

Pharma Group, European Chamber of Commerce in Vietnam

Pharma Group Code of Pharmaceutical Marketing 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.

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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 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 Pharmaceutical Marketing 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 them. This Code applies to all PG members and becomes effective on 1 January, 2019, except for the clause 19.1 “Ethical Committee” which will become effective on 28 February, 2019. Prior to 28 February, 2019, The Ethical Committee will follow the provisions in Pharma Group Code of Ethics version amended for the first time by the Pharma Group General Assembly on 27 January 2016, effective 1 June 2016.
- 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 representative”** means a qualified person as defined by Vietnamese laws, to introduce medicines to HCP.
- 3.5 “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.
- “**Informational or educational items that enhance Patient Care**” are items for education to HCP or for them to educate their patients.
- 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

11.1 Gifts

Gifts for personal benefit (such as sporting or entertainment tickets, electronic items, social courtesy gifts etc.) of HCP (either directly or through clinic and institutions) 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 profession and that confer a personal benefit to the HCP.

11.2 Promotional aids

Providing or offering promotional aids to HCPs in relation to the promotion of prescription-only medicines is prohibited.

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 shall only show the company name, logo and/or tagline of the company.

Company name, logo and/or tagline of the company are allowed to be printed on promotional aids (for OTC products). Product-specific and/or franchise-specific promotional message are not allowed to be printed on promotional aids.

Only pens and notepads can be provided to HCPs in the context of company organized or third-party events as long as they are company branded only, of minimal total value per attendant (not exceeding VND 100,000) and only the necessary quantity for the purpose of the event are distributed.

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

Items of medical utility may be offered or provided to HCP if such items are of modest value, do not offset routine business practices, and are directly beneficial to enhancing the provision of medical services or for patient care, and in line with Vietnamese laws.

Items of medical utility can include the company name but must not be branded product, 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 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 branded product, 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 8,000,000 per HCP per year and must be less than VND 2,000,000 per HCP per occasion.
- Companies must notify HCP of their obligation to report items over VND 500,000 in accordance with Vietnamese laws.

Items of medical utility that enhance Patient Care should be given to HCP on an occasional basis only.

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 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

- 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.
- PG members must not deliberately interfere or undermine an event organized or sponsored by another PG member.

- 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.
- Any materials handed out during or after the event should be in line with sections on medical information and claims.
- If the event is organized and initiated by a medical association or another professional organization, then that organization is responsible for the program content. Any support from the pharmaceutical industry must be sufficiently stated or disclosed.

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

- Any sponsorship provided to individual HCP must not be conditional upon any obligation to promote, recommend, prescribe or purchase, supply or administer any pharmaceutical product.
- Sponsorship to HCP to attend to scientific events is limited to the payment of travel to and from the event, meals, accommodations and registration fees.
- Companies must not pay any costs associated with individuals accompanying invited 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 organized by PG members
- Travel and accommodation should be provided as per reasonable standards considering the nature and venue of the event and the level of involvement of the HCP. For example, business class tickets for local travel, luxurious or extravagant accommodation must not be provided. Sponsorship to stand-alone entertainment, side trips or other leisure or social activities are not allowed.
- Hospitality offered to the HCP 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 event lunch. Refreshment during dinner can have alcohol drinks, with reasonable limit. Applicable laws should be respected.
- Expenses for travel, accommodation, meals or event registration must be paid directly to the service provider. Payments must not be made to HCP either directly or indirectly in any form except for reimbursement to HCP for reasonable expenses including travel, meals and accommodation. No payments are made to compensate HCPs for time spent in

attending the Event.

- PG members can organize or sponsor HCP to attend international events that derive participants from many countries. The sponsorship must be limited and have substantial legitimate scientific or educational purpose and strictly follow applicable Vietnamese laws.
- PG members aim to create transparency towards the HCPs employer about invitations or sponsorships for HCP to attend events including details of the sponsorship and the agenda of the event. PG members have to ensure that when inviting or sponsoring HCPs to attend events, they do not interfere with interest of the HCPs employer. For engaging with HCPs, PG member companies should be aware that HCPs might have obligations to their institutions.
- When inviting HCP to attend International event, PG members must make sure that they have obtained the official permit from the HCP's institution for the HCP to attend that event.

