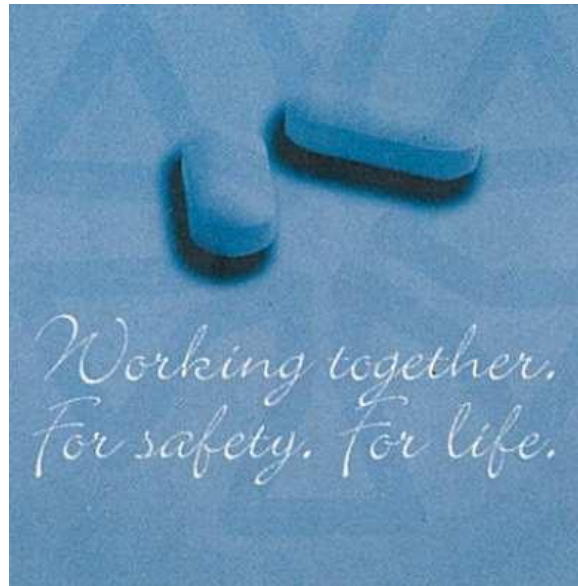


**IPMG CODE OF ETHICS**  
**October 2021 Revision**



**International Pharmaceutical Manufacturers Group**

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## FOREWORD

Jakarta, 1 October 2021

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 an equal level playing field in the Indonesian pharmaceutical industry as well as ensuring a uniform interpretation of the Code, the Ethics and Compliance Task Force, after careful considerations, has revised several articles and points in IPMG Code of Pharmaceutical Ethical Practices in Indonesia issued on September 1, 2019. 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 October 1, 2021, will improve healthcare services and benefit patients in Indonesia.

Yours sincerely,

**IPMG**

**Dr. Ait-Allah Mejri**  
Chairman

**Khalid Ibrahim**  
Head of Ethics & Compliance Task Force

## TABLE OF CONTENTS

P R E A M B L E .....	4
CHAPTER I OBJECTIVE .....	5
CHAPTER II CODE OF ETHICS.....	5
Article 1 Implementation of the Code .....	5
Article 2 Information and Claims .....	8
Article 3 Medical Representatives.....	12
Article 4 Interaction with Healthcare Professionals .....	12
Article 5 Interactions with Healthcare Organization.....	17
Article 6 Medical Education (“ME”).....	18
Article 7 Interactions with Patient, Caregiver and Patient Organization .....	20
Article 8 Donation and Grant .....	22
Article 9 Promotional or Advertising Materials .....	23
Article 10 Items.....	24
Article 11 Product Samples .....	26
Article 12 Market Research .....	26
Article 13 Communication to Public.....	26
Article 14 Telemedicine .....	26
Article 15 Interactions with Third Party Intermediaries.....	28
Article 16 Data Ethics Principles.....	29
Article 17 Infringements and Complaints.....	30
APPENDIX I OPERATING PROCEDURES OF THE CODE.....	31
QUESTIONS & ANSWERS .....	38

# IPMG CODE OF ETHICS

October 2021 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 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 on October 1, 2021.
- (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 healthcare in Indonesia.
- (v) It is a requirement of IPMG Member Company 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, Patients, Caregivers, and Patient Organizations.

#### 1.2 Exclusion: This Code does not seek to regulate the following activities:

- 1.2.1 A disease awareness campaign targeted at the public. Such campaign shall comply with local regulations issued by Competent Authorities.
- 1.2.2 Promotion of Non-Prescription Pharmaceutical Products that is not addressed to Healthcare Professionals.
- 1.2.3 Pricing or other trade terms for the supply of Member Company's products (see Q&A 1).
- 1.2.4 The conduct of clinical trials, clinical research, and development process.
- 1.2.5 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.

#### 1.3 Definition

For the purpose of this Code:

- 1.3.1 **Authorized Person** means director or an individual who is empowered by the institution to make decision or act on behalf of the institution.
- 1.3.2 **Caregivers** means a Patient's friends, family, or other supporters who provide care to the Patient. May also include individuals who provide services to a patient on a compensated basis, such as a home health aide, companion, or social worker.

