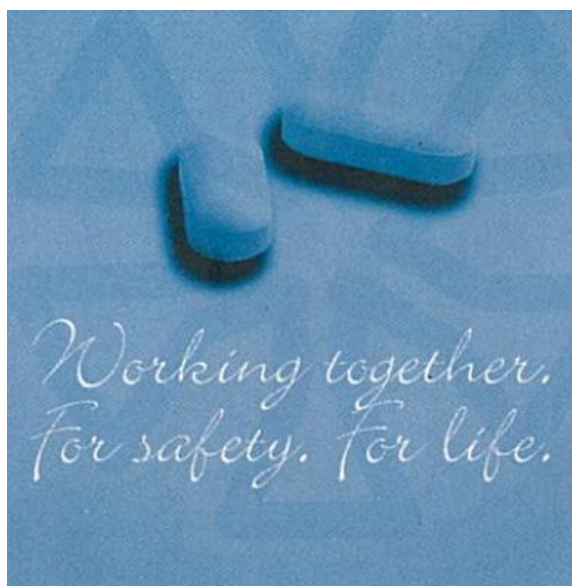


**IPMG CODE
OF PHARMACEUTICAL
MARKETING PRACTICES**
June 2015 Revision



IPMG

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FOREWORD

Jakarta, 1 June 2015

International Pharmaceutical Manufacturers Group (IPMG), an association representing 24 international research-based pharmaceutical companies operating in Indonesia, has been steadfast in its commitment to providing the public with safe, high quality and efficacious medicines and the healthcare community with adequate information about the value and potential risks of their products.

All IPMG members are fully committed to supporting the medical community in a scientific manner and complying with respective laws and regulations, especially the code of ethics in marketing practices.

In our continuous effort in creating a level playing field in the Indonesian pharmaceutical industry as well as ensuring a uniform interpretation of the Code, the Marketing Practices Sub-Committee, after careful considerations, has revised several articles and points in IPMG Code of Pharmaceutical Marketing Practices in Indonesia issued in July 2013. As for this revision it is focused on several articles and points concerning payments to institutions, hotel restrictions for holding company meetings involving HCPs, and penalties (fines). This revision is necessary to ensure full alignment with the new International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code of Practices, as well as the "Mexico City Principles for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector".

IPMG has been adopting stringent practices and taking compliance measures over the past years. These standard practices should also apply to all companies operating in the pharmaceutical industry in Indonesia.

We believe that the 2015 Revised Code of Conduct, effective as of June 1, 2015, will help medical services in Indonesia progress to the benefit of all the stakeholders, especially the patients in Indonesia.

Thank you for your kind attention.

Yours sincerely,

IPMG

Luthfi Mardiansyah
Chairman

Anne Belcher
Head of Sub-Committee Marketing Practices

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CODE OF PHARMACEUTICAL MARKETING PRACTICES IN INDONESIA

June 2015 Revision

P R E A M B L E

- (i) The ethical promotion of prescription medicines is vital to the pharmaceutical industry's mission of helping patients by discovering, developing and marketing new medicines. Ethical promotion helps to ensure that healthcare professionals have access to information they need, that patients have access to the medicines they need and that medicines are prescribed and used in a manner that provides the maximum healthcare benefit to patients.
- (ii) IPMG and its members are committed to educational and promotional efforts that benefit patients and promotional programs and collaborations that enhance the practice of medicine. IPMG also seeks to preserve the independence of the decisions taken by healthcare professionals in prescribing medicines to patients. The pharmaceutical industry has an obligation and responsibility to provide accurate information and education about its products to healthcare professionals in order to establish a clear understanding of the appropriate use of prescription medicines. Industry relationships with healthcare professionals must support and be consistent with the professional responsibilities healthcare professionals have towards their patients. Pharmaceutical companies must maintain high ethical standards when conducting promotional activities and comply with applicable legal, regulatory and professional requirements. Through the promotion of this Code, IPMG seeks to ensure that ethical promotional practices are established nationwide.
- (iii) The IPMG Code of Pharmaceutical Marketing Practices (the "Code") sets forth standards for the ethical promotion of pharmaceutical products to healthcare professionals and for IPMG member companies' interactions with them. Effective June 1, 2015, this Code will be applied to all members of IPMG.
- (iv) IPMG acknowledges the role of relevant codes of ethics developed by all other health care associations. IPMG also commits to adhere to the prevailing laws and regulations related to health care in Indonesia.
- (v) It is a requirement of IPMG membership to accept and implement the conditions of the Code.
- (vi) IPMG member companies are accountable for addressing and correcting infringements under relevant codes. They should also ensure that internal structures and procedures (including adequate training of employees) are created to ensure responsible and ethical promotional activities.
- (vii) IPMG is open to receive genuine complaints from any source on any aspect of the Code in accordance with its operating procedures. Where it is determined that there has been a breach of the Code, the objective is to correct the matter as rapidly as possible.
- (viii) IPMG is a non-profit, non-governmental organization representing multinational research-based pharmaceutical companies in Indonesia. IPMG member companies are committed to the ethical standards set out in this Code.

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CHAPTER I OBJECTIVE

The objective of this Code is to define the high standards that must be abide by the industry in the ethical promotion of pharmaceutical products to healthcare professionals as well as to establish the process of self-discipline to ensure that IPMG member companies' interactions with healthcare professionals are appropriate and perceived as such to serve best the public interests toward an improved health level of the society and promotes the rational use of drugs.

If there are contradictions between English and Indonesian translation, the English version shall prevail.

CHAPTER II CODE OF CONDUCT

Article 1 IMPLEMENTATION OF THE CODE

1.1. Scope

1.1.1. The Code applies to IPMG member companies including other 3rd party organizations engaged by IPMG member companies to promote and/or market their pharmaceutical products.

1.1.2. The Code covers any interactions with Healthcare Professional, Healthcare Organization, Patient Organization and the promotion of pharmaceutical products.

1.1.3. **Exclusions:** This Code does not seek to regulate the following activities:

- A public disease awareness campaign targeted at the public. Disease awareness campaigns must not promote specific pharmaceutical products and shall comply with local regulations issued by Competent Authorities.
- Promotion of OTC products that is not addressed to Healthcare Professional.
- Pricing or other trade terms for the supply of pharmaceutical products (see Q&A 1).
- The engagement of a Healthcare Professional to provide genuine consultancy or advisory services to a Member Company (see Q&A 2).
- The conduct of clinical trials.
- The provision of non-promotional information by Member Company; such as correspondences which may be accompanied by material of a non-promotional nature, the need to answer a specific question about a particular pharmaceutical product; general information about companies (e.g. information directed to investors or to current/prospective employees), including financial data, descriptions of research and development program, and discussion of regulatory developments affecting the company and its pharmaceutical products.

1.2. Definition

For the purposes of this Code:

1.2.1. **Pharmaceutical product** means any pharmaceutical or biological product (irrespective of patent status and/or whether it is branded or not), which is intended to be used in the prescription of or under the supervision of a Healthcare Professional, and which is intended for use in the diagnosis, treatment or prevention of disease in humans, or to affect the structure or any function of the human body, including OTC products.

1.2.2. **OTC product** means self-medication pharmaceutical products that are provided "over the counter" without prescription.

