Association of Pharmaceutical Companies Representatives in Georgia

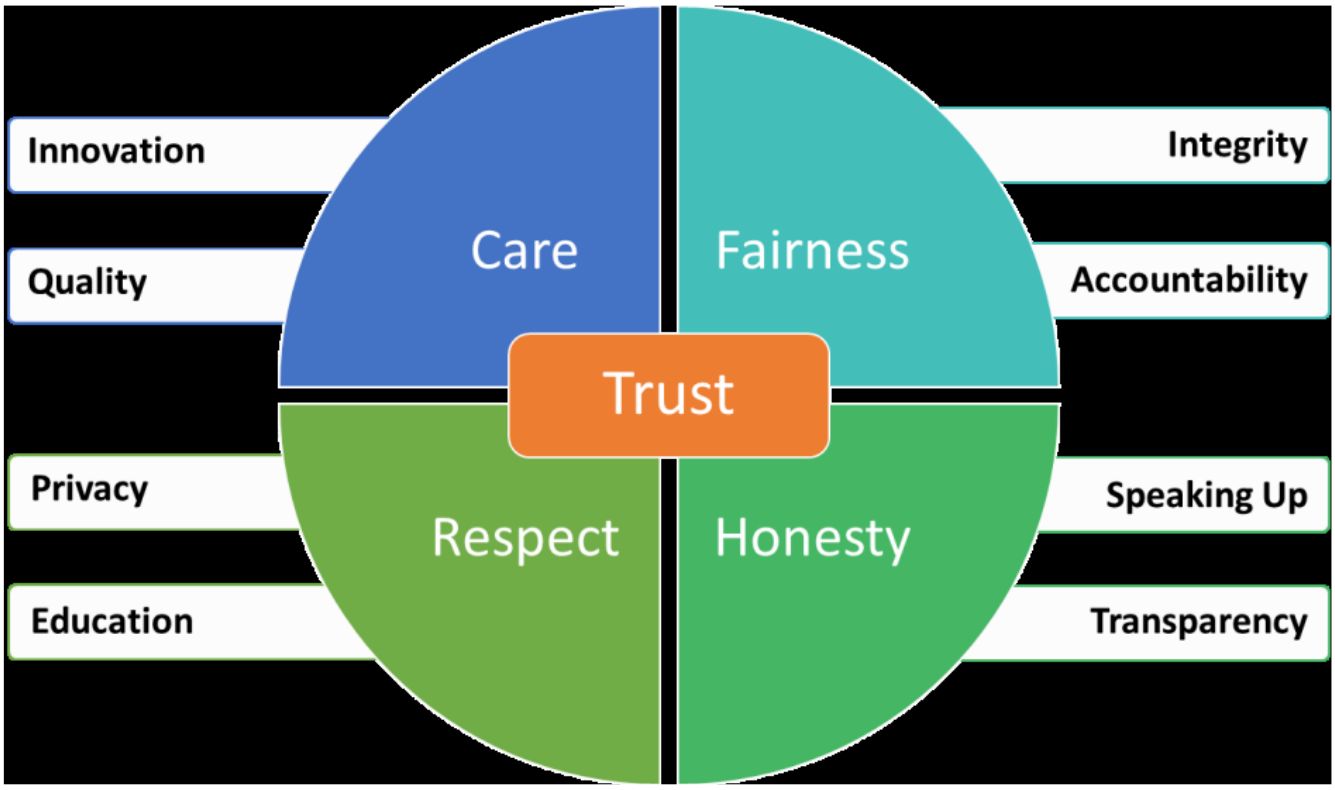
APCRG's Ethos

Project – 2019

Table of Contents:

Main Principles of the Association within Issues of Ethic Promotion and Marketing

The **Ethos** of Association of Pharmaceutical Companies Representatives in Georgia (hereinafter referred to as "Association") is based on principles which – principles ensure that all member companies and anyone acting on their agent's behalf promote and distribute their products in an ethical manner and in accordance with all the rules and regulations