- 1.3.3 **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).
- 1.3.4 **Competent Authorities** means Badan Pengawas Obat dan Makanan (BPOM) or Kementerian Kesehatan (Kemenkes).
- 1.3.5 **Donation** means financial or physical contribution given typically for charitable purpose and/or patient benefit.
- 1.3.6 **Grant** means financial support for education or research purposes given to Healthcare Organization.
- 1.3.7 **Healthcare Organization** or known as “**HCO**” means any entity 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.

A group of unaffiliated HCPs practicing together in one place is not classified as an HCO.

- 1.3.8 **Healthcare Professionals** or known as “**HCP**” means any member of the medical, dental, pharmacy or nursing professions or any other person who during his or her professional activities may prescribe, recommend, purchase, supply, or administer a pharmaceutical product (see Q&A 2).
- 1.3.9 **Institution** is the employer of HCP, whether it is owned by government or private.
- 1.3.10 **Medical Education** or known as “**ME**” means scientific educational activities to ensure Healthcare Professionals obtain the latest and most accurate information and insights on therapeutic areas and related interventions that are critical to the improvement of Patient care and overall enhancement of the healthcare system. This will be elaborated more in Article 6
- 1.3.11 **Member Company** means any company that is a member of IPMG.
- 1.3.12 **Non-Prescription Pharmaceutical Product** means any pharmaceutical products which are not defined in Article 1.3.19.
- 1.3.13 **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.
- 1.3.14 **Patient** means an individual with personal experience of living with a disease, who is solely representing him/herself and his/her views/opinions/experiences.
- 1.3.15 **Patient Advocates** means an individual who speaks on behalf of Patients; may or may not be affiliated with a Patient Organization.
- 1.3.16 **Patient Expert** means an individual with personal experience of living with a disease and has other technical expertise (i.e., a Patient who develops expertise on the regulatory process through training and experience), who is solely representing him/herself and his/her views/opinions/experiences.
- 1.3.17 **Patient Organization Representative** means an individual authorized to represent the interests and views of a Patient Organization (e.g., a director, officer, spokesperson).

- 1.3.18 **Patient Organization** means typically a non-profit organization that primarily represents the interests and needs of Patients, and/or Caregivers. Patient Organizations may be comprised of volunteers and/or professional staff; they may or may not be formally constituted entities. Patient organizations may focus on broad or narrow disease states and may engage in a variety of activities including, but not limited to, disease and treatment education, pre- and post-diagnosis support and counseling, advocacy, funding of medical research, and partnering with sponsors in R&D to bring the Patient perspective to the development of new medicines. Patient Organizations may be described as patient organizations, patient advocacy groups, or healthcare consumer organizations depending on the country/region.
- 1.3.19 **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.
- 1.3.20 **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.
- 1.3.21 **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.
- 1.3.22 **Telemedicine** is the practice of medicine over a distance, in which interventions, diagnostics and treatment decisions and recommendations are based on data, including voice and images, documents and other information transmitted through telecommunication systems.
- 1.3.23 **Transfer of Value (ToV)** means any benefit provided to HCP including but not limited to HCP sponsorship to attend meeting, HCP engagement by Member Company as Speaker/Moderator/Consultant/Advisory Board, business meals, item of medical utility, promotional reminders.

#### 1.4 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.

#### 1.5 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.

Any third party which has licensing or agency agreements with Member Company in Indonesia is legally bind to this Code.

#### 1.6 General Principles of Promotion

- 1.6.1 **Appropriate Use:** Promotion should encourage the appropriate use of Member Company's products by presenting them objectively and without exaggerating their properties.

- 1.6.2 **Transparency of Promotion:** Promotion should not be disguised. Clinical assessments, post-marketing surveys 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 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:
    - 2.5.3.9.1 which have been selectively presented to misleadingly highlight advantages,
    - 2.5.3.9.2 which are presented or quoted beyond or out of context,
    - 2.5.3.9.3 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 Limitation 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 HCP insists on discussing an off-label indication, all non-medical department employees should inform their medical department to contact such 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.
- 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.
- 4.1.5 A written agreement shall be made in advance before engagement of HCP as Speaker, Moderator, Advisor or Consultant, etc. An agreement at least contains of HCP’s roles and responsibilities, compensation, obligation to declare as a Speaker, Moderator, Advisor or Consultant, etc., to the member company when writes or speaks, maintaining confidentiality, data privacy protection, and transparency report.

