

## IPMG CODE OF ETHICS January 2019 Revision



*Building good reputation through high standards of ethical behavior*



**IPMG**

*Perkumpulan International Pharmaceutical Manufacturers Group*

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## FOREWORD

Jakarta, 1 January 2019

International Pharmaceutical Manufacturers Group (IPMG), is a non-profit, non-governmental organization representing 25 international research-based pharmaceutical companies operating in Indonesia (“**Member Company**”), 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.

IPMG Member Company is fully committed to supporting the medical community in a scientific manner and complying with respective laws and regulations.

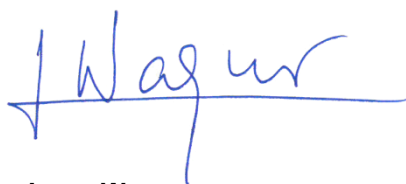
In our continuous effort in creating a level playing field in the Indonesian pharmaceutical industry as well as ensuring a uniform interpretation of the Code, the Ethical Practices Sub-Committee, after careful considerations, has revised several articles and points in IPMG Code of Pharmaceutical Ethical Practices in Indonesia issued in May 1, 2017. This revision is necessary to ensure full alignment with the revision of International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code of Practices.

IPMG has been adopting stringent practices and taking compliance measures over the past years. These standard practices should apply to IPMG Member Company.

We believe that the IPMG Code of Ethics, effective as of January 1, 2019, will improve healthcare services and benefit patients in Indonesia.

Yours sincerely,

**IPMG**



**Jorge Wagner**  
Chairman



**Angel Michaelo Luna Evangelista**  
Head of Sub-Committee Ethical Practices

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# IPMG CODE OF ETHICS

January 2019 Revision

## P R E A M B L E

- (i) The ethical promotion of prescription pharmaceutical products is vital to the pharmaceutical industry's mission of helping patients by discovering, developing and marketing new products. Ethical promotion helps to ensure that Healthcare Professionals have access to information they need, that patients have access to the products they need and that products are prescribed and used in a manner that provides the maximum healthcare benefit to patients.
- (ii) IPMG and its Member Company are committed to educational and promotional efforts that benefit patients and promotional programs and collaborations that enhance the practice of healthcare services. IPMG also seeks to preserve the independence of the decisions taken by Healthcare Professionals in prescribing medicines to patients. Member Company 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 their products. Member Company relationships with Healthcare Professionals must support and be consistent with the professional responsibilities of Healthcare Professionals towards their patients. Member Company 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 and its Member Company seek to ensure that ethical promotional practices are established nationwide.
- (iii) The IPMG Code of Ethics (the "**Code**") sets forth standards for the ethical promotion of pharmaceutical products to Healthcare Professionals and for IPMG Member Company's interactions with them, effective January 1, 2019.
- (iv) IPMG acknowledges the role of relevant codes of ethics developed by all other healthcare 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 Company is accountable for addressing and correcting infringements under relevant codes. They should also ensure that internal structures and procedures (including adequate training of employees) are developed 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) This Code is available in English and Bahasa. If there are contradictions between English and Bahasa, the English version shall prevail.

\* \* \* \* \*

## CHAPTER I OBJECTIVE

The objective of this Code is to define the high standards that must be abide by Member Company in the ethical promotion of their products to Healthcare Professionals as well as to establish the process of self-discipline to ensure that Member Company 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.

## CHAPTER II CODE OF ETHICS

### Article 1 Implementation of the Code

#### 1.1. Scope

- 1.1.1. The Code applies to Member Company including other third-party organizations engaged by Member Company to promote and/or market their products to Healthcare Professionals.
- 1.1.2. The Code covers any interactions of Member Company with Healthcare Professionals, Healthcare Organizations and Patient Organizations.
- 1.1.3. **Exclusion:** This Code does not seek to regulate the following activities:
  - A disease awareness campaign targeted at the public. Such campaign shall comply with local regulations issued by Competent Authorities.
  - Promotion of non-prescription pharmaceutical products that is not addressed to Healthcare Professionals.
  - Pricing or other trade terms for the supply of Member Company's products (see Q&A 1).
  - 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 Member Company's product; general information about Member Company (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 Member Company and its products.

