

KAPI

KENYA ASSOCIATION OF PHARMACEUTICAL INDUSTRY



Vision and Mission



OUR VISION

To be leading in the provision of innovative world class quality healthcare solutions, products and services.



OUR MISSION

Promote an ethical, innovative and responsible health-care industry.



OUR CORE VALUES

Relationships, Ethics, Excellence; Integrity

CURRENT MEMBERS





KENYA ASSOCIATION OF
CAL INDUSTRY



COMMITMENT FROM MEMBER COMPANIES

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

KAPI

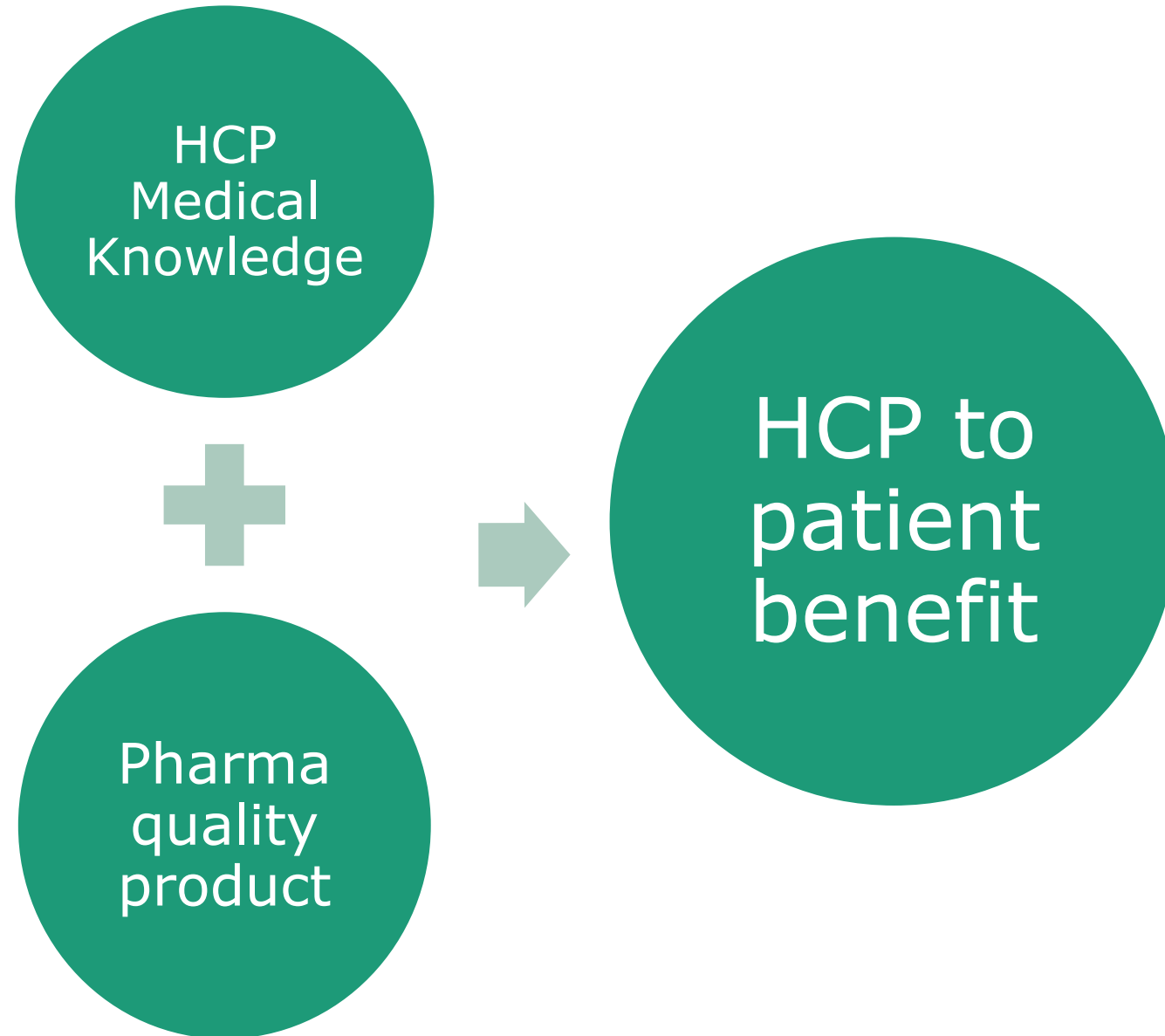
KENYA ASSOCIATION OF PHARMACEUTICAL INDUSTRY



