International Research-Based Pharmaceutical Manufacturers Association (IRPMA)

中華民國開發性製藥研究協會

IRPMA

市場行銷規範

Code Of Practice

2025 IRPMA Code of Practice

(Oct 2024 Revision)

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IRPMA Guiding Principles on Ethical Conduct and Promotion

The International Research-based Pharmaceutical Manufacturers Association (IRPMA) member companies engage in medical and biopharmaceutical research in order to benefit patients and support high-quality patient care. Pharmaceutical companies, represented by IRPMA, promote, sell and distribute their products in an ethical manner and in accordance with all the rules and regulations for medicines and healthcare.

The following Guiding Principles set out basic standards to inform the 2012 IRPMA Code of Practice which applies to the conduct of IRPMA Member Companies and their agents. This helps ensure that their interactions with stakeholders are appropriate.

1. The healthcare and well-being of patients are the first priority for pharmaceutical companies.
2. Pharmaceutical companies will conform to high standards of quality, safety and efficacy as determined by regulatory authorities.
3. Pharmaceutical companies' interactions with stakeholders must at all times be ethical, appropriate and professional. Nothing should be offered or provided by a company in a manner or on conditions that would have an inappropriate influence.
4. Pharmaceutical companies are responsible for providing accurate, balanced, and scientifically valid data on products.
5. Promotion must be ethical, accurate, balanced and must not be misleading. Information in promotional materials must support proper assessment of the risks and benefits of the product and its appropriate use.
6. Pharmaceutical companies will respect the privacy and personal information of patients.
7. All clinical trials and scientific research sponsored or supported by companies will be conducted with the intent to develop knowledge that will benefit patients and advance science and medicine. Pharmaceutical companies are committed to the transparency of industry sponsored clinical trials in patients.
8. Pharmaceutical companies should adhere to both the spirit and the letter of applicable industry codes. To achieve this, pharmaceutical companies will ensure that all relevant personnel are appropriately trained.

Preamble

i The ethical promotion of prescription medicines is vital to the pharmaceutical industry's mission of helping patients by discovering, developing and promoting new medicines. Ethical promotion helps to ensure that healthcare professionals globally have access to information they need, that patients have access to the medicines they need and that medicines are prescribed and used in a manner that provides the maximum healthcare benefit to patients.

ii The IRPMA is a non-profit, non-governmental organization comprising European, American, Japanese, and Taiwanese research-based pharmaceutical companies. Member companies and distributors, commissioned agents or representatives acting on behalf of any IRPMA member company, are committed to the ethical standards set out in this Code.

iii The IRPMA Code of Practice (the "IRPMA Code") based on the IFPMA Code of Practice 2012 version includes standards for the ethical promotion of pharmaceutical products to healthcare professionals, and helps ensure that member companies' interactions with healthcare professionals and other stakeholders, such as medical institutions and patient organizations, are appropriate and perceived as such.

iv The IRPMA Code is consistent with local laws and regulations.

v IRPMA member companies are accountable for addressing and correcting infringements under relevant codes. They should also ensure that internal structures and procedures (including adequate training of employees) are created to ensure responsible and ethical promotional activities. Companies not in membership with IRPMA may elect to be subject to the IRPMA Code and its complaints handling processes.

vi The IRPMA is open to receive genuine complaints from any source on any aspect of the IRPMA Code, in accordance with its operating procedures. Where it is determined that there has been a breach of the IRPMA Code, the objective is to correct the matter as rapidly as possible.

vii Effective 1st September 2012, the IRPMA Code of Practice (Updated 2012) replaces the 2007 IRPMA Code of Marketing Practices. Member companies of IRPMA must incorporate this Code into existing internal codes no later than 1st September 2012.

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THE IRPMA CODE

1. Scope and Definitions

1.1 Scope

The IRPMA Code covers interactions with healthcare professionals, medical institutions and patient organizations, and the promotion of pharmaceutical products. Member companies should of course, comply with these local laws, regulations and/or codes.

Q&A 1-3

1.2 Definitions

For the purposes of the IRPMA Code:

- "Pharmaceutical Product" means all pharmaceutical or biological products (irrespective of patent status and/or whether they are branded or not) which are intended to be used on the prescription of, or under the supervision of, a healthcare professional, and which are 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.
- "Promotion" means any activity undertaken, organized or sponsored by a member company which is directed at healthcare professionals to promote the prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s) through all methods of communications, including the internet.
- "Healthcare Professional" 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.
- "Patient Organization" means typically a not-for-profit institution that primarily represent the interests and needs of patients, their families and/or caregivers.
- "Medical Institution" means typically an organization that is comprised of healthcare professionals and/or that provides healthcare or conducts healthcare research.
- "Member Company" means all corporate members and individual members of IRPMA

and distributors, commissioned agents or representatives acting on behalf of any IRPMA member company.

- "Virtual Event" means an event in which healthcare professionals attend remotely and the member company does not designate or arrange a physical meeting place.

**The definition of "Virtual Event" added on Aug 2022; It becomes effective from Jan 01, 2023.*

2. Basis of Interactions

2.1 Basis of Interactions

Member companies' relationships with healthcare professionals and other stakeholders are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing healthcare professionals about pharmaceutical product, providing scientific and educational information and supporting medical research and education.