- 1.2.3. **Promotion** means any activity undertaken, organized or sponsored by a Member Company which is directed to Healthcare Professional to promote the prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s) through all media, including the internet.
- 1.2.4. **Off-label Promotion** means promotion of unapproved product or unapproved product information. Product approval must be granted by the Competent Authorities as per their regulations.
- 1.2.5. **Healthcare Professional** or known as **HCP** means any member of the medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, recommend, purchase, supply, or administer a pharmaceutical product (see Q&A 3).
- 1.2.6. **Civil Servant** means people receiving salaries or wages from state finance or regional finance, and/or from corporation which receives assistance from state/regional finance or from corporations which use capital or facilities from the state or from the public (see Q&A 3).
- 1.2.7. **Institution** means any structures and mechanisms of cooperation or organization governing a set of individuals within a given community that can be either profit or non-profit, government or private; including but not limited to hospital, university, Patient Organization, Non-Government Organization (NGO). However, medical association is not considered as Institution as referred in this Code.
- 1.2.8. **Authorized person** means an individual who is empowered by the Institution to make decision or act on behalf of the Institution.
- 1.2.9. **Healthcare Organization** or known as **HCO** means typically organization that is comprised of Healthcare Professionals and/or that provides healthcare services or conducts healthcare research. Medical association is considered as a HCO, but a group of unaffiliated HCPs practicing together in one place is not classified as a HCO.
- 1.2.10. **Patient Organization** means typically a non-profit organization that primarily represents the interests and needs of patients, their families and/or caregivers.
- 1.2.11. **Social Media** means online technologies and applications where users can share and/or exchange news, views, photo and video. Social Media platforms include blogs, wikis, internet communities, message board, video sharing sites and networking applications.
- 1.2.12. **Pharmacy Survey** means activity conducted in order to gather information regarding prescription habit of any HCP.
- 1.2.13. **Donation** means a physical gift given typically for charitable and/or education purposes and not in a form of cash or cash equivalent.
- 1.2.14. **Grant** means financial support for charitable and/or education purposes made to Institution.
- 1.2.15. **Competent Authorities** means Badan Pengawas Obat dan Makanan (BPOM) or Kementerian Kesehatan (Kemenkes).
- 1.2.16. **Member Company** means any company that is a member of IPMG.
- 1.2.17. **Transfer of Value** means any benefit provided to HCP including but not limited to HCP sponsorship to attend meeting, HCP's speaking engagement, business meals, item of medical utility, promotional reminders, cultural courtesy gift, etc.

1.3. **Application and Execution**

In all matters related to the application, interpretation and execution of any part of this Code, it is to be understood that adherence to the prevailing laws and regulation should come first.

1.4. **Responsibility**

Full adherence to this Code is a pre-requisite for a membership in the IPMG.

The President Director and other Board members of each of the Member Company are responsible for the implementation of this Code.

Member Company with licensing or agency agreements in Indonesia must legally bind to this Code.

1.5. **General Principles**

1.5.1. **Basis of interaction:** Member Company relationships with HCP and HCO are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing HCP about products, providing scientific and educational information and supporting medical research and education.

1.5.2. **Independence of Healthcare Professional:** No financial benefit or benefit-in-kind (including grants, scholarships, subsidies, support, consulting contracts or educational or practice related items) may be provided or offered to a HCP in exchange for prescribing, recommending, purchasing, supplying or administering products or for a commitment to continue to do so. Nothing may be offered or provided in a manner or on conditions that would have an inappropriate influence on a HCP's prescribing practices (No quid pro quo).

1.5.3. **Appropriate Use:** Promotion should encourage the appropriate use of pharmaceutical products by presenting them objectively and without exaggerating their properties.

1.5.4. **Transparency of Promotion:** Promotion should not be disguised. Clinical assessments, post-marketing surveillance and post-authorization studies must not be disguised promotion. 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 Member Company should clearly indicate by whom it has been sponsored (see Q&A 4).

1.5.5. **Interaction with Patient Organization:** All programs with Patient Organization must have written agreement, be ethical, respect the independency of Patient Organization, and the nature of involvement is clear from the outset. Financial support may be provided to support Patient Organization meetings which primarily for the purpose of professional, educational, and scientific in nature, or otherwise supports the mission of the Patient Organization. Venue, location, and refreshments provided by Member Company must comply with Article 4.5. No Member Company may request that it be the sole funder of the Patient Organization or any of its programs, unless it is offered or required by the Patient Organization itself, as long as that company did not make its support conditional on it being the sole funder.

Article 2
INFORMATION AND CLAIMS

2.1. General Criteria

Information and claims for pharmaceutical products should be fair, objective, and accurate and represent a balance of the evidence.

Information and claims should also be presented to a high ethical standard, in compliance with the latest authorized product information from relevant Competent Authorities and in such a way as not to be misleading or ambiguous.

2.2. Scientific Evidence

Information provided should be based on the latest evaluation data which are supported by scientifically valid evidence, accurate, clear and presented in a way that is not misleading. The scientific data should be referenced and traceable. In-vitro and animal test data should be clearly marked as such, in order not to give an incorrect or misleading impression. These criteria are applicable for product(s) being promoted as well as for other products being quoted for reference or comparative purpose.

Quotations from medical and scientific literature should include the identification of the relevant valid sources.

2.3. Request for Information

Member Company should handle requests for information from HCP with objectivity and good intention by providing accurate and relevant data.

2.4. Safety Data

2.4.1. All information related to product safety, as well as contraindications, warnings and side effects should conform to those currently approved by Competent Authorities.

2.4.2. The word “safe” and “no side effects” should generally be avoided and should not be used without adequate qualification or explanatory notes.

2.4.3. All Member Companies are obliged to report Adverse Drug Reactions (ADR) associated with their products in accordance with related regulation of Competent Authorities. Member Company should have appropriate systems and procedures to collect, monitor and report on ADR in order to comply with internationally accepted requirements.

2.5. Incorrect or Misleading Claims

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

2.5.2. Information should be based on scientifically valid evidence and in conformity with product information as approved by Competent Authorities.

2.5.3. Some examples of what is not permissible and therefore considered as violations of this Code:

2.5.3.1. Quoting vague references from clinical evidence or experience that cannot be validated. Therefore, it is recommended to quote results only from published studies.

2.5.3.2. Using or quoting data from a study, which is not relevant to the claim(s) being made. Presenting data to support a claim without a reference to the published study.

- 2.5.3.3. Claims based on data that are no longer valid, e.g. that have been proven invalid or replaced by the results of more recent published research.
- 2.5.3.4. Dosage recommendations or claims for an indication that do not comply with the product information approved by the Competent Authorities.
- 2.5.3.5. Using in-vitro data or data from animal studies which are not clearly identified as such or which are presented in a way that are misleading or implying that they are in-vivo and/or human data.
- 2.5.3.6. Presentations or layouts that lead to an incorrect or misleading interpretation. For example, important and relevant data relegated to fine print; manipulated scales on graphs and charts, distorted comparisons with competitor's product or clinical trials or studies.
- 2.5.3.7. Negative statements concerning competitive products that bear no scientific data or are refutable based on current evidence or having no relevance to the product being promoted.
- 2.5.3.8. Claims implying a product's efficacy for a certain indication but ignoring the warning or caution applicable to its use in such circumstances.
- 2.5.3.9. Claims utilizing evidence or quotations:
 - (i) which have been selectively presented to misleadingly highlight advantages,
 - (ii) which are presented or quoted beyond or out of context
 - (iii) which are quoted or presented in such a way as to distort the meaning or objective of the author.
- 2.5.3.10. Non-medical or non-scientific claims with no evidence.
- 2.5.3.11. Unqualified superlative claims or hanging comparatives (see Article 2.6. below).
- 2.5.3.12. Comparisons with competitive products that are not based on scientifically valid evidence or which distort the evidence or which are not objective and reasonable (see Article 2.7 below).

2.6. Unqualified Superlative Claims and Hanging Comparative Claim

- 2.6.1. Making unqualified superlative claims are not allowed, e.g.:
 - “Product X is the best treatment for condition Y.”
 - “Product X is the fastest treatment for condition Y.”
 - “Product X is the strongest / most powerful treatment for condition Y”
 - “Product X is the safest treatment for condition Y.”
 If these or other superlatives are used, then the claims must be referenced and supported by current scientifically valid evidence
- 2.6.2. Hanging comparative claims should not be made, e.g.:
 - “Product X is better/stronger/faster/safer for condition Y”
 A comparative claim must include a statement that indicates against what the product is better/stronger/faster/safer etc., and that this superiority is supported by current scientifically valid evidence. (For more on comparisons see Article 2.7 below).

