

# PhIRDA Code of Ethics

## 1. General Rules

### 1.1 Goals

In comply with laws, regulations and rules of the People's Republic of China, China Pharmaceutical Innovation and Research Development Association (PhIRDA) drafted this Code of Ethics to help ensure that the interactions among member companies, their employees, representatives and stakeholders are appropriate and beneficial to patients to promote the development of pharmaceutical industries in a healthy and ordered way.

### 1.2 Scopes

In the development, research, manufacturing, marketing, distribution, and/or sale of medicines, member companies are committed to following the Code of Ethics in interactions with HCPs, medical institutions, patient groups and other stakeholders.

## 2. Basis and Standards of Interactions

### 2.1 Modes and Contents of Interactions

Contents of interactions between pharmaceutical representatives and HCPs include academic promotion, technical consultation, help HCPs advice of rational administration for HCPs, collection of and response on medical usage in clinical practice and adverse drug reactions.

Interactions between pharmaceutical representatives and HCPs may be conducted in following modes:

- communications in medical institutions;
- organizing academic meetings and events;
- providing academic promotion materials;
- communications by Internet or teleconference; and

- other modes approved by medical institutions.

## **2.2 Ethical Interactions**

Interactions between pharmaceutical representatives and HCPs should be professional and ethical.

- Academic promotions should deliver accurate and up-to-date information about approved indications, benefits and risks of medicines, and also encourage reasonable clinical administration, and comply with laws, regulations, rules and the Code of Ethics;
- Medical usage should not be unreasonable and misleading, clinical effects should not be exaggerated or misled, and adverse drug reactions should not be disguised.
- Interactions should not cause inappropriate effects on HCPs.
- HCPs should not be provided with any items or services in exchange for prescribing, whether this is with intent, or by actual impact, on prescribing.
- HCPs should not be provided any fees for prescription such as clinical promotion fees, prescription fees or total prescription fees.

## **3. Promotional Information**

### **3.1 Consistency of Product Information**

Promotional information should be consistent with the product information, labels and dispensatory approved by the drug administration department of the State Council. Indications, contraindications and adverse drug reactions should also be marked clearly. Promotional information should not be disguised.

### **3.2 Accurate and Not Misleading**

Promotional information should be clear, 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.

Every effort should be made to avoid ambiguity. Unscientific or all-embracing claims related to drug safety should generally be avoided.

### **3.3 Substantiation**

Promotional information should be based on relevant evidence and reflect that evidence clearly.

Promotional information should not be misleading by distortion, exaggeration, undue emphasis, omission or in any other way.

Labels and dispensatory approved by drug administration department of the State Council could be used as substantiation. Such evidence should be made available on request to HCPs. Member companies should objectively deal with requests for information made in good faith and should provide data which are appropriate to the source of the inquiry.

### **3.4 Pre-Approval Communications and Off-Label Use**

No pharmaceutical product or indication shall be promoted for marketing usage until the requisite approval for such usage has been given by the drug administration department of the State Council. However, complying with local law and regulations, member companies are allowed to organize scientific symposia or use public media to disclose information and result of the research to the stakeholders and others relevant to the drug for science development.

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, nor should it restrict public disclosure of information to stockholders and others concerning any pharmaceutical product, as may be required or desirable under law, rules or regulations.

### **3.5 Printed Promotional Material**

All printed promotional materials should include :

- the name of the product;
- the active ingredients;
- the name and address of the manufacturer, distributor and marketing authorization holder;
- date of production of the promotional material; and
- “abbreviated prescribing information” which should include an approved indication, dosage, method of use, and a succinct statement of the contraindications, precautions, and side-effects.

When printed promotional materials refers to some publications, clear reference should be provided. Quotations from medical and scientific literature or personal comments should not be distorted.

Promotional materials should be provided to HCPs in reasonable frequency and quantity.

Materials sponsored by a company relating to medicines and their uses, whether promotional in nature or not, should clearly indicate by whom they have been sponsored.

### **3.6 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 the intended audience should be readily apparent;
- the content should be appropriate and readily apparent for the intended audience; and
- specific information should comply with current laws, regulations and rules.

### **3.7 Transmission and Subscription Cancellation**

Electronic materials should not be transmitted to HCPs without consent or inquiry from audience in advance.

Senders should clearly marked their identities, contact information, and how to cancel subscription, when they send electronic materials to HCPs.