Benchmark 2

2.2 Transparency of Promotion

Material relating to pharmaceutical products and their uses, whether promotional in nature or not, which is sponsored by a company should clearly indicate by whom it has been sponsored. Promotion should not be disguised.

3. Pre-Approval Communications and Off-Label Use

No pharmaceutical product shall be promoted for use in a specific country until the requisite approval for marketing for such use has been given in that country.

This provision is not intended to prevent the right of the scientific community and the public to be fully informed concerning scientific and medical progress. It is not intended to restrict a full and proper exchange of scientific information concerning a pharmaceutical product, including appropriate dissemination of investigational findings in scientific or lay communications media and at scientific conferences. Nor should it restrict public disclosure of information to stockholders and others concerning any pharmaceutical product, as may be required or desirable under law, rule or regulation.

4. Standards of Promotional Information

4.1 Consistency of Product Information

It is understood that national laws and regulations usually dictate the format and content of the product information communicated on labeling, packaging, leaflets, data sheets and in all promotional material. Promotion should not be inconsistent with locally approved product information.

Respecting the requirement that promotion should be consistent with the label and approved uses locally, healthcare professionals in developing countries should have access to similar data to those being communicated in developed countries.

4.2 Accurate and Not Misleading

Promotional information should be clear, legible, accurate, balanced, fair, and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the pharmaceutical product concerned. Promotional information should be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It should not mislead by distortion, exaggeration, undue emphasis, omission or in any other way. Every effort should be made to avoid ambiguity. Absolute or all-embracing claims should be used with caution and only with adequate qualification and substantiation. Descriptions such as 'safe' and 'no side effects' should generally be avoided and should always be adequately qualified.

4.3 Substantiation

Promotion should be capable of substantiation either by reference to the approved labeling or by scientific evidence. Such evidence should be made available on request to healthcare professionals. Companies should deal objectively with requests for information made in good faith and should provide data which are appropriate to the source of the inquiry.

Q&A 4-5

5. Printed Promotional Materials

Where local regulations or codes are in force which define requirements, those take

precedence.

5.1 Printed Promotional Materials

Printed promotional materials other than those covered in 5.2 below must include:

- the name of the product (normally the brand name);
- the active ingredients, using approved names where they exist;
- the name and address of the pharmaceutical company or its agent responsible for marketing the product;
- date of production of the printed promotional materials;
- "Abbreviated Prescribing Information" which should include an approved indication or indications for use together with the dosage and method of use; and a succinct statement of the contraindications precautions and side effects.

Q&A 6

**This Article revised in May, 2019.*

5.2 Reminder printed promotional materials

A "reminder" printed promotional materials is defined as a short printed promotional materials containing no more than the name of the product and a simple statement of indications to designate the therapeutic category of the product. For "reminder" printed promotional materials, "abbreviated prescribing information" referred to in 5.1 above may be omitted.

Q&A 7

**This Article revised in May, 2019*

6. Electronic Materials, including Audiovisuals

The same requirements shall apply to electronic promotional materials as apply to printed materials. Specifically, in the case of pharmaceutical product related websites:

- the identity of the pharmaceutical company and of the intended audience should be readily apparent;
- the content should be appropriate for the intended audience;
- the presentation (content, links, etc.) should be appropriate and apparent to the intended audience; and
- country-specific information should comply with local laws and regulations

7. Interactions with Healthcare Professionals

7.1 Events and Meetings

7.1.1 Scientific and Educational Objectives

The purpose and focus of all symposia, congresses and other promotional, scientific or professional meetings (an "Event") for healthcare professionals organized or sponsored by a company should be to provide scientific or educational information and/or to inform healthcare professionals about products.

Q&A 8

7.1.2 Events Involving Foreign Travel

No company may organize or sponsor an Event for healthcare professionals (including sponsoring individuals to attend such an Event as described in Article 7.2) that takes place outside of their home country 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.

Q&A 9

7.1.3 Promotional Information at Events

Promotional information which appears on exhibition stands or is distributed to participants at international scientific congresses and symposia may refer to pharmaceutical products which are not registered in the country where the Event takes place, or which are registered under different conditions, provided that the following conditions are observed:

- Host country regulations should permit such an arrangement;
- The meeting should be a truly international, scientific Event with a significant proportion of the speakers and attendees from countries other than the country where the Event takes place;
- Promotional material (excluding promotional aids as described in Article 7.5.2) for a pharmaceutical product not registered in the country of the Event should be accompanied by a suitable statement indicating the countries in which the product is registered and make clear that such product is not available locally;

- Promotional material which refers to the prescribing information (indications, warnings, etc.,) authorized in a country or countries other than that in which the Event takes place but where the product is also registered, should be accompanied by an explanatory statement indicating that registration conditions differ internationally; and
- An explanatory statement should identify the countries in which the product is registered and make it clear that it is not available locally.

7.1.4 Appropriate Venue

All Events should be held in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the Event or meeting. Companies must avoid using extravagant or venues renowned for their leisure offerings or entertainment facilities.

Benchmark 4
Q&A 10-11

**This Article revised in May, 2021; This article becomes effective from Jan 01, 2022.*

7.1.5 Limits of Hospitality

Refreshments and/or meals incidental to the main purpose of the Event can only be provided:

- exclusively to participants of the Event; and
- if they are moderate and reasonable as judged by local standards.

Q&A 12

7.1.6 Entertainment

No entertainment or other leisure or social activities should be provided or paid for by member companies.

