, purchased, ordered, recommended, or prescribed or that the pharmaceutical company or any of its products will receive any form of preferential treatment.

Items in this section, where permissible, must never constitute an inducement to prescribe, recommend purchase, supply, sell or administer a pharmaceutical product.

Informational or educational items provided to HCPs for their education or for the education of patients on disease and its treatments may be offered by member companies to HCP's. These must be items that will specifically be used for aiding in the treatment of patients (e.g. anatomical model, memory sticks with educational data, medical textbooks / journals / magazines). These items may be given, provided that the items are primarily for educational purposes and do not have independent value.
Informational and educational items provided to HCPs for patient use can include the company name, but must not be product branded, unless the product's name is essential for the correct use of the item by the patient on condition that it is given post-prescription.
The value of books and subscriptions must be reasonable. Other informational or educational items must be of modest value. Memory sticks pre-loaded with educational or informational data may be appropriate if the storage capacity is commensurate with the materials provided. Tablet computers have independent value to a HCP and must not be provided, even if they could also be used to deliver education to patients.

4.5. Prohibition of Cash and Personal Gifts

Payments in cash or cash equivalents (such as gift certificates) 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, whether provided directly or through clinics and institutions. Cultural courtesy gifts are also prohibited.

4.6. Promotional Aids

A promotional aid is a non-monetary item given for a promotional purpose (which does not include promotional materials as defined in section 3). Providing or offering them to

HCPs in relation to the promotion of prescription-only medicines is prohibited.
Pens and notepads may be provided to HCPs in the context of company organized events for purpose of taking notes during the meeting (only company branded, of minimal value and in the necessary quantity for the purpose of the event).

Promotional aids of minimal value and quantity may be provided or offered to HCPs solely for the promotion of over-the-counter medicines if relevant to the practice of the HCP.

4.7. Guidance on values

"Minimal value" for promotional aid items shall be defined locally as USD 25.;

"Modest value" for items of medical utility shall be defined locally as USD 25.

"Reasonable value" for scientific books & journal subscriptions shall be defined by each company individually.

4.8. Mail, Faxes, Email and Text Messages

These communications must comply with all relevant provisions of the Code.

Prior consent must be obtained from a HCP prior to sending out promotional information in any of these formats. Requests to be removed from promotional mailing lists must be complied with promptly, and no name should be restored except upon specific request or with written permission.

Mailing lists should be kept up-to-date. The owner of the mailing list must provide the option for un-subscription.

Exposed mail, including postcards, envelopes, and wrappers, must not carry matter that might be regarded as advertising to the general public or that could be considered unsuitable for public view.

4.9. Medical Representatives

Medical representatives MUST be duly registered/licensed by the health authority.

They should, at all times, maintain a high standard of ethical conduct in discharging their duties. Apart from possessing sufficient medical and technical knowledge to present information on the company's products in an accurate, current, and balanced manner, member companies must also ensure that they are sufficiently aware and abide by, the contents of this code. Whenever a promotional claim is made, the medical representative must provide the Product Information, as approved locally

They must ensure that calls do not inconvenience or hinder the healthcare professionals' performance of their duties and they must adhere to institutional regulations governing their calls for as long as adhering to these regulations does not contradict the content and spirit of this code.

Interactions with Patients and Patient associations 5

5.1. No advice on personal medical matters

In the case of requests from individual members of the general public for advice on personal medical matters, the enquirer should be advised to consult a healthcare professional.

Member companies and their employees should never suggest a name of a specific HCP for consultation.

Member companies should never provide information on other patients, the number of patients enrolled in a support program, etc.

5.2. Patient Organizations

The pharmaceutical industry has many common interests with patient organizations. All interactions with patient organizations must be ethical and guided by the principles below:

5.2.1. Independence & mutual respect

The independence of patient organizations must be respected. Relationships between member companies and patient organizations shall be based on mutual respect and views and decisions held on equal value.

Aggressive/assertive words like "leverage", "drive", "target" is discouraged in the context of patient organizations.

It is not appropriate for companies to set up or establish patient organizations as these must be born and function autonomously. Similarly it is inappropriate to fund the operational running costs of a patient organization.

5.2.2. Declaration of involvement

When working with patient organizations, companies must ensure that the involvement and the nature of that involvement is clear and transparent from the outset.

No company may require that it be the sole funder of the patient organization or any of its programs. Pharma Industry welcomes funding of Patient Organizations from multiple sources.

5.2.3. 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.

The Objectives, scope, purpose of funding and amount of funding of any partnership shall be transparent and documented.
Each company must put in place an internal ethical review and approval process.