## 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:
  - 4.2.2.1 agenda should have legitimate scientific content; and
  - 4.2.2.2 no entertainment or other leisure or social activities should be provided or paid for by Member Company as explained in 4.3.10; and
  - 4.2.2.3 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 providing scientific and/or education information. Therefore, Member Company cannot sponsor HCP to attend it.
- 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:
  - 4.2.5.1 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.
  - 4.2.5.2 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.
  - 4.2.5.3 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.

## 4.3 HCP Attending an Event

- 4.3.1 Criteria of HCP selection:
  - 4.3.1.1 must be related to medical expertise and experience of the selected HCP in the medical field particularly covered by the Event; or
  - 4.3.1.2 has possible cooperation with the HCP for future scientific projects as consultant or 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:
  - 4.3.3.1 provided in association with such permitted meetings,
  - 4.3.3.2 provided with a level that is secondary to the purpose of the meeting, and
  - 4.3.3.3 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:
  - 4.3.7.1 Overnight accommodation may only be given, under specific circumstances where the eligible one-day 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.
  - 4.3.7.2 Accommodation should be modest and appropriate for business purpose.
  - 4.3.7.3 In Indonesia, the room charge/room/night with maximum of IDR 2,500,000 (before tax and service) is allowed.
  - 4.3.7.4 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:
  - 4.3.8.1 Transportation of HCP where the routes and schedule differ from the venue of scientific Event is not allowed.
  - 4.3.8.2 Tickets must be booked through the Member Company's appointed travel agent(s).
  - 4.3.8.3 First class flight for HCP is not allowed.
  - 4.3.8.4 Car rentals for HCP's personal purposes are not allowed. However, car rental is allowed strictly for transportation from airport to hotel vice versa and/or hotel to venue vice versa.

#### 4.3.9 Meal shall be:

4.3.9.1 exclusively to HCP relevant to the Event and/or to the purpose of the meeting; and

4.3.9.2 incidental to the main purpose of the event or meeting; and

4.3.9.3 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

4.3.9.4 such meal is not excessive and only for the purpose to be consumed during the meeting. Non-perishable item, e.g., cookies jar/candies jar/fruit basket is not allowed, because such meal is considered as entertainment (refer to Article 4.3.10); and

4.3.9.5 Provision of meals to HCPs participating in Member Company's own virtual interactions/meetings/event e.g., product detailing, webinar, scientific events, etc. shall be:

- Does not include HCPs who are attending the meetings from their home as they are already expected to be accessible to their daily meals.
- Meals provided in the form of food vouchers is prohibited in any initiatives as it is equivalent or interchangeable with providing cash value.

#### 4.3.10 Entertainment

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

- 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
- Small gifts/souvenir/*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 / Consultant**

4.4.1 Qualifications of HCP as speaker/moderator/consultant should be based on the HCP'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/consultant 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 HCP, assuming multiple presentations for the same Member Company.

4.4.3 The honorarium for foreign HCP in Indonesia should be at the level of normal practice in the foreign HCP'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 Advisory Board Member**

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:
  - 5.1.2.1 agenda should have legitimate scientific content; and
  - 5.1.2.2 no entertainment or other leisure or social activities should be provided or paid for by Member Company as explained in Article 4.3.10; and
  - 5.1.2.3 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 shall respect any prevailing regulation or guidance issued by government and/or HCO relevant to event organized by HCO, to the extent such regulation or guidance does not contradict with this Code.
- 5.1.4 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.
- 5.1.5 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.
- 5.1.6 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.
- 5.1.8 Member Company should consider implementing contractual agreements with the third-party organizer of the event (e.g., Medical Society) stating that industry funding is exclusively used for advancement of science and provision of medical education and not for activities like entertainment and ideally this should be clearly stated in the program and on the organizations web page.

#### **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 10.3.

- 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 hospital.
- 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 can 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 Medical Education ("ME")**

- 6.1 If Member Company provide content to ME activities and programs, such material must be fair, balanced and objective, and designed to allow the expression of diverse theories and recognized opinions.
- 6.2 Key stakeholders in ME accountable for providing or supporting the provision of ME include government and policy makers, academic institutions, professional associations, scientific organizations, logistics agencies, hospitals, third-party medical education providers and pharmaceutical, biotechnology, and medical device/technology companies.