## **4. Meetings, Events and Other Sponsorship**

### **4.1 Events and Meetings**

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

All Events where member companies provide funding or other support must be held in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the Event or meeting. Member companies must not use renowned or extravagant venues or resorts.

Refreshments and/or meals incidental to the main purpose of the Event can only be provided exclusively to the participants of the Event be moderate and reasonable as judged by local standards.

Member companies should not pay any costs associated with individuals (including spouse and children) accompanying invited HCPs except in cases of medical necessity.

Costs of travel, meals, and accommodation during the events should be directly paid to service provider by member companies. Payment of cash is prohibited. Reimbursement through official channel (company to HCP wire transfer) is acceptable, but certain travel and transportation payment, which is unrelated to the events must be excluded.

## **4.2 Sponsorships**

Member companies may sponsor HCPs with the written approval of medical institutions or superior departments to attend Events in accordance with the following requirements:

- The Event complies with the requirements in this Code as described in 12 (Events and Meetings) ;
- Sponsorship to HCPs is limited to the payment of travel, meals, accommodation and registration fees that is directly paid to the service providers;
- No payments are made to compensate HCPs for time spent in attending the Event;
- Any sponsorship provided to individual HCP must not be conditional upon an obligation to prescribe, recommend, purchase, supply, administer or promote any pharmaceutical product ;
- Any sponsorship provided to individual HCP must not be intended to affect some important decision process, for example, governmental procurement.

## **4.3 Consultation and other services**

HCPs may be engaged as consultants and advisors for services such as speaking at and/or chairing meetings and events, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, 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;
- 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 be less 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;
- the hiring of the consultant to provide the relevant service must not be intended to affect some important decision process, for example, government procurement;
- meetings with the consultant or the speakers should be appropriate environment and venue, they should also not be provided with other benefits in the names of travel;
- the compensation for the services must be reasonable and reflect the fair market value of the services provided;
- fees should be paid by bank transfer and individual income tax should be deducted before payment.

#### **4.4 Entertainment**

Interactions between HCPs and member companies must be professional in nature and are intended to facilitate the exchange of medical or scientific information that will benefit patient care.

To ensure the appropriate focus on education and informational exchange and to avoid the appearance of impropriety, member companies should not provide any form of entertainment or recreational items, such as tickets to the theater, sporting equipment, or vacation trips to any HCP. Such entertainment or recreational benefits should not be offered in regardless of the value of the

items, whether the member company engages the HCP as a speaker or consultant, or whether the entertainment or recreation is secondary to an educational purpose.

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

#### **4.5 Gifts and other items**

Gifts for the personal benefit (such as sporting or entertainment tickets, electronics items, social courtesy gifts, etc.) of HCPs (either directly or through clinics and institutions) are prohibited. Providing or offering cash, cash equivalents (such as gift cards) or personal services is also prohibited.

A promotional aid is a non-monetary item given for a promotional purpose. Providing or offering them to HCPs in relation to the promotion of prescription-only medicines is prohibited. Promotional aids of minimal value and quantity may be provided or offered to HCPs solely for the promotion of over-the-counter medicines if relevant to the practice of the HCP.

Items of Medical Utility to enhance the Provision of Medical Services and Patient Care may be offered or provided by member companies after approval of medical institutions if such items are of modest value, do not offset routine business practices and are beneficial to enhancing the provision of medical services and patient care. Items of medical utility must not be directly provided to HCPs for usage in medical institutions. They should not be offered on more than an occasional basis, even if each individual item is appropriate. 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.

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 and do not have independent value.



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.

The value of books and subscriptions must be reasonable. Other informational or educational items must be of modest value.

#### **4.6 Support for Continuing Medical Education**

The primary purpose of the Continuing Medical Education (CME) is to enhance medical knowledge and therefore financial support from companies is appropriate.

Companies should develop objective criteria for making CME grant decisions to ensure that programs funded are helpful and qualified and the financial support is not an inducement to prescribe or recommend a particular medicine or course of treatment.

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.

Grants, scholarships, subsidies, support, consulting contracts, educational or practice related items should not be provided or offered to a HCP in exchange for recommending and prescribing medicines, or otherwise in a manner that would interfere with the ethics and the independence of a HCP's prescribing practices.