#### 1.2. Definition

For the purpose of this Code:

- 1.2.1. **Prescription 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 Professionals, 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.
- 1.2.2. **Non-prescription pharmaceutical product** means any pharmaceutical products which are not defined in Article 1.2.1.
- 1.2.3. **Promotion** means any activity undertaken, organized or sponsored by Member Company which is directed to Healthcare Professionals to promote the

prescription, recommendation, supply, administration or consumption of its product(s) through all kind of media.

- 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 Professionals** 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 2).
- 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 2).
- 1.2.7. **Authorized Person** means director or an individual who is empowered by the institution to make decision or act on behalf of the institution.
- 1.2.8. **Healthcare Organization** or known as **HCO** means any entity (i) that is a healthcare, medical / scientific association or organization (irrespective of a legal or organization form) such as hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organizations within the scope of IPMG Code) whose business address, place of incorporation or primary place of operations is in Indonesia or (ii) through which one or more HCPs provide services.  
  
A group of unaffiliated HCPs practicing together in one place is not classified as a HCO.
- 1.2.9. **Institution** is the employer of HCP, whether it is owned by government or private.
- 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 but not limited to blogs, wikis, internet communities, message board, video sharing sites and networking applications.
- 1.2.12. **Donation** means financial or physical contribution given typically for charitable purpose and/or patient benefit.
- 1.2.13. **Grant** means financial support for education or research purposes given to HCO.
- 1.2.14. **Competent Authorities** means Badan Pengawas Obat dan Makanan (BPOM) or Kementerian Kesehatan (Kemenkes).
- 1.2.15. **Member Company** means any company that is a member of IPMG.
- 1.2.16. **Transfer of Value (ToV)** 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.

### 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 IPMG.

Member Company's President Director and other Board members 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. **Appropriate Use:** Promotion should encourage the appropriate use of Member Company's products by presenting them objectively and without exaggerating their properties.

1.5.2. **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 Member Company's products and their uses, whether promotional in nature or not, which is sponsored by Member Company should clearly indicate by whom it has been sponsored (see Q&A 3).

### Article 2 Information and Claims

#### 2.1. General Criteria

Information and claims for Member Company's products should be fair, objective, 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 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. Member Company is 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 Claims**

- 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 Member Company's 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 Member Company's Materials**

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

## **2.9. Healthcare Professionals 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**

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 3).

## **2.11. Pre-Approval Communications and Off-Label Promotion**

2.11.1. A product shall not be promoted until the Marketing Authorization License or known as "*Nomor Ijin Edar*" ("**NIE**") to market for such use has been granted by the Competent Authorities. For Special Access Scheme ("**SAS**") program, see Q&A 4.

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 to 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 public to have complete information on advances in the scientific and medical progresses, provided that the results of the research have been acknowledged.

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.

Any such information or activity should not constitute promotion, is unbranded, balanced, up-to-date and has the intention on improving the quality of patient care. Such activities must be led by Medical Department.

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 or indication 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.

- 2.11.6. Legitimate training of speakers on product can occur in the pre-approval period and must be under Medical Department oversight. However, the speaker cannot deliver such external presentations on behalf of Member Company prior to NIE is granted.

## **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 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.

President Director of Member Company is 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 IPMG acknowledged independent institution (see Q&A 5).
- 3.3. MR should be able to give technical explanations on their company’s products in an accurate, fair, and in an ethical manner and good conduct to HCP.
- 3.4. MR should be prohibited to give or offer rewards to HCP.

### **Article 4 Interaction with Healthcare Professionals**

#### **4.1 General Principles**

- 4.1.1. Member Company’s interaction with HCP is 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.
- 4.1.2. No ToV may be provided or offered to 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 HCP’s prescribing practices (**No “quid pro quo”**).
- 4.1.3. According to the prevailing law and regulations, any sponsorship given to HCP must be reported by Member Company to the relevant government institutions.

To uphold transparency, advance written approval must be obtained for sponsorship and service engagement with individual HCP. Written approval must be obtained by the authorized person of the HCP's employer (See Q&A 2).

Written approval is not required for self-employed HCP.

The detail of sponsorship and service engagement must be clearly stated in written documentation by both parties.

