Pharma Group, European Chamber of Commerce in Vietnam

Pharma Group Code of Ethical Practices

Adopted on 1 January 2014;

Amended for the first time by the Pharma Group General Assembly on 27 January 2016, effective 1 June 2016
Amended for the second time by the Pharma Group General Assembly on 6 December 2018, effective 1 January 2019
Amended for the third time by the Pharma Group General Assembly on 7 August 2020, effective 1 October 2020

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1. PREAMBLE

1.1 The Pharma Group ("PG") is a non-profit, non-governmental group, and setup as a sector committee of the European Chamber of Commerce in Vietnam (EuroCham). PG members ("PG members") represent European as well as non-European multinational research-based pharmaceutical companies and their partners in Vietnam. PG members are committed to the ethical standards set out in this Code of Ethical Practices ("Code").

1.2 The ethical promotion (also referred to as "Promotion" in the context of this code) of medicines is vital to the pharmaceutical industry's mission of helping patients by discovering, developing and marketing innovative and high-quality medicines. Ethical promotion helps to ensure that healthcare professionals ("HCP") have access to the information they need, that patients have access to the medicines they need and that medicines are prescribed and used in a manner that provides maximum healthcare benefits to patients, to the extent allowed by Vietnamese laws.

1.3 PG members are committed to educational and promotional efforts that benefit patients; continuous medical education for healthcare professionals, promotional programs and collaborations that enhance the practice of medicine. PG members also seek to preserve the independence of the decisions taken by HCP in prescribing medicines to patients. The pharmaceutical industry has an obligation and responsibility to provide accurate information and education about its products to HCP in order to establish a clear understanding of the appropriate use of medicines. PG members' relationships with HCP must support and be consistent with the professional responsibilities HCP have towards their patients. PG members must maintain high ethical standards when conducting promotional activities and comply with applicable legal, regulatory and professional requirements. Through the promotion of this Code, PG members seek to ensure that ethical promotional practices are established nationwide.

1.4 This Code sets forth standards for the ethical promotion of medicines to HCP, and for PG members' interactions with HCP and medical institutions. This Code applies to all PG members, effective on 1 October 2020 and replaces the previous version of the Code (version amended for the second time by the Pharma Group General Assembly on 6 December 2018, effective 1 January 2019).

1.5 PG members commit to adhere strictly to all laws and their implementing regulations relevant to the healthcare and pharmaceutical industry of Vietnam ("Laws"). The main purpose of this Code is to give guidance to PG members and their employees and to define high level ethical and professional standards which PG members commit themselves to follow. This Code does not aim to replace or override any Laws. The content of this Code has been checked to ensure that it is compatible with the International Federation of Pharmaceutical Manufacturers' Association ("IFPMA") Code of Practice and applicable Laws related to pharmaceutical marketing practices. However, this Code does not constitute legal advice and does not replace member companies' internal regulations. Besides committing themselves to follow the guidance given in this Code, PG members take their own responsibility to ensure strict adherence to any applicable law and regulations and to set their own company internal guidelines.

1.6 To the extent that the activities contained within this code are permissible under local law, the PG members will act according to the standards documented. Even when certain activities are not directly performed by PG members, instead they are performed by third parties on behalf of PG members, they still should be according to the standards documented herein.

1.7 This Code contains provisions relating to scope, applicability and general principles; the content of medical information and promotional materials, the role of medical representatives, interactions with HCP through symposia and congresses; printed, audio visual and electronic, promotional or advertising material; sample; market research; communication with the public and mass media; and operation and enforcement of the Code. It also includes a Q&A section to assist in interpretation of the Code and details the operating procedures for Code complaints.

1.8 PG member companies are accountable for addressing and correcting infringements of the Code. They must also ensure that internal structures and procedures (including adequate training of employees) are created to ensure responsible and ethical promotional activities.

1.9 The PG is open to receive genuine complaints from any source on any aspect of the Code, in accordance with its operating procedures. Where there has been a breach of the Code, the objective is to correct the matters as rapidly as possible.

2. SCOPE

2.1 This Code applies to all PG members and all employees (whether indefinite term, definite term or seasonal labor contracts) as well as third party agencies representing the interest of PG member companies.

2.2 This Code is applicable to medicines, as defined in Article 3.2.

2.3 This Code regulates activities undertaken, organized or sponsored by PG members which are directed to HCP to promote the prescription, recommendation, supply, administration or consumption of its medicines through whatever medium or communication channel.

2.4 This Code does not seek to regulate the following activities:

- Promotion of food supplement and nutritional products;
- Promotion of cosmetics;
- Promotion of medical equipment;
- Promotion of products other than medicine (as defined in article 3.2.)
- Pricing or other trade terms for the supply of pharmaceutical products.

2.5 Interaction with Government officials: This Code applies to all interactions with Government Officials (as defined by Vietnamese laws). Such interactions must comply with Vietnamese laws and international anti-bribery standards.

3. DEFINITIONS

3.1 **"Promotion"** refers to the informational and marketing activities undertaken, organized or sponsored by a pharmaceutical company, through whatever medium or channel, with the objective to provide information to HCP about their medicine, its appropriate use and scientific information, and to support medical research and education. Promotion does not refer to trade activities such as trade events and/or trade promotion activities under Vietnamese law.

3.2 **"Medicine", "Product"** means a substance or combination of substances used for humans for the purpose of preventing, treating or diagnosing illness and for correcting physiological or physical functions. Medicine includes finished products, raw materials used to manufacture medicines, vaccines and biological products, but excludes foodstuffs and traditional medicines.