#### **4.7 Support for Research Programs**

Member companies may support medical institutions for clinical assessments, post-marketing surveillance programs and post-authorization studies, which must not be disguised as promotion. Such assessments, programs and studies should not include inappropriate benefit transfer.

Member companies should not sponsor HCP to conduct individual research when supporting research program. Companies should sign contracts with medical institutions or professional medical organization that conduct research (eg. medical association) for support for research programs. A contract for that support should include essential provisions, such as special requirements, leader of that program, budget management, execution and terminal conditions, and responsibility for breach of contract, etc.. Funds should be transferred from accounts of companies to accounts of medical institutions or associations, and be used in accordance with program budgets.

#### **4.8 Communications in Medical Institutions**

Pharmaceutical representatives of member companies are allowed to present drug information in appropriate time (including mealtimes) in accordance with HCPs' schedules and working status. Information presented may include scientific/medical knowledge relevant to the products, medication methods and prevention for side effects, but therapeutic effects must not be exaggerated.

Pharmaceutical representatives entering medical institutions for information presentation should ensure to be compliant with relevant regulations of medical institutions.

## **5. Samples**

### **5.1 Samples**

Sampling is given for the purpose of patients assessing tolerability to treatment before purchase. According to GSP requirements, samples are provided through qualified delivery channels to medical institutions (not individual HCPs), who are equipped to handle the delivery of product.

When used appropriately, samples can be an important tool for HCPs to help them accumulate clinical experience.

Free samples of approved medicines may be provided to HCPs in order to

enhance patient care. Samples should be marked as such so that they cannot be resold or otherwise misused. Samples should be provided to HCPs in reasonable time, frequency and quantity.

Member companies should hire qualified the third party for the delivery of samples. The management of delivery and preservation must comply with GSP. Adequate accountability system for the control of samples provided to HCPs and pharmaceutical representatives must be established.

Samples cannot be paid as service fees, response to prescriptions, or other inappropriate inducement.

## **6. Company Responsibilities**

### **6.1 Compliance Obligations**

Member companies should establish and maintain appropriate procedures to ensure compliance with applicable laws, regulations, rules and national and local industry codes of ethics and to review and monitor all of their activities and materials in that regard. Those procedures should be documented and provided to employees to further enhance compliance.

Companies should register on platforms designated by regulatory agencies for their pharmaceutical representatives.

### **6.2 Conduct and Training of Pharmaceutical Representatives**

Member companies should provide their representatives and employees with training about compliance and product information to ensure that they have sufficient knowledge to relevant laws, rules, regulations, regulatory documents, Code of Ethics and internal regulations. In addition, member companies should train their employees and representatives to ensure that they have sufficient knowledge to general science and product-specific information to provide accurate, up-to-date information, consistent with applicable laws and regulations. Those internal training should be recorded and documented by

member companies. For pharmaceutical representatives who visit HCPs, companies should provide updated or additional training in all of the areas needed.

Member companies should also assess their representatives periodically to ensure that they comply with relevant company policies and standards of conduct.

## **7. Supervision for Compliance and Punishments for Breach of the Code**

### **7.1 Supervision for Compliance**

PhIRDA should establish a complaints working group for the Code to supervise relevant conducts of member companies on the base of their compliance annual reports. If a member company believes another member company violated the Code, it can submit a complaint to the PhIRDA and provide the evidence. The working group will require that complaint for explanation and necessary information, and then provide its decision and reasons with PhIRDA.

### **7.2 Punishments for Breaches**

When a breach of the PhIRDA Code by a member company happened, PhIRDA may adopt one or more following actions:

- PhIRDA should record its infringement in credit files and disclose to the public;
- PhIRDA may demand that company to make a written representation with the topic of *Self-examination for Infringement of the Code*, and to ensure that it will not violate the code in the future;
- PhIRDA may demand that company to conduct internal training about the code, and external professionals may be invited as trainers;
- PhIRDA may disqualify membership of that company with approval of more than half of the member companies.

## 8. Miscellaneous

### 8.1 Definitions

For the purpose of the PhIRDA Code of Ethics:

“pharmaceutical product” means all kinds of materials with provided indication, usage and dosage, which are intended for use in the prevention, treatment and diagnosis of disease in humans, or to affect any function of the human body, including herbal medicines, Traditional Chinese Medicine decoction pieces, Chinese patent medicine, API drugs and their preparations, antibiotics, radiopharmaceuticals, biochemical products, serum, vaccine, blood products, and diagnostic medicines etc..