- 4.1.4. Member Company is prohibited from offering any kind of inducement, door prize, incentive, financial reward to HCP.

## 4.2 Scientific Event

- 4.2.1. The objective of all scientific and promotional events for HCP organized or sponsored by Member Company (an "**Event**") should be to provide balanced scientific or educational information and/or to inform HCP about products.
- 4.2.2. The following criteria shall be met to organize or sponsor an event by Member Company:
- (i) agenda should have legitimate scientific content; and
  - (ii) no entertainment or other leisure or social activities should be provided or paid for by Member Company as explained in 4.3.10; and
  - (iii) held in appropriate location and venue which is conducive to the scientific or educational objectives and the purpose of the event.
- 4.2.3. HCO's internal meeting which is focus on their organization operational objectives is not considered as scientific and/or education information.
- 4.2.4. The participation of Member Company in a symposium, congress or the like should be declared clearly at the meeting or in proceedings of the meeting.
- 4.2.5. Location and venue for event organized and/or sponsored by Member Company:
- (i) The location of event (i.e.: province or city) should be geographically in or near a city or town which is a recognized scientific or business center and is easily accessible for the intended audience.
  - (ii) The venue of event (i.e. hotel, convention center) should not be primarily known for its touristic or recreational offering. Venue 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 event.
  - (iii) It 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 or beach with restricted access to public.
- 4.2.6. No Member Company may organize or sponsor 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. International scientific congresses and symposia that derive participants from many countries are therefore justified and permitted if majority of the invited HCP are from outside of Indonesia, and it makes greater logistical or security sense to hold the Event in another country.
- 4.2.7. Payment related to Event shall be made to the legitimate party based on valid documentation. Please refer to Article 5.1.4 and/or 5.1.6.

### 4.3 HCP Attending an Event

- 4.3.1. Criteria of HCP selection:
- (i) must be related to medical expertise and experience of the selected HCP in the medical field particularly covered by the event; or
  - (ii) has possible cooperation with the HCP for future scientific projects as consultant/speaker.
- 4.3.2. Sponsorship of HCP to attend an event is limited to the payment of transportation, accommodation and/or registration fees, which shall be directly paid to the legitimate party. It is strictly prohibited to reimburse to HCP for any costs related to such event.
- 4.3.3. Hospitality to HCP must be:
- (i) provided in association with such permitted meetings,
  - (ii) with a level that is secondary to the purpose of the meeting, and
  - (iii) appropriate and not out of proportion to that occasion, in the context of time spent and cost.
- 4.3.4. The hospitality cost should not exceed the level which most recipients might normally adopt when paying for themselves.
- 4.3.5. Hospitality should not extend beyond the invited HCP unless that person is a member of the health professions and qualifies as a proper delegate or participant at the meeting.
- 4.3.6. No payment or support of any nature for accompanying of the sponsored HCP can be made by Member Company. The invitation shall describe such intention that the invitation is valid for HCP only.
- 4.3.7. Accommodation:
- (i) 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.
  - (ii) Accommodation should be modest and appropriate for business purpose.
  - (iii) In Indonesia, the room charge/room/night with maximum of IDR 2,500,000 (before tax and service) is allowed.
  - (iv) 5-star hotel outside of Indonesia is not allowed unless permitted by host country regulation or due to it is the venue of event.
- 4.3.8. Transportation:
- (i) Transportation of HCP where the routes and schedule differ from the venue of scientific event is not allowed.
  - (ii) Tickets must be booked through the company's appointed travel agent(s).
  - (iii) First class flight for HCP is not allowed.
  - (iv) 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.
- 4.3.9. Meal shall be:
- (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 of 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 4.3.10)

4.3.10. Entertainment

No entertainment or other leisure or social activities should be provided or paid by Member Company. For example:

- A concert
- Sport activities, including the purchase of entertainment or sport tickets
- A sightseeing tour
- High profile, inappropriate or expensive entertainers; such as a well-known TV or pop star; even if their performance is secondary to a necessary meal
- Stand-alone dinner (not dinner symposium)
- Cruise
- *Oleh-oleh*
- Providing meals ( e.g. snack, lunch box) without scientific discussion
- Excessive meals

4.3.11. 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.