5.2.4. Non-promo of prescription only medicines

The promotion of prescription only medicines by member companies to the general public is prohibited. Member companies shall not request nor shall Patient Organizations undertake to promote a particular prescription-only medicine.

5.2.5. Use of logos and propriety materials

For a member company to use a Patient Organization's logo or materials, it must get written permission from that organization stating the specific purpose and the way the material will be used.

5.2.6. Editorial control

Member companies must not seek to influence the text of the Patient Organization's material they are sponsoring to favor their interests. Member companies can contribute to the drafting of the text in a fair and balanced manner.

5.2.7. Transparency

a. Each Company must avail, on request, the list of Patient Organizations to which it provides support and include a description of nature of support. The ethics committee shall be kept in copy of any such requests.
b. Sponsorship must be clearly acknowledged and apparent from onset.
c. Companies must disclose text contributed to wording of Patient Organization publications/materials.

5.2.8. Contracted services

a. Services should be provided for purposes of supporting healthcare orresearch.
b. Member companies can engage a Patient Organization as experts and advisors for services such as Advisory boards, disease advocacy and speaker agreements.

5.2.9. Events &hospitality

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, conducive to informational communication and as per the requirements on venues set out in this code. In addition, any meals or refreshments provided by a company must be modest as judged by local standards.

5.2.10. Enforcement

Enforcement of requirements for interactions with patients and patient organizations set in this code shall be enforced by the ethics committee. Any complaints raised shall also be through the ethics committee.

Grants and Other Forms of Support 6

6.1. Grants

Local law does not prohibit the provision of grants (Infrastructure, Educational, Health Policy & Other Research grants etc.) and neither will this code preclude a company from providing support to an institution for the betterment of patients. Grants should however generally be provided as contributions to healthcare or healthcare related institutions/organizations. The following conditions are to be complied with:

a. The member company must be in receipt of an external, non-solicited written request for a grant from a healthcare or healthcare related institution, stating the specific type of support required.
b. Grants must only be given to reputable healthcare or healthcare-related organizations for the general purpose of supporting healthcare
c. Sufficient due diligence must be conducted in regards to the healthcare/healthcare related institution/organization by the member company, to ascertain the reputation of this institution so as not to place the local industry in disrepute.
d. Any such support provided by a company must be relevant to the practice of medicine or pharmacy
e. Grants must be provided without agreement or intent to receive a tangible benefit in exchange and they must not be given for promotional purposes.
f. Grants must not interfere with the independent judgment of grant recipients and/or their associates. No commitment must be sought or given in relation to the prescribing, supply or use of the company's products.
g. Any such support must be reasonable, modest and in proportion to the scale and scope of the recipient institution. Grant must be reasonable in light of activity being funded and amount of other previous funding to any one individual requestor. This includes considering the perception that while support of each individual grant may be legitimate and appropriate when viewed in isolation, the aggregate amount provided to a recipient must not be able to be perceived as an attempt to inappropriately influence the requestor.

h. A Grant may not fund expenses incurred by a requestor for activities which occurred prior to the time of request.
i. Grants must be paid directly to an institution rather than to an individual healthcare professional;
j. Grants for conducting local research and/or realizing medical survey(s) must be accompanied with a protocol/justification and an intended deadline of completion. In the event of failure to conduct or complete the purpose or using the grant for a purpose rather than the requested, the member company will reserve the right to withdraw the support.

6.2. Donations

This is a benefit (cash or kind e.g. product donation) granted by a company for an altruistic, non-business related purpose, and where the company does not receive or will not be perceived to receive a direct or indirect consideration or service in return.

a. Donations may be given to a reputable healthcare related or non-healthcare related institution. The overall purpose is to support activities/projects with an affinity in the fields of healthcare and medicine or to support various initiatives, projects or non-profit organizations in communities.
b. Donations are non-promotional activities and should be treated by companies as such.
c. Donations must not interfere with the independent judgment of the recipients and/or their associates.
d. Donations targeted to private practices should be channeled through medical associations, industry bodies, non-governmental organizations or government bodies.

Additional requirements for product donations:

a. Product information/package inserts must be provided and be available in official languages locally used/recognized;
b. Any required drug safety monitoring must comply with all applicable local regulations;
c. Donations must be in line with the local authority code on donations.
d. Donating products with short expiry dates must be avoided, absent extraordinary circumstances. Consistent with the recommendations in the "WHO Guidelines for Drug Donations" all products should have a remaining shelf-life of at least one year upon arrival to the receiving entity.

e. Refurbished or used Medical Equipment donated for use must be in usable condition and must meet the "WHO Guidelines for
f. Healthcare Equipment Donations, March, 2000".
Delivery, importation, storage, handling and final dispensation of products must meet all applicable local regulations.