Q&A 13-14

7.1.7 Guidance

As a general rule, the hospitality provided should not exceed what healthcare professional recipients would normally be prepared to pay for themselves.

7.2 Sponsorship

Member companies may sponsor healthcare professionals to attend Events provided such sponsorship is in accordance with the following requirements:

- The Event complies with the requirements in this Code as described in 7.1;
- Sponsorship to healthcare professionals is limited to the payment of travel, meals, accommodation and registration fees that are reasonably and necessarily related to the format, location and timing of the events;
  ** This Article revised in Aug, 2022; This Article becomes effective from Jan 01, 2023.*
- No payments are made to compensate healthcare professionals for time spent in attending the Event; and
- Any sponsorship provided to individual healthcare professionals must not be conditional upon an obligation to prescribe, recommend, purchase, supply, administer or promote any pharmaceutical product.

Benchmark 5
Q&A 15-16

7.3 Guests

Companies should not pay any costs associated with individuals accompanying invited healthcare professionals.

Q&A 17

7.4 Fees for Services

Healthcare professionals may be engaged as consultants and advisors for services such as speaking at and/or chairing meetings and events, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration. The arrangements which cover these genuine consultancies or other services must, to the extent relevant to the particular arrangement, fulfill all the following criteria:

- a written contract or agreement must be agreed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis for payment of those services;
- a legitimate need for the services must be clearly identified and documented in advance;

- the criteria for selecting consultants must be directly related to the identified need and the consultants must have the expertise necessary to provide the service;
- the number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need;
- the hiring of the consultant to provide the relevant service must not be an inducement to prescribe, recommend, purchase, supply, and/or administer any medicine; and
- the compensation for the services must be reasonable and reflect the fair market value of the services provided.

Benchmark 3
Q&A 18-20

7.5 Gifts and Other Items

7.5.1 Prohibition of Cash & Personal Gifts

Payments in cash, cash equivalents (such as gift certificate) or personal service (any service unrelated to the HCP's profession and that confer a personal benefit to the HCP) must not be offered to healthcare professionals. Gifts for the personal benefit of healthcare professionals (such as sporting or entertainment tickets, electronic items, etc.) must not be provided or offered.

7.5.2 Prohibition of Promotional Aids

Promotional aids (defined in benchmarks 6. (2)) should not be provided to healthcare professionals.

**This Article becomes effective from May 16, 2018.*

7.5.3 Items of Medical Utility

In accordance with local laws and regulations, items of medical utility may be offered or provided if such items are of modest value, do not offset routine business practices and are beneficial to enhancing the provision of medical services and for patient care. A Medical Utility must not bear the name of product (both of branded and generic name) but may bear the company logo.

Q&A 24

8. Samples

8.1 Samples

In accordance with local laws and regulations, free samples of a pharmaceutical product may be supplied to healthcare professionals authorized to prescribe that product in order to enhance patient care. Samples should be marked as such so that they cannot be resold or otherwise misused.

8.2 Control and Accountability

Companies should have adequate systems of control and accountability for samples provided to healthcare professionals. Companies should not collect clinical data and should not make any payment to physicians.

**This Article revised in Sep, 2019*

9. Clinical Research and Transparency

9.1 Transparency

Companies are committed to the transparency of clinical trials which they sponsor. It is recognized that there are important public health benefits associated with making clinical trial information more publicly available to healthcare practitioners, patients, and others. Such disclosure, however, must maintain protections for individual privacy, intellectual property and contract rights, as well as conform to legislation and current national practices in patent law.

Companies disclose clinical trial information as set out in the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases (2009) and the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature (2010) issued by the IFPMA, the European Federation of Pharmaceutical Industries and Associations (EFPIA), the Japanese Pharmaceutical Manufacturers Association (JPMA) and the Pharmaceutical Research and Manufacturers of America (PhRMA).

9.2 Distinct from Promotion

All human subject research must have a legitimate scientific purpose. Human subject research, including clinical trials and observational studies, must not be disguised promotion.

Benchmark 9
Q&A 30-33

10. Support for Continuing Medical Education

Continuing medical education (CME) helps ensure that 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. The primary purpose of an educational meeting must be the enhancement of medical knowledge and therefore financial support from companies is appropriate.

When companies provide content to CME activities and programs, such material must be fair, balanced and objective, and designed to allow the expression of diverse theories and recognized opinions. Content must consist of medical, scientific or other information that can contribute to enhancing patient care.

Companies must follow Article 7 of the IRPMA Code where applicable.

Benchmark 5
Q&A 15-16

11. Interactions with Patient Organizations

11.1 Scope

The pharmaceutical industry has many common interests with patient organizations. All interactions with patient organizations must be ethical. The independence of patient organizations must be respected.

11.2 Declaration of Involvement

When working with patient organizations, companies must ensure that the involvement of the company and the nature of that involvement is clear from the outset. No company may require that it be the sole funder of the patient organization or any of its programs.

Benchmark 10
Q&A 34

11.3 Written Documentation

Companies that provide financial support or in-kind contribution to patient organizations must have in place written documentation setting out the nature of support, including the purpose of any activity and its funding.

11.4 Events

Companies 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. When companies hold meetings for patient organizations, companies must ensure that the venue and location is appropriate and conducive to informational communication. In addition, any meals or refreshments provided by a company must be modest as judged by local standards.