Preamble

a) The Association member-companies and anyone acting on their agents behalf do recognize that pharmaceutical industry mission is helping patients by discovering, developing and promoting new medicines. Ethical promotion gives guarantees that for healthcare professionals is available ~~of~~ information they need, that patients have access to the medicines they need and that medicines are prescribed and used in a manner that provides maximum benefit for patients.

b) The Association and its members and anyone acting on their agent's behalf are engaged in educational and promotional activities for the benefit of patients. The Association does its best in order to ensure the independence of healthcare specialist's decision to prescribe medicines. The pharmaceutical industry is liable to provide healthcare professionals with accurate information about medicinal products for introducing the correct methods of product use. The industry interaction with healthcare professionals must support the idea, that pharmaceutical industry liability towards patients must be on the same level as healthcare professional's liability towards their patients. Pharmaceutical companies should maintain high standards of special promotion while carrying out promotional activities and should meet legal, regulatory and professional requirements currently in force in Georgia.

c) The Code of Pharmaceutical Marketing Practice ("Association Code", hereinafter referred to as "Code") set out standards on ethical promotion of pharmaceutical products for healthcare professional. This Code comes into force on the date of its endorsement by the General Meeting of the Association Members.

d) The Association acknowledges the role of codes of ethics developed by International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), World Medical Association, the international council of Nurses and the International Federation of Pharmacists. The Association also recognizes the role of Ethical Criteria for Medicine Drug Promotion provided by World Healthcare Organization in 1988.

e) The Association Code embraces information on main principles of its usage, about content of promotional materials, about interaction with Healthcare Professionals, about procedure

and responsibilities for campaign with patient's organizations and Code enforcement. Code contain questions & answers part (Appendix 2) which helps to interpret the Association Code and its Operational Procedures (Appendix 1).

f) The Association membership requires from member companies recognition of the terms and conditions of the Code, considering the local legislation and regulations.

g) The Association member-companies are taking an obligation to response on any infringement of the Code. The companies, which are not the Association members may be voluntarily guided by the Code and by the procedure for code complaint.

h) The Association is ready to accept complaints from any sources about any aspects of the Code infringement according to the operational procedures. Than code infringement confirmed, the Association will aim to eradicate infringement as soon as possible.

i) The Association is non-profit, non-governmental organization - non-commercial legal entity representing the companies of the pharmaceutical industry in Georgia. The member pharmaceutical companies take an obligation to accomplish the ethical standards stipulated in the present Code.

j) In case any disconformities between legislation acts or state regulations existing in Georgia presently or will be adopted in the future and any particular term of Code then will be applied the legal acts and regulations established by Government of Georgia.

k) The Code is prepared in Georgian and English languages. In case of dispute owing to disconformities between the texts the priority will be given to Georgian version.

1.Definition of Goal and Terminologies

1.1 Objective

The Association Code defines the standards for ethical promotion of pharmaceutical products for Healthcare Professional, medical institutions, and the patient organizations aiming to create appropriate interactions between member-companies and Healthcare Professional.

- **Question & Answer 1 , 2, 3**

1.2 Terminologies

Definition of terminology used in the Code:

„Pharmaceutical Product“–all medicines or physiologically active biological and chemical substances or their combinations, obtained by natural way or by synthesis permitted for medical use irrespective of patient status and/or whether they are branded or not-offered under the general name or not and etc., which are intended to be used by the Healthcare Professionals or under their observation and which are intended for use in the diagnoses, treatment or prevention in humans, or to affect structure any functions of the human body.

„Promotion“ means any activity, including activity via mass media and internet, undertaken, organized or sponsored by a company which is directed at Healthcare Professionals to promote the prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s).

„Healthcare Professionals“ – Physician, nurse, pharmacists and other persons which professional activity is connected to prevention of diseases, diagnostics, treatment, rehabilitation, palliate care, forensic expertise and public health professionals, medical and healthcare specialists, medical and healthcare services managers .

„Patient Organization" –non-commercial, non-profitable organization representing interests and needs of patients, their families and/or their caregivers.