3.3 **"HCP"** (healthcare professional) refers to individuals who in the course of their professional activities are authorized to or may recommend, prescribe, purchase, supply, administer or dispense medicines or who may influence the purchase, supply or use of medicines, including but not limited to doctors, dentists, nurses, midwives, reproductive healthcare providers, pharmacists, pharmacy assistants, hospital management, primary care managers, members of formulary committees and payer bodies such as staff in health appraisal agencies, reimbursement bodies, pricing bodies and sick funds. Pharmacies' sellers/ owners are considered as HCPs in promotional and scientific activities/ events. Trade events are not covered by this Code.

3.4 "**Medical institution**" refers to a licensed organization that is comprised of HCPs and/or that provides healthcare services or conducts healthcare research.

3.5 **"Medical representative"** means a qualified person as defined by Vietnamese laws, to introduce medicines to HCP.

3.6 **"Events"** means all types of scientific congress, conferences, symposia, meetings or any type of similar activity, including but not limited to expert meetings, roundtable meetings, training meetings, etc. organized or sponsored by a pharmaceutical company.

3.6 "**Donations**" are non–refundable aid provided for not-for-profit purposes by donors to achieve development and humanitarian objectives.

3.7 "**Items of medical utility**" are medical items to enhance the provision of medical services and patient care "Informational or educational items that enhance Patient Care" are items for education to HCP or for them to educate their patients.

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3.8 . **"Promotional aids**" is a non-monetary item given for a promotional purpose (which does not include promotional materials as described in Section 7 & 8 of this Code).

3.9 . **"MOH"** means the Ministry of Health of Vietnam.

4. GENERAL PRINCIPLES

4.1 Laws and Codes

PG members must observe all applicable Laws, provisions of this Code as well as other relevant industry codes, and are responsible for establishing and maintaining appropriate procedures to ensure full compliance, and to regularly review, monitor, and adjust if necessary the planning, implementation and materials of their promotions and events.

4.2 Basis of Interaction

PG members' relationships with HCP are intended to benefit patients and to enhance the practice of medicine. Interactions must be focused on informing HCP about products and their appropriate use, on providing scientific information and/or on supporting medical research and education.

4.3 Independence of HCP

No financial benefit or benefit-in-kind (including grants, scholarships, subsidies, supports, consulting contracts or education or practice related items) may be provided or offered to a HCP that inappropriately influences prescribing, recommending, purchasing, supplying or administering medicines or for a commitment to continue to do so (i.e. no quid pro quo).

PG members must ensure that all their employees are adequately trained and possess sufficient medical and technical knowledge to present information on their company's products in an accurate, responsible and ethical manner. They must also feedback to their company information received on the use of products and particularly reports of side effects.

4.4 Appropriate Use

Promotion should encourage the appropriate use of medicines by presenting them objectively and accurately.

4.5 Transparency of Promotion

Promotion must not be disguised as another activity. Clinical assessments, post-marketing surveillance and post-authorization studies must not be promotional activities in disguise. Such assessments, programs and studies must be conducted with a primarily scientific or educational purpose. Material relating to pharmaceutical products and their uses, whether promotional in nature or not, which is sponsored by a company, must clearly indicate by whom it has been sponsored.

4.6 Pre-Approval Communications and Off-Label Use

No off-label use for a medicine must be promoted in Vietnam until the requisite approval for marketing such use has been given by the MOH. This provision is not intended to prevent the right of the scientific community and the public to be fully informed about scientific and medical progress. It is not intended to restrict a full and proper exchange of scientific information concerning a pharmaceutical product, including appropriate dissemination of investigational findings in scientific or lay communications media and at scientific conferences. Nor should it restrict public disclosure of information to stockholders and others concerning any medicine as may be required or desirable under the applicable Laws.

4.7 Implementation

This Code is to be applied in the spirit as well as in the letter.

5. MEDICAL INFORMATION AND CLAIMS

5.1 General Criteria

Information and claims for pharmaceutical products must be true, accurate, clear and objective, as substantiated by scientific evidence.

Such information and claims must be presented with a high ethical standard, in compliance with the latest product information approved by the MOH, and in such a way as not to be misleading or ambiguous.

5.2 Scientific Evidence

The scientific evidence must be based on proven scientific data, fully available, referenced and traceable, and scientifically valid. In-vitro and animal test data must be clearly marked as such, in order not to give an incorrect or misleading impression.

5.3 Requests for information

Companies must handle requests for information from HCP ethically and with objectivity by providing information that is true, accurate, clear and objective.

5.4 Safety Data

Information on product safety, as well as contra-indications, warnings and side effects must conform to those approved by the MOH. Descriptions such as “safe”, “harmless”, “no contra-indications”, and “no side effects” are prohibited. All PG members must report adverse drug reactions associated with their products in accordance with applicable Laws.

5.5 Incorrect or Misleading Claims

Information, promotional claims, supporting data, and audio, graphic or other visual presentations must not be directly or indirectly misleading by omission of certain parts or by the distortion of evidence or expert opinion.

5.6 Unqualified Superlative Claims and Hanging Comparative Claims

Making unqualified superlative claims (e.g. “Product X is the best treatment for condition Y.”) or making comparative claims, hanging (e.g. “Product X is better/stronger/faster/safer for condition Y”) or non-hanging (e.g. “Product X is better/stronger/faster/safer than Product Z for condition Y”), is prohibited.