12. Company Procedures and Responsibilities

12.1 Procedures

Companies should establish and maintain appropriate procedures to ensure compliance with relevant codes and applicable law and to review and monitor all of their activities and materials in that regard.

12.2 Training

Companies should also ensure that relevant employees receive training appropriate to their role.

12.3 Responsibilities for Approving Promotional Communications

A designated company employee, with sufficient knowledge and appropriate qualifications should be responsible for approving all promotional communications. In the alternative, a senior company employee(s) could be made responsible provided that he or she receives scientific advice on such communications from adequately qualified scientific personnel.

13. Infringement, Complaints, and Enforcement

13.1 Complaints

Genuine complaints relating to infringements of the IRPMA Code are encouraged.

13.2 Measures to Ensure and Enforce Compliance

IRPMA strongly encourages member companies to adopt procedures to assure adherence to this code.

IRPMA

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Benchmarks of Code of Practice

Approved on July 18, 2012

Effective from September 1, 2012

The benchmarks of IRRMA Code is set referring to the Code of Practice of European countries, United States, Japan, and other neighboring countries, current local market common rules, and the social expectation to the pharmaceutical industry. This Implementing Regulations should be periodically reviewed and revised by the COP Committee of IRPMA (once half a year). The revision will be adopted after being discussed and resolved by the Board of Directors and Supervisors.

1. The marketing of OTC drugs is excluded, but OTC drugs used under physician prescriptions or in hospitals are included.

2. Company representatives should at all times maintain a high standard of ethical conduct and professionalism and should follow hospital policies in their respective territory.

Q&A 3

3. HCP Payment for Service: the honorarium of the Lecturer/ Moderator/ Chairperson/ Panelist/ Members of Focus Group or Advisory Board of symposia, congresses and alike may be paid up to **NT$5,000**/hr (might include the time spent for discussion. The time calculation can be round up as half hour if less than 30 minutes and one hour for time more than 30 minutes.)
   Moderator/ Chairperson: up to **NT$10,000**/specific venue.
   Panelist/ Members of Focus Group: up to **NT$10,000**/event.
   Additional payment to a lecturer for concurrently serving as Moderator/ Chairperson/ Panelist/ Members of Focus Group or Advisory Board in the same event at the same venue should not exceed **NT$10,000**.
   The number of moderator/chairperson cannot exceed the number of the lecturers. The number of moderator/chairperson, and lecturers needs to be properly balanced with the number of participants. In principle, the moderator/chairperson should at the minimum moderate questions and facilitate discussions, not just introduce the lecturers.
   (International norms will be applied for international speakers/advisors).

Q&A 18-20

**This Article becomes effective from January 1, 2013.*
**This Article revised in February, 2016.*

4. Appropriate venue: venues for the Event or meeting must not be lavish or deluxe. The selection of the location must be based on the following criteria:
   - should be easy for the majority of participants to reach

- should avoid venues renowned for their leisure offerings or entertainment facilities or extravagant
- be limited to the venue that is under/equivalent to 5-star hotel
- blanket reservation and/or utilization of the entire place for entertainment or hospitality, e.g., shows, movies, etc. are prohibited
- The following venues are considered inappropriate and not permitted (not limited to):
  - Sports and Leisure Venues: e.g., Golf courses, Sport Clubs, Stadiums, Campsites, etc.
  - Tourist Attractions: e.g., Sun Moon Lake, Kenting, Taroko Gorge, etc.
  - Venues renowned for their entertainment facilities: e.g., theme parks, venues renowned for hot spring, etc.

Q&A 10-11

**This Article revised in May, 2021; This Article becomes effective from Jan 01, 2022.*

5. In the case of sponsoring domestic or international symposia, congresses or alike:
   - The travel reimbursement and registration fee should be exclusively limited to the attendees, not to family members or accompanied guests.
   - The flight tickets being sponsored should be up to business class only.
   - There must be at least 3-hour educational programs per half day to justify an overnight CME program. It does not apply if the program is held as a virtual event.
     ** This Article revised in Aug, 2022; This Articles becomes effective from Jan 01, 2023.*
   - Programs, daily sign-in sheet of participants, documents/invoices of expenses in relation to the event (such as hotel expenses, meeting expenses, speaker fee, and speaker contract/agreement) must be provided as evidences when there is a dispute.

Q&A 15-16

6. Gifts and Other Items:
   (1) Prohibition of Cash & Personal Gifts: Payments in cash or cash equivalent (such as gift certificate) must not be offered to healthcare professionals. Gift for the personal benefit of healthcare professionals (such as sporting or entertaining tickets, electronic items, etc.) must not be provided or offered.
   (2) Prohibition of Promotional Aids: Promotional aids (such as gimmick) should not be provided to healthcare professionals. A promotional aid is a non-monetary item, printed with names of companies and/or products, given to healthcare professionals for a promotional purpose.

**This article becomes effective from May 16, 2018.*

(3) Items of Medical Utility: Medical journal or textbooks for academic use can only be offered to individual hospital departments. Other items of medical utility with modest value may be offered to hospital or clinics if such items do not offset routine business practices and are beneficial to enhancing the provision of medical services and for patient care. Other items of medical utility must not be provided to individuals for their personal benefit.

(4) Cultural courtesy gifts are not allowed, including but not limited to, gifts offered to healthcare professionals on traditional festivals or flowers and funeral scrolls for funeral.