Market Research, Post Marketing Surveillance & related Activities 7

Market research activities, post-marketing surveillance programs, pharmaco-economic studies, observational and post-authorization studies, non-interventional trials, clinical audit programs and the like must not be promotional in nature. Such assessments, programs and studies should not be carried out for any other purpose than collecting information on own or competitive products, with primarily scientific or educational purpose.

Methods used for market research must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry. The following provisions set out in this clause apply whether the research is carried out directly by the company or by an organization acting on its behalf.

a. Access to respondents must not be gained by subterfuge.
b. Any incentives given must be kept to a minimum and be commensurate with the work involved.
c. Questions intended to solicit disparaging references to competing products or companies must be avoided.
d. Market research must not be used as a form of disguised sales promotion.
e. Market research results should not be used in promotion neither should data from market research be used for referencing promotional materials.
f. Post marketing studies should not be carried out and used in order to influence physicians. It should not be disguised as research.
g. Market research material, which need not reveal the company name to protect the integrity of the research, must state nevertheless that a pharmaceutical company sponsors it.

Observational/Non-Interventional Studies 8

8.1. A non-interventional study of a marketed medicine is defined as:

a. A study where the medicine is prescribed in the usual manner in accordance with the terms of its marketing authorization and where;
b. The assignment of the patient to a particular therapeutic strategy is not decided by a study protocol but falls within current practice and where;
c. The prescription of the medicine is clearly separated from the decision to include the patient in the study, and where;
d. No additional diagnostic or monitoring procedures are applied to the patients included in the study other than those which are ordinarily applied in the course of the particular therapeutic strategy in question and epidemiological methods are used for the analysis of collected data.

8.2. The objective of a non-interventional study is to observe the treatment aspects of a medicine in routine usage conditions by the physician and the patient and to collect additional information about the product in larger populations compared to clinical trials.

8.3. In principle the therapy of the patient should have started before the decision to include the patient to the non-interventional study. The assignment of the patient to a particular therapeutic strategy should not be decided in advance by a trial protocol but should fall within current practice and the needs of the patient.

8.4. The prescription of the medicine should be clearly separated from the decision to include a patient in the study. This distinction is performed by including a patient into the study only after the treatment has begun.

8.5. A medicine should not be prescribed to include a patient into a particular non-interventional study.

8.6. Companies must publish the summary details and results of non-interventional studies of marketed medicines in a manner consistent with their parallel obligations with respect to clinical trials.

8.7. Non-interventional studies that are prospective in nature and involve the collection of patient data must be conducted for a scientific purpose. They must comply with the following criteria:

a. Must be approved and carried out as required by the health authority
b. There must be a written protocol and written contracts between the health professionals and/or the institutes at which the study will take place and the pharmaceutical company sponsoring the study, which specify the nature of the services to be provided and the payment for those services
c. Any remuneration must be reasonable and reflect the fair market value of the work.
d. Should always protect patient private data
e. The study must not constitute an inducement to prescribe, supply, administer, recommend, buy or sell any medicine
f. The company's scientific service must approve the protocol and must supervise the conduct of the study
g. The study results must be analyzed and summaries must be made available within a reasonable period of time to the company's scientific service, which service shall maintain records of such reports; the summary report should be sent to health professionals who participated in the study.
h. Sales representatives may only be involved in an administrative capacity and such involvement must be under the supervision of the company's scientific service which will also ensure that the representatives are adequately trained for the role; such involvement must not be linked to the promotion of any medicine.
i. Non-Interventional Studies with primary data collection from patients and/or HCPs should screen for adverse events. Any adverse event found during the study, new or already known, must be reported to the local authority.

8.8. Non-interventional studies shall not be planned or carried out by the sales and marketing departments of pharmaceutical companies but only by the medical departments.

8.9. Non-interventional study planned and/or conducted / monitored purely by marketing departments is considered as a Non Ethical Promotional Activity and related sanctions will be applied.

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 protection for individual privacy, intellectual property and contract rights, as well as conform to legislation and current national practices in patent law.
Companies disclose clinical trial information as set out in Recognized international guidelines.

Enforcement/Administration of the Code 9

9.1. Introduction

This is a self-regulatory Code. Members of KAPI, are signatories to the Code.

Where a non-KAPI member/ person or body is concerned that the promotional activities of any signatory to the Code may be in breach, a complaint may be submitted to KAPI for consideration. Documents may be submitted to KAPI in either soft copy to the email address: compliance@kapikenya.org or hardcopy. For member companies, please refer to section 9.2.