- 6.3** When working with providers as stated in Article 6.2., Member Company must ensure that they take time to assess potential partners (e.g., due diligence).
- 6.4** Member Company must follow Article 4 and 5 of the IPMG Code where applicable.
- 6.5** Member Company may assist with the provision of ME in a variety of ways:
  - 6.5.1 Third-party led medical education, which is:
    - 6.5.1.1 funded by Member Company,
    - 6.5.1.2 its scientific program, speakers and content are always decided independently from the Member Company,
    - 6.5.1.3 the audience is identified and invited by the organizer and not by the Member Company,
    - 6.5.1.4 the role of the Member Company must be declared as required.
  - 6.5.2 Medical education through collaboration or partnership, which is:
    - 6.5.2.1 provided by one or more Member Company and other key stakeholders,
    - 6.5.2.2 working together towards mutually established ME goals in a collaborative setting,
    - 6.5.2.3 such arrangements should be formalized by a written agreement, and effective collaborations and partnerships should have clear intent and objectives clearly defined areas of responsibility and deliverables for each party and transparency.
  - 6.5.3 Member Company led medical education is:
    - 6.5.3.1 activities which may address specific disease-related topics and/or product-specific topics.
    - 6.5.3.2 Although these activities are initiated and provided by Member Company, disease-related educational activities might also involve scientific organizations or professional associations.
- 6.6** Both quality and an ethical approach to ME must be the key priorities for all ME providers. ME providers should consider the following criteria as a minimum:
  - 6.6.1 Program should have clear educational objectives to support high-quality patient care.
  - 6.6.2 Content should be balanced, fair, ethical, and up to date.
  - 6.6.3 Roles and responsibilities of the parties should be agreed, documented, and clearly communicated.
  - 6.6.4 Ongoing evaluation should be an integral component of the program.
  - 6.6.5 The ability of the intended audience to access programs.
  - 6.6.6 Funding by Member Company should be reasonable and appropriate and disclosed according to transparency principles and requirements.

**Article 7**  
**Interactions with Patient, Caregiver and Patient Organization**

**7.1 Principles of Interactions**

- 7.1.1 All interactions and/or programs with Patients, Caregivers, and Patient Organizations must be ethical and conducted with integrity, mutual respect, ensuring privacy rights and appropriately manage and protect personal information, and full transparency.
- 7.1.2 The independence of Patient, Caregivers, and Patient Organizations must be respected.
- 7.1.3 Interactions between Patients and Member Company must not interfere the physician-patient relationship, and must be voluntary.
- 7.1.4 Patient support provided by Member Company can never be an inducement to prescribe, recommend, purchase, supply, sell or administer a pharmaceutical product.

**7.2 Declaration of Involvement**

When working with Patients, Caregivers and Patient Organizations, Member Company must ensure that the involvement of the Member Company and the nature of that involvement is clear from the outset.

**7.3 Written Agreement**

Member Company that provides financial support or in-kind contribution to Patient Organization or service engagement fees to Patient, their families and Caregiver and must have in place written agreement setting out the nature and purpose of its funding, support, contribution, or service engagement.

**7.4 Patients and Caregivers as Individuals**

- 7.4.1 Member Company may interact with Patients, Patient Advocates, Patient Organization Representatives, Patient Experts, and Caregivers in several ways, for example engaging them as consultant/advisors and/or as speakers/panelists.
- 7.4.2 Member Company should ensure activities are carried out for a legitimate purpose.
- 7.4.3 Member Company should have a guidance on how to select and engage individuals for consulting/advisory services including fair and justified compensation levels and frequency of engagements.
- 7.4.4 Member Company can support Patients, Patient Advocates, Patient Experts, and Patient Organization Representatives to travel to symposia, congresses and other educational or professional meetings may be appropriate based on the facts and circumstances of the meeting and the information being conveyed, including prohibitions on direct-to-consumer promotion.
- 7.4.5 Member Company are encouraged not to directly provide individual patient travel to attend third-party meetings as a delegate; if direct travel and support is provided such should be consistent with standards applicable to HCP.