5.7 Comparison

Comparison between one product with another competitor product is not allowed. Comparison between two substances by way of clinical trial data graphs which are used in the presentation or in the promotional materials to HCP are subject to the approval of the MOH.

Companies may incorporate a comparison between their products and counterfeits or intellectual property right-infringing products after obtaining the regulatory authorities' certification that such counterfeit or intellectual property right-infringing products are used for comparison.

5.8 Imitation or Copying of Materials

A PG member must not imitate or copy other companies' promotional or advertising materials, such as imitating or copying logos and slogans, or layouts adopted by any other company.

5.9 HCP in Promotion Materials

Names or photographs of HCP or examination and treatment establishments must not be used in medicine promotional or advertising materials.

It is, however, acceptable to use such names and photographs in proceedings of events, if it is permitted by the HCP or the examination and treatment establishment (e.g. brochures, invitations, etc., for an event in which the HCP is identified).

5.10 Hidden Promotion/Advertising

Promotional materials, such as mailings and medical journal advertisements, must be clearly marked as such so that its real nature is not disguised, e.g. advertisements in journals which are part of the editorial should be marked as "PROMOTIONAL ADVERTISEMENT" or "ADVERTORIAL" in capital letters of the largest pitch used in the body text of the advertisement.

Company name, logo, tagline of the company are allowed to be printed on Promotional Aids. Product-specific and/or franchise-specific promotional message are not allowed to be printed on Promotional Aids.

6. PRODUCT INFORMATION TO HCP IN MEDICAL JOURNALS

6.1 The contents of the product information and/or product advertising provided to HCP must satisfy the requirements of the drug information and advertisement regulations issued by the MOH.

6.2 It must conform, both in text and illustration, to standards of good taste and should recognize the professional standing of the HCP recipients.

6.3 The requirements in Section 5 and this Section 6 apply also to advertisements in MIMS and other similar references.

7. PRINTED PROMOTIONAL MATERIALS

7.1 General

This section defines printed material directed to HCP. Printed material must be presented in a legible manner. Information and claims for pharmaceutical products must be true, accurate, clear and objective, as substantiated by scientific evidence. Information and claims must also be presented with a high ethical standard, in compliance with the MOH authorized product information, and in such a way that is not misleading or ambiguous.

7.2 Contents of Product Information

The contents of the product information provided to HCP must satisfy the requirements of the drug information and advertisement regulation issued by the MOH.

7.3 References/Quotations

Promotional materials or other materials containing information in the form of abstracts or quotations derived from other authors or sources must include clear and traceable references, and

must not be modified or distorted so as to mislead, confuse or alter the intended meaning of the author. Any reproduction or translation must have the formal authorization of the author in those cases where the information is not publicly available.

7.4 Mail, Faxes, Email and Text Messages

Communications must comply with all relevant provisions of the Code. Communications must be sent only to HCP if it can be reasonably assumed that HCP would need or have an interest in this particular information. In order to control the information given to HCP, HCP contact details have to be kept confidential and HCP has the right to demand removal of his or her contact details from distribution lists. When managing distribution lists/ contact details, data privacy must be considered, laws must be observed.

Requests to be removed from mailing lists must be complied with promptly, and no name should be restored except upon specific request or with written permission. Mailing lists must be kept up-to-date.

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

8. ELECTRONIC PROMOTIONAL MATERIALS

8.1 All requirements for printed materials also apply to other materials, regardless of the medium used for communication

8.2 For electronic, interactive, or audio-visual materials or systems, product information must be provided either by a document included in the packaging materials, or by including the information directly in the recording or system. When audio-visual presentations are made, full product information must be available and provided to any HCP who requires a copy.

8.3 Any communication through websites has to be in line with applicable MOH regulations. For communication through websites, following guidelines must be observed:

- All information must comply with the applicable Laws and be consistent with the product information as approved by the MOH.
- Each page or item must identify the author and the date of last update.
- The identity of the pharmaceutical company, initiating or supporting the websites, must be clearly visible.
- The intended audience must be clear and the information must be appropriate for such audience.
- Content intended for the public must be clearly separated from content intended for HCP. In addition, measures must be taken to ensure that the product information for HCP is only accessible to HCP (e.g., via the use of passwords).
- There must not be links to other websites without the permission of the respective website owner.
- PG members must conduct regular reviews of web content and have an appropriate contract in place with website providers to ensure that they can exert appropriate control over the websites.

9. MEDICAL REPRESENTATIVES

9.1 Medical representatives must be adequately trained, must possess sufficient medical and technical knowledge, and must be qualified to present information on the PG members' products in an accurate and objective manner, with a high ethical standard, in compliance with the latest

product information approved by the MOH, and in such a way as not to be misleading or ambiguous.

9.2 Medical representatives must at all times maintain a high standard of ethical conduct in the discharge of their duties. They are required to be instructed in and to possess a copy of the Code. Furthermore, they must be aware of and comply with any applicable Laws.

9.3 Medical representatives must not employ any inducement or subterfuge to gain a call; neither should any fee be paid for that purpose. Registration or administration fees for participation in hospital meetings or group presentations in hospitals are allowed. Such registration fees must be paid directly to the official account of the organizing hospital.

9.4 PG members have the responsibility to ensure that the medical representatives have adequate training on a regular basis to provide product information. PG members are also responsible for correcting breaches of this Code by the medical representatives.

9.5 The system of remuneration of medical representatives must not encourage unethical behavior and must not adversely influence the proper prescription and usage of medicines.