Interactions with HCPs



HCP Independence



Interactions with healthcare Professionals

Independence of HCPs

- No financial benefit or benefit in kind 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.
- Gifts of any kind are not allowed, irrespective of value, kind or occasion. The only exceptions are as follows; items of medical utility, medical books as well as subscriptions, donations of equipment, tools, devices, computers and educational materials to medical training institutions. Clinics belonging to doctors are not considered medical institutions.

Interactions with healthcare Professionals

Events and Meetings

- Companies may legitimately provide assistance that is directly related to bonafide 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 judgment manifestly unimpaired

Interactions with healthcare Professionals

Scientific and Educational Objectives

- The purpose of all scientific or professional meetings with HCPs organized or sponsored by member company should be to provide scientific or educational information and/ or inform HCPs about products.
- The scientific content of any such meetings should be at minimum 2/3 of the entire program.
- Hospitality should be secondary to the meeting program.

Interactions with healthcare Professionals

Events organized outside Kenya

- No company may organize or sponsor an Event for HCPs that takes place outside the HCP's country of practice unless it is appropriate and justified to do so as per the conditions logistical sense below;
 - a. Most of the invitees are from outside Kenya and given the countries of origin of most of the invitees.
 - b. Given the location of the relevant resource or expertise that is the object or subject matter of the event.
 - c. There is significant and obvious security risk of holding such event in Kenya
 - d. There is a significant epidemic outbreak that justifies restricted travel to Kenya

Interactions with healthcare Professionals

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.
- For Rx Products, only product information is allowed in booth
- For OTC products, one may issue authorized reminder items

Interactions with healthcare Professionals

Appropriate Venue

- All promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events 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

Interactions with healthcare Professionals

Appropriate Venue

- Venues that are renowned for their entertainment or leisure facilities or are extravagant must not be used.

Interactions with healthcare Professionals

Considerations when Selecting Venues.

- The meeting facilities should only be accessible to the intended audience.
- The venue should not be the main attraction of the conference.
- 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.
- The venue must not be one that predominantly markets itself as exclusive and high end.

Interactions with healthcare Professionals

Smaller Meetings

- The sponsorship of local medical meetings e.g. monthly meetings, initiated by an organizing body of the healthcare professions
- 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.

Interactions with healthcare Professionals

Smaller Meetings

- Support must not extend beyond:
 - Cost of room/venue hire
 - Cost of equipment hire and meeting materials
 - Actual travel expenses of speaker(s)
 - Honorarium to speaker(s) if appropriate
 - Modest meals and/or light refreshments

Interactions with healthcare Professionals

Smaller Meetings

- 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.

Interactions with healthcare Professionals

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.
- 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.

Interactions with healthcare Professionals

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:
 - Exclusively to participants of the event; and
 - 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.

Interactions with healthcare Professionals

Hospitality

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

Interactions with healthcare Professionals

HCP Sponsorships

- Member companies may sponsor healthcare professionals to attend Events provided such sponsorship is in accordance with the following requirements:
 - The Event complies with the requirements in this Code as described in 4.1 and that the scientific agenda is the primary basis for the company's sponsorship of or participation in the event;
 - 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;

Interactions with healthcare Professionals

HCP Sponsorships

- No payments are made to compensate healthcare professionals for time spent in attending the Event;
- Any sponsorship provided to individual healthcare professionals must not be conditional upon an obligation to prescribe, recommend, purchase, supply, administer or promote any pharmaceutical product.
- Cash assistance or check vouchers are not acceptable under any circumstances. Neither is payment of expenses for spouses, family members or guests.
- Per-diems shall not be offered to HCPs attending meetings and training by companies.