2.7. Comparisons

- 2.7.1. Comparisons between products should be honest, based on facts proven by current scientific evidence. In presenting the results there should be no attempt to deceive by distortion, unreasonable emphasis or other means. Inappropriate or insulting comparisons against competitors' or their products should be avoided.

2.7.2. Comparisons on efficacy and safety between different pharmaceutical products should be based on valid published data to include all the aspects of efficacy and safety; e.g., head to head data or non-comparison data or data based on one parameter only should be clearly stated in the reference.

2.7.3. Data used to support comparative claims should satisfy the requirements of statistical significance. If data do not meet these requirements, then they should be clearly marked as such and should not be used to generalize or to support claims indicating equality or superiority against another product. The statistical significance indicator (i.e. the “p” value) should accompany comparative data.

2.8. Imitation or Copying of Other Companies’ Materials

A Member Company should not deliberately imitate or copy other company’s marketing/promotional/advertising materials, which might lead to misleading or confusion.

2.9. Healthcare Professional in Promotional Materials

2.9.1. Names or photographs of HCP or HCO should not be used in promotional/advertising materials in a way that violates the Indonesian medical code of ethics (Kode Etik Kedokteran Indonesia).

2.9.2. It is, however, acceptable to use the names and photographs in proceedings of scientific meetings (e.g. where a HCP has made a presentation), but it is not acceptable to do so in promotional brochures, journal advertisements and the like.

2.10. Hidden Promotion/Advertising

2.10.1. Promotional materials such as mailings and medical journal advertisements should 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 “PROMOTIONAL ADVERTISEMENT” or “ADVERTORIAL” in capital letters of the largest pitch used in the body text of the advertisement (see Q&A 4).

2.10.2. All Clinical Trials, including but not limited to Post-Marketing Surveillance (PMS) also refer as Non Interventional Study (NIS), must be conducted in accordance with the Good Clinical Practice (GCP) guidelines; in this case following a medically approved Clinical Trial protocol and be conducted for regulatory, scientific or educational purposes. Post-Marketing Surveillance should not be conducted merely as a means to promote a product or to influence HCP with little or no scientific basis.

2.11. Pre-Approval Communications and Off-Label Promotion

2.11.1. A product shall not be promoted until the requisite license to market for such use has been granted by the Competent Authorities.

2.11.2. All non-medical department employees are prohibited to talk or trigger a discussion about off-label indications. If a HCP insists on discussing an off-label indication all non-medical department employees should refer their medical department to engage with the HCP.

2.11.3. This provision, however, is not meant to limit the rights of the scientific community and the general public to have complete information on advances in the scientific and medical progresses, provided that the results of the research have been acknowledged internationally. It is also not meant to limit the full and proper exchange of scientific information on a product, including the dissemination of research findings in the scientific or general communications media or through scientific congresses.

2.11.4. Likewise, this provision should not limit public disclosure to shareholders and other parties concerned with the product as may be required by law or regulation.

- 2.11.5 It should also be accompanied by:
- (i) an explanatory statement indicating that the product has not yet been approved by the Competent Authorities in Indonesia, or
 - (ii) an explanatory statement indicating that registration conditions differ internationally, and,
 - (iii) an explanatory statement should identify the countries in which the product is registered and make it clear that it is not available locally.

2.12. Company Procedures

Member Company should establish and maintain appropriate procedures to ensure full compliance with relevant codes and applicable law and to review and monitor all of their promotional activities and materials. A designated employee of Member Company, with sufficient knowledge and appropriate scientific or healthcare qualifications should be responsible for approving all promotional communications. Also, a senior employee of Member Company could be made responsible, provided that scientific advice is taken.

Article 3 MEDICAL REPRESENTATIVES

- 3.1. Member Company is fully responsible for the quality and conduct of their Medical Representatives (MR).
- 3.2. MR must be adequately trained and possess sufficient medical and technical knowledge, evidently by possessing a certificate issued by acknowledged independent institution (see Q&A 6).
- 3.3. MR should be able to give technical explanations on their company's products in an accurate, fair, and in an ethical manner to the members of the HCP's organization.
- 3.4. MR should be prohibited to give or offer rewards to the members of HCP, other than as specified in the Article 6 below.
- 3.5. MR in doing their duties should show good conducts when visiting the members of HCP.
- 3.6. The ruling on MR should be adjusted from time to time in order to be in compliance with the prevailing regulations/laws issued by the relevant government institutions governing the manufacturers and distributors (PBF) or other similar companies.

Article 4 INTERACTIONS WITH HEALTHCARE PROFESSIONAL

4. 1. General Principles

- 4.1.1. Any Transfer of Value given to Civil Servant HCP is considered as gratification. Anti-Corruption Law and Ministry of Health Decree No. 14/2014 stipulate that gratification-reporting obligation lies with the recipients of the gratification.
- 4.1.2. Member Company to set its own process to attest the employment status of the HCP: civil servant or private (see Q&A 3).
- 4.1.3. In support of upholding compliance towards anti corruption regulations (to the effect of creating transparency of the gratification to protect parties including member companies), where the HCP is civil servant, the Member Company shall take reasonable steps to remind Civil Servant HCP of their obligation to report gratification. Such reminding steps can be through various forms, such as written documentation, invitation, slide presentation, attendance list, etc. We appreciate that there are exceptional situations

(such as one on one permitted business meal) where such a reminder may not be possible.

- 4.1.4. Underlying conditions when engaging a civil servant HCP as a speaker or consultant (e.g. advisory board) or providing travel, accommodation and/or registration support for a civil servant HCP to attend a meeting:
- (i) Member Company to channel HCP's sponsorship to attend Events and HCP's speaking engagement through the Institution where the respective HCP is employed, and
 - (ii) Written documentation between Member Company and the Institution; signed by authorized person of both parties, and
 - (iii) Details of support provided by Member Company must be clearly stated in the written documentation with Institution.

In this context, Medical Association is not considered as Institution where the HCP is employed.

All further detailed conditions and process for interaction with HCP as set forth in this Code shall also apply to the engagement of HCP who is Civil Servant.

4. 2. Scientific and Educational Meetings (“EVENTS”)

4.2.1. Understandings and Objectives

The purpose and focus of all symposia, congresses and other promotional, scientific or professional meetings (an “Event”) for HCP organized or sponsored by a Member Company should be to inform HCP about products and/or to provide balanced scientific or educational information (see Q&A 7).

Ratio of scientific or educational content versus hospitality should be at minimum 2/3 from total activity time.

- 4.2.2. The participation of a Member Company in a symposium, congress or the like should be declared clearly at the beginning of the meeting and in any printed proceedings from the meeting.

Printed, audio, visual or electronic material from the meeting should accurately reflect the presentations and discussions of the event.

- 4.2.3. If the meeting program is accredited for post graduate education by a medical association or other professional organization, the responsibility for the program content remains with that organization. Any support from the pharmaceutical industry should be sufficiently stated or disclosed.

- 4.2.4. Member Company is prohibited from offering any kind of induction, door prize, incentive, financial reward to the HCP.

4.2.5. Meals:

Any meal provided to HCP shall be performed under the following requirements:

- (i) exclusively to HCP relevant to the event and/or to the purpose of the meeting; and
- (ii) incidental to the main purpose of the event or meeting; and
- (iii) shall be moderate and reasonable with maximum value of IDR 500,000 (before tax and service) per HCP per meal in Indonesia. If outside Indonesia, the maximum value shall follow the host country limit; and
- (iv) such meal is not excessive and only for the purpose to be consumed during the meeting. Otherwise, such meal will be considered as entertainment (refer to Article 4.5.3).