10. SAMPLES

10.1 PG members are prohibited from giving samples to HCP, except for (i) samples for tender as requested by the hospitals, or (ii) samples of vaccines and biological products for the purpose of quality safety testing by the National Institution for Control of Vaccines and Biologicals before circulation in the market, or (iii) other requests by the health authorities.

11. GIFTS, PROMOTIONAL AIDS, ITEMS OF MEDICAL UTILITY AND INFORMATIONAL OR EDUCATIONAL ITEMS THAT ENHANCE PATIENT CARE

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

11.1 Prohibition of gifts and/or any items of value and/or services for personal benefit

Gifts (examples include but not limited to sporting or entertainment tickets, sight-seeing travels including sight-seeing travels in conjunction with events, electronic items, social courtesy gifts, wreaths etc.) provided to HCP, medical institutions, Government officials (either directly or indirectly) are prohibited. Providing or offering cash, cash equivalents or personal services is also prohibited. For these purposes, personal services are any type of service unrelated to the HCP's or Government official's profession and that confer a personal benefit to the HCP or Government official.

11.2 Promotional aids

Prescription-only medicines:

- Providing or offering promotional aids to HCPs in relation to the promotion of prescription-only medicines is prohibited.
- For prescription-only medicines, only pens, notepads (may only show the company name, logo and/or tagline of the company) for the purpose of taking notes during the event, and blank bags (without any company or product branding) can be provided to HCPs in the context of company organized events as long as they are of minimal total value per attendant (not exceeding VND 100,000) and only the necessary quantity are distributed.

Over-the-counter medicines:

- Promotional aids of nominal value (not exceeding VND100,000) and minimal quantity, and are not formative of a quid pro quo arrangement, may be provided or offered to HCPs solely for the promotion of over-the-counter medicines if relevant to the practice of the HCP. Such promotional aids may only show the company name, logo and/or tagline of the company.
- Product-specific and/or franchise-specific promotional message are not allowed to be printed on promotional aids.

11.3 Items of Medical Utility, Informational and Educational items that enhance Patient Care

Items of medical utility:

- Items of medical utility may be offered or provided by member companies to HCP if such items are of modest value (no independent value and not for personal benefit), do not offset routine business practices, are directly beneficial to enhancing the provision of medical services and patient care, and in line with Vietnamese laws.
- Items of medical utility should be given to HCP on an occasional basis only, 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, and in line with Vietnamese laws.

Informational and educational items that enhance Patient Care:

- Informational and educational items that enhance Patient Care provided to HCPs for their education or for the education of patients on disease and its treatments may be offered by member companies provided that the items are primarily for educational purposes and do not have independent value.
- These informational and educational items 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.

The total value for items of medical utility, informational and educational items that enhance Patient Care given to HCP must be less than VND 2,000,000 per HCP per year (cumulative).

Items of medical utility, informational and educational items that enhance Patient Care must never be given to HCP or medical institutions, organizations or associations for the personal benefit of the HCP or to influence the recommendation, prescription, purchase or usage of medicines and must never be formative of a quid pro quo arrangement..

12. HOSPITALITY AND EVENTS

12.1 General principles

i. The purpose and focus of an event for HCPs organized or sponsored by a PG member must be to inform HCP about products and/or to provide scientific or educational information. PG members must not organize or sponsor recreational events such as tours, sports, leisure activities, year-end parties for medical institutions, anniversary events of medical institutions etc. PG members are prohibited from offering any kind of compensation to HCP for participation in the events.

ii. PG members must not deliberately interfere, undermine, or improperly attend an event organized or sponsored by another PG member.

iii. The participation or the type of involvement (e.g. organizer or sponsor) of a PG member in an event must be declared clearly during the event and in any printed proceedings from the event.

iv. Any materials handed out during or after the event should be in line with sections on medical information and claims.

v. If the event is organized and initiated by a medical association or another professional organization, then that organization is responsible for the program content (including but not limited to obtaining approval for the content with relevant authorities) as the registrant and organizer of the event in line with Vietnamese laws and subject to Article 12.1 (vi). Any support from the pharmaceutical industry must be sufficiently stated or disclosed.

vi. For an event for HCPs as described in this Code, co-organised or organised by a medical association or another professional organization, where a PG member is effectively the sole industry sponsor, this PG member must ensure, and be able to demonstrate reasonable, transparent and documented efforts of such PG member to ensure, that ethical standards set forth in this Code are applied.

- This principle is applicable, but not limited to: event location, program content, materials, display(s), communication, speakers and participants.
- The PG member, who is effectively the sole industry sponsor of the event, is responsible to ensure that the program content is represented in accordance with Article 5 and Article 4.6 of this Code.
- The PG member, who is effectively the sole industry sponsor of the event, assumes responsibility in case a breach of the Code occurs, and it fails to demonstrate reasonable, transparent and documented efforts of such PG member to prevent such from happening.

12.2 Event location

- PG members must not organize or sponsor HCP to attend events that take place outside of their home country unless it is appropriate and justified to do so from a logistical or security point of view. PG members can organize or sponsor HCP to attend international events, as these derive participants from many countries in this case the host country regulations and standards can be applied, unless otherwise provided by Vietnamese Laws.
- All events organized or sponsored by PG members must be held in an appropriate venue that is conducive to the scientific or educational objectives of the event. PG members must not organize or fund events at extravagant or luxury venues or at places which are associated by the public primarily with sport, luxury, exclusivity or entertainment/ recreational attraction/ gaming location or leisure facilities (e.g. golf clubs, karaoke, bars, beer restaurant) and the venue location should be easily accessible to all event participants, taking into account the residential locations of the origin of HCPs/participants.