4.3.12. It is prohibited to give honorarium to compensate HCP for time spent in attending event.

#### 4.4 HCP Engagement as Speaker / Moderator

4.4.1. Qualifications of HCP as speaker/moderator should be based on the speaker's medical or scientific expertise, professional credentials, academic and clinical expertise, professional society affiliations and ability to deliver a quality meeting.

4.4.2. The amount of the honorarium for Indonesian speakers/moderators at any meetings should reflect the Fair Market Value (FMV) and not be more than IDR 6,000,000 net per presentation, whether it is arranged by Member Company or by a third party. The honorarium is limited to maximum IDR 12,000,000 net per day per speaker, assuming multiple presentations for the same Member Company.

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

4.4.4. The honorarium can be paid to HCP's bank account, evidenced by a contract. Honorarium could be paid to the respective HCP's employer, if officially requested.

4.4.5. Payments of honorarium should not be made in advance. As an exception, advance payment is acceptable in the case whereby the event is organized by a third party, where the honorarium is included in the lump sum payment requested by the event's organizing committee. Nevertheless, the maximum honorarium stated in Article 4.4.2 is applied.

4.4.6. Payments of honorarium should be made via bank transfer. Cash payment is prohibited.

4.4.7. Member Company may provide hospitality to the engaged HCP following the standards set forth in this Code (see Article 4.3).

#### **4.5 HCP Engagement as Advisor / Consultant**

- 4.5.1. Engagement must be entered only when a legitimate need and purpose for the service is identified in advance, for example to seek advice and guidance, to understand medical scientific development in a country and have a two-way dialogue with external experts.
- 4.5.2. The purpose and rationale of the engagement must be clearly defined and documented before the service starts.
- 4.5.3. The result of such engagement should be documented.
- 4.5.4. The honorarium must be reasonable and reflect the Fair Market Value (FMV) on the service performed with maximum IDR 12,000,000 net per day.
- 4.5.5. For advisory board, the number of external experts engaged must be justifiable. The selection of an external expert must be exclusively based on objective criteria such as expertise and experience in a therapeutic area.

### **Article 5 Interactions with Healthcare Organization**

#### **5.1. General Principles**

- 5.1.1. The objective of event organized by HCO should be to provide balanced scientific or educational information and/or to inform HCP about products.
- 5.1.2. The following criteria shall be met to sponsor an event organized by HCO:
  - (i) agenda should have legitimate scientific content; and
  - (ii) no entertainment or other leisure or social activities should be provided or paid for by Member Company as explained in 4.3.10; and
  - (iii) held in appropriate location and venue which is conducive to the scientific or educational objectives as set forth in Article 4.2.5 of this Code and the purpose of the event
- 5.1.3. Member Company cannot sponsor HCO's internal meeting which is focus on their organization operational objectives as it is not considered as scientific and/or education information.
- 5.1.4. Payment to HCO must be paid to HCO's bank account. Payments made to a HCP's private bank account which serve as a HCO's bank account are prohibited.
- 5.1.5. Any fee related to activity conducted in hospital facility should only be paid to the hospital bank account.
- 5.1.6. 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.
- 5.1.7. According to prevailing law and regulation, any sponsorship given to HCO must be reported by Member Company to the relevant bodies.

#### **5.2. Sponsorship to HCO**

- 5.2.1. Sponsorship to HCO could be in the form of but not limited to sponsorship package, congress/symposium/workshop and exhibition stand

- 5.2.2. 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 HCP to gain scientific information related to the topics of the event. Modest food and beverages may be offered.
- 5.2.3. Member Company is prohibited to provide, support or sponsor a room which serves leisure activities with no scientific related.
- 5.2.4. Scientific quiz prizes shall only be given in the form of items as per Article 9.3.
- 5.2.5. 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.
- 5.2.6. Member Company should not deliberately interfere or attempt to undermine other company sponsored scientific event.