## **7.5 Patient Organization**

- 7.5.1 Member Company may provide financial support for patient organization meetings provided that the primary purpose of the meeting is professional, educational, and scientific in nature, or otherwise supports the mission of the Patient Organization.
- 7.5.2 Member Company must ensure that the venue, location and any meals or refreshments provided by a company must comply with Article 4.2.5, Article 4.3.9, and Article 4.3.10.
- 7.5.3 No Member Company may require 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 to the extent that company did not make its support conditional on it being the sole funder.
- 7.5.4 Member Company should avoid being the majority annual funder of a Patient Organization, and Patient Organizations should be encouraged to seek financial support from a wide variety of sources. In some circumstances, such as rare diseases afflicting small patient populations and with limited treatment options, it may not be possible for a Member Company to avoid being the majority or sole funder of a Patient Organization.
- 7.5.5 It may be appropriate for Member Company and Patient Organizations to partner or collaborate on specific projects where a Member Company provides all financial support for the project.
- 7.5.6 Member Company support for Patient Organizations should be meaningfully disclosed in a manner that provides reasonably adequate information of Member Company support and/or collaboration at the occasion of the relevant event. Member Company and Patient Organizations are encouraged to voluntarily report support on their websites.
- 7.5.7 Interactions between Member Company and Patient Organizations should be structured to enable knowledge sharing unless there are legitimate intellectual property, competitive, or regulatory restrictions that may restrict public dissemination of the collaboration.
- 7.5.8 Non-HCP representative of Patient Organization is prohibited to attend as participant in a promotional or scientific meeting or event.

## **7.6 Patient Support and Assistance Programs**

- 7.6.1 All Patient support and assistance programs offered by Member Company are varied depending on the nature of different products, therapies, disease states, laws, and regulations.
- 7.6.2 Patient programs offered by Member Company should be designed for the benefit of Patients and not HCPs or others.
- 7.6.3 It should be designed to support the Patient who is treated or potentially treated with Member Company products, including support for the management of disease outcomes (e.g., adherence, awareness, education).
- 7.6.4 These programs must always be established in compliance with the highest ethical standards and should be reviewed and approved by Medical Department.
- 7.6.5 Member Company involvement in Patient programs should be meaningfully disclosed to Patients and HCPs.
- 7.6.6 Patient programs should not interfere with the HCP-Patient relationship or undermine treatment decisions.

- 7.6.7 Patient confidentiality and privacy should be always maintained, and proper privacy practices should be exercised in connection with any potential collection, use or transfer of Patient data.
- 7.6.8 Patient programs should be structured to ensure Patient safety is maintained through pharmacovigilance procedures and controls.
- 7.6.9 Transfers of value to HCPs or others in connection with Patient programs should be commensurate with the work performed and payments should never constitute an inducement (or appearance of an inducement) to prescribe, recommend, purchase, supply, sell or administer a pharmaceutical product.
- 7.6.10 HCPs should not be compensated for proposing that their Patients participate in a Patient program. Patient programs should not be used for inappropriate direct or indirect transfers of value to HCPs who prescribe medicines to the Patient benefiting from the Patient program.

## **Article 8 Donation and Grant**

### **8.1 Donation**

- 8.1.1 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.
- 8.1.2 Donation is strictly prohibited to be given directly to HCP or to a charity nominated by HCP.
- 8.1.3 Donation should entail a benefit for patients.
- 8.1.4 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.

### **8.2 Grant**

- 8.2.1 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

- 8.2.2 Grant may not be made for promotional purposes.

## **Article 9**

### **Promotional or Advertising Materials**

#### **9.1 General Principles**

9.1.1 This section focuses on promotional or advertising materials of Member Company's product to HCP.

9.1.2 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.

9.1.3 Promotional or advertising materials can be presented in full or short/brief version.

##### 9.1.3.1 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

##### 9.1.3.2 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

##### 9.1.4 References:

9.1.4.1 Promotional materials containing information from published studies should include clear and traceable references to those studies.

9.1.4.2 The use of reprints, abstracts and quotations should be compliant with the copyright conditions of such material.

9.1.4.3 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.

## **9.2 Printed Materials**

9.2.3 Any printed material should comply with requirements set out in Article 9.1.

9.2.4 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.