„Event"– professional, scientific or marketing meetings intended for Healthcare Professionals and organized and sponsored by pharmaceutical companies aiming to provide information for Healthcare Professionals on pharmaceutical products and/or scientific educational information.

„Member Company" any company member of Associations

1.3 Exception

This Code doesn't regulate the following actions:

Advertisements for wide range of public communities (non-healthcare specialists, e.g. direct advertising for customers).

- **Question & Answer 1,3,4**

Issues connected with prices and commercial conditions.

- **Question & Answer 5**

supply/distribution/ of non-promotional information by member Companies.

- **Question & Answer 7**

2. General Principles

2.1 Grounds for relations with Healthcare Professionals and Organizations for patients

Relationship of member-companies with healthcare Professionals and the patient organizations are intended to benefit patients and improve medical practice. Interaction should be focused on informing healthcare Professionals and patient's organizations about pharmaceutical products, providing scientific and educational information, supporting medical researches and education.

2.2 Independence of Healthcare Professionals

Financial or other kind of benefits (including grants, financing of education, funding, support, consulting contracts and with education or practice), must not be offered or provided to healthcare Professionals with a conditions to prescribe, recommend, supply, administrate or consume pharmaceutical product.

It is prohibited any kind of offer or action that would have an inappropriate influence on the medicines prescription done by healthcare professionals.

●Question & Answer 6

2.3 The Appropriate use

Promotion must encourage appropriate use of pharmaceutical product by providing of accurate and non-exaggerated information about product.

2.4 Local Regulation

All companies must get in advance sufficient knowledge of legislation and regulations in Georgia and must follow them before the preparation of promotional materials and events.

2.5 Promotion Transparency

Promotion shouldn't be veiled. Clinical post marketing surveillance and post-authorized studies must not represent disguised promotion. Such studies first of all are to be conducted with scientific and educational aims.

All promotional and non- Promotional Materials sponsored by pharmaceutical company and relating to pharmaceutical products, and its use, should clearly indicate the name of company by whom it has been sponsored.

●Question & Answer 6 , 8

3. Distribution of Information on Medicines before Registration and Off-Label use

Registration and Off-label use

Promotion of unregistered pharmaceutical product is forbidden on the territory of Georgia.
This prohibition is not intended to prevent the right of scientific community and the public to be fully informed concerning scientific and medical progress. Exchange of details on scientific information about pharmaceutical product should not be restricted as well, including the results of research which must be provided in scientific language by media and conferences. Dissemination of information concerning pharmaceutical product to public is not restricted for those who are interested and in case it is required by Law or any regulation.

●Question & Answer 8

4. Standards of Promotional Information

4.1 Sequence/ Matching of Information about Products

Law of Georgia on Drugs and Pharmaceutical Activity defines the format and content of the information to be placed on the product labeling, packaging, leaflets and other printed materials attached to product.

Promotional information should not be inconsistent with information approved by Ministry of Labor, Health and Social Affairs of Georgia.

●Question & Answer 9, 10, 11

4.2 Accuracy of Promotional Information

Promotional information should be clear, legible, accurate, balanced, fair, impartial and sufficiently complete in order to enable the recipient to form his or her own unbiased opinion of the therapeutic values importance of the pharmaceutical product concerned. Promotional information should be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It should not mislead by distortion, exaggeration, undue emphasis, omission or in any other way. Every effort should be made to avoid ambiguity. Absolute or all-embracing claims should be used with caution and only with adequate qualification and substantiation. Descriptions such as "safe" and "no side effects" should generally be avoided and should always be adequately qualified.

●Question & Answer 9,10,11

4.3 Substantiation of Information

Promotional information should be adequately substantiated by the information given in leaflet and approved by Ministry of Labor, Health and Social Affairs of Georgia or by scientific evidence. Such scientific evidence should be available for the Healthcare Professionals upon demand. The companies must respond impartially to requirements concerning information and must present the appropriate details of such requirements.