Q&A 22-26

7. Donation and educational grants must be clearly separated from business. The intention of making a donation or providing an educational grant must not be associated with influencing purchasing, prescribing and pricing of medicines.
   Donation and educational grants must not be given to personal accounts or the accounts of individual departments of hospitals.
   Donation or educational grants must only be given to the government registered medical institutions, medical societies, associations and foundations.
   IRPMA strongly recommends each member company establishes a proper review and approval process for Donation & Educational Grant.

   Q&A 29-29-1

8. The expenses of hospitality should be limited to refreshments and/or meals incidental to the main purpose of the Event and should not exceed **NT$3,500** person/day. For overseas events, the principle is that the amount should not exceed NT$3,500 person/day. However, if the amount limits of the international/local regulations in the visiting countries exceed NT$3,500 person/day, the regulations of the visiting can be followed.
   If healthcare professionals attend the virtual event remotely, member companies may refer to【IRPMA Guidance on Meals Provided to Attendees of Virtual Events】

   Q&A 12

   ****This Article revised in Aug, 2022; This Article becomes effective from Jan 01, 2023.***

9. All PMS shall go through JIRB, IRB or Ethics Committee.

All human studies including PMS must be approved and managed by Medical Director or equivalent CR Manager of member companies.

Q&A 30

Mandatory Medical Components for Post-Marketing Studies:

(1) Protocol to address scientific objectives
   - To have specific scientific interest

(2) Pre-determined sample size justification based on study description
   - Should be based on clinical & statistical significant meaning

(3) Patient consent obtained

(4) IRB approval secured

(5) Follow GCP Guideline
   - At a minimum, health authority requirements must be complied with.

(6) Payment must be appropriate and according to study design. It must not be set to influence prescribing behavior.
   - Must reflect time & efforts from investigators

Post-Marketing Surveillance Studies must be non-interventional, no interference on treatment decision:

(1) PMS studies must have scientific or medical merit and objectivity and not be designed for, or conducted as, a promotional exercise.

(2) PMS studies must be research which is intended to generate data on safety parameters of a product that has been approved for registration when used in accordance with the product information.

(3) PMS studies are part of clinical research and the only extent of involvement of medical representatives is in recommending or identifying healthcare professionals to participate in the study. The study must be managed through the company's medical department.

(4) PMS studies must have a formal protocol, a requirement for data collection and generation of a report.

(5) Only patients being treated for approved indications of the product are to be enrolled in the PMS study.

(6) Decisions by HCPs to prescribe the product should be based solely on their clinical judgment. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. Starter packs or free trade packs must not be distributed as part of the PMS study.

(7) Any payment to a healthcare professional must be reasonable and commensurate with the work involved and not based upon the number of prescriptions written.

(8) A prompt report on the outcome of the study should be provided to participating healthcare professionals without undue delay.

(9) IRB approval code or approval date should be shown on study-related documents.

(10) Relevant research and data collection regulations must be strictly followed
(11) Patient consent should be obtained in accordance with the regulations set by IRB

Essential Components for Market Research:

(1) With scientific research methodology:
    - Sampling techniques
    - Data collection techniques
    - Analysis techniques
(2) Samples size: usually relatively small, and representative
(3) Subjects (respondents) consent required
(4) Must not collect medical information (e.g., efficacy, effectiveness or safety data) which can be linked to identifiable individuals
    - Individual data collection is prohibited
(5) If the subjects are patients, the research must be conducted by independent third party
(6) Must not be used as a tool for direct patient promotion
    - Brand and/or compound name should not be mentioned
(7) Can only be used for research purposes; with one-way communication from subjects to the sponsors
    - No communication from sponsor to individual subjects (patients/physicians)
    - General report sharing allowed
(8) Must not be used to influence subjects' view or behaviors
(9) Payment must be appropriate and according to study design. It must not be set to influence prescribing behavior.

** This Q&A revised in Oct, 2024; This Q & A becomes effective from Jan 01, 2025*

Definition of a Patient Support Program (PSP)

A PSP is defined as a service for direct patient or patient carer interaction/engagement designed to help management of medication and/or disease outcomes (e.g. adherence, awareness and education), or to provide HCPs with support for their patients.

PSPs may also include the companies providing assistance to ease patients' financial burden of their medication (e.g., reimbursement or discount schemes).

PSPs should be designed and used to enhance patient care, benefit healthcare system and achieve healthcare outcome rather than to promote pharmaceutical products and/or to influence the prescribing decisions.

This Article revised in Jan, 2019

Basic Requirements for PSP

- Patients and physicians written informed consent required if PSPs involve the collection of personal data
- Patient privacy must be protected
- Recommended to be conducted by a third party, and that third party is capable of ensuring appropriate patient data privacy protection and identifying and reporting of AEs
- Initiation and management of PSPs requires the involvement of the personnel in charge of PV to ensure appropriate monitoring and reporting of AEs
- HCPs should not be paid or obtain anything of value for enrolling patients in PSPs

Q&A 35

10. Educational activities towards the general public

It is the responsibility of pharmaceutical companies to adhere to highest ethical standards and applicable laws and regulations when educating the general public on general medical related aspects, e.g. by conducting disease awareness programs.