4.2.6. Events Involving Foreign Travel:

4.2.6.1. No Member Company may organize or sponsor an Event for HCP that take place outside of Indonesia unless it is appropriate and justified to do so from the logistical or security point of view.

4.2.6.2. International scientific congresses and symposia that derive participants from many countries are therefore justified and permitted if more than 50% of the invited HCP are from outside of Indonesia, and it makes greater logistical or security sense to hold the event in another country.

4. 3. **Sponsoring Healthcare Professional**

4.3.1 Member Company may sponsor HCP to attend events provided such sponsorship is in accordance with the following requirements:

4.3.1.1. Any sponsorship provided to HCP must not be conditional upon any obligation to promote, recommend or prescribe any pharmaceutical product.

4.3.1.2. Any sponsorship provided to HCP must:

- be related to medical expertise and experience of the selected HCP in the particular medical field covered by the event or
- have possible cooperation with the HCP for future scientific projects as consultant/speaker.

4.3.1.3. Sponsorship of HCP by Member Company is limited to the payment of transportation to and from the event, meals, and accommodation and registration fees for the scientific related events which shall be directly paid to relevant third party (e.g. travel agency or congress organizer). Reimbursement to HCP for any costs related to such meetings or event logistics (registration, meals, accommodation, and transportation) is strictly prohibited.

4.3.1.4. It is not allowed for Member Company to pay:

- accompanying person/s of invited HCP;
- registration fee for meetings/events where tour package is bundled/included into the meeting or registration fee.

4.3.1.5. Certain rules with regards to providing transportation for HCP sponsorship:

- First class flight for HCP is not allowed.
- Transportation of HCP where the routes and schedule differs from the venue of scientific event is not allowed.
- Tickets must be booked through the company's appointed travel agent(s).
- Car rentals for HCP's personal purposes are not allowed. However, car rental is allowed strictly for transportation from airport – hotel vice versa and/or hotel – venue vice versa.

4.3.1.6. Certain rules with regards to providing accommodation for HCP sponsorship:

- 5-star hotel outside of Indonesia is not allowed unless permitted by host country regulation or due to it is the venue of the event.
- In Indonesia, the room charge/room/night with maximum of IDR 2,500,000 (before tax and service) is allowed.
- Overnight accommodation may only be given, under specific circumstances where the eligible travel arrangement may cause the HCP cannot attend the full agenda of the meeting. If the overnight accommodation is needed in this case, the maximum length of hotel stay in the sponsored hotel is one day before and up to one day after the official dates of the scientific event.

4.3.1.7. Any accompanying person of the sponsored HCP shall not be invited to join any meal invitation that follows or that is connected with and part of the agenda of a scientific event. This must be clearly stated on the relevant invitation. The standard statement in said invitation shall be along these lines: **“This invitation is valid for Healthcare Professionals only. Other accompanying persons are not invited”**. No payment or hospitality of any nature can be made by IPMG members for accompanying people.

4.3.1.8. It is prohibited to give honorarium to compensate HCP for time spent in attending scientific meetings (honorarium is however permitted for speakers/ moderators at a meeting – see Article 4.4.1).

4.3.2. Sponsorship which is not related with scientific activities such as any Pre-and Post-Congress tours and/or any supported sports activities is not allowed.

4. 4. Fees for Services

4.4.1. Payment to HCP's bank account is allowed only for genuine services; such as speaker, moderator, advisory board or investigator; evidenced by a contract as explained in Article 4.1.4. Service fee could be paid to the respective HCP's Institution, if requested.

4.4.2. Member Company may provide meals, transportation and accommodation to the engaged HCP who is providing genuine services.

4.4.3. The amount of the honorarium for Indonesian speakers/moderators at any meetings should not be more than IDR 6,000,000 net per presentation, whether it is arranged by the Member Company or by a 3rd party. The honorarium is limited to maximum IDR 12,000,000 net per day per speaker, assuming multiple presentations for the same Member Company. For Member Company organized meetings, payments of speaker's fee should not be made in advance. As an exception, advance payment is acceptable in the case whereby the event is organized by a 3rd party, where the speaker's fee is included in the lump sum payment requested by the event's Organizing Committee.

4.4.4. Honorarium for Indonesian HCP acting as speakers, presenters or moderators at overseas meetings should be not more than IDR 12,000,000 net per day.

4.4.5. The honorarium for foreign speakers at local meetings should be at the level of normal practice in the foreign speaker's home country.

4.4.6. Payments for any genuine HCP's services must not be in the form of cash payment, but shall be processed through bank cheque or bank transfer.

4. 5. Events/Meetings Managed by Member Company

4.5.1. **General principles:** Hospitality to HCP must be (a) provided in association with such permitted meetings, (b) with a level that is secondary to the purpose of the meeting, and (c) appropriate and not out of proportion to that particular occasion, in the context of time spent and cost. The hospitality cost should not exceed that level which the majority of recipients might normally adopt when paying for themselves.

Hospitality should not extend beyond the HCP unless that person is a member of the health professions or appropriate administrative staff and qualifies as a proper delegate or participant at the meeting in their own right (See Q&A 8).

4.5.2. **Appropriate venue:** All events should be held in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the event or meeting. Member Company is prohibited to use venues which are known or perceived for their entertainment image or are considered extravagant. For example: hotels incorporated with any theme / amusement park, golf course, providing private beach as venue for events/meetings managed by the Member Company (see Q&A 9). The additional requirements set forth in this Article 4 of this Code also apply accordingly.

4.5.3. **Entertainment:**

4.5.3.1 No stand-alone entertainment or other leisure of social activities should be provided or paid by Member Company. For example:

- A concert, as this would be self-standing and not incidental to the refreshments
- Purchase of entertainment or sport tickets
- A self-standing sightseeing tour, but this would not prohibit a commentary about sights of interest en-route to a restaurant
- High profile, inappropriate or expensive entertainers - even if their performance is secondary to a necessary meal; such as a well-known TV or pop star
- Gala dinner
- Dinner associated with event held by Medical Association
- Cruise
- Souvenirs (*oleh-oleh*)
- Providing meals (e.g. snack, lunch box) without scientific discussion or excessive meals.

4.5.3.2 At events, entertainment of modest nature which is secondary to refreshments and/or meals is allowed. For example:

- An evening meal for a meeting which is scheduled for more than one day, it would be permitted to provide some background music during the meal or to have an interlude when some low-key local singers perform.
- A folk dance display or performance by a local singer as entertainment for a meal interlude or during opening/closing of the event.

4.5.4. **Exhibition Stands**

4.5.4.1. Exhibition booths, stalls, counters and the like should be secondary to – and not distract 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. Modest food and beverages may be offered.

Member Company is prohibited to provide, support or sponsor a room which serves leisure activities with no scientific related.

4.5.4.2. Scientific quiz prizes, e.g. gimmick (see Article 6.2.1), should not be worth more than IDR 100,000 / participant except if the prize is in the form of scientific/medical materials e.g. medical textbook, medical devices or items of medical utility (should not be worth more than IDR 5,000,000 / participant, see Article 6.2.2), and maximum for 10 participants in each event.

4.5.4.3. Distribution of product samples should refer to the applicable regulation as stipulated by Competent Authorities.

4.5.4.4. Other activities in exhibition booth should not be held at times when the scientific sessions are in progress to avoid disturbing or distracting participants from the prime objectives of the meeting.

4.5.4.5. Member Company should not deliberately interfere or attempt to undermine other company sponsored scientific event.