●Question & Answer 9,10,11

5. Printed Promotional Materials

(Priority is given to the current regulations of Georgia)

5.1. All printed materials including promotional materials

All printed promotional materials with exclusion of those presented in Clause 5.2. should contain the following information:

- name of a product (normally the trade name);

- complete description of active substances, using of approved names if they exist;
- the name and address of the pharmaceutical company or its agent responsible for marketing of the product
- date of production of promotional material;
- „ abbreviated prescribing information" which should include an approved indication or indications for use together with the dosage and methods of use; and a succinct statement of the contraindications, precautions, and side-effects.

5.2 Reminder Printed materials-Leaflet.

A "reminder" printed materials is defined as a short leaflet containing no more than the name of the product and a simple statement of indications to designate the therapeutic category of the product. For "reminder" printed materials, "abbreviated prescribing information" referred to in Article 5.1 above may be omitted.

6. Electronic materials, including Audio-Visuals

The same requirements shall apply to electronic promotional materials, including audiovisuals (TV and Radio stories, video-audio spots and etc) as apply to printed materials. Specifically, in the case of pharmaceutical product related websites:

- identity of a pharmaceutical company and intended audience should be readily apparent;
- the content of information should be appropriate for the intended audience;
- the presentation (content, links, etc.) should be appropriate and apparent to the intended audience.
- the presentation (content, links, etc.) should be appropriate and apparent to the intended audience;
- country-specific information should comply with local laws and regulations

●**Question & Answer 12**

7. Interactions with Healthcare Professionals

7.1 Events

7.1.1 Scientific and Education Objectives

The purpose of all symposiums, congresses and other marketing, scientific and professional meeting organized and sponsored by the pharmaceutical company should be to provide scientific or educational information and/or inform healthcare professionals about products.

7.1.2 Events Including Foreign Travel

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

●Question & Answer 13

7.1.3 Promotional Information at events

Promotional information placed on exhibition stands or disseminated to participants of international scientific congresses or symposiums held in Georgia may refer to the pharmaceutical product which is not registered in Georgia or registered with other indications with consideration to meet the following conditions:

- such meeting should be really international scientific event where considerable portion of those who attend (speakers and participants) visit Georgia as guests;

- all promotional materials, intended for a pharmaceutical product which is not registered in Georgia (with exception of gift promotional materials) should be accompanied by suitable information indicating the countries where this medication is registered and make clear that such product is not available in Georgia.
- Promotional material which refers to the prescribing information (indications, warnings, etc.) authorized in a country or countries other than Georgia, but where the product is also registered, should be accompanied by an explanatory statement indicated that registration conditions differ internationally

7.2. Sponsorships

Member-Companies may sponsor participation of Healthcare Professionals in events with consideration of following requirements:

- the event meets requirements presented in Clause 7.5 of this Code;
- Sponsorship to healthcare professionals is limited to the payment of travel, meals, accommodation and registration fees;
- the healthcare Professionals are not reimbursed for the time spent during their participation in an 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;
- Tickets purchased for transportation of the healthcare professionals for participation in an event should match the dates of holding of a conference. It is allowed to arrive earlier than the date of opening and/or leave later than the fixed date in case it caused by transportation schedule and is proved by authentic document.

7.3. Guests

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

7.4. Fees for services for Speakers and Presenters

The value of compensation paid to speakers should be in conformity with the actual scope of the works done by them (either of a speaker or presenter) based on a document agreed in written with the Company.

Expenses incurred by a speaker (presenter and/or moderator) including transportation and accommodation costs can be reimbursed within reasonable limits in accordance of the event range, location of venue (distance from the place of residence of speaker/ presenter/moderator) the duration of presentation, qualification and academic rank of speaker.

Member-companies of the Association should establish clear procedures for the calculation of service fees volume considering above criteria.

●Question & Answer 14

7.5 Hosting Event

7.5.1 Appropriate Venue

Companies should hold all events in the appropriate venue which will uphold scientific and educational aims and will serve the meeting or the event objectives. The companies should avoid venues mainly considered as place for entertainment events and mass performances.