In according with the Pharmaceutical Affairs Act in Taiwan, the promotion of prescription drugs to the general public is prohibited. Direct-to-consumer materials that are not product specific, but are disease state or therapy area related, should not be used to promote a specific product but must nonetheless still be accurate, truthful and fair balanced, by ensuring pros / cons of available treatment alternatives are fully referred to.

The principal responsibility of educational activities to the general public is to provide the most current, evidence-based and unbiased information available. Important information must not be omitted if relevant. Claims should not be stronger than scientific evidence can support, and every effort should be made to avoid ambiguity. Only information that is based on the most up-to-date evidence that is scientifically valid and endeavor to avoid incorrect or misleading impressions of scientific information can be included and must be well-documented by reference to scientifically valid, verifiable data. All educational materials must contain a recommendation to consult with a healthcare professional to seek for guidance on their health status or disease treatment.

When sponsoring materials and/or activities, member companies shall undertake every effort to clearly indicate the sponsor.

Q&A 32

**This article becomes effective from January 1, 2013.*

Questions & Answers

1. Application Scope

Q1: Does the IRPMA Code regulate communications with the public?

A1: Yes. The IRPMA Code provides guiding principle for patient education materials. However, according to Article 69 of "Pharmaceutical Affairs Act", direct promotion to the public is not allowed. Member companies should of course, comply with the local law.

Q2: What is IFPMA?

A2: The IFPMA is a non-profit, non-governmental organization comprising 27 leading international companies and 51 national and regional industry associations.
It is a requirement of IFPMA membership that member companies and member associations accept the conditions of the IFPMA Code and, subject to local laws and regulations, adopt codes that meet local requirements but are consistent with, and as comprehensive as, the IFPMA Code.
IFPMA Website: www.ifpma.org

Q3: Which interactions or activities of pharmaceutical companies are specifically outside the scope of the IRPMA Code?

A3: This Code specifically does not seek to regulate the following activities:

- Promotion of self-medication products that are provided "over-the-counter" (OTC) directly to consumers without prescription;
- Pricing or other trade terms for the supply of pharmaceutical products, including promotion and marketing of pharmaceutical products to commercial customers;
- Certain types of non-promotional information or activities; and
- Promotion of medical devices

2. Medical Education

Q4: Does the IRPMA Code allow for comparisons between different products to be included in promotional materials?

A4: Yes. Comparative statements must be used carefully. Any comparison made between different pharmaceutical products must be clear, accurate, balanced, fair, up-to-date and objective based on credible scientific data and be capable of substantiation. Comparative data and/or claims should mainly be based on well-established, head-to-head randomized controlled clinical trial (RCT) results or meta-analysis of RCTs or both, and these results

should be consistent with each other. Alternative high quality evidences, i.e. systematic review of cohort studies that can be substantiated by peer-reviewed journals, should also be considered acceptable, but its conclusion should not overwhelm that from evidence, such as head-to-head RCT(s) or their meta-analysis, if they existed; the context of overall evidence of the topic should be considered for fair justification. Care must be taken to ensure that there is a sound statistical basis. Differences which do not reach statistical significance must not be presented in such a way as to mislead. Under no circumstances should comparative data and/or claims be misleading. It must be consistent with the local health authority-approved package insert. Any disparaging reference to other product or manufacturer must be avoided. The information of the comparison drug should be sufficiently mentioned in the promotional material in order for a fair and objective judgement. The use of comparison drug's brand name requires written consent from that company.

**This Q&A revised in Mar, 2019.*

Q5: Does the IRPMA Code allow for quotations to be included in promotional materials?

A5: Yes. Quotations from medical and scientific literature or from personal communications should be faithfully reproduced (except where adaptation or modification is required in order to comply with any applicable codes, in which case it must be clearly stated that the quotation has been adapted and/or modified) and the precise sources identified. Quotations should not change or distort the intended meaning of the author or the significance of the underlying work or study.

Q6: Are reprints considered as printed promotional materials under the IRPMA Code?

A6: No. Reprints of scientific and medical articles, when used and presented to healthcare professionals as stand-alone documents, are not developed by pharmaceutical companies and as such cannot be considered as printed promotional materials. If, however, they are proactively presented to a healthcare professionals together, with other, printed promotional materials, they then become part of the printed promotional materials. It has to be ensure the whole package of the printed promotional materials should be presented in align with Code 5. In all cases, where promotion refers to, includes, or is presented together with scientific or medical articles or studies, clear references should be provided. Any reprint of artwork (including graphs, illustrations, photographs or tables) taken from articles or studies and included or presented with printed promotional materials should clearly indicate the source of the artwork and be faithfully reproduced.

**This Q&A revised in May, 2019.*

Q6-1: If printed promotional materials include the “Approved Package Insert” in an electronic format (e.g. QR Code link to the Approved Package Insert on the TFDA website), does the member company still need to print the “Abbreviated Prescribing Information” (API) on the material?

A6-1: Abbreviated Prescribing Information (API) is summarized by the member company based on the complete Approved Package Insert. Therefore, if the complete Approved Package Insert is available in its entirety to HCPs via the QR Code printed on the promotional material, then the member company is not required to also print the approved indication, dosage and method of use from the API. However, the succinct statement of contraindications, precautions, and side effects are still required to be printed on the material. Please note that, if any updates in the electronic format of the Approved Package Insert results in differences with the contents of the printed promotional material, the Member Company should immediately cease using all print materials containing the outdated information.