12.3 Sponsorship to individual HCP to attend events

- PG members can organize or sponsor HCPs (either directly to HCPs or through their organization) to attend in-country events or international events, provided that such international events derive participants from many countries. Any sponsorship for HCPs to attend such events must not be conditional upon an obligation to promote, recommend, prescribe or purchase, supply or administer any pharmaceutical product. Such sponsorship must:

  - Always be in line with the primary purpose of enhancement of scientific and medical knowledge, through obtaining information that is critical to the improvement of patient care and overall enhancement of healthcare delivery, and such sponsorship must be supported by written documentation;

- Avoid any conflict of interest as stipulated in relevant Vietnamese laws and conform to the internal regulations of the HCP's organisation; and
- Comply with this Code and applicable laws.

- PG member's sponsorship for HCPs to attend events must be subject to the following conditions:
  - The sponsorship must have legitimate scientific and medical knowledge enhancement purpose, and strictly follow applicable Vietnamese laws;
  - PG member must inform the HCP's organization and ensure full transparency about invitation or sponsorship for HCPs to attend events, including details of the sponsorship and the agenda of the event; and
  - The event program must not include standalone entertainment, sight-seeing or side trips, or other inappropriate activities or located at an inappropriate venue.
- PG member's sponsorship for HCPs to attend events must comply with the following requirements:
  - The selection of HCPs must be based on the expected added value of the event for their area of expertise, following a fair selection process and not give any potential appearance of inappropriateness or bias, and avoid any issue of conflict of interest. PG member must ensure that the HCPs have obtained the official permission from their organization to attend the event;
  - Transportation and accommodation should be provided as per reasonable standards considering the nature and venue of the event and the level of involvement of the HCPs. For example, business class tickets for local travel, luxurious or extravagant accommodation must not be provided. Sponsorship to stand-alone entertainment, sight-seeing or side trips or other leisure or social activities are not allowed. There must be a reasonable and justified timeframe for the departure and return of the HCPs to and from the event location;
  - Hospitality provided to the HCPs must be limited to refreshments and/or meals incidental to the main purpose of the event and its value must be moderate and reasonable as judged by local standards. Alcohol drinks are not allowed during the event lunch. Refreshment during dinner can have alcohol drinks, with reasonable limit. Applicable laws must be respected;
  - Companies must not pay any costs associated with individuals accompanying the HCP, except in cases of medical necessity. HCPs can have accompanying individuals with them at their own expense, but PG members will not involve in logistic arrangement for accompanying people. Accompanying people (except in cases of medical necessity) should not be allowed to attend any event for HCPs;
  - All sponsorship arrangements must be appropriately documented before and after the event.

  Specifically regarding sponsorship for HCPs to attend international events, there must be commitment from HCPs who attend the event to share the benefit of knowledge gained on their return to Vietnam, such as through presentation to other HCPs (no honorarium shall be provided) or a report to their organization or other academic/medical institution.

12.4 Exhibitions Stands and Quiz

- Exhibitions, hospitality booths, stalls, counters, etc., must be secondary to and not detract from the scientific objectives of the event. Exhibitions are to be organized solely for the purpose of HCP to gain scientific information related to the topics of the event. The name of the company/exhibitor must be clearly visible and the exhibitions must comply with the provisions as set by organizing committee.
- Quizzes linked to product information and conducted during scientific events are allowed.

The quiz prizes are limited to promotional aids which are defined and described in Article 11.2 (for OTC product only). Lucky draw in events for HCPs are not allowed.

13. HONORARIUMS FOR SERVICES PROVIDED BY HCP

13.1 HCPs 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, translating medical documents, interpretation at medical meetings, writing a medical article and/or giving medical training, and participating in market research, where such participation/services, involves honorariums. Such services are not constituted as gifts as defined in this Code.

13.2 The arrangements covering legitimate provisions of such services must meet the following conditions:

i. The engagement does not interfere with the interest of the HCPs employer and the employer has no objection against the engagement;

ii. A written contract with the engaged HCP is put in place which specifies the nature of the services to be provided and the basis for payment of those services;

iii. Payment to HCP service providers must be based on market criteria and be proportionate to the time devoted, the work done and the responsibilities assumed and must be adequately documented. Payments of service fees must not be made in advance. Cash payment is prohibited;

iv. Only engage HCP service providers where there is a legitimate need for their services clearly identified and documented in advance: and the criteria for selecting consultants must be directly related to the identified need; 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 compensation for the services must be reasonable and reflect the fair market value.

13.3 The amount of the honorarium for local speakers/moderators at local meetings should be at fair market value. The honorarium for foreign speakers at local meetings or local speakers at international meetings should be at the level of normal practice in the speaker's home country.

14. MARKET RESEARCH

14.1 The sole purpose of these activities must be to collect data and not be a means to promote to and/or reward HCP.

14.2 Market research must rely on scientific research methodologies, such as sampling, data collection and analysis techniques, and not on methods which risk discrediting or reducing confidence in the pharmaceutical industry. The following provisions apply whether the research is carried out directly by the company concerned or by an organization acting on the company's behalf.

14.3 Market research must not be used as a disguised form of sales promotion, and in itself, the research must not have a direct objective of influencing the opinions of the informant. The research design should be done in such a way that the data is unbiased and non-promotional.

14.4 The identity of an informant must be kept confidential, unless he/she has specifically agreed otherwise. In the absence of this agreement, it follows that the information provided (as distinct from the overall results of the research) must not be used as the basis upon which a subsequent approach is made to that informant for the purpose of sales promotion.