Article 5
PAYMENT TO HEALTHCARE ORGANIZATION (HCO)

- 5.1. Payment to HCO must be paid to HCO's bank account.
- 5.2. Payments made to a HCP's private bank account which serve as a HCO's bank account are prohibited.
- 5.3. If HCO appoints third party as their beneficiary, Member Company shall set its own process to conduct Due Diligence to assess the risk of potential bribery and corruption, and determine whether the payment is appropriate. Payment to third party account as a conduit for indirect payment is not permissible.
- 5.4. Institutional Fee & Listing Fee
 - 5.4.1 As a common local practice, a reasonable institutional fee for the use of the Institution's premises is allowed if supported by an original official document from the Institution.
 - 5.4.2 As a general practice, institutional fees should not be more than the total speaker fees paid for the same event. However, in some cases institutional fees may exceed the total speaker fees only if there is an official tariff certified by the Institution signed by the authorized person.
 - 5.4.3 In compliance with Government Regulation No. 27 Year 2014 on Management of State's Assets (any amendment/renewal thereof), when using facilities in government/regional owned hospitals, the Member Company shall only pay institutional fee for the usage of such facilities provided that the Institution agrees to record and deposit such fees as Non Tax State Revenue.
 - 5.4.4 Listing Fees may also be known as hospital formularium, product listing, hospital listings, product registration and other similar terms with the same nature. Government/regional owned hospitals under MOH management no longer have any right to charge listing fees.
 - 5.4.5 Institutional fee and listing fee must be paid to the Institution's bank account, not to any other alternative bank account (including but not limited to bank account of Division, Department, Sub-Department, and Medical Association).
 - 5.4.6 The following is minimum principle statement to be included in the document for the payment of institutional and listing fees to state owned/regional owned hospital:
"The fee payment shall be recorded and deposited by the respective hospital into the Non Tax State Revenue account or any other classification/account as required under applicable government regulations".

Article 6
GIFT, ITEM OF MEDICAL UTILITY, DONATION AND GRANT

6.1 General Principles

No gift/rewards, incentives, donations, financial, and the like shall be offered or given to HCP in return for prescriptions or recommendations for a company's medicines(s) / product(s).

6.2 Gift

Personal gift to HCP is strictly prohibited, unless in the form of promotional reminder (gimmick) and/or Items of Medical Utility.

6.2.1. Promotional reminder (Gimmick)

- 6.2.1.1. Gimmick shall be relevant to the practice of the HCP and/or benefiting patients; with minimum quantity and value (maximum of IDR 100,000 per item) (see Q&A 10).
- 6.2.1.2. During scientific events/symposium, Member Company may only provide seminar kits in the form of pen, notepad and symposium bag to HCPs.

6.2.2. Item of Medical Utility

- 6.2.2.1. Item of Medical Utility may be offered or provided free of charge provided that such items are of modest value and are beneficial to the provision of medical services and for patient care.
- 6.2.2.2. Item of Medical Utility which primarily involves a patient's benefit such as:
- anatomical model for use in an examination room;
 - medical educational CDs, DVDs, VCDs or the like;
 - selected medical utilities, including but not limited to items such as stethoscope, sphygmomanometer, otoscope, ophthalmoscope, laryngoscope, reflex hammer, head mirror, rhinoscope, medical thermometer, glucometer, tongue refractor, magnifier lens for medical use, weight and height scales;
 - medical textbooks;
 - medical journals.
- 6.2.2.3. Conditions for Item of Medical Utility are as follows:
- (i) They should be of modest value and primarily involve a patient's benefit, except for medical text books or medical journals.
 - (ii) Value of items offered shall not be more than IDR 5,000,000 per year per HCP per company.
 - (iii) Item of Medical Utility must not bear product name, but should bear a company logo and/or name.
- 6.2.2.4. Patient bed, wheel chair and office equipment such as HCP's chair and table are not considered as Item of Medical Utility. Therefore, those items cannot be provided to HCP.

6.2.3. Cultural Courtesy Gift:

It is prohibited to give any Cultural Courtesy Gift to HCP, except for funeral of HCP in the form of one condolence flower arrangement at a maximum value of IDR 750,000 per Member Company.

It is also prohibited to give any cultural courtesy gifts (be it in cash, cash equivalent or flowers or advertisement) to HCO, including but not limited to inauguration, appointment of new committee of HCO, opening of new clinic/hospital, anniversary.

6.3 Donation and Grant

- 6.3.1. Donation is permissible only if given to nonprofit/government Institution, and is strictly prohibited to be given directly to HCP.
- 6.3.2. The Donation should entail a benefit for patients and/or benefit the work or education of the HCP of the Institution.
- 6.3.3. No Donation shall be given in return for products purchased or products standardization, prescriptions or use of a Member Company's product(s) at the Institution.

Fees for products standardization are permitted only if there is an official letter from the Institution and the payment of hospital standardization fee should be transferred to the hospital or Institution's bank account, not to the bank account of Division, Department, Sub-Department, and Medical Association.

- 6.3.4. Member Company products are allowed to be provided free of charge to Institution only for:
- (i) Emergency or disaster or poor patients.
 - (ii) Standardization requirement for initial listing, with a limit of maximum 10 units per SKU per hospital.
- 6.3.5. For standardization purpose, it is required to obtain an original official letter from the Institution (on Institution's letterhead, signed and stamped). This letter should be signed by the authorized person of the Institution.
- 6.3.6. Member Company must only provide Grant to an Institution in response to an unsolicited request, for the purposes of supporting healthcare or medical education or scientific research. For example, but not limited to:
- Grant to accredited providers of postgraduate medical education
 - Fellowships and similar programs
 - Development and dissemination of educational materials or medical equipment for training purposes
- 6.3.7. Grant may not be made for non-educational or promotional purposes and must never be given to individual HCP or to a charity nominated by HCP.

Article 7 PRINTED PROMOTIONAL OR ADVERTISING MATERIALS

7.1. General Principles

- 7.1.1. This section takes care of printed promotional or advertising material of each ethical product directed to HCP. Printed promotional or advertising material should be presented in a legible manner.
- 7.1.2. The scientific basis and presentation of the information on a product should conform to the principles as described in Article 2 of this Code and should conform to the product information approved by Competent Authorities.

7.2. Full/complete Printed Promotional Material or Advertisements

Where the objective is to supply the HCP with adequate information to make a rational decision on the prescription or use of product, the information provided must include, clearly and concisely, the following:

- (i) Product name (Brand/Trade Name)
- (ii) Generic name of active ingredient(s) or INN (International Non-proprietary Name)
- (iii) Name and address of the marketing company
- (iv) Code of production date of the printed material
- (v) Approved indications for use of the product (Minimum of 1 indication)
- (vi) Dosage, method of use/recommended application
- (vii) A brief statement on side effects, clinically important cautions and warnings, contra indications and major interactions at the recommended dosage.
- (viii) A statement that further information is available upon request (see Q&A 11).

7.3. Brief (Reminder) Promotion/Advertisement

In short promotional materials and advertisements which provide only a simple statement on the indications to denote the relevant therapeutic category and why the product is recommended for that indication, the following minimum information should be provided:

- (i) Product name (Brand/Trade Name)
- (ii) Generic name of active ingredient(s) or INN (International Non-proprietary Name)
- (iii) Name and address of the marketing company

- (iv) Code of production date of the printed material

7.4. Promotional reminder (Gimmick)

On small items with limited space for printing and where no promotional message or scientific information is presented, it is acceptable for just the brand or company name/logo to appear.

7.5. References

- 7.5.1. Promotional materials containing information from published studies should include clear and traceable references to those studies.
- 7.5.2. The use of reprints, abstracts and quotations should be compliant with the copyright conditions of such material.
- 7.5.3. Quotations or opinions from medical literature or from personal communications must not be modified or distorted so as to mislead or confuse or alter the intended meaning of the author.

7.6. Mailings

- 7.6.1. Promotional materials should only be sent to appropriate individuals considered to have a professional interest in the information being supplied.
- 7.6.2. The frequency and volume of promotional mailings to HCP should be reasonable. Requests from HCP to be removed from the mailing lists for promotional materials must be respected. However, Member Company must maintain a complete mailing list for other important information such as contra-indications, adverse reactions, cautions etc.