### **5.3. Institution Fee and Listing Fee**

- 5.3.1. Institution fee is a reasonable fee for the use of the institution's premises. Institution fee is allowed if supported by an original official document from the institution. Such fee on using facilities in government owned hospitals; the institution should comply with the related laws/regulations on management of state's assets.
- 5.3.2. Institution fee should not be more than the total speaker fee paid for the same event. However, in some cases it may exceed the total speaker fees only if there is an official tariff certified by the institution signed by the authorized person.
- 5.3.3. Listing fees may also be known as hospital formularies, product listing, hospital listings, product registration and other similar terms with the same nature; is not allowed for government owned.
- 5.3.4. 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).
- 5.3.5. For listing 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.
- 5.3.6. Member Company is allowed to provide its product with a limit of maximum 10 units per SKU per hospital, if required for initial listing only.

### **5.4. Association Fee**

- 5.4.1. Member Company can collaborate with Medical Association in conducting Member Company's scientific event, provided there is a legitimate business need.
- 5.4.2. A reasonable association fee for such collaboration is allowed if supported by an official letter from Medical Association.
- 5.4.3. Association fee must be paid to the Medical Association's bank account.



**Article 6**  
**Interaction with Patient and Patient Organization**

- 6.1. 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.
- 6.2. Financial support may be provided to support Patient Organization meetings which primarily for professional, educational, and scientific in nature, or otherwise supports the mission of the Patient Organization.
- 6.3. Venue, location, and refreshments provided by Member Company must comply with Article 4.2.5.
- 6.4. 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, if that company did not make its support conditional on it being the sole funder.
- 6.5. Non-HCP representative of Patient Organization is prohibited to attend as participant in a promotional or scientific meeting or event.
- 6.6. All patient support programs should be designed to support the patient who is treated with Member Company marketed products, including support for the management of disease outcomes (e.g. adherence, awareness, education). These programs must always be established in compliance with the highest ethical standards and should be reviewed and approved by Medical Department.

**Article 7**  
**Donation and Grant**

**7.1. Donation**

- 7.1.1. Donation is permissible only if given to government or nonprofit organization in response to an unsolicited request. Except in the event of catastrophic situation, Member Company may voluntarily provide donation to any eligible third party.
- 7.1.2. Donation is strictly prohibited to be given directly to HCP or to a charity nominated by HCP.
- 7.1.3. Donation should entail a benefit for patients.
- 7.1.4. No donation shall be given in return for products purchased or product standardization, prescription or use of a Member Company's product at the institution.

**7.2. Grant**

- 7.2.1. Member Company must only provide grant to HCO 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

- 7.2.2. Grant may not be made for promotional purposes.

## **Article 8 Promotional or Advertising Materials**

### **8.1. General Principles**

- 8.1.1. This section focuses on promotional or advertising materials of Member Company's product to HCP.
- 8.1.2. The content of promotional material should conform to the principles as described in Article 2 of this Code and the product information approved by Competent Authorities.
- 8.1.3. Promotional or advertising materials can be presented in full or short/brief version.
- 8.1.3.1. Full promotional or advertising materials  
To make a rational decision on the prescription or use of product, the minimum following information is needed:
- (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 materials production date
  - (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
- 8.1.3.2. Short/brief promotional or advertising materials  
In short promotional or advertising materials 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 materials production date
- 8.1.4. References:
- (i) Promotional materials containing information from published studies should include clear and traceable references to those studies.
  - (ii) The use of reprints, abstracts and quotations should be compliant with the copyright conditions of such material.
  - (iii) Quotations or opinions from medical literature or from personal communications must not be modified or distorted to mislead or confuse or alter the intended meaning of the author.

### **8.2. Printed Materials**

- 8.2.1. Any printed material should comply with requirements set out in point 8.1.
- 8.2.2. Reprints of scientific and medical articles, when used as stand-alone documents and are not developed by pharmaceutical companies are not considered as promotional materials. If, however, they are combined in one document with company-originated materials, they then become promotional materials.

### **8.3. Digital Materials**

- 8.3.1. Promotional information for the HCP using these media should comply with the requirements set out in point 8.1.
- 8.3.2. Specifically, in the case of pharmaceutical product related websites:
  - (i) The identity of the pharmaceutical company and of the intended audience should be clear.
  - (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 Items**

### **9.1. General Principles**

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

### **9.2. Gift**

- 9.2.1. Personal gift to HCP is strictly prohibited.
- 9.2.2. Membership fee of professional association is considered as a personal gift, therefore cannot be supported.