14.5 Precautions should be taken to ensure that informants do not suffer as the result of embarrassment following an interview, or from any subsequent communication concerning the research project. Fees for research respondents should be modest and in proportion with the work involved.

15. POST MARKETING SURVEILLANCE

15.1 Post marketing surveillance ("PMS") for approved medicines are important to ensure their rational use. Such assessments, programs and studies must be conducted with a primarily scientific or educational purpose.

15.2 PMS studies must not be misused as a disguised form of promotion.

15.3 Substantiated information on serious hazards or adverse events associated with medicines must be reported to the appropriate authority as required by applicable regulations

16. RELATION WITH NON-HCP/PUBLIC

16.1 Prescription medicines must not be advertised to the general public. This prohibition does not apply to public health activities done in cooperation with medical associations, such as disease awareness, or vaccination campaigns, provided that the product name is not mentioned and the campaign is approved by the MOH

PG members may support public disease awareness campaigns by providing a grant or sponsorship or partnership with an appropriate medical association. Such disease awareness campaigns should not be misused as any forms of disguised promotion. Patient information should carry the advice "Please consult your physician". Company addresses and telephone numbers should not be part of the information given to the public. An acknowledgement of company sponsorship must be included, but should be limited to an appropriate statement with the company name and logo.

16.2 For prescription products, it is not permitted to link HCP-directed promotional materials to public disease awareness campaign materials.

16.3 PG members must not answer requests from individual members of the public for advice on personal medical matters. Enquirers must be referred to their personal physicians. This includes toll-free information services. Medical representatives must never discuss medical matters with patients in any forum, including health fairs, pharmacies, hospitals, and physicians' waiting rooms, even if approached directly by a patient, nor may they instruct patients on how to use company products. Patients must be advised to seek advice directly from their physician, who, in turn, may contact PG members for further information. Disease awareness campaigns or patient education programs can be supported by PG members by providing a grant to a competent medical association which is authorized to conduct such campaigns.

16.4 PG members may support the work of independent patient associations but must ensure that their involvement has been declared and is transparent, that all of the arrangements comply with this Code and applicable Laws, and that a written agreement is in place. PG members must not influence the operation of the funded patient associations. The independence of this association must be fully kept.

16.5 Written agreements must be in place and clearly stipulate the nature and intended duration of the relationship and every significant activity or on-going relationship with these organizations.

16.6 Patient support programs for patients using company products must be structured in such a way that they are consistent with the requirements of this Code and applicable Laws. Patient support programs must only be administered with the participation of HCP involved in the treatment of appropriate patients and each program. PG companies must never contact patients directly and have to fully respect confidentiality of patient data.

16.7 PG members can invite patients to have a talk in Company's events, with written consent from patients obtained in advance. The talk should be done for internal purpose only and should not be used for promotional intention. Photo and recording of the talk should get the permission from the patients in advance.

17. DONATIONS

17.1 Donations as specified in article 3.6, must entail a benefit for patients, examination and treatment establishments, or social organizations and/or public interest. Donation can be given as, but not limited to, financial and non-financial support. Nothing may be offered or provided in a manner or on conditions that would lead to inappropriate advantages for PG members.

17.2 Donations are prohibited to be given directly to individuals.

17.3 No donations must be given in return for products purchased or product standardization, prescriptions or the use of a company's product(s) at examination and treatment establishments or social organizations.

17.4 Donations must be in written agreement with examination and treatment establishments, public hospital and non-profit organization. It must be clearly stipulated that the donation recipients have to (i) follow the procedures for the preparation, evaluation and approval of the foreign non-governmental aid amount in compliance with applicable regulations; and must (ii) manage and use the donation only for humanitarian objectives in accordance with its commitments in the agreement and to not use the donation for any other purposes.

17.5 Donations must be transparent, documented and tracked. Donated items or services must have clear and obvious benefits on patient care or for communities. Such items or services must be appropriate and fit for the purpose specified and must not carry product or therapeutic area branding. Donations should be defined clearly on the amount and frequency.

18. TRADE PROMOTION

18.1 This Code does not restrain or regulate commercial trade terms and/or trade promotion activities in accordance with Vietnamese law_for the supply of medicines. The PG encourages healthy competition among companies.

18.2 Trade promotion must be in line with applicable Laws and must not be misused as a tool to influence the prescription of drugs, e.g. switching of prescriptions.

19. ADMINISTRATION AND COMPLAINTS PROCEDURE OF THIS CODE

19.1 Ethical Committee ("EC")

The EC shall comprise five members of which:

- one member shall be a representative from EuroCham or a business association in Vietnam; and
- four members shall be PG's Member Representatives, as defined in the PG Bylaws, amongst whom one must be the PG Chairperson. For clarity, only PG's Member Representatives with voting rights, as defined by the PG Bylaws, can be elected to the EC.

The EC members are elected on an annual basis by the PG General Assembly; in case there is no nomination from the PG General Assembly, the nominations to the EC will be nominated by the PG Board. The EC, once elected by the PG General Assembly, elects its Chairperson (the "EC Chairperson") amongst EC members.

The EC will have two back-up members who will be elected on an annual basis by the PG General Assembly; in case there is no nomination from the PG General Assembly, EC back-up members will be nominated by the PG Board. Unless otherwise agreed by the EC, for any meeting or discussion of the EC, the EC must invite PG's legal counsel to attend. PG's legal counsel's opinion is only for reference by the EC but will not be deemed as a vote on the subject matter.