Article 8 AUDIO-VISUAL AND ELECTRONIC PROMOTION MATERIAL

- 8.1. Promotional information for the HCP using these media should comply with the requirements relevant to printed materials, i.e. as described in Article 7.
- 8.2. Product information may be omitted provided the full product/prescribing information is available on request from interested parties.
- 8.3. Specifically, in the case of pharmaceutical product related websites:
 - (i) The identity of the pharmaceutical company and of the intended audience should be readily apparent.
 - (ii) The content should be appropriate for the intended audience.
 - (iii) The presentation (content, links, etc.) should be appropriate and apparent to the intended audience.
 - (iv) Country-specific information should comply with local laws and regulations.

Article 9 SAMPLE

- 9.1. Providing free sample of pharmaceutical products as defined in the Decree of Ministry of Health No. 437/MENKES/SK/VI/1987 to the medical professional is prohibited.
- 9.2. Hence, Member Company is prohibited from providing free pharmaceutical samples to HCP, except in the case of exceptional approval granted by the Competent Authorities.

Article 10
MARKET RESEARCH

- 10.1. Market research should not employ method that in any way discredit, or reduce public trust in the industry. This requirement applies in any case, whether the research is being conducted by marketing company or other organizations acting on its behalf.
- 10.2. Devious or coercive methods to influence respondents are prohibited.
- 10.3. Member Company shall not pay any fees to respondents for market research conducted directly by Member Company.
- 10.4. Pharmacy Survey is not allowed unless conducted by a third party and the information is presented in such a way that the data gathered is pooled.

Article 11
COMMUNICATIONS WITH PUBLIC AND MASS MEDIA

- 11.1. Unless stipulated otherwise by Competent Authorities, ethical product may only be promoted and advertised to the HCP and shall not be advertised to the general public.
- 11.2. Member Company should not place articles or advertorials in the mass media to promote a prescription medicine or for the purpose of encouraging the general public to request a certain product through their physician.
- 11.3. However, Member Company is allowed to have official public website limited to member Company profile and/or disease awareness of therapeutic area.
- 11.4. Member Company must prohibit their employees from conducting any promotional activities in their personal Social Media for any reason. Example of Social Media included but not limited to Facebook, Twitter, You Tube, LinkedIn, etc. Example of unacceptable information to be uploaded is, but not limited to ethical product related; such as name, generic name, image, product logo and product information.

Article 12
INFRINGEMENT AND COMPLAINTS

- 12.1. Each individual IPMG member is encouraged to conduct active self-assessment on the implementation of the Code.
- 12.2. Genuine complaints relating to infringements of the Code are encouraged. Detailed procedures for complaints and the handling of complaints (including the respective roles and jurisdiction of IPMG) are set out in *Appendix 1: Operating Procedures of the Code*.
- 12.3. Initial complaint and final decision letter should be sent to IPMG via Sub Committee Marketing Practices.

**APPENDIX I
OPERATING PROCEDURE OF THE CODE**

1. PROCEDURE FOR CODE COMPLAINTS

The time lines identified here are intended to ensure there is certainty of process and clear enforcement, for the best interest of all parties. All relevant parties must comply with the identified time lines in this section. Only if a Force Majeure occurs, then time line may be deferred / delayed upon mutual agreement between the Alleged Company, IPMG Executive Committee and IPMG Marketing Practices Sub Committee. If the Alleged Company fails to adhere to the required time line, then it shall lose its opportunity to provide information / evidence / response / defense; and the IPMG Executive Committee and IPMG Marketing Practices Sub Committee shall decide on the complaint which decision shall be final and binding.

1.1. Member Company Dialogue Procedures

Complainant is encouraged to contact directly the Alleged Company for dialogue and clarification prior to filing a complaint to IPMG Marketing Practice Sub Committee. The dialogue between the Complainant and the Alleged Company shall be done in good faith to consider each other's position and concerns with due consideration of applicable laws and the Code. IPMG Marketing Practice Sub Committee can act as mediator/facilitator should the companies' desire.

If companies involved do not reach any resolution, then proceed to point 1.2.

1.2. Submission of Complaints

IPMG Marketing Practices Sub Committee will only accept a complaint from a Complainant where the complaint is submitted in writing by the General Manager or the authorized person of the Complainant.

Complaints must include:

1.2.1. Complainant details

The identity of the complainant, with a full mailing address (including fax number and e-mail) for correspondence. The identity of the complainant must be kept confidential to all parties outside the IPMG Marketing Practices Sub Committee. To maintain the neutrality of Marketing Practices Sub Committee as well as to keep the confidentiality of the Complainant, any member of Marketing Practices Sub Committee who is representing the Complainant or the Alleged Company shall be excluded in any process, handling and decision making of the complaint, ever since the complaint is received by IPMG.

1.2.2. Alleged Company

For each case, the identity of the company which is alleged to be in breach of the Code and the name of any product or products should be specifically mentioned.

1.2.3. Reference material

For each case, a specific reference to the source of the advertisement/activity which is the subject of the complaint, of printed material or other evidence should be provided.

1.2.4. Date, location and name of the event

Complaint shall include at minimum date, location and name of the event, where relevant, of the alleged breach of the Code.

1.2.5.

Summary

For each case, a brief description of the complaint, a specific reference to the part of the Code under which the complaint is being made (section and paragraph number(s)).

All correspondences should be addressed to:

Head of IPMG Marketing Practices Sub Committee

Wisma Pondok Indah 1st floor Suite 102

Jl. Sultan Iskandar Muda Kav. V / TA

Jakarta Selatan 12310

Phone : +62 (21) 769 7531

Fax : +62(21) 769 7532

Email : ipmg@ipmg-online.com

1.3. **Acknowledgement of Complaints**

Marketing Practices Sub Committee will acknowledge the receipt of complaints in written to complainants within 5 (five) working days after receiving the complaints.

1.4. **Validation**

Marketing Practice Sub-Committee has 10 (ten) working days after sending such written acknowledgement to the Complainant to validate the complaint to ensure if:

- (i) it appears to be a genuine matter, submitted in good faith; and
- (ii) if there is sufficient indication of the Code violation to enable the complaint to be processed.

The Marketing Practices Sub Committee validate by examining the reference materials given by the Complainant (see point 1.1 above).

1.5. **Notification to and Response from the Alleged Company**

After completion of validation, the Marketing Practices Sub Committee have 5 (five) working days to:

- (i) Notify in writing the Complainant that the complaint has no strong basis for further process and the process is closed; or
- (ii) Notify in writing the Alleged Company (cc the Complainant) that the complaint is valid and potentially violates the Code and request the Alleged Company to provide explanation of the potential violation.

In the case of point (ii) above, within 10 (ten) working days as of receiving the written notification from Marketing Practices Sub Committee, the Alleged Company has the right to:

- (i) respond in writing to the Marketing Practices Sub Committee providing their explanation on the complaint; and/or
- (ii) request and have a face to face meeting with Marketing Practices Sub Committee members to explain on the complaint.

1.6. **Marketing Practices Sub Committee Decision on the Compliant**

Upon receiving the information/explanation from the Alleged Company (within the period mentioned in point 1.5 above), the Marketing Practices Sub Committee has 15 (fifteen) working days:

- (i) to review the explanation and information from Alleged Company;
- (ii) to conclude if the complaint is a violation of the Code; and
- (iii) to send letter to the Alleged Company and the Complainant.