Interactions with healthcare Professionals

HCP Sponsorships

- 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.
- The sponsored HCP must give their evidence of attendance to the sponsoring organization

Interactions with healthcare Professionals

Guests

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

Interactions with healthcare Professionals

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.

Interactions with healthcare Professionals

Fees for Service

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 written contract or agreement must be agreed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis for payment of those services
- A legitimate need for the services must be clearly identified and documented in advance of requesting the service and entering into arrangements with the prospective consultant;

Interactions with healthcare Professionals

Fees for Service

- The criteria for selecting consultants must be directly related to the identified need and the consultants must have the expertise necessary to provide the service;
- The number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need;
- The hiring of the consultant to provide the relevant service must not be an inducement to prescribe, recommend, purchase, supply, and/or administer any medicine; and

Interactions with healthcare Professionals

Fees for Service

- 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.

Interactions with healthcare Professionals

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.

Interactions with healthcare Professionals

Samples

- The following conditions shall be observed in the provision of samples to a person qualified and authorized to prescribe such a product:
 - 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.
 - Any supply of such samples or any extra samples, should ideally be in response to a signed and dated request from the recipient;

Interactions with healthcare Professionals

Samples

- Each sample shall be no larger than the smallest commercial presentation or pack size on the market;
- Each sample shall be appropriately marked as recommended by the health authority;
- Each sample shall be accompanied by a copy of the most up-to-date approved version of the full prescribing information to that product.
- Prescription product samples must not be given to healthcare professionals attending congresses or symposia.

Interactions with healthcare Professionals

Samples 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

Interactions with healthcare Professionals

Items of Medical Utility

- Items of Medical Utility are items that are:
 - Intended for the direct education of HCPs or patients and
 - Do not have value to HCPs or healthcare organizations outside of the scope of their practice and educational need.

Interactions with healthcare Professionals

Items of Medical Utility

- Un-branded Items of Medical Utility may be provided to a HCP provided by member companies provided the items:
 - Do not offset the operating or routine business expenses that a HCP might otherwise incur;
 - Are offered only on an occasional basis to a HCP, even if each individual item is appropriate; and
 - 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.
- 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

Interactions with healthcare Professionals

Items of Medical Utility

- Items of Medical Utility may include the company name or product name, logo or contact information ONLY if:
 - It is required by local law or the health authority; or
 - The product's name is essential for the correct use of the item by the patient

Interactions with healthcare Professionals

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

Interactions with healthcare Professionals

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.

Interactions with healthcare Professionals

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 at **company organized or third-party events, (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.

Pop-Quiz – Session 1

- Time – 10 min discussion
- 2 questions on menti.com

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Interaction with patients and patient associations (PA)

Interaction with patients and patient associations (PA)

Advice on personal medical matters

- Individual members of the general public should be advised to consult a healthcare professional when requesting from for advice on personal medical matters
- Member companies and their employees should never suggest a name of a specific HCP for consultation or provide information on other patients, the number of patients enrolled in a support program, etc

Principles of interaction with PA

Independence & mutual respect

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

Declaration of involvement

- When working with PA, companies must ensure that the involvement and the nature of that involvement is clear and transparent from the outset

Principles

Written documentation

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

Non-promo of prescription only medicines

- The promotion of prescription only medicines by member companies to the general public is prohibited

Use of logos and propriety materials

- Member companies must get written permission to use a PA's logo or materials, stating the specific purpose and the way the material will be used

Principles

Editorial control

- Member companies must not seek to influence the text of the Patient Organization's material they are sponsoring to favor their interests

Transparency

- Each Company must avail, on request, the list of PAs 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
- Sponsorship must be clearly acknowledged and apparent from onset
- Companies must disclose text contributed to wording of PA publications/materials.