## **9.3 Digital Materials**

9.3.3 Promotional information for the HCP using these media should comply with the requirements set out in Article 9.1.

9.3.4 Specifically, in the case of pharmaceutical product related websites:

9.3.4.1 The identity of the pharmaceutical company and of the intended audience should be clear.

9.3.4.2 The content should be appropriate for the intended audience.

9.3.4.3 The presentation (content, links, etc.) should be appropriate and apparent to the intended audience.

9.3.4.4 Country-specific information should comply with local laws and regulations.

## **Article 10 Items**

### **10.1 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).

### **10.2 Gift**

10.2.1 Personal gift to HCP is strictly prohibited.

10.2.2 Membership fee of professional association is considered as a personal gift, therefore cannot be supported.

### **10.3 Seminar Kit**

10.3.1 Seminar kit is a non-monetary item given to HCP limited to Member Company's organized events. A symposium slot in a third party event which is exclusively sponsored by one Member Company is considered as a company organized event. The aim of providing seminar kit is to allow the participant taking notes during a seminar session. Seminar kit cannot be provided in booth.



10.3.2 Seminar kit can only be provided in the form of pens and/or notepads during face-to-face company organized events.

10.3.3 Seminar kit for prescription pharmaceutical product can include Member Company's name but must not be product branded.

10.3.4 The maximum value of seminar kit shall be IDR 50,000 per item and only the necessary quantity for the event.

## **10.1 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.

## **10.2 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.

## **10.3 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.

## **10.4 Cultural Courtesy Gift**

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

**Article 11**  
**Product 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 12**  
**Market Research**

- 12.1 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.
- 12.2 Devious or coercive methods to influence respondents are prohibited.
- 12.3 Member Company shall not pay any fees to respondents for market research conducted directly by Member Company.
- 12.4 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 5.

**Article 13**  
**Communication to Public**

- 13.1 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 public.
- 13.2 Member Company should not place articles or advertorials in the mass media to promote prescription pharmaceutical product or for the purpose of encouraging the public to request the prescription pharmaceutical product through their physician.
- 13.3 Member Company can have official public website limited to Member Company profile and/or disease awareness of therapeutic area.
- 13.4 Member Company may conduct a disease awareness or public health campaign with no promotion in nature.
- 13.5 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, YouTube, LinkedIn, etc.

**Article 14**  
**Telemedicine**

**14.1 General Principles**

- 14.1.1 Member Company can support access to third party telemedicine programs or platforms, providing financial support for these platforms, and investing in education for HCPs, payors, and patients.

14.1.2 Examples of Member Company activities in the telemedicine space include:

14.1.2.1 Education and awareness:

- Educating HCPs on the availability and provision of telemedicine,
- Sharing informational and/or disease awareness materials with Patients to support their access to and experience around telemedicine,
- Engaging with stakeholders (e.g., governments, payors) to optimize approaches to telemedicine for Patients.

14.1.2.2 Supporting access:

- Supporting access to telemedicine programs or platforms for the benefit of Patients through the provision of licenses and/or subscriptions where these are not considered routine business expenses,
- Supporting the development of third-party telemedicine platforms.

14.1.3 Member Company is prohibited to provide anything of value to inappropriately influence a decision or gain an unfair advantage.

14.1.4 Member Company should be transparent with the support they provide and in the materials they produce.

14.1.5 Member Company may not provide any support to offset routine business/operational costs; therefore, careful analysis is required to ensure that projects intended to support access to telemedicine do not offset an individual HCP or HCO routine business expenses.

14.1.6 Member Company must ensure that services must serve a legitimate need and be remunerated at Fair Market Value ("FMV").

## **14.2 Education and Awareness**

14.2.1 Education and awareness activities will likely take the form of events, meetings, or print and digital content provided to HCPs, HCOs, Patients, and payors, and will therefore be subject to the relevant provisions of this Code depending on the nature of the activity and recipient.

14.2.2 Member Company to share only appropriate and up to date information, engage speakers and consultants with the requisite expertise and support only high-quality third-party programs.

14.2.3 Member Company should ensure that materials shared with HCPs, HCOs, Patients, and payors are non-branded, impartial, objective and evidence based. Member Company must also disclose their involvement in the development of such materials.