KAPI shall establish an Ethics Committee to oversee the self-regulatory process and administration of this code. Complaints will be heard in the first instance by the Ethics Committee. The committee will receive any alleged breaches of this code and arbitrate any disputes brought forward.

9.2. Inter-Company Resolution

Member companies are encouraged to settle matters among themselves first before escalating the issue to the Ethics Committee. It is recommended that every reasonable effort should be made to resolve differences between companies directly. These efforts may range from but is not limited to, the two involved companies amicably talking to each other and taking corrective action (without collusion to turn a blind eye to requirements of this code or any other local or international applicable legislation and good practices), to the engagement of mediation professionals.

Only after such efforts have been exhausted, should the matter be referred to the Ethics Committee for resolution. Evidence of an attempt to resolve issues between members must be provided before the Ethics Committee can take up a matter.

9.3 Complains Handling at KAPI Executive Level

Where inter-company dispute resolution is not satisfactory or not an option, the complainant shall report the matter to the Compliance Committee in writing. At least 3 members of the committee (excluding the parties in the matter) shall hear, evaluate and decide

on the matter within a reasonable time period and then share this with KAPI Executive Committee who shall also give input. Once a resolution is agreed upon, it shall be communicated in writing to the concerned parties by the KAPI Executive Committee within a reasonable time period.

9.3. The Ethics Appeals Board

9.4. Where a decision from the KAPI Executive level is not agreed by either of the parties, the complainant has the right to appeal to the Ethics Appeals Board in writing within 30 days upon receipt of the decision from KAPI Executive.

9.4.1. Composition

The Ethic Committee shall comprise of members made up of the following:

a. 1 Representative from KAPI compliance Committee nominated by the Committee Chair
b. 1 Representative from KAPI Executive Committee nominated by the Chairperson of KAPI
c. 1 independent physician nominated by Kenya Medical Association.
d. 1 independent pharmacist nominated by the Pharmaceutical Society of Kenya.
e. 1 independent representative from a private hospital nominated by the EC.
f. If required, an independent lawyer nominated by Law Society of Kenya (if required e.g. where specific legal interpretation or input is needed in a matter). This person shall only serve as an advisor and shall not have voting rights in the matter at hand

The nomination of the above shall be coordinated by the EC. This committee will be at liberty to request for external expertise from consultants when required.

A number of 4 members shall be considered minimum quorum to transact business for the Ethics Appeals Board.

9.4.2. Selection of the Ethics Appeals Board members

The Chair of KAPI Executive Committee shall coordinate the establishment of this body.

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9.4.3. Term of Office

The Ethics Appeals Board will serve for a 3-year term. All members are eligible for re-selection.

9.4.4. Chairpersons

The committee, when constituted, will nominate their own chair. This is to ensure that the work of the committee remains independent.

Consultation

The Ethics Appeal Board has the right to consult external experts.

9.4.5. Conflict of Interest

If a Panel member is employed by a company directly involved in a complaint, referral or appeal, either as Complainant or Respondent, such member cannot participate in the Compliance Committee or the Ethics Appeals Board established to consider that complaint, referral or appeal.

It is recognized that, on occasion, members of the Compliance Committee or Appeals Board while not employed directly by a company involved in a complaint, referral or appeal, may have some degree of conflict of interest (e.g. direct competitor, same therapeutic area, etc.).

However, it may not be feasible or practicable to require such a member to stand down for consideration of a given complaint, referral or appeal. Any member should declare his or her interest to enable the relevant Chairperson to make an appropriate decision.

In cases where a significant number of the memberships declares conflict of interest, to a level that compromises quorum, the KAPI Executive Committee shall reserve the right to co-opt other members.

Confidentiality must be maintained.

9.4.6. Substitution

No substitution or replacement is allowed on the Ethics Appeals Board or during the hearing of a particular complaint, referral or appeal.

9.4.7. Autonomy

Panel members must have autonomy vis-à-vis their company/employer in the context of their participation in the Ethics Committee and/or the Appeals Board.

9.4.8. Confidentiality

Absolute confidentiality must be maintained by Panel members.

As a rule, parties to proceedings before the Ethics Committee shall maintain confidentiality concerning any matters before the committee, until a final decision is reached.
In exceptional circumstances, parties involved in a matter, may discuss issues before them with a third party with express permission of the Compliance Committee or Appeals Board. The party must prove that is necessary to do this due to the involvement of the third party in the matter. Such discussion must be factual, fair and balanced.