Principles:

Contracted services

- Services should be provided for purposes of supporting healthcare or research
- Member companies can engage a PA as experts and advisors for services such as Advisory boards, disease advocacy and speaker agreements

Events & hospitality

- Companies may provide financial support for PA meetings provided that the primary purpose of the meeting is professional, educational, and scientific in nature, or otherwise supports the mission of the PA.

Promotional Communication

Guiding Principles

- ✓ I. The health and well-being of patients are the first priority
- ✓ II. The member companies(MC) will conform to high standards of quality, safety and efficacy as determined by regulatory authorities.
- ✓ IV. MC are responsible for providing accurate, balanced, and scientifically valid data on products.
- ✓ VIII. MC 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.

Marketing Authorization and Off-Label Promotion

The Spirit

- ✓ 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.

General Principles on Promotion

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

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

Other considerations:

- ✓ Appropriateness of the recipient
- ✓ Data Privacy

Product Information

Key Principle

Full Disclosure of Product Information

- ✓ Full disclosure of up to date Product Information must be made available upon request

Promotional Information

Principles:

- ✓ Accuracy of Scientific Claims
- ✓ Substantiation
- ✓ Use of quotations from medical journals in promotion
- ✓ Unqualified Superlatives e.g. 'unique' 'safe'
- ✓ 'New' Product
- ✓ Comparative Statements

• **Principles cont...**

- ✓ Imitation
- ✓ Disparaging references
- ✓ Transparency of Promotion
- ✓ Provision of Substantiating Data to HCPs

Digital Media

Electronic Materials, including Audio-visuals

- ✓ The same requirements shall apply to electronic promotional materials as apply to printed materials.
- ✓ Specifically, in the case of pharmaceutical product related websites:
 - The identity of the company and of the intended audience should be readily apparent
 - The content should be appropriate for the intended audience
 - The presentation (content, links, etc.) should be appropriate and apparent to the intended audience.

Q&A



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Code Enforcement and Administration

- Self-Regulation by Member Companies
- Inter-Company Resolution
- Compliance Committee & Executive Committee level

- Ethics Appeals Board
 - 5 member team
 - 1 EC member, 1 member of compliance committee
 - 1 independent physician nominated by KMA
 - 1 independent pharmacist nominated by PSK
 - 1 independent representative from a private hospital appointed by EC
 - +/- any expert required

Any Complaints may be submitted to KAPI to the email address:
compliance@kapikenya.org or in hardcopy.

THANK YOU



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Poll questions

- Pre-training
 - Have you heard of the KAPI Code before?
 - How conversant are you with the KAPI Code (somewhat, very well etc)
 - Have you received any compliance training this year referencing the KAPI Code?
- Post training
 - Has the training content met your expectations? (include the topics in the slide deck and a rating of 0-10 per item – where 0 is not at all, 10 is yes, vey well)
 - Interactions with HCPs
 - Interaction with patients and patient associations (PA)
 - Promotional Communication
 - Code Enforcement and Administration
 - Please rate the training content on a scale of (excellent, very good, good , fair, poor)
 - I would recommend the training to other colleagues - (on a scale, strongly disagree to strongly agree)
 - I will confidently apply the code going forward (on a scale, strongly disagree to strongly agree)

Menti Questions

1. What are the key considerations to make when selecting a venue?

(type your answer)

1. Which of the following gifts are allowable for issue to HCPs on key occasions?

- Cake and flowers
- Bottle of wine
- Company branded bags and cups
- Product branded pens and notepads
- None of the above

1. Any supply of samples should be in response to a signed and dated request from the recipient.

True or False?