“member companies” means members of PhIRDA.

“promotion” means any commercial activity undertaken, organized or held by a member company which is directed at HCPs or the public to promote the prescription, recommendation, supply, or consumption of its pharmaceutical product(s) through certain method of communications.

“Healthcare Professional (HCP)” refers to the medical technology practitioners of the Traditional Chinese Medicines, western medicines, epidemic prevention, pharmacy, nursing, and maternal and child health care, etc., who have been approved and recognized by the health administration department and obtained the corresponding qualifications and practice certificates and during whose course of the activity, various types of health technicians at all level such as prescription, drugs recommendation, and distribution to patients may happen.

“patient organizations” means typically a not-for-profit institution that primarily represents the interests and needs of patients, their families and/or caregivers.

“medical institution” means the institution with the Practice License of Medical Institution of the People’s Republic of China that comprises HCPs and complies to the requirement of the *Regulations on the Administration of*

*Medical Institutions* and the *Detailed Rules for the Implementation of the Regulation on the Administration of Medical Institutions*, including hospital, health-center, sanatorium, outpatient department, clinics and first-aid station that conducts diagnosis and treatment for disease.

“pharmaceutical representatives” means professionals engaging in delivery, communication and response of medical information who represent member companies.

## **8.2 Enter into Force**

The Code of Ethics will enter into force at September 18, 2018 for member companies of PhIRDA.

# Appendix

## Complaints and punishments for breaches of the PhIRDA Code

### 1. Complaints Working Group

Complaints Working Group under the Secretariat of PhIRDA is responsible for administering complaints for breaches of the PhIRDA Code.

The responsibilities of the Complaints Working Group include to (1) conduct Complaint validation; (2) preside over mediation between the two Parties, where applicable; (3) facilitate the Compliance Specialty Committee with its adjudication; and (4) facilitate/conduct execution of Compliance Specialty Committee decisions.

Complaints Working Group should report to the Secretariat on the integrity, transparency and openness of the proceedings.

Because the power of Complaints Working Group is entrusted by the Secretariat, the decision will be published in the name of the Secretariat.

### 2. Compliance Specialty Committee

Compliance Specialty Committee under the Secretariat of PhIRDA should include compliance managers and legal managers from member companies, and outside experts and scholars.

### 3. Complaints

All Complaints must be filed in writing and include the following content:

- The identity of the complaining Member Company or others("Complainant"), with full mailing address including fax number and email address for correspondence.
- The identity of the Member Company alleged to be in breach of the Code (the "Respondent"), the date of the alleged breach of the Code, and the name of the product(s) involved, if any,

- A clear description of the activity or practice (including any written or printed material) alleged to be in breach of the Code, supported by clear evidence wherever possible, and with reference to the article(s) of the Code alleged to be violated by the Respondent.
- An verification of the Complaint in writing by the General Manager of the complaining Company.

Any Complaint hereunder should be sent to either the physical address or the email address of PhIRDA as set forth below:

Add: the Secretariat of PhIRDA

Room 601, CTYS Plaza, No. 5 Dongzhimen South Street

Dongcheng District, Beijing

Postal Code: 100007

E-mail: phirda@phirda.com

#### **4. Complaint Validation**

Upon receipt of a Complaint, the Complaints Working Group should validate the claim(s) in the Complaint to ensure that:

- (1) both the Complainant and the Respondent are member companies of the PhIRDA;
- (2) it appears to be a genuine matter submitted in good faith;
- (3) the complained behavior can be identified as violation or breach of the Code;
- (4) there is sufficient evidence or information to enable the Complaint to be processed.
- (5) the Complaint has been verified in writing by the GM of the Complainant.

#### **5. Dismissal of a complaint**

Where a Complaint fails to establish a prima facie case for a breach of the PhIRDA Code of Ethics, such Complaint should be dismissed with respect to the Code. In addition, Complaints which pursue an entirely or predominantly commercial interest should be dismissed.

#### **6. Notice to the Respondent**



The Complaints Working Group should send a copy of the Complaint and all the supporting evidence or information to the Respondent's GM at the mailing address or email address that the Respondent-Company has registered with PhIRDA in 10 working days after validation of the Complaint.