7.5.2 Limits

Hosting event has to be limited with refreshments and/or meal, incidental to the main purpose of the event can only be provided exclusively to participants of the Event and not for the accompanied persons and must be moderate and reasonable as judged by local standards.

7.5.3. Entertainment

No entertainment or other leisure or social activities should be provided or paid for by member companies

●Question & Answer 15

7.6 Gifts and Items of Medical Utility

Items in this section, where permissible, must not ever constitute an inducement to prescribe, recommend purchase, supply, sell or administer a pharmaceutical product.

●Question & Answer 16,17

7.6.1 Cash

Reimbursement by cash or its equivalent (such is a gift certificate, card or voucher) must not be offered to the healthcare professionals in any manner.

7.6.2. Prohibition of Personal Gifts

Gifts for the personal benefit (such as sporting or entertainment tickets, electronics items, social courtesy gifts, etc.) of HCPs (either directly or through clinics and institutions) are prohibited.

●Question & Answer 18

7.6.3. Items of Medical Utility

Items of medical utility may be offered or provided by member companies if such items are of modest value, do not offset routine business practices and are beneficial to enhancing the provision of medical services and 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.

●Question & Answer 17

7.6.4 Promotional Materials

Promotional materials (non-monetary item given for a promotional purpose) or the product reminder items can be provided or offered to healthcare professionals and administrative stuff.

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

●Question & Answer 16

8. Samples

8.1. Approved Samples

In accordance to the local laws and regulations, free samples of a pharmaceutical products may be supplied to healthcare Professionals in order to enhance quality of medical care. The free sample should be marked as such so that they are not for commercial purpose. It is forbidden to resold or otherwise misuse free samples.

Healthcare Professionals can be supplied with free samples in reasonable qty sufficient for the evaluation of product effectiveness by healthcare Professional.

8.2 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.

9. Support for Continuing Medical Education

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

10. Interactions with Patient Organizations

The pharmaceutical industry and Patients Organizations have a lot of common interests. Any kind of relations with patient organizations should be ethical, rely on ethic norms.

Support to patients organizations may be delivered either by group of pharmaceutical companies or by separate companies independently.

The nature, purpose and content of any funding or service delivered by Company should be described in corresponding documentation.

11. Company Internal Procedures and Responsibilities

The companies should establish appropriate procedures and take appropriate actions ensure their activity and promotional materials are in compliance with relevant codes and applicable laws. Each company should involve an employee with sufficient knowledge and medical qualification, responsible for approval of promotion communication in the company. Such assignment may be fulfilled by a high-rank employee of the Company without medical education with consideration that he/she will receive an appropriate medical advice.

12. Infringement, Complaints, and Enforcement

The Association is ready to review any kind of complaints concerning infringement of the Association Code. Detailed procedures on complaints are presented in the Appendix 1; Operation procedures of the Association Code.

Appendix 1

APCRG's Ethos Operating Procedures

1. Principles

1.1 The Association Code and its operation procedures are applicable to all entities running activity in Georgia

1.2 The Association Code and its operation procedures are applicable to all cases of code infringement done by Association Member and/or non-member company operating in Georgia

1.3 Association shall ensure that its website contains information on codes and its amendments

1.4 In case Association receive type of complaint not described in code operating, the Association will examine such as the complaint.

2. The Procedure for Ethos Complaints

2.1 Use of complaints procedures

After the reception of complaint regarding the probable breach of the Code, the claim should be reviewed first by the Association Board in order to confirm that:

- the complaint describes the case with credibility and is submitted in good faith;
- there are sufficient data to proceed the case (see clause 3.1. below);
- it is not known that the identical breach of code is under the examination in another appropriate body;

In case the Association Board is not able to confirm the complaint it will be rejected and applicant will be notified accordingly.

One complaint can combine several cases (more than one case) for instance complaint may concern several advertising statements made by company regarding different products. Each case will be considered separately by the Association.