### **9.3. Seminar Kit**

- 9.3.1. Seminar kit is a non-monetary item given to HCP limited to company organized or third-party events.
- 9.3.2. Seminar kit can only be in the form of pens and/or notepads.
- 9.3.3. Seminar kit for prescription pharmaceutical product can include Member Company's name but must not be product branded.
- 9.3.4. The maximum value of seminar kit shall be IDR 50,000 per item and only the necessary quantity for the event.

### **9.4. Educational Items**

Informational or educational items 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.

Informational and educational items provided to HCPs for patient use can include the company name, but must not be product branded, unless the product's name is essential for the correct use of the item by the patient.

An example of educational item is memory stick pre-loaded with educational or informational data that will be appropriate if the storage capacity is commensurate with the materials provided.

### **9.5. Medical Books**

Medical scientific books and medical journal subscription may be provided by Member Company to an institution in response to an unsolicited request and not to individual HCP. Such items should be beneficial to enhancing the provision of medical services and patient care be, of modest value and not be provided on more than an occasional basis. The item should not exceed IDR 5,000,000 per items and IDR 10,000,000 per institution per year.

### **9.6. Medical Utility**

Items of medical utility may be provided by Member Company to a government institution in response to an unsolicited request, not to individual HCP and should not be provided on more than an occasional basis, even if each individual item is appropriate.

Such items are of modest value with maximum of IDR 5,000,000 per items and IDR 10,000,000 per institution per year, do not offset operational or capital expenditures, and are beneficial to enhancing the provision of medical services and patient care. Example of routine business expenses include but not limited to stethoscopes, surgical gloves, blood pressure monitors, needles, ultrasonography device, or insulin pump.

Items of medical utility can include the company name, but must not be product branded, unless the product's name is essential for the correct use of the item by the patient.

### **9.7. Cultural Courtesy Gift**

It is prohibited to give any cultural courtesy gift to both HCP and HCO.

## **Article 10 Samples**

Providing free sample of pharmaceutical products as governed by applicable regulation to HCP is prohibited, unless in the case of exceptional approval granted by the Competent Authorities.

## **Article 11 Research**

- 11.1.** 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.
- 11.2.** Devious or coercive methods to influence respondents are prohibited.
- 11.3.** Member Company shall not pay any fees to respondents for market research conducted directly by Member Company.
- 11.4.** Pharmacy Survey for gathering information regarding prescription data of individual HCP is not allowed, unless gathered by a third party whose line business is in market research. The survey report shall be in aggregate. The data collection shall not violate any third party's confidential information or anti-trust law and regulation. See Q&A 6.

**Article 12**  
**Communication to Public**

- 12.1. Unless stipulated otherwise by Competent Authorities, prescription pharmaceutical product may only be promoted and advertised to the HCP and shall not be advertised to the general public.
- 12.2. Member Company should not place articles or advertorials in the mass media to promote prescription pharmaceutical product or for the purpose of encouraging the general public to request the prescription pharmaceutical product through their physician.
- 12.3. Member Company is allowed to have official public website limited to Member Company profile and/or disease awareness of therapeutic area.
- 12.4. Member Company may conduct a disease awareness or public health campaign with no promotion in nature.
- 12.5. Member Company must prohibit their employees from using any prescription pharmaceutical product name, generic name, image, logo, tag line, and other product information, in their social media for any reason. Example of social media includes but not limited to Facebook, Twitter, You Tube, LinkedIn, etc.

**Article 13**  
**Infringements and Complaints**

- 13.1. Each individual IPMG member is encouraged to conduct active self-assessment on the implementation of the Code.
- 13.2. 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*.

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## **APPENDIX I OPERATING PROCEDURES 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 Ethical Practices Sub Committee.

#### **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 Ethical Practices 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.

#### **1.2. Submission of Complaints**

IPMG Ethical 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:

- (i) **Complainant details**  
The identity of the complainant, with a full mailing address (including fax number and email) for correspondence. The identity of the complainant must be kept confidential to all parties outside the IPMG Ethical Practices Sub Committee.  
  