9.4.9. Accountability

The Compliance Committee and Ethics Appeals Board are accountable to the Executive Committee of KAPI for their satisfactory performance. The Compliance Committee and the Ethics Appeals Board are responsible for their own conclusions and deliberations.

9.5. Code Complaints Procedure

9.5.1. Who can make a complaint?

Complaints may be made by a member company, healthcare professional, patient, patient organization or any other aggrieved body or individual.

9.5.2. Submission of Complaints

The following requirements must be satisfied when filing a complaint:

a. The identity of the complainant including contact details (email, telephone etc.), for correspondence, must be made available. Anonymous complaints will not be considered.
b. The complaint must be legible.
c. Specific complaints from member companies must be fully referenced indicating sections of the code that are alleged to have been breached.
d. The dates of the alleged breach must be provided.
e. The complaint must be signed off by the senior-most company official or designate where a member company is making a complaint.
f. All complaints must be accompanied with evidence.

9.5.3. Complaints handling and Timelines

Complaints will be judged on the materials provided by the parties and it is for the complainant to show there has been a breach on the balance of probabilities.

The Committee and Board will endeavor to consider and deal with complaints in accordance with the following procedure and timelines:

9.5.4. Withdrawal of complaints

The Complainant may withdraw the complaint at any time up until the response has been received by the Compliance Committee. If a complaint is withdrawn before it has been sent to the Respondent, the Respondent will not be informed about the complaint. Where the Compliance Committee Chairperson is of the view that the alleged breach is serious or may have a potential of breaching section 3.1 (a) of this code, he or she may choose to continue the investigation of the matter in the manner outlined under the referral system (see Section 9.4.5) regardless of the withdrawal of the complaint.

a. The "clock" starts when a complaint is received by the KAPI secretariat/Compliance Committee Chairperson.
b. The Committee shall validate the complaint within 10 working days to ensure that:
    - It appears to be genuine, submitted in good faith.
    - There is sufficient information to enable the complaint to be processed.
c. If the information provided is insufficient, the complainant must provide additional information within the 10 working days (above), allocated for validation. If the complaint cannot be validated, it shall not be processed, and the complainant shall be notified accordingly.
d. Once validated, a copy of the complaint is sent to the company alleged to have breached the Code (i.e. the Respondent) within 5 working days. The respondent is requested to:
    - Provide a written response within 10 working days (No extensions of time shall be granted);
    - Provide an unqualified undertaking that the company will comply with every reasonable request of the
    - Compliance Committee or Ethics Appeals Board, if
    - relevant;

      Confirm that the company will accept the final decision of the Compliance committee or the Ethics Appeals Board, if relevant (although it may reserve the right to have recourse to law should it consider that route necessary).

    Failure by the Respondent to provide the required written undertaking of compliance and confirmation of acceptance of the Decision of the Compliance committee or Ethics Appeals Board, if relevant, will result in the matter being referred to the KAPI Executive Committee.
e. Following receipt of the document(s) and prior to the first meeting of the Compliance Committee, the Compliance Committee Chair, after consultation with the Committee members, shall have the discretion to ask either party to supply any additional information considered necessary to establish the full facts of the alleged breach so as to enable the Committee to reach a decision on the matters complained of;
f. Prior to the meeting of the Compliance Committee, the Chair of the Committee will issue a copy of the complaint (and the response, if received) to each member of the Compliance Committee
g. A meeting of the Compliance Committee will be arranged within 30 working days of the date of receipt of the complaint (i.e. whether or not the Respondent has replied). If the Respondent has provided a Response but not the required written undertaking of

compliance and confirmation of acceptance of the Decision of the Compliance Committee or Appeals Board, if relevant, the clock will stop until the KAPI Executive Committee has considered the matter and advised how the complaint is to be dealt with;

It is desirable but not always possible to reach a decision at that meeting. From time to time, subsequent meetings may be required;

h. The Complainant and Respondent shall be kept informed of progress with the complaint. The names of the members of the Compliance Committee hearing the complaint may only be made available to either party subsequent to the completion of a case and only then on request;
i. If necessary, the KAPI Executive Committee may convene a panel of experts to provide medical or technical advice and may therefore extend the timelines. However, for all cases, the Compliance Committee must resolve the case and transmit its ruling to both the complainant and respondent within 60 working days from receipt of respondent's reply, or if respondent fails to submit a written response, from the lapse of the period for submitting such a response.
j. The Compliance Committee will issue its final decision in writing to the complainant, together with any suggested sanctions as per section 9.7 of this code.
k. The Respondent will have 10 working days from the date on which the decision is issued to either lodge an appeal or to confirm in writing its intention to comply with any recommendations/sanctions imposed. Failure by the company concerned to do so will result in the matter being referred to the KAPI Executive Committee for further action.;
l. The KAPI Executive committee shall at this point reserve the right to inform the above country/headquarters of the respondents' company and request for a response/intervention.
m. The above time frame for the Ethics Committee procedure can be shortened or lengthened at the discretion of the Committee Chairperson, depending on the complexity of the issues presented and having regard to the availability of the Chairperson and members of the Committee.