2.2 Appeal to the Company

The complaint including any evidence (e.g. copy of an advertisement statement suspected in breaching of the Association Code) accompanied with letter ("letter") must be sent by the Association to local supreme management of the Company concerned within 5 days from the date of complaint reception. The Association retains the right to forward the above mentioned documents to the Company headquarters than it is necessary

2.3 Time Limits

The Letter sent to the Company must indicate the deadline for the feedback regarding the case under review. Normally it is 15 calendar days from receipt of letter by the Company. As an exception, the Association Board may change established time limit.

2.4 Company Response

When the Company recognizes the fact of Code violation, the response should contain information about measures taken or to be taken to remedy the situation. In case of denial of complaints company has to indicate clearly the reason and enclose evidential material where is possible.

2.5Adjudication

When the Company denies the complaints Association takes Decision on the case. Cases are normally decided within 30 calendar days from receipt of company's response. If necessary, Association can ask the complainant or the respondent company for additional information, in which case the timelines may be extended.

Executive Director of the Association presents the complaint to the Association Board. If necessary, external medical and technical expertise/advice can be appointed. The decision is made by simple majority. If the case concerns activities of the company which representative is a member of the Association Board, this member will be eliminated-from decision making process. Temporarily eliminated board member will be replaced by other member of Association appointed by Executive Director.

2.6. Appeal against the Decision

When the respondent company or complainant disagrees with the Association decision and can provide new facts and arguments, a new trial can be requested within 30 days

2.7 Sanctions

If a company is found in breach of the Association Code, the company has 10 working days to stop inappropriate activity and provide written details of the action taken to comply with the ruling the Compliance Statement. The Compliance Statement must be signed or authorized by a senior employee of company and must include the last date on which the activity took place

2.8. Publication of the outcome

Where a breach is ruled a summary of the case will be published on the Association website (Brief–description of the basic facts, identity of the company in breach).

3. Use of the Complaint Procedures

3.1 Submission of Complaints

The complaint must be submitted in writing or by e-mail and include:

- **The complainant details:** complete information about complainant with mailing address for correspondence (phone, fax, e-mail). On the request of the complainant, the identity of complainant, if not from a pharmaceutical company, can be kept confidential to all parties outside the Association Board.

- **Information about Company:** For each case, the identity of the company which is alleged to be in breach of the Association Code and the name of any product or products which are specifically involved information on violations of the relevant article(s) of the code: the complaint should contain specific reference to the part of the Association Code under which the complaint is being made (code article(s));
- **Reference material:** For each case specific reference to the source of the advertisement/activity which is the subject of the complaint.
- **Date:** Date or time period of the alleged breach of the Association Code

All Correspondence should be addressed to:

Association of Pharmaceutical Companies Representatives in Georgia,

Beliashvili 6th floor, Office.1
0159., Tbilisi
Georgia

Phone: +995 32 214 45 10
Fax: +995 32 243 00 69
e-mail : info@apcrg.org.ge

Appendix 2

Questions & Answers

1. Communication with the public

Question: Does the Association Code regulate communications with the public?

Answer: No. The Association Code covers interactions with healthcare professionals and other stakeholders, such as patient organizations. Where direct promotion to the public is allowed, this is covered by local laws, regulations and/or relevant codes of practice. Member companies should of course, comply with these local laws, regulations and/or codes.

2. Code Application

Question: To whom does the Association Code apply?

Answer: The Association Code applies to Association member companies. Pharmaceutical companies that are not members of Association fall outside the reach of the Association Code. Association encourages such companies and other organizations marketing healthcare products or services to healthcare professionals, or those having interactions with healthcare professionals, medical institutions and patient organizations to follow ethical standards for promotion and interactions, similar to those set forth in the Association Code.

3. Disease Awareness Campaigns

Question: why the Association Code doesn't cover public disease awareness campaigns?

Answer: The Association Code covers interactions between pharmaceutical companies and healthcare professionals and the patient organizations and the promotion of pharmaceutical products. A public disease awareness campaign targeted at the public must not promote specific pharmaceutical products. Whilst not covered by the Association Code, disease awareness campaigns must of course comply with local laws, regulations, and/or Self-medication products.