## **7. Response**

The Respondent should respond to the Complaint ("Response") within 20 working days after its receipt of the Complaint from the Complaints Working Group. After sending the Complaint and supporting evidence, the Complaints Working Group should contact the GM of the Respondent and urge the Respondent to clarify the matter in question and/or respond to the Complaint within the above time limit.

The Response received by the Complaints Working Group should be forwarded to the Complainant upon receipt of the same.

Where the Respondent acknowledges that the claimed activity or practice is in breach of the Code, such acknowledgement should be in writing indicating the action(s) it has taken or plans to take to correct or remedy the breach. The Complainant may choose to, through written reply to the Complaints Working Group after its receipt of acknowledgement in 10 working days, (a) withdraw the Complaint or (b) refuse to accept the remedial actions proposed by the Respondent. If the Complainant fails to inform the PhIRDA whether it chooses to withdraw the Complaint, the Complaint will be deemed withdrawn.

Where the Respondent insists that the claimed activity or practice is not in breach of the Code, such refusal should be in writing indicating its reason providing with appropriate supporting materials.

## **8. Mediation**

In the case of the Respondent's denial of the Complaint, or failure to respond within due time prescribed hereunder, or the Complainant refuses to accept the Response by the Respondent indicating its remedial actions or action plans, the Complaints Working Group should preside over mediation or consultation between the two Parties within 20

working days after receipt by both the Complainant and the Secretariat, whichever is later, of Respondent's denial, or its failure to respond, or Complainant's refusal to accept the Response.

Upon failure of any agreement from the mediation between the Parties, Complaints Working Group should then submit the Complaint to the Compliance Specialty Committee for Panel Review.

## **9. Panel Decision**

The Panel should be formed by three experts. Each Party should appoint one Panelist from the Compliance Specialty Committee, and then they should jointly appoint the Chairman of the Panel (or the "Chairman") from the Compliance Specialty Committee. In the event where the two Parties disagree on the appointment of the Chairman, the Secretariat may then nominate an expert from the Compliance Specialty Committee as the Chairman. Upon notification of his/her appointments by the Parties, each panelist should provide a statement regarding conflict of interest to indicate that he/she has no conflict of interest with the Complainant and the Respondent.

The Panel should state in the Panel Decision, where applicable, the facts on which the Decision is based, the reasoning of the Decision and the conclusion drawn therefrom, as well as the sanctions imposed. The timeline for the offending Company to take any of the sanctioned actions should also be stated in the Decision, where applicable.

The Panel Decision, once issued and signed by all three Panelists, should be final and binding on both Parties.

Upon failure of any agreement from the mediation as prescribed above, the complaint should be submitted to Compliance Specialty Committee for Panel Review. Where the panel decides that the claimed activity or practice is in breach of the Code, the Respondent should undertake cost and expenses incurred from the Panel review. Where the panel decides that that claimed activity or practice is not in breach of the Code, the Complainant should undertake cost and expenses incurred.

## **10. Sanctions**

When a breach of the PhIRDA Code by a member company happened, PhIRDA may demand that company stop that breach and adopt one or more following punishments:

- PhIRDA should record its infringement in credit files and disclose to the public ;
- PhIRDA may demand that company to make a written representation with the topic of Self-examination for Infringement of the Code on forthcoming General Assembly, and to ensure that it will not violates the code in the future;
- PhIRDA may demand that company to conduct internal training about the code, and external professionals may be invited as trainers;
- PhIRDA may disqualify membership of that company with approval of more than half of the member companies.

## **11. Publication of Outcome**

Where a breach is ruled a summary of the case must be made public immediately on the PhIRDA website. The information to be disclosed is the identity of the company in breach of the PhIRDA Code, a summary of the key facts, the names of the product or products where relevant, and punishments for that breach.

Where no breach is ruled a summary of the case must be made public immediately on the PhIRDA website. The information to be disclosed is a brief summary of the key facts. The respondent company, the product and the complainant are not named.

A copy of the material to be published is provided to the respondent company for information only.

## **12. Supervision for compliance**

Complaints working group should contact with the Respondent, validate termination of that breach, and urge the Respondent to adopt correction or remedies or internal training about the Code.

PhIRDA may disqualify membership of that company with approval of more than half of the member companies, voting organized by the Secretariat on annual meeting of the General Assembly, if some member company breach the code several times without

intention of correction.