The letter to the Alleged Company and the Complainant can be in the following form/content:

- (i) If the Marketing Practices Sub Committee decides there is **insufficient evidence of a violation**, this will be communicated separately to both the Alleged Company and the Complainant and the case will be closed. The decision of the Marketing Practices Sub Committee will be **final and binding**.
- (ii) If the Marketing Practices Sub Committee decides that it is a **minor violation** this will be communicated separately to both the Alleged Company and the Complainant; and reported to the Executive Committee. The decision of the Marketing Practices Sub Committee will be **final and binding**.
- (iii) If the Marketing Practices Sub Committee decides that it is a **major violation** this will be communicated to the Alleged Company.
 - a. If the Alleged Company **agrees with the decision** of the Marketing Practices Sub Committee, it will be communicated to the Complainant, and will also be reported to the Executive Committee. The decision of the Marketing Practices Sub Committee will be **final and binding in this instance**
 - b. If the Alleged Company **disagrees with the decision** of the Marketing Practices Sub Committee and would like a second review they can request for a **panel hearing**. A request for panel hearing should be made in writing within 15 (fifteen) working days as of receipt of the Marketing Practices Sub Committee's decision.

1.7. Panel Hearing

- 1.7.1. The panel will consist of 5 (five) representatives who are knowledgeable on the Code and represent the following functions – Medical, Legal, Compliance, Regulatory and a General Manager. The panel members will be mutually appointed and endorsed by the Executive Committee and informed to the Alleged Company and the Complainant, within 5 (five) working days after receipt of the request of a panel from the Alleged Company (see point 1.6 above). In any instance, the Alleged Company representative (whatever function) should not decide and/or sit on the panel.
- 1.7.2. Both the Alleged Company and representatives of Marketing Practices Sub Committee (excluding any member who is representative from the Alleged Company) will attend the hearing to be observer, witness and/or resources.
- 1.7.3. The panel hearing must be done within 5 (five) working days as of the panel being appointed and endorsed and hearing should not last more than 1 (one) working day.
- 1.7.4. The panel will then deliberate a **written summary and a final decision**; which will be reported to IPMG Marketing Practices Sub Committee and to IPMG Executive Committee within the next business day after the actual panel hearing.

1.8. Communication of the Decision

Based on panel final decision, at the following Executive Committee meeting, IPMG Executive Committee will review the summary and decision of the panel and decide to:

- (i) Agree with the panel decision; or
- (ii) Disagree with the panel decision; and makes independent decision to the case at the same Executive Committee meeting.

The Executive Committee decision will be **final and binding** and will be communicated to the Alleged Company and the Complainant within 5 (five) working days after the said Executive Committee's meeting.

1.9. Status Reports

IPMG Marketing Practices Sub Committee will issue an Annual Report on the IPMG Marketing Practices, summarizing its activities. The report will be distributed to all IPMG members every first quarter of the following year.

1.10. Whistleblower

There could be situation where the allegation comes from anonymous or external sources outside IPMG members. If this occurs then the above process of managing allegation also applies but with the conditions below:

- a. Identity of source must be kept confidential and the IPMG Marketing Practices Sub Committee and members of the Panel must provide effort to maintain protection of retaliation to the whistleblower;
- b. The whistleblower allegation must not be shared widely amongst all IPMG members, but only to the IPMG Marketing Practices Sub Committee;
- c. Identified persons within the IPMG Marketing Practices Sub Committee should make attempt to reach out to the whistleblower to gain more concrete information, by email or phone call, but preferably by phone call first.
- d. If no concrete information can be gathered from the whistleblower, then the allegation should not be processed further for review by the IPMG Marketing Practices Sub Committee;
- e. In any event where situation on managing the whistleblower becomes more complex and risky, then the IPMG Marketing Practices Sub Committee should consult with relevant legal counsel of the IPMG members.

1.11. Managing Information

In any and all situation, the IPMG Marketing Practices Sub Committee and members of the Panel shall only review and discuss information on the allegation that is relevant to the alleged non-compliance marketing practices/activities. In no event should the IPMG Marketing Practices Sub Committee and members of the Panel discuss, review and make use for any purpose any other information that relates with pricing, margin, discount, cost of goods, supplier/vendor performance, or other commercial terms in nature that may be at risk of violating antitrust laws/principles, which may be received during the process of managing such allegation. In such receipt or knowledge of such information, the IPMG Marketing Practices Sub Committee and members of the Panel must disregard, delete and/or destroy said information. In any doubt, the IPMG Marketing Practices Sub Committee and members of the Panel should consult with relevant legal counsel of the IPMG members.

2. OFFENCES and PENALTIES

2.1. Type of Violations

2.1.1. Violations of this Code are categorized into minor and major.

2.1.2. Violations which impact other members are categorized as minor violations. For example, but not limited to:

- Flowers to HCP other than for funeral purposes,
- Provides courtesy gift,
- Undermine other company sponsored scientific event,
- Door prize, etc.

2.1.3. Violations which impact other members and/or patients and/or IPMG reputation and/or have the intention of bribery are categorized as major violations. For example, but not limited to:

- Incorrect claims in promotional material,
- Off-label Promotion,
- Sponsoring spouses of HCP,
- Provides extravagant facilities to HCP,
- Paying cash for prescriptions

2.1.4. The above examples are not an exhaustive list. The purpose of this list is to give an illustration of the types of violations. IPMG Marketing Practices Sub Committee together with IPMG Executive Committee shall have discretion to decide the category of the violation.

2.2. First Offence

If the violation by the Member Company is the first offence, then following will apply:

- (i) A warning letter issued by IPMG Marketing Practices Sub Committee to General Manager (GM) concerned upon final and binding decision. Cc. IPMG secretariat; and
- (ii) Additionally, for a major violation the violating company must pay USD 2,000 fine.

2.3. Second Offence

If the violation by the Member Company is the second offence, then following will apply:

- (i) A warning letter will be sent by IPMG Executive Committee to the GM concerned, if the violation is categorized as minor; or
- (ii) An official letter shall be sent by IPMG Executive Committee to the Senior Management at the Global Head Quarters of the violating company, if the violation is categorized as major; and
- (iii) The IPMG Executive Committee will invite the GM to a meeting with the Executive Committee to explain their company's behavior; and
- (iv) The violating company must pay fines of:
 - USD 2,000 for minor violation; or
 - USD 5,000 for major violation.

2.4. Further Offence

If the violation by the Member Company is further offence, then following will apply:

- (i) An official letter shall be sent by IPMG Executive Committee to the Senior Management at the Global Head Quarters of the violating company; and
- (ii) The IPMG Executive Committee will invite the GM to a meeting with the Executive Committee to explain their company's behavior; and
- (iii) The violating company must pay fines of:
 - USD 5,000 for minor violation; or
 - USD 20,000 for major violation.

2.5. In Summary

Violation Types	Examples of Violations, Not Exhaustive List	First Offence	Second Offence	Further Offence
Minor: Impact to other IPMG member(s)	<ul style="list-style-type: none"> • Cultural Courtesy Gift • Undermine other company sponsored scientific event • Door prize 	<ul style="list-style-type: none"> • Warning letter from IPMG to GM 	<ul style="list-style-type: none"> • Warning letter from IPMG to GM • USD 2,000 fine 	<ul style="list-style-type: none"> • Official letter to Head Quarter • USD 5,000 fine
Major: Impact to other IPMG member(s) and one or more of following: <ul style="list-style-type: none"> • Impact to IPMG reputation • Impact to patients • Intention to bribe or corrupt 	<ul style="list-style-type: none"> • Incorrect claims in promotional material • Off-label Promotion • Sponsoring spouses of HCP • Provides extravagant facilities to HCP • Paying cash for prescriptions 	<ul style="list-style-type: none"> • Warning letter from IPMG to GM • USD 2,000 fine 	<ul style="list-style-type: none"> • Official letter to Head Quarter • USD 5,000 fine 	<ul style="list-style-type: none"> • Official letter to Head Quarter • USD 20,000 fine

Any financial penalties must be settled to IPMG's bank account within 30 calendar days as of receipt of the FINAL AND BINDING decision.