Any decision of the EC on a matter shall be made if approved at a meeting or in writing by a simple majority of the members of the EC eligible to vote in relation to such matter.

19.2 Review of the Code

This Code must be reviewed at least every three years. After three years, the EC must perform a full review of this Code and propose amendments to the General Assembly of the PG. The General Assembly will then vote on the new revision of this Code.

At any time, the PG Board, based on input from any PG member, or change in applicable Laws, can decide to initiate a revision of this Code. The revision will subsequently be carried out by the EC and proposed to the General Assembly of the PG for voting.

19.3. Complaints and Procedures

The EC shall be responsible and have authority to handle and resolve complaints of PG members and non-PG members, e.g., the health authorities, HCP, professional organizations, patients or patient groups (each "Complainant") related to the involvement of PG members in breaches of this Code submitted to the EC in accordance with this Code (a "Complaint"). The scope of authority of the EC in considering a Complaint shall be limited to determining, in line with the provisions of this Code, whether there has been a breach of this Code by a PG member and if any the consequences of any such breach.

The review, acceptance or rejection and adjudication (including any initiation of dialogue) by, and any decision of, the EC on any Complaint shall not be deemed or interpreted as a judicial, arbitration, conciliation or otherwise legal proceeding of any sort.

An elected EC that has validated the start of the adjudication of any given Complaint shall, with the same EC members remaining PG's Member Representatives subject to any replacement by EC back-up members elected or appointed in accordance with this Code, continue adjudicating such Complaint until it is resolved in accordance with this Code despite any annual election of new members of the EC after the decision by the EC of validation of the start of the adjudication of such Complaint.

Before the EC may validate the start of the adjudication of any Complaint, the one submitting the Complaint must be able to evidence it has put actual efforts into organizing or attempting to organize an open dialogue between the relevant stakeholders at the highest possible management level (if practicable, country level in respect of PG members), in writing or recorded in minutes of meeting if held at a meeting, about the subject matters of the Complaint aiming at resolving such matters, and that such dialogue or attempt of dialogue has not been successful. Any such dialogue or attempt of dialogue should be refer to this dialogue requirement of the Code. In case of conflict between the PG Bylaws and this Code in relation to the Inter-Company Dialogue and this dialogue requirement of the Code, this dialogue requirement of the Code shall prevail.

Unless otherwise provided in this Article 19 and Article 20, in the process of validation and adjudication of a Complaint, the EC may be represented by some or all, as the EC may decide, of the EC Chairperson, the PG Secretariat and the PG's legal counsel, and any notification by or to the EC may be done by or to (as the case may be) the EC Chairperson, the PG Secretariat and the PG's legal counsel acting on behalf of the EC.

The procedures for filing formal complaints via the PG are as follows:

- Complaint Submission - Any Complaint must be submitted in writing (in electronic or hard copy form) directly to PG Secretariat on behalf of the EC.

- Upon receipt of the Complaint, PG Secretariat must inform the EC about the Complaint and the details of parties that are involved. The PG Secretariat must then call for an EC meeting to consider validating the start of the adjudication of the Complaint.
- If a particular case involves a company of which a representative is a member of the EC, then that particular EC member must be replaced by one of the back-up EC members selected and informed by PG Secretariat for the assessment of this case.
- The PG Secretariat must send a written acknowledgement to the Complainant within 5 working days to confirm that the Complaint has been received.
- A Complaint against one or more parties alleged to be in breach of the Code (each, a "Subject Company") that are not PG members or persons acting on behalf of PG members shall not be considered by the EC, and the PG Secretariat would inform the Complainant accordingly.

Complaint Validation

The EC shall consider whether validating the start of the adjudication of a Complaint and decide on validation or rejection, within 30 working days from the date of receipt of the Complaint by the PG Secretariat. In doing so the EC must consider and ensure that:

- The Complaint appears to be a genuine and substantive matter (as determined by the EC), submitted in good faith and in a timely manner;
- Each Subject Company in the Complaint is a PG member or a person acting on behalf of a PG member.
- There is sufficient information to enable the Complaint to be processed.
- It is not a duplication of a previous Complaint that has already been processed under the Code.
- There is sufficient evidence of the dialogue requirement of the Code having been implemented with the Subject Company in relation to the matters leading to the Complaint.

The minimum information required is:

- Complainant details: If the Complaint is from a company or an organization, it must be printed on the company's or organization's letter head or stamped with the company's seal and signed off by its representative (legal representative or chief representative) or sent from the company's or organization's representative's email address. For a Complaint from an individual, the full name, contact details and telephone number of the individual must be provided.
- Subject Company: The identity of the Subject Company and the name of any product(s) or marketing activities which are specifically involved must be specified in the Complaint.
- Summary: A brief description of the Complaint with, if possible, a specific reference to the part of the Code under which the Complaint is being made (section and paragraph number(s))
- Reference material: A specific reference to the source of the advertisement, activity or printed material which is the subject of the Complaint as well as any other evidence must be provided in the Complaint.
- Date: The date of the alleged breach of the Code must be provided in the Complaint.

If a simple majority of the EC agrees to accept validating the start of the adjudication of the Complaint based on aforementioned criteria, then the Complaint will be processed as provided in the Complaint Adjudication section below.

If the EC considers the start of the adjudication of a Complaint cannot be validated because the information provided is inadequate, the EC must give the Complainant an opportunity to provide the additional information needed within 10 working days ("10-working-day deadline") from the receipt of the request of the EC to the Complainant to provide the additional information.