**This Q&A added on Sep 2023; It becomes effective from Jan 01, 2024.*

Q7: What is the definition of “simple statement of indication”?

A7: Simple statement of indication should relate to the PI label and must not contain promotional claims.

**This Q&A revised in May, 2019.*

Q8: Is there any restriction for accommodation, number of participants, or ceiling when sponsor a symposium, congress or other medical health care or educational program?

A8: According to IRPMA Code 7.1, the purpose and focus of all events for healthcare professionals organized or sponsored by a company should be to provide scientific or educational information. The venue and accommodation should be selected appropriately; member companies should avoid using renowned or extravagant venue.

Q9: When is it appropriate and justified for a company to organize or sponsor an event for healthcare professionals outside of their home country?

A9: A company can only organize events involving travel if it is justified, i.e.:

(a) A significant proportion of the invited healthcare professionals are from outside of the company’s home country, and it makes greater logistical or security sense to hold the event in another country; or

(b) The relevant resource or expertise that is the object or subject matter of the event is located outside of the company’s home country.

Q10: In case of one-day program, if participants who have difficulties to return to their hometown on that day due to traffic problem, what shall we do?

A10: Basically companies should select an appropriate venue that is in city areas for convenient transportation. However, if the case above happens, we may provide accommodation for limited participants who cannot return on the same day. In this case, on the 2nd day, no other social program should be arranged for those participants.

Q11: One medical society schedules its annual scientific conference to be held at a hotel by Sun Moon Lake. In addition to HCPs based in Taiwan, HCPs from China have also been invited to join the event. Can member companies sponsor the event?

A11: The intent of initiating or sponsoring a scientific program at an independent meeting is to support continuous professional development of HCPs that will lead to improve patient care or healthcare delivery. Therefore, in the choice of venue, no matter the event is initiated or sponsored by member companies, and no matter the invited participants are from Taiwan or foreign countries, the same standard should be applied, and avoid extravagant or venues renowned for their leisure offerings or entertainment facilities.

**This Q & A added in February, 2016.*
**This Q & A revised in May, 2021; This Q & A becomes effective from Jan 01, 2022.*

Q12: "Hospitality should be limited to refreshments and/or meals incidental to the main purpose of the Event". What is the definition of "the Event"?

A12: An Event is as defined by the IRPMA Code 7.1.1. Lunch and dinner meetings with healthcare professionals are allowed as healthcare professionals have very limited time allocated for information. Provided the main purpose of the lunch or dinner meeting is educational, to provide scientific information, or to discuss a business issue, it is not considered an Event (Article 7). The particulars of a meeting over a meal should either be agreed in advance or recorded retrospectively. Refreshments and meals connected with these activities should not cost more than NT$3,500 person/ day.

Q13: The IRPMA Code prohibits companies from providing entertainment, leisure and social activities to healthcare professionals and other stakeholders. Are there exceptions to this rule?

A13: No. When a company organizes a meeting, refreshments and/or meals incidental to the main purpose of the event can be provided. It would not be appropriate for a company to fund

attendance at a concert, purchase of entertainment tickets or pay for entertainment in any form. However, if there is background music or a local performance at the venue where the event is taking place, which is not paid for by a pharmaceutical company and not interfering the main purpose of the meeting or event, this may be permitted.

Q14: Are individual social activities with healthcare professionals such as golf, music concert, etc. allowed?

A14: According to the IRPMA Code 7.1.6, no entertainment or other leisure or social activities should be provided or paid for by member companies. Hospitality should be limited to refreshments and/or meals incidental to the main purpose of the Event.

Q15: Is there any consideration for sponsoring HCPs attending overseas event?

A15: Sponsorship of HCP to international events is limited to 2 meetings per year. This limitation does not include or apply to programs where a HCP's attendance has been funded (paid for his/her services) because the individual is giving a presentation at the international event on behalf of member company. Clinical trial related meetings are out-of-scope.
Sponsorship of HCPs to international events is not limited to 2 meetings per year if they attend the meetings remotely instead of physically attending abroad.

**This Q&A becomes effective from January 1, 2013.*
** This Q&A revised in Aug, 2022; This Q & A becomes effective from Jan 01, 2023.*

Q16: In regard to flight tickets under sponsorship, in case that there is no business class but only economy and first class available, what shall company do?

A16: According to the COP Benchmark Article 5, the flight tickets being sponsored should be up to business class only. Therefore, in this case the traveler must take economy class only.

Q17: While attending an event, are the invitees allowed to bring guests?

A17: Member companies must discourage invitees from bringing guests to company-organized events. In case they do, or in case an uninvited guest shows up, the company must not make any payments or reimburse/subsidize any costs associated with an individual accompanying an invitee, and uninvited guests are not permitted for the company hosted dinner/meal events. For example, the uninvited guests are not allowed to be part of the sponsored dinner and/or the meeting where business discussions must occur.

Q18: Is it necessary to have a contract with the invited healthcare professional as speakers or presenters for the payment of honorarium and related travelling and boarding expenses?

A18: Yes. The IRPMA Code 7.4 states that there should be a written contract about the payments to speakers or presenters. The contract can also be used as a reference to decide who should pay the expenses.

Q19: For the honorarium for local speaker to lecture in international symposia, should the international norms or a limit of up to NT$5,000/hr be applied?