14.2.4 FMV compensation for telemedicine experts engaged as speakers or consultant should comply with Article 4.4.2.

## **14.3 Support for Development of Third-Party Telemedicine Platform**

14.3.1 This type of support is categorized as an independent grant or partnership which cannot be provided to individual HCPs.

14.3.2 Member Company should assess whether there is a true objective need for the support provided based on the local healthcare system and infrastructure.

- 14.3.3 Member Company should consider the primary beneficiaries of the telemedicine support to understand whether they are permitted to receive this kind of support, whether this support is appropriate, and how the support should be documented and disclosed.
- 14.3.4 Consideration should be given to the rationale for supporting specific recipients, and the duration and frequency of the support to avoid the perception of reward for past, or as undue influence on future, prescribing or other business-related decisions.
- 14.3.5 Member Company should consider how to assess the support.
- 14.3.6 Member Company should take care to address any data privacy/information security risk, and not seek or receive any information that would violate confidentiality/privacy rights.

#### **14.4 Supporting patient access to a telemedicine platform**

- 14.4.1 This support may also be permissible as part of a Patient Support Program (“PSP”). Key considerations include an assessment of the true beneficiary of the support (e.g., Patient, HCP, or HCO) and an analysis of whether the support is appropriate, permissible and in line with PSP principles.
- 14.4.2 Member company should carefully consider, articulate, and document the business rationale to ensure that it is:
  - 14.4.2.1 Guided by Patients’ legitimate unmet needs.
  - 14.4.2.2 Intended to enhance access and/or reduce existing health disparities.
  - 14.4.2.3 Not intended to promote or be perceived as promoting the company’s products.
  - 14.4.2.4 Does not interfere with the HCP/Patient relationship or dialogue.

### **Article 15 Interactions with Third-Party Intermediaries**

- 15.1** Third Party Intermediary’s (“TPI”) interactions on behalf of Member Company, including interactions with HCPs, HCO, and government agencies and officials, must adhere to applicable laws, regulations, and codes.
- 15.2** TPI can operate as clinical research organizations, distributors, wholesalers, distribution or sales agents, consultants, brokers, commission agents, and/or independent sales representatives.
- 15.3** They serve an integral role in the biopharmaceutical sector and health systems, helping ensure {patients, HCPs, institutions, and associations have access to Member Company products and services.
- 15.4** Member Company is encouraged to develop and adopt a TPI Risk Management Program as part of their overall compliance program. The risk assessment should be element anti-bribery or anti-corruption, appropriate promotion, data protection, information security and conflicts of interest.
- 15.5** The outcome of risk assessment consists of due diligence program, written contract, training and education, monitor/audit, appropriate corrective actions.

## Article 16 Data Ethics Principles

- 16.1** Principles of ethical data use:
- 16.1.1 **Autonomy:** Respect individuals' privacy, protect their rights, and honor confidentiality.
  - 16.1.2 **Transparency:** Individuals should be able to understand how their personal data are used.
  - 16.1.3 **Data quality:** The best quality data available should be used to make decisions.
  - 16.1.4 **Fairness and non-discrimination:** Data acquisition should be inclusive, equitable, and seek to support the industry's mission of responding to the needs of all Patients.
  - 16.1.5 **Ethics by design:** Controls to prevent harm and risks to individuals should be built into the design of data architecture and data processing.
  - 16.1.6 **Responsible data sharing:** Data sharing should be based on processes that actively and consistently consider, prioritize, and protect individual rights.
  - 16.1.7 **Responsibility and accountability:** Data Ethics Principles should be operationalized through effective governance, clear standards, training, monitoring activities, and disciplinary sanctions.
- 16.2** The data ethics principles are intended to help the Member Company to use data responsibly and sustainably.
- 16.2.1 Ethical data use is critical to innovation, advancing scientific and medical understanding, ensuring patient safety, and improving healthcare for the benefit of individual Patients and broader society
  - 16.2.2 Ethical data use helps build a culture of trust with our stakeholders. Conversely, unethical data use can harm individuals and society, and damage that trust.
- 16.3** Data in scope:
- 16.3.1 The data ethics principles cover all types of data collected, analyzed, stored, shared, and otherwise processed by Member Company.
  - 16.3.2 Generally, these data relate to, or are derived from, data gathered from individuals, whether the data are directly identifiable, pseudonymized, anonymized, or aggregated. This includes, for example:
    - 16.3.2.1 Patient data stemming from clinical research projects, various types of patient support programs, as well as real world data from healthcare settings, apps and social media, and safety reporting.
    - 16.3.2.2 HCP data stemming from scientific education, and marketing and sales activities.
    - 16.3.2.3 Employee and business partner data.
  - 16.3.3 The data ethics principles should also be read to apply to data that did not originally relate to an individual (e.g., data on sales, production speed, etc.) to the extent processing of such data can potentially harm or benefit individuals and society.