Any request for an extension of the 10-day timeline for submitting an appeal will be a matter for consideration by the Committee Chairman.

9.5.5. Referral Matters (i.e. alleged breaches of Code where there is no formal written complaint)

Alleged breaches of the Code by a Code signatory which come to KAPI's attention other than by way of a formal written complaint are defined as "referrals". This could be for instance through a phone call or word of mouth from a non-KAPI member who is not aware of the complaints process as explained in this code or a member company with no documented evidence accompanying the complaint. Member companies are however encouraged to follow the process as described in section 9.4.2 and 9.4.3.

Such matters shall be dealt with in accordance with the following procedure:

a. Establishment that the referral is appropriate and has substance.
b. Use of the referral mechanism by a code signatory
c. In order to expedite matters and while maintaining good will, the Compliance Committee Chairperson shall write to the company that is alleged to have breached the Code before the first meeting of the Compliance Committee seeking preliminary information for the Committee to consider at its first meeting;
d. In any case, the company will be required to provide the standard undertakings that apply to complaints, i.e. an unqualified undertaking that it will comply with every reasonable request of the Compliance Committee and confirmation that it will accept the final decision of the Compliance Committee (or Appeals Board if relevant);
e. After its first meeting, the Compliance Committee will issue a letter to the company setting out the alleged breaches of the Code and it will be required to submit a written response. The Compliance Committee has the authority to seek any further additional information considered necessary from the company which is alleged to have breached the Code;
f. All information requested by the Compliance Committee must be provided within 10 working days.
g. The company shall have a right of appeal to the Appeals Board in relation to the decision of the Compliance Committee, including any sanctions applied. The procedures outlined in Section 9.5 of this Code will apply to such appeals;
h. "Self-referrals" from Code signatories will not be accepted in any circumstances, i.e. it shall not be open to Code signatories to seek the views of the Compliance Committee on any of their own activities.

9.6. The Appeals Process

9.6.1. Valid Appeal

The following requirements must be satisfied for an Appeal to be considered valid:

a. The Appeal must be in writing;
b. It must specify which aspects of the Compliance Committee's Decision are being appealed and also the grounds for the Appeal which must be one or more of the following:
    I. the finding(s) is(are) wrong
    II. the sanction(s) is(are) excessive
    III. Presence of a procedural flaw or irregularities in the adjudication process.
c. It may refer to documentation already submitted to the Compliance Committee and include any further material, including new evidence;

1.5.2. Who can lodge an Appeal?

Only the Respondent to a Complaint may lodge an Appeal to the Appeals Board in respect of the Decision of the Compliance Committee on the Complaint.

9.5.3. Establishment of Appeals Board

On receipt, in the KAPI secretariat, of a written Appeal from the Respondent in respect of a Decision of the Compliance Committee, the KAPI Executive Committee will establish an Appeals Board having due regard to conflicts of interest and other relevant matters. Depending on the specific matter, the Executive Committee shall from time to time be at liberty to seek expert advice.

A quorum of three is required to hear an Appeal and arrive at a final Decision.

9.5.4. Material Supplied to Members of the Appeals Board

Appeals shall be conducted as follows:

a. In the case of an Appeal on the ground described in Section 9.5.1(b)(i), the role of the Appeals Board is to reach a Decision based on the rehearing of those aspects of the Complaint under Appeal, conducted and heard as though at first instance, taking into account the original submissions to the Compliance Committee and any additional evidence submitted by either party in the Appeal that the Appeals Board deems to be relevant.
b. In the case of an Appeal on either of the grounds described in Section 9.5.1(b)(ii) and (iii), the role of the Appeals Board is to reach a Decision taking into account the grounds of the Appeal, the original submissions to the Compliance Committee, the compliance Committee Decision and any additional evidence submitted by either party in the Appeal that the Appeals Board deems to be relevant. The Appeals Board will not rehear the original Complaint. A copy of the Appeal and Response thereto and the original written decision of the Compliance Committee will be sent to each member of the Appeals Board. The Appeals Board will also be sent the original documentation supplied by the Complainant and Respondent to the Compliance Committee, i.e. the Complaint and the Response thereto.