4. Self-Medication Products

Question: Does the Association Code apply to the promotion and marketing of over-the-counter (OTC) products that may also be prescribed by healthcare professionals?

Answer: Yes, the Association Code covers promotion of over the Counter (OTC) products for the healthcare professionals. However promotion of over the Counter (OTC) products to customers falls outside scope this code.

5. **Pricing and terms of Trade**

Question: Does the Association Code Prohibit member companies from offering discounts or other favorable trade conditions for the supply of the Pharmaceutical Product?

Answer: The Association Code doesn't restrict and doesn't regulate commercial conditions of trade for the supply of pharmaceutical products. The Association upholds an ethic competition between the companies.

Question: Does the Association Code concern promotion and marketing of pharmaceutical products to commercial customers who are also practicing healthcare professionals?

Answer: Yes, the Association Code covers promotion and marketing of pharmaceutical products for such as clients, however the Association Code does not restrain and does not regulate commercial trade terms for supply of pharmaceutical products to customers. In any dealing with such as customer should be considered the customer's role as healthcare professional.

Question: Does the Association Code concern promotion and marketing of pharmaceutical products to commercial customers who are not healthcare Professionals? If the customer is the healthcare personnel by qualification, but is not practicing?

Answer: No, The Association Code covers the interactions only with practicing healthcare professionals. The promotion and marketing to commercial customs (despite their medical education) may be regulated by other laws; for instance with the regulations limiting or prohibiting provision of inaccurate, misleading and erroneous information, non-ethical stimulation of public persons and etc.

Question: Does the Association Code cover the price list or other documents describing terms of trade?

Answer: No

Question: Could a false price claim or a misleading price comparison in promotional material be processed under the Association Code?

Answer: Yes, it is possible, when a Company may use information on prices in inappropriate way within its Promotional materials.

6. Consulting Agreements

Question: What is the appropriate way of the implementation of the interactions with healthcare Professionals, providing legal consultation services for company (including participation in clinical trials) if such relations are not regulated by local laws?

Answer: for consultants, providing service to the pharmaceutical companies, may be offered appropriate reimbursement of service, transportation, accommodation and meals costs incurred within the service period. Reimbursement of the healthcare Professionals under false consultation service agreement is not allowed. Authenticity of the provided service is confirmed by following factors (all factors may not be in conformity with some particular service):

- Agreement in writing specification of the service, its duration and grounds for reimbursement;
- Justification of the need of service should be clearly identified prior to service demand and must be agreed with possibly consultants;

- Criteria for selection of consultants should be in conformity with established goal;
- Quantity of the healthcare Professional should be in conformity with reasonable number of persons, required to achieve the established goal;
- A Company should keep records about delivered service and must use the consultants service in appropriate way;
- The goal of healthcare Professional hiring for the appropriate service shouldn't represent stimulation of the condition to prescribe particular pharmaceutical product;
- Then consulting service agreement is signed within framework of the clinical trial, the trial should be held in accordance with ICH-GCP guidelines and should be endorsed by Ministry of Labor, Health and Social Affairs.

7. Non-Promotional Information

Question: what type of non-promotional information is not covered by the Association Code?

Answer: Correspondence, needed to answer a specific question about a particular medicinal product and possibly accompanied by material of a non-promotional nature.

The Code does not cover the general information about the company: such as information directed to investors or to current/prospective employees, including financial data, description of research and development programs and other information of a similar character.

8. Disguised Promotion

Question: is it appropriate for a company to publish a promotion material where the interest and identity of the pharmaceutical company is disguised and appear to be independent editorial content?

Answer: No. Where a company finances or otherwise secures or arranges the publication of promotional material in journals, such promotional material must not resemble independent editorial matter

Question: How does the prohibition of pre-approval promotion affect compassionate use programs?