* * * * *

QUESTIONS & ANSWERS

1. Pricing and Terms of Trade

- Q:** Does the Code prohibit Member Company from giving its customers discounts or other favorable trade terms for the supply of pharmaceutical products?
- A:** No. The Code does not restrain or regulate commercial trade terms for the supply of pharmaceutical products. IPMG encourages competition among Member Company.
- Q:** Does the Code apply to the promotion and marketing of pharmaceutical products to commercial customers who are also practicing as HCP, such as a pharmacist who operates his/her own practice?
- A:** The Code does apply to the promotion and marketing of pharmaceutical products to such a customer. However, the Code does not restrain or regulate commercial trade terms for the supply of pharmaceutical products, to customers. In any dealings with such a customer, Member Company should respect the customer's role as a HCP and, if applicable, comply with the requirements of the Code.
- Q:** Does the Code apply to the promotion and marketing of pharmaceutical products to commercial customers who are not HCP? What if the customer is a HCP by qualification but is not practicing?
- A:** No. The Code only applies to interactions with practicing HCP. Promotion and marketing to commercial customers (whether or not they are HCP) may of course be governed by other laws and regulations, such as those that restrict or prohibit inaccurate, misleading or deceptive advertising and promotion or restrict or prohibit the giving of inducements to public officials or employees.
- Q:** Does the Code cover price lists or other documents describing terms of trade?
- A:** No.
- Q:** Could a false price claim or a misleading price comparison in promotional material be processed under the Code?
- A:** Yes, this is possible when a Member Company is inappropriately using pricing information in its promotional materials or activities.

2. Consultancy Agreements

- Q:** In the absence of any formal industry guidelines or local laws, how should Member Company interact with HCP who is offering legitimate consultancy services?
- A:** It is appropriate for consultants who provide genuine services to be offered reasonable compensation for those services to include travel, lodging, and meal expenses incurred as part of providing those services. The following factors support the existence of a genuine consulting arrangement:
- a written confirmation which specifies the nature of the services to be provided and the basis for payment of those services;
 - a legitimate need for the services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants;
 - the criteria for selecting consultants are directly related to the identified purpose and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular HCP meet those criteria;
 - the number of HCP retained is not greater than the number reasonably necessary to achieve the identified purpose;
 - the retaining company maintains records concerning and makes appropriate use of the services provided by consultants;
 - The hiring of the HCP to provide the relevant service is not an inducement to prescribe a particular product.

3. Health Care Professional (HCP)

- Q:** Are front liner, cashier, owner of a pharmacy considered as HCP? What types of interactions can Member Company do with them?
- A:** If those persons have no formal pharmacy education background as regulated in Government Regulation No. 51 Year 2009 on Pharmacist Duties, they are not considered as HCP. Therefore, they are not entitled to attend any promotion, scientific or professional meeting as regulated in this Code. They can only be exposed with information in relation to product handling, disease awareness and counterfeit.
However, as they are working in highly regulated pharmaceutical business and the objective of this Code is to define high standards that must be abide by the industry, the prohibitions and obligations under this Code which govern how interaction should be made between the Member Company and HCP shall to the extent applied to those persons.
- Q:** Will HCP who is the registered civil servant yet he/she practices also in private clinic and Medical Representative only visit that HCP in his/her private practice still be considered as civil servant?
- A:** Yes. Status of civil servant is permanently attached to HCP.
- Q:** What should Member Company do to determine HCP status if the situation as follows:
- HCP is only practicing in private hospital. He receives honorarium as guest lecturer from Government University.
 - Pensioned Civil Servant HCP is serving Government Hospital as honoree.
- A:** Member Company to attest HCP status.

4. Disguised Promotion

- Q:** Is it ever appropriate for a Member Company to publish promotional materials that appear to be independent editorial content?
- A:** No. Where a Member Company finances or otherwise secures or arranges the publication of promotional material in journals, such promotional material must not resemble independent editorial matter.
- Q:** How does the prohibition of pre-approval promotion affect compassionate use programs?
- A:** The clause does not prevent compassionate use programs which must of course comply with all applicable laws, regulations and codes. Care should be taken to ensure that communications for a compassionate use program are not, in effect, advertisements for an unlicensed medicine or use.

5. Hidden Promotion

- Q:** Is it allowed for employees of Member Company wearing uniform (shirt, jacket, hat, towel, scarf, tie, etc.) with ethical product logo/name in any event?
- A:** No. In order to protect Member Company from negative perception of conducting hidden promotion to public, such activity shall be avoided.

6. Medical Representative

- Q:** Do all MRs have to be certified?
- A:** All MRs needs to be certified within 2 years of being employed in the same company. Due to natural turnover, 10% of total company MRs Population not being certified is acceptable. If the including employment termination to rectify this situation.

7. Scientific and Educational Meetings

- Q:** Can Member Company sponsor HCO's internal meeting?
- A:** HCO's internal meeting which is focus on their organization operational objectives is not considered as scientific and/or education information.
- Q:** What are the factors that Member Company need to consider in determining to sponsor/participate in an event?
- A:** Member Company to review the purpose of meeting, agenda and venue of the meeting.

8. Events/Meetings Managed by Member Company

- Q:** If Member Company conducts a meeting (example: Round Table Discussion, small group discussion, launching symposium etc.) with participants coming from government institutions, will it need notification sending to each institution of participants?
- A:** No, as long as such participant does not receive accommodation, transportation and registration fee from Member Company. If the participant receives one of such benefit, then it will be considered as sponsorship (see Article 4.1.4).

9. Appropriate Venues

- Q:** What are some examples of appropriate or inappropriate venues for holding stand-alone scientific events?
- A:** Hotels which are incorporated with an amusement park, golf course, extravagant entertainment or private beach can create negative perceptions in the pharmaceutical industry stakeholders. Some examples, including but not limited to:
- Trans Hotel, Bandung
 - Mercure Hotel, Ancol, Jakarta
 - Hard Rock Hotel, Bali
 - Discovery Kartika Plaza Hotel, Bali
 - Novotel Golf Resort & Convention Center, Manado

For any new hotel(s) which may not incorporated herein but fulfill the above criteria will be deemed to be considered as inappropriate hotel under this section.

Hotels which can provide relevant meeting facilities, convenient location for majority of attendance to reach, easy access to the airport or located downtown can be categorized as appropriate venues for holding a scientific meeting. Some examples, but not limited to:

- Mulia Hotel, Jakarta
- Ritz Carlton Hotel, Jakarta
- Shangri-La Hotel, Jakarta
- Pullman Hotel, Bali
- Harvest Land Mercure , Bali
- Novotel Nusa Dua, Bali
- Westin Hotel, Bali

10. Gimmick

Q: What are some examples of gimmick? And what are the examples of unacceptable items?

A: The examples of gimmick are - but not limited to - pens, notepads, agenda, surgical gloves, nail brushes, clocks, and calendars.

Examples of unacceptable items are, included but not limited to:

- Business card
- Prescription pad
- Anything for supporting the HCP's routine operational expenses or his/her capital expenditures
- Office supplies: perforator, stapler, paper weight
- Non-medical device electronic items: Handy cam, DVD, CD players, TV sets, computer equipment, hair dryer, hand phone, refrigerator, tablet computer.
- Vouchers
- Subscription of general magazines
- Sport equipment, membership, ticket
- Entertainment and hobbies goods/items
- Member Company pharmaceutical products for HCP's personal use
- Vehicle and its accessories

11. Reprints

Q: Are reprints considered as promotional material under the Code?

A: No. Reprints of scientific and medical articles, when used as stand-alone documents, are not developed by pharmaceutical companies and as such cannot be considered as promotional materials. If, however, they are presented to a HCP together with other, company-originated documents, they then become promotional materials. In all cases, where promotion refers to, includes, or is presented together with scientific or medical articles or studies, clear references should be provided. Any reprint of artwork (including graphs, illustrations, photographs or tables) taken from articles or studies and included or presented with promotional materials should clearly indicate the source of the artwork and be faithfully reproduced.

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