9.5.5. Appeals Board Procedures & Timelines

The Appeals Board will endeavor to consider and deal with Complaints in accordance with the following procedure and timelines:

a. The "clock" starts when a valid Appeal is received at the KAPI secretariat;
b. A copy of the Appeal is sent to the other party involved in the Complaint, who is requested to provide a written Response, within 10 working days.
c. Upon receipt of the Response to the Appeal, the Executive issues the documentation to each member of the Appeals Board, i.e. Appeal, Response to Appeal, Compliance Committee Decision, as well as the original Complaint and Response to the Complaint, both of which will be included in the Appeals document provided by both parties;
d. A meeting of the Appeals Board is arranged within 30 working days of the date of receipt of the Appeal (i.e. whether or not the other party has replied);
e. It is desirable but not always possible to reach a Decision at the first meeting of the Appeals Board. From time to time, additional meetings may be required;

f. The two parties involved in the Appeal shall be kept informed of progress with the Complaint;
g. The Appeals Board may limit its deliberations to selected relevant additional evidence, at its discretion;
h. The names of the members of the Appeals Board hearing the Appeal may only be made available to either party subsequent to the completion of a case and only then on request;
i. The Appeals Board issues a final Decision within 10 working days of its last meeting. The Appellant is also provided with a copy of the Response and gets a chance to have the last word on the result of the appeal e.g. if in agreement or if they would like the matter escalated to the KAPI Executive Committee
j. Where a breach of the Code is confirmed by the Appeals Board, the company concerned has 10 working days to confirm in writing its intention to comply with the recommendations/sanctions imposed and to provide details of any actions taken in that regard. Failure by the company concerned to do so will result in the matter being referred to the KAPI Executive Committee;
k. The above time frame can be shortened or lengthened at the discretion of the Appeals Board Chairperson in conjunction with the Appeals Board members depending on the complexity of the issues presented and having regard to the availability of the Chairperson and members of the Appeals Board.

9.5.6. Decision of the Appeals Board

The Decision of the Appeals Board is final and binding.

9.5.7. Personal Representation during Appeals

Each party involved in an Appeal has the right to make an oral presentation to the Appeals Board. The following conditions will apply to all such personal representations:

a. The KAPI Executive Committee must be notified in writing if the relevant party intends to exercise this right at least five working days before the date of the first meeting of the Appeals Board;
b. Details of the company representatives who will be in attendance must also be provided in writing. External advisors (including barristers or representatives from firms of solicitors) are not permitted to attend on behalf of either party. Additionally, the Appeals Board Chairperson has the right to limit the number of representatives;

c. A summary of each party's representations to the Appeals Board shall be submitted as soon as possible after the request for such representations and in any event, no later than five working days before the Appeals hearing. Each party to the Appeal will receive the summary of the other's representations in advance of the hearing;
d. Each party's presentation shall be limited in duration (generally to a maximum of 20 minutes followed by 10 minutes for questions from the Appeals Board);
e. No new material or data may be introduced during the oral presentation that was not previously included in the written documentation provided to the Appeals Board.

9.5.8. Withdrawal of Appeals

The Appellant may withdraw the Appeal at any time up until the Response has been received by KAPI. If an Appeal is withdrawn before it has been sent to the Respondent, the Respondent will not be informed about the Appeal.

9.6. Requirement for Complaints to Have Substance

All complaints submitted for consideration must have substance. In the event of doubt about whether a complaint has substance, the KAPI Chairperson will be asked to adjudicate.

Inter-company complaints should not be used as a competitive tool or abused by companies for any hidden motives. The spirit of this self-regulatory code and the protection of the reputation of the pharmaceutical industry as a whole should remain paramount at all times.

9.6.1. Complaints concerning promotional activities other than printed matter

The difficulty in particular of establishing evidence for the Compliance Committee to consider in relation to complaints concerning promotional activities such as meetings, hospitality, samples etc. is recognized. The following requirements will therefore apply to such complaints:

a. Any complaint in relation to such activity must have substance;
b. The complaint must be in writing and should contain enough detail about the activity alleged to be in breach of the Code, as to justify the Compliance Committee's consideration;
c. Any available material evidence must be included e.g. invitation or correspondence from the Respondent's company. The absence of such material evidence will not preclude the Compliance Committee's consideration of the complaint.

If the Compliance Committee considers that such a complaint justifies investigation, it will have the right to ask the Respondent's company to demonstrate that it was in compliance with the Code. These provisions shall also apply in the case of appeals concerning promotional activities other than printed matter.