Answer: Association Code does not prevent compassionate use programs which must of course comply with all applicable laws, regulations and codes. Care should be taken to ensure that communications with healthcare Professionals for a compassionate use program are not, in effect, advertisements for an unlicensed medicine or its use.

9. Compliance of Information

Question: what kind of information should be included on labeling, packaging, leaflets and other Promotional Materials?

Answer: the content and format of information placed on a labeling, packaging and leaflet is regulated by current legislation of Georgia

The companies bear responsibility to provide the essential information on the product (contraindications, warnings, side effects and dosage)

10. Use of Comparison

Question: Does the Association Code restrict comparison of different products in promotional material?

Answer: no, it doesn't restrict. Any comparison made between different pharmaceutical products should concern the appropriate and comparative features of products and must be evidential. Comparative promotion must not be misleading.

11. Use of Quotations

Question: Does the Association Code limit use of quotations in promotion material?

Answer: Quotations from the medical and the scientific literature or out of personal communications should be set in the promotional materials in honest way, in case of changes of their content should be clearly mentioned that the quotation has been adapted or modified and

precise sources must be identified. Quotations should not change or distort the intended meaning of the author of the significance of the underlying work or study

12. Reprints

Question: Does the Association Code consider reprints as a promotional material?

Answer: The reprints of the scientific and medical articles when used as stand-alone documents, are not developed by the pharmaceutical companies and cannot be considered as promotional material. If reprints are provided to healthcare Professionals together with company originated documents, it is considered as the promotional material. In any case if the promotion is linked with scientific-medical articles or studies it is required to provide clear reference. Reprints of any artworks taken from articles or studies (including graphics, illustrations, photographs and tables) and its presentation together with promotional material is possible when the source of the artworks is clearly indicated.

13. Events involving foreign travel

Question: When is it appropriate and justified for a company to organize or sponsor an event for healthcare Professionals outside of Georgia?

Answer: A company can only organize or sponsor events involving travel if it is justified, i.e.:

a) A significant proportion of the invited healthcare Professionals are not residents of Georgia and it make greater logistical or security sense to hold the event in another country

b) In exceptional circumstances where the relevant resource or expertise that is the object or subject matter of the event is located outside of Georgia

14. Fees for service for Speakers and– Presenters

Question: What is the maximum value may be offered on event to speaker (moderator) as a service fee?

Answer: Considering all criteria listed on 7,4 the service fee amount ranges from 200 to 1500 GEL (from 100 up to 700 USD) (excluding tax). This conditions are not applicable for foreign speakers and moderators and for speakers and moderators who are citizens of Georgia and are invited to provide service abroad.

15. Entertainment

Question: The APCRG Code prohibits companies from providing entertainment, leisure and social activities to HCPs and other stakeholders. Are there exceptions to this rule?

Answer: No. It would not be appropriate for a company to fund attendance at a concert, purchase of entertainment tickets or pay for entertainment in any form.

16. Promotional Aids

Question: Which items are allowed to be used as a promotional aid (applicable for OTC medicines only)?

Answer: The promotional material should be of minimal value (should not exceed 45 GEL for one ime supply and 90 GEL per year) and should be in relevant to the practice of the healthcare professionals. Possible examples: pen, notebook, they must not bear the name of any medicine but may bear the name of the company providing them.

These conditions are not applicable to scientific-medical literature (printed or digital) offered for the healthcare professionals for continues medical education purposes.

It is unacceptable to provide promotional materials for the personal benefit of healthcare professionals, e.g. musical CD, painting, teapot or similar items.

17. Items of Medical Utility

Question: What are examples of items of medical utility which offset business practices?

Answer: Items such as stethoscopes, surgical gloves, blood pressure monitors and needles are examples of routine business expenses, and they are expected to be supplied by the HCPs themselves or their employers.

18. Prohibition of Personal Gifts

Question: Are Cultural Kind-Hearted Gifts to HCP s allowed? (Gifts having even minimum value -lowers, confection, for the important, national, cultural and religious holiday)

Answer: No, Cultural Kind-Hearted Gifts to HCP s are prohibited as all other types of personal gifts