**Article 17**  
**Infringements and Complaints**

- 17.1** Each individual IPMG member is encouraged to conduct active self-assessment on the implementation of the Code.
- 17.2** 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 timelines 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 timelines in this section. Only if a Force Majeure occurs, then timeline may be deferred /delayed upon mutual agreement between the Alleged Company, IPMG Executive Committee and IPMG Ethics & Compliance Task Force.

#### **1.1. Member Company Dialogue Procedures**

Complainant is encouraged to directly contact the Alleged Company for dialogue and clarification prior to filing a complaint to IPMG Ethics & Compliance Task Force.

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 Ethics & Compliance Task Force can act as mediator/facilitator should the companies' desire.

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

IPMG Ethics & Compliance Task Force 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 email) for correspondence. The identity of the complainant must be kept confidential to all parties outside the IPMG Ethics & Compliance Task Force.

To maintain the neutrality of Ethics & Compliance Task Force as well as to keep the confidentiality of the Complainant, any member of Ethics & Compliance Task Force 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 Ethics & Compliance Task Force**

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

Ethics & Compliance Task Force will acknowledge the receipt of complaints in written to complainants within 5 (five) working days after receiving the complaints.

### 1.4. Validation

Ethical & Compliance Task Force 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 Ethics & Compliance Task Force 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 Ethics & Compliance Task Force 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 Ethics & Compliance Task Force, the Alleged Company has the right to:

- (i) Respond in writing to the Ethics & Compliance Task Force providing their explanation on the complaint; and/or
- (ii) Request and have a face-to-face meeting with Ethics & Compliance Task Force members to explain on the complaint.

If the Alleged Company fails to adhere to the required timeline, then it shall lose its opportunity to provide information / evidence / response / defense; and the IPMG Executive Committee and IPMG Ethics & Compliance Task Force shall decide on the complaint which decision shall be final and binding.



## 1.6. Ethics & Compliance Task Force Decision on the Complaint

Upon receiving the information/explanation from the Alleged Company (within the period mentioned in point 1.5 above), the Ethics & Compliance Task Force 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 Ethics & Compliance Task Force 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 Ethics & Compliance Task Force will be **final and binding**.
- (ii) If the Ethics & Compliance Task Force 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 Ethics & Compliance Task Force will be **final and binding**.
- (iii) If the Ethics & Compliance Task Force 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 Ethics & Compliance Task Force, it will be communicated to the Complainant, and will also be reported to the Executive Committee. The decision of the Ethics & Compliance Task Force will be **final and binding in this instance**.
  - b. If the Alleged Company **disagrees with the decision** of the Ethics & Compliance Task Force 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 Ethics & Compliance Task Force'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 Ethics & Compliance Task Force (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 Ethics & Compliance Task Force 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 Ethics & Compliance Task Force 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 Ethics & Compliance Task Force 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 Ethics & Compliance Task Force.
- (iii) Identified persons within the IPMG Ethics & Compliance Task Force 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 Ethics & Compliance Task Force.
- (v) In any event where situation on managing the whistleblower becomes more complex and riskier, then the IPMG Ethics & Compliance Task Force 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 Ethics & Compliance Task Force 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 Ethics & Compliance Task Force 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 Ethics & Compliance Task Force and members of the Panel must disregard, delete and/or destroy said information. In any doubt, the IPMG Ethics & Compliance Task Force 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 Ethics & Compliance Task Force 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 Ethics & Compliance Task Force 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 an 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 if 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. 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. Pharmacy Survey

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