To maintain the neutrality of Ethical Practices Sub Committee as well as to keep the confidentiality of the Complainant, any member of Ethical 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.
- (ii) **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.
- (iii) **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.
- (iv) **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.

- (v) **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 Ethical Practices Sub Committee**  
Wisma Pondok Indah 1<sup>st</sup> 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](mailto:ipmg@ipmg-online.com)

### **1.3. Acknowledgement of Complaints**

Ethical 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**

Ethical Practices 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 Ethical 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 Ethical 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 Ethical Practices Sub Committee, the Alleged Company has the right to:

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

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 Ethical Practices Sub Committee shall decide on the complaint which decision shall be final and binding.

### **1.6. Ethical Practices Sub Committee Decision on the Complaint**

Upon receiving the information/explanation from the Alleged Company (within the period mentioned in point 1.5 above), the Ethical 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 Ethical 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 Ethical Practices Sub Committee will be **final and binding**.
- (ii) If the Ethical 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 Ethical Practices Sub Committee will be **final and binding**.
- (iii) If the Ethical 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 Ethical Practices Sub Committee, it will be communicated to the Complainant, and will also be reported to the Executive Committee. The decision of the Ethical Practices Sub Committee will be **final and binding in this instance**.
  - b. If the Alleged Company **disagrees with the decision** of the Ethical 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 Ethical 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 Ethical 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 Ethical 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 Ethical Practices Sub Committee will issue an Annual Report on the IPMG Ethical 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:

- (i) Identity of source must be kept confidential and the IPMG Ethical Practices Sub Committee and members of the Panel must provide effort to maintain protection of retaliation to the whistleblower;
- (ii) The whistleblower allegation must not be shared widely amongst all IPMG members, but only to the IPMG Ethical Practices Sub Committee;
- (iii) Identified persons within the IPMG Ethical 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;
- (iv) If no concrete information can be gathered from the whistleblower, then the allegation should not be processed further for review by the IPMG Ethical Practices Sub Committee;
- (v) In any event where situation on managing the whistleblower becomes more complex and risky, then the IPMG Ethical Practices Sub Committee should consult with relevant legal counsel of the IPMG members.

Communication from whistleblower can be directed to:

### **IPMG Office**

Wisma Pondok Indah 1<sup>st</sup> 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](mailto:ipmg@ipmg-online.com)

## 1.11. Managing Information

In any and all situation, the IPMG Ethical 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 Ethical Practices/activities. In no event should the IPMG Ethical 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 Ethical Practices Sub Committee and members of the Panel must disregard, delete and/or destroy said information. In any doubt, the IPMG Ethical 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

Violations of this Code are categorized into minor and major.

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

- Provides cultural courtesy gift,
- Undermine other company sponsored scientific event,
- Door prize, etc.

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

The above examples are not an exhaustive list. The purpose of this list is to give an illustration of the types of violations. IPMG Ethical 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 Ethical 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. Summary

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

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 cover price lists or other documents describing terms of trade?
- A:** No.
- Q:** Does the Code prohibit Member Company from giving its customers discounts or other favorable trade terms for the supply of Member Company's products?
- A:** No. The Code does not restrain or regulate commercial trade terms for the supply of Member Company's products. IPMG encourages fair competition among Member Company.
- Q:** Does the Code apply to the promotion and marketing of Member Company's 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.

### 2. Healthcare Professionals (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.
- Q:** Will HCP who is registered as 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? From which institution the permission letter must be obtained?
- A:** Yes. Status of civil servant is attached to HCP. The permission letter must be obtained from government institution
- 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.
- 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.

### 3. Disguised / Hidden 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:** 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.

#### **4. Special Access Scheme Program**

- Q:** How does the prohibition of pre-approval promotion affect compassionate use programs?
- A:** The clause does not prevent compassionate use programs, such as Special Access Scheme (SAS) must comply with all applicable laws, regulations and codes.

#### **5. 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 MR population not being certified is acceptable. If the MR is not certified within 2 years, IPMG encourages the Member Company to take all necessary actions, including employment termination, to rectify this situation.

#### **6. Pharmacy Survey**

- Q:** What is prescription data?
- A:** Any information about HCP prescription of Member Company's products.