If the EC decides to reject the Complaint after evaluation of the information available, or the EC considers the EC has not received adequate further information at the end of the 10-working-day deadline, then PG Secretariat or the PG's legal counsel shall promptly inform the Complainant of the same including the reasons. The matter shall be considered closed and the Complainant shall not be entitled to submit another Complaint for the same or similar facts.

At any time in the process provided above and below, the Complainant can retract and withdraw the Complaint by written notice to the PG Secretariat, which will, then, inform the EC.

On the request of the Complainant that is not from a pharmaceutical company, the identity of the Complainant can be kept confidential to all parties outside the PG Secretariat and the EC.

Complaint Adjudication

No later than 15 working days after the date the EC validates start of the adjudication of the Complaint, the EC must notify to the higher level of management at country level of each Subject Company on behalf of such Subject Company, a copy of the Complaint and any supporting evidence along with any questions the EC may have to the Subject Company in relation to the Complaint. Such notice must:

- ask the Subject Company whether a similar complaint is under investigation by a regulatory body;
- record that if the Subject Company rejects the allegations of the Complaint, Subject Company must in its response clearly state the reasons and, where appropriate, provide supporting data;
- record that if the Subject Company acknowledges that it has breached this Code, the Subject Company must indicate what action has been taken or will be taken to remedy the matter;
- set a timeline for the Subject Company to respond to the EC. Such timeline would normally be 15 working days from the date of the notice of the EC to the Subject Company.
  The Subject Company must respond in writing to the EC by the timeline set by the EC in the notice or request the EC for an extension of the timeline. The EC shall consider and approve or reject any such request of extension of the Subject Company, and notify its decision on this to the Subject Company.

The EC can ask the Complainant and the Subject Company for additional information or arguments, and at any time may organize an informal dialogue at physical meetings or otherwise with representatives(s) of the Complainant and the Subject Company to gain better understanding of the case. Such dialogue may involve either or both the Complainant and the Subject Company. The PG's Member Representative of the Complainant (if it is a PG member) and the Subject Company are expected to attend to and openly cooperate in any such dialogue. The EC can also ask the PG Secretariat to obtain expert advice on this Complaint. In such circumstances, the time limit can be extended.

The EC must complete the adjudication of the Complaint and render a decision on the Complaint within 30 working days from the date the EC considers it has received sufficient information and supporting evidence from the Complainant and the Subject Company or it is not likely to receive such information and documents.

Unless decided otherwise by the EC, the EC shall make its decision, without the presence of any member of PG Secretariat and PG's legal counsel. The EC must prepare a written transcript of its decision on adjudication of the Complaint.

Complaint Handling Decision

- The PG Secretariat and PG's legal counsel must notify the Subject Company and the Complainant the written transcript of the decision of the EC on the Complaint and inform them of the process for accepting that decision including the provision of a Compliance Statement (as defined in Article 20.1) where required, of the process for appealing the first decision.

Appeal

- The Complainant or a Subject Company may, within 20 working days from the receipt of the EC decision, appeal against the ruling. If new facts or arguments are put forward, the other party has 20 working days in which to comment on them.
- Upon receipt of such appeal letters, the PG Secretariat must forward the files of the case to PG General Assembly. The General Assembly will review the case during a General Assembly meeting. The decision will be taken by simple majority, without participation by any member of the PG Secretariat, the Complainant and the Subject Company. The General Assembly will provide the PG Secretariat with its decision and reasons for it. The decision of the General Assembly shall be final and definitive.
- The PG Secretariat will contact the parties with details of the decision and inform the parties of the process for accepting that decision, including the provision of a Compliance Statement (as defined in Article 20.1) where required.

Communication of the outcome

- When a complaint is upheld and a breach of this Code is finally determined after all appeal processes have been concluded, then the decision, including a summary of the key facts, the name of the Subject Company, the name(s) of the products(s) when relevant, will immediately be communicated to the country representatives of all PG members. A copy of the material to be published is provided to the Subject Company for information only.
- In case the Subject Company fails to respond within the specified timeline as prescribed in Article 20.1 of this Code, such absence of response by the Subject Company shall be communicated to PG members.
- EC and all PG members shall keep all information exchanged during the procedures confidential.

20. SANCTIONS

20.1 If the Subject Company is found in breach of this Code, the Subject Company has 10 working days to provide written details of the action taken to comply with the ruling (the "Compliance Statement"). As a minimum, the Subject Company will be asked to confirm that the activity or use of the material in question, and any similar material if not already discontinued or no longer in use, will cease immediately and that all possible steps will be taken to avoid a similar breach of the Code in the future. The Compliance Statement must be signed or authorized by the representative of the Subject Company and must include the date on which the material was finally used or appeared and/or the last date on which the activity took place.

20.2 Actions that may be taken by the EC as sanctions against the Subject Company:

i. Refer the complaint and the EC's findings to the head office and the regional office of the Subject Company.

ii. Request the Subject Company to issue a written undertaking that the practice complained of will be discontinued on or before a date to be determined by the EC.

iii. Request the Subject Company to issue retraction statements, including corrective letters and advertising, subject to the approval of the EC prior to release. It is the Subject Company's responsibility to ensure that the requirements of the EC are met and to immediately inform and provide evidence to the PG of their fulfilment.

iv. Suspend the Subject Company's membership for no more than 3 years.

21. COMPLIANCE PROCEDURES

21.1 It is the responsibility of PG members to ensure that all employees are familiar with and all their actions are in accordance with the Code.

21.2 All internal compliance procedures and company guidelines must be in line with all provisions of the Code and the spirit it embodies.