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.
- 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 comprises of 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 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.

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 Meeting of the PG. The general Assembly will then confirm 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 confirmation.

19.3. Complaints and Procedures

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

- Complaint Submission - All complaints must be submitted in writing (in electronic or hard copy form) directly to PG Secretariat (the “Complaint”). Complaints can be made by either PG

members or by non-member sources, e.g., the health authorities, HCP, professional organizations, patients or patient groups (“Complainant”).

- Upon receipt of the Complaint, PG Secretariat informs the EC about the Complaint and the details of companies that are involved. The PG Secretariat then calls for an EC meeting to open and to validate 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 for the assessment of this case. The PG Secretariat should select and inform such back-up EC member.
- The PG Secretariat must send a written acknowledgement to the complainant within 5 working days to confirm that the complaint has been received.
- Complaints against companies that are not PG members cannot be processed. A note will be sent to the Complainant accordingly.
- Companies are encouraged to report potential violations of this Code to the company alleged to be in breach, prior to submitting a complaint to Pharma Group.

Complaint Validation - Any complaints submitted must be validated by the EC to ensure that:

Any Complaints submitted must be validated by the EC, within 15 working days from the receipt from the PG Secretariat, to ensure that:

- It appears to be a genuine matter, submitted in good faith and in a timely manner;
- There is sufficient-information to enable the Complaint to be processed.
- It is not a duplication of a case, which has already been resolved under the Code.

The minimum information required is:

- 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 complaints from an individual, the full name, contact details and telephone number of the individual must be provided.
- Subject Company: The identity of company which is alleged to be in breach of the Code (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 the claim based on aforementioned criteria, then the claim will be processed as provided in the Complaint Processing section below.

If a Complaint cannot be validated because the information provided is inadequate, the Complainant must be given an opportunity to provide the additional information needed within 10 working days (“10-working-day deadline”) from the receipt of instructions to provide the additional information.

If the EC does not agree to accept the Complaint after evaluation of the additional information, or the EC did not receive further information at the end of the 10-working-day deadline, then the Complainant must be informed accordingly within 15 working days after the end of the 10-working-day deadline.

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, the identity of the complainant, if not from a pharmaceutical company, can be kept confidential to all parties outside the PG Secretariat and the EC;

Complaint Processing

- The Complaint and supporting evidence must be sent to the senior management of the Subject Company within 15 working days from the date the EC validates the Complaint. The PG Secretariat must state the time within which a response must be received. This will normally be 15 working days from the Subject Company's receipt of the documentation; however, in exceptional cases, the PG Secretariat and the EC can grant an extension to the time allowed.
- The Subject Company must be asked if a similar complaint is under investigation by a regulatory body.
- The Subject Company must be asked for full details if it rejects the allegations, the reasons must be clearly stated and, where appropriate, supporting data must be provided.
- The Subject Company must be informed that, if it acknowledges that it has breached this Code, it must indicate what action has been taken or will be taken to remedy the matter.

Complaint Adjudication

- The Complaint must normally be reviewed within 20 working days from the receipt of the Subject Company's response. Following requests from the EC, the PG Secretariat can ask the Complainant or the Subject Company for additional information or arguments. In such circumstances the time limit can be extended.
- Decision by the EC is made by a simple majority, without participation by any member of PG Secretariat. The EC can ask the PG Secretariat to obtain expert advice. The EC will then provide the PG Secretariat with its decision and reasons for it.

Complaint Handling Decision

- 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, 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 final decision will be taken by simple majority, without participation by any member of the PG Secretariat. The General Assembly will provide the PG Secretariat with its decision and reasons for it.
- 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 head of all PG members. A copy of the material to be published is provided to the Subject Company for information only.

- Information may also be communicated to PG members in case where a company fails to respond within the specified timeline.

EC and all PG members shall keep all information exchanged during the procedures confidential.

20. SANCTIONS

- 20.1 If a 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 Breaching Company:
- (i) Refer the complaint and the EC’s findings to the head office and the regional office of the Breaching Company.
 - (ii) Request the Breaching 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 Breaching Company to issue retraction statements, including corrective letters and advertising, subject to the approval of the EC prior to release. It is the Breaching 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 Breaching 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.