9.7. Sanctions

Where the Compliance Committee, having considered a complaint or referral, has found that the Code has been breached it shall, without prejudice to the right of any affected party to have the matter resolved through the judicial process, have the authority to:

a. Require the company concerned to cease the practice found to be breach of the Code and take all necessary steps to avoid a similar breach in the future;
b. Reprimand the company for the breach of the Code;
c. Order the recovery of material found to have been in breach of the Code;
d. Order the correction of inaccurate information by way of a corrective notice in terms approved by the Compliance Committee/Appeals Board;
e. Order the immediate publication of the decision in whole or in part and specify how and to whom the decision is to be sent.
f. In the case of difficult and/or persistent breaches of the Code, refer the matter to the Member company's Headquarters, The Minister for Health and PPB;
g. Recommend to the KAPI Executive Committee, the suspension or expulsion from KAPI of the offending party.
h. Impose financial penalties as per the penalty scheme in 9.7.1 below:

This list is not exhaustive and other sanctions may be applied by the Compliance Committee/Appeals Board as appropriate.

In the event that the decision of the Compliance Committee is appealed, the Appeals Board shall assume responsibility for the application of any or all of the above sanctions. In addition, the Appeals Board may uphold the decision of the Compliance Committee but vary the sanctions applied.

As soon as a decision of the Compliance Committee becomes the subject of an appeal, the decision and any sanctions imposed by the Compliance Committee is deemed to be suspended.

9.7.1. Penalty Scheme

Financial penalties shall be imposed as follows:

a. First time offender shall be fined KSh. 500,000/-
b. A second similar offences shall be fined KSh. 1,500,000/=
c. Consequent similar offences will attract a fine not less than 5 times the already imposed fine.
d. Member companies will be required to pay the penalty within a month of the penalty being imposed either by the Compliance committee or in cases of Appeal or by the Executive Committee were natters have gone beyond the appeals process.

The Ethics Committee has the mandate to fine beyond the penalty scheme depending on the severity of the offences even for a first time offence.

The reckoning date for all violations is the date when a decision was issues by either the Compliance Committee or the Appeals Board.

If the member company refuses to pay the penalty, the matter will be referred to the KAPI Executive Committee. The Executive Committee will deliberate on actions to take.

9.8. Abuse of Code

Abuse of the Code procedure shall in itself be a breach of the Code.

9.9. Recourse to Legal System

A company's right to have recourse to the legal system is not affected by participation in, and compliance with, the Code of Practice and the Compliance Committee and the Appeals Board's decisions. However, it is envisaged that the transparency of procedures in this Code will ensure that the necessity for such action will not arise.

A Complainant/Respondent must advise the Compliance Committee and the Appeals Board in the unlikely event of recourse to the legal system before or during a complaint. The Compliance Committee or the Appeals Board, as appropriate, will have the right to take whatever action it sees fit under the circumstances.

Appendices 10

10.1. Appendix 1:

Criteria to consider when deciding whether to support an event organized by a third party such as a medical society (non-exhaustive):

a. Scientific Program (Article 7.1.1 of the IFPMA Code)

If the answer to any of the questions below is 'no', then pharmaceutical companies should consider obtaining further information or suggesting amendments before agreeing to any involvement with the meeting:

- Is the scientific program available on the event organizer's website well in advance of the meeting?
- Does the scientific program cover the whole duration of the event with content generally filling the business hours each day?
- Is the program content scientifically grounded and adapted to the targeted audience?

b. Entertainment, leisure activities, meals (Articles 7.1.5 and 7.1.6 of the IFPMA Code)

If the answer to any of the questions below is 'yes', then pharmaceutical companies should consider obtaining further information or suggesting amendments before agreeing to any involvement with the meeting.

- Is any entertainment (such as sightseeing tours or leisure activities) organized in connection with the event either before, during or after it
- Is there unreasonable or frequent traveling for meals during the event?
- Are meals arranged in tourist or heritage/cultural attractions?
- Are any of the descriptions on the program such that they appear to be excessive (e.g. champagne reception, gala dinner, etc.)?

c. Accompanying Persons (Article 7.3 of the IFPMA Code)

If the program mentions accompanying persons/guests of the healthcare professional attendees, consider the following:

- Are they required to pay the full reasonable costs which are not subsidized in any way?
- Are healthcare professionals expected to participate in the meeting rather than encouraged to join any program for accompanying persons?
- Is it clear that attendees are not being encouraged to arrive before the meeting starts or stay on after it ends?

If the answer to any of the questions above is 'no', then pharmaceutical companies should consider obtaining further information or suggesting amendments before agreeing to any involvement with the meeting.

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