A19: International norms may be applied to international symposia; the followings can be taken into consideration when determining whether an event is an international symposia:

- The main purpose of the event is to promote domestic and foreign academic research exchange and cooperation; or
- The event helps to improve the sharing and discussion of new international medical knowledge among domestic and foreign participants; or
- A significant proportion of speakers and attendees from countries other than the country where the event takes places; or
- non-native languages are used.

Otherwise, the honorarium for local speaker should be limited up to NT$5,000/hr.

** This Q&A revised in Aug, 2022; This Q & A becomes effective from Jan 01, 2023.*

Q20: How to calculate additional payment?

A20: Chairperson/ Moderator of the advisory board and concurrently serve as advisory board member: may be paid up to NT$20,000 (up to NT$10,000 per event as member, up to NT$10,000 as the Chairperson).

Chairperson/ Moderator and concurrently serve as a Lecturer: NT$5,000/hr as a Lecturer, up to NT$10,000 as the Chairman/ Moderator per event.

There is no additional payment for preparation time.

Q21: What types of topics are considered appropriate as part of a program agenda for IRPMA member company-supported events targeting healthcare professionals?

A21: Event topics should be related to professional capability building for the benefit of HCPs' daily healthcare practice.

For events that involve non-product / disease-related topics, the recommended ratio for the time spent on "product/disease-related educational topics" versus time spent on "topics related to healthcare practice capability building" is 3:1.

**This Q & A added in October, 2013.*

3. Gifts and Other Items

Q22: (Deleted)
Q23: (Deleted)

Q24: What kinds of items are envisaged as being items of medical utility?

A24: Items might include an anatomical model for use in an examination room, or medical textbooks, as they are of modest value and both primarily involve a patient benefit.

However, items would not be permissible if such items are

- Provided to offset routine business practice including but not limited to surgical gloves, tissues, stethoscopes and the like.
- Provided to individual HCP for personal benefit including but not limited to DVD or CD player, mugs, backpacks, stationary, diaries, calendars and the like.

Items should not be offered on more than an occasional basis, even if each individual item is appropriate.

Q25: Are lucky draws allowed?

A25: No. Member companies are not allowed to organize or sponsor events that include any draws that are luck based.

**This Q & A revised in Sep, 2023; It becomes effective from Jan 01, 2024.*

Q26. Could we provide cash gifts or gifts for "Wedding"?

A26: IRPMA Code indeed prohibits payments in cash to healthcare professionals. Providing gifts for wedding is not allowed.

Q27. What should I do if I am invited to a wedding party?

A27: The wedding party is a personal event, and any expense incurred from this should not be at the cost of the company.

Q28. Are sales representatives allowed to send or provide refreshments for healthcare professionals if the meetings are unplanned?

A28: The purpose of the IRPMA COP is to improve the professional image of medical representatives. Refreshments for HCPs are allowed only if the meeting is for educational purpose or to provide scientific information as HCPs have very limited time allocated to meetings.

4. Donation and Educational Grants

Q29: If the department requests sponsorship for a foreign speaker's expenses (airfare, honorarium, etc.), what shall we do?

A29: Companies can provide actual expenses to hospitals or associations organizing the events, but not through the department nor to the speaker directly.

Q29-1: What principles should member companies consider when participating in consensus meetings related to treatment consensus or guidelines organized by medical societies?

A29-1: Member companies may sponsor consensus meetings related to treatment consensus or guidelines. In order to maintain medical independence, member companies should not participate in those decision-making meetings or be involved in drafting or editing of treatment consensus or guidelines. Member companies also cannot request standalone sponsorship as a condition for being the sole sponsor. In the case that the guideline contains insufficient or incorrect medical information, the member company could provide the society with the correct information, but the society retains the final editorial decision.

**This Q & A added on Sep 2023; It becomes effective from Jan 01, 2024.*

5. PMS (Post-Marketing Study)

Q30: The definition of PMS?

A30: In order to stop commercial exercise under the different name of clinical studies (observational study, retrospective study...etc.), any study involving human subjects should be reviewed and approved by IRB to protect patients' right.

The types of trials include, but are not limited to:

- Phase IV clinical studies
- Pharmacoeconomic / Healtheconomic related studies (excluding PE studies using existing computerized database only)
- Pharmacoepidemiologic studies
- Non-interventional post marketing surveillance
- Retrospective data collection and analysis

** This Q&A revised in Oct, 2024; This Q & A becomes effective from Jan 01, 2025*

Q31: (Deleted)

Q32: (Deleted)

Q33: (Deleted)

6. Interactions with Patient Organizations

Q34: What happens if only one pharmaceutical company wishes to support a particular patient organization? Is this allowed?

A34: Yes. Many patient organizations are supported by a number of pharmaceutical companies. There may, however, be situations where only one pharmaceutical company wishes to support a particular patient organization or one of its activities. It would be acceptable under the IRPMA Code for that pharmaceutical company to be the only pharmaceutical company providing funding as long as that company did not make its support conditional on it being the sole funder.

Q35: The examples of PSP?

A35: Common examples of PSPs include:

- Compliance programs where consenting patients on a medication are contacted to see how they are managing with their medication.
- Call centers where patients or patient carers can contact the Companies to obtain further information on medication or a particular disease area.
- "Nurse Educator" programs where the Companies have hired third party nurses to interact directly with patients to help them properly administer medications and/or manage their disease.