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PhIRDA
中国药促会

PhIRDA
Code of Practice

H A N D B O O K

中国医药创新促进会
医药企业伦理准则

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中国医药创新促进会 医药企业伦理准则

(2018年9月17日第十届会员大会第五次会议审议通过)

第一章 总则

第一条 制定目标

为规范会员单位及其代表和雇员的从业行为，依照我国现行法律、法规和规章要求，本着确保会员单位与利益相关者的有效沟通、使患者受益并促进医药产业健康有序发展，中国医药创新促进会（以下简称“中国药促会”）特制定本伦理准则。

PhIRDA Code of Practice

(Adopted at the Fifth Meeting of 10th PhIRDA General Assembly on September 17, 2018)

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 Practice 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.

第二条 适用范围

中国药促会会员单位及其代表或雇员在中华人民共和国境内从事药品的开发、研究、上市销售和配送过程中，与医务人员、医疗机构、患者组织等人员及机构沟通，应遵守本准则的要求。

第二章 推广形式与行为规范

第一条 沟通形式和内容

医药代表与医务人员沟通的具体内容包括：学术推广，技术咨询，协助医务人员合理用药，收集、反馈药品临床使用情况和药品不良反应信息等。

医药代表可以通过以下形式与医务人员沟通：

1.2 Scopes

In the development, research, manufacturing, marketing, distribution, and/or sale of medicines, member companies are committed to following the Code of Practice 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 and response of medical usage in clinical practice and adverse drug reactions.

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

- (一) 在医疗机构当面沟通；
- (二) 举办学术会议、讲座；
- (三) 提供学术推广资料；
- (四) 通过互联网沟通或电话会议；
- (五) 医疗机构同意的其他形式。

第二条 合乎伦理的沟通

医药代表与医务人员的沟通应以专业并合乎伦理的方式进行。

(一) 学术推广活动应传递关于药品的利益和风险以及获得批准适应症的准确、最新信息，在遵守现行法律、法规、规章及本伦理准则要求下，促进合理临床用药；

(二) 不得误导医生不合理使用药品，不得夸大或误导疗效，不得隐匿药品不良反应；

- 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 Practice;
- Medical usage should not be unreasonable and misleading, clinical effects should not be exaggerated or misled, and adverse drug reactions should not be disguised.

(三) 不得对医务人员造成不当影响;

(四) 不得向医务人员提供任何物品或服务以干扰医务人员的处方行为;

(五) 不得向医务人员提供临床促销费、处方费、统方费或其他提成性质的费用。

第三章 推广信息

第一条 与产品信息一致

药品推广信息应与国务院药品监督管理部门批准的产品信息和标签、说明书保持一致，并应当显著标明适应症、禁忌症和不良反应。推广信息不得粉饰。

- 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.

第二条 准确和不误导

药品推广信息应当清晰、准确、易懂，并尽可能的公正、客观和完整，使接受者足以理解产品特性及其治疗价值。

药品推广信息应当努力避免模糊不清的表述。不得含有不科学的安全性保证和断言。

第三条 推广信息的证据

药品推广信息应当清晰地反映所有相关证据。

相关证据不得通过歪曲、夸大、不当的强调、忽略或其他方式造成误导。

已获得国务院药品监督管理部门批准的标签和说明书可以作为本条第一款所称的“证据”。根据医务人员要求，可以客观地提供与推广药品相关的其他证据和信息。

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.

第四条 许可前沟通和标签外使用

未获得国务院药品监督管理部门批准的药品或药品新适应症，会员单位不得对该药品或药品新适应症进行商业目的的推广。

但是，为了促进医学进步，在符合国家相关法律、法规等规定下，可以通过组织科学研讨会或利用公众传播媒介，向利害关系人及其他与药品相关人员披露药品研究结果和信息，以确保相关科学组织及公众的充分知情权，相关机构与利害关系人对药品科学信息的合法交流，以及依照相关法律法规或准则要求向利害关系人或公众公开披露药品相关信息。

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.

第五条 书面推广材料

书面推广材料通常应包括：

- (一) 产品正式名称；
- (二) 有效成分；
- (三) 药品生产、销售企业或药品上市许可持有人的名称和地址；
- (四) 推广材料的制作日期；
- (五) “处方信息概要”包括获得批准的适应症、剂量和用法，以及关于禁忌症、注意事项及不良反应的描述。

推广材料引用证据应当标明出处。引用医学和科学文献或个人论述时，不得进行曲解。

向医务人员寄送推广材料的频率和数量应适当。

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.

无论目的是否为推广相关药品，关于药品及其用途的材料中应当标明制作单位或人员。

第六条 电子推广材料（包括视听资料）

电子推广材料适用与书面推广材料同样的要求，包括相关网站的药品宣传，同时还应符合以下要求：

（一）制药公司和指向受众应易于理解；

（二）内容应适合指向受众并易于理解；

（三）发布信息应当遵守现行法律、法规和规章的要求。

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.

第七条 电子推广材料的推送与退订

未经当事人同意或请求，不得以电子信息形式向医务人员发送电子版推广材料。

以电子信息方式发送推广材料，应当标明发送者的真实身份和联系方式，并向接受者提供拒绝继续接收电子材料的方式。

第四章 会议、活动和其他资助

第一条 会议和活动

会员单位组织或资助针对医务人员的专题研讨会和其他推广、科学或教育活动，应当以提供科学或教育信息、使医务人员了解产品为目标。

由会员单位提供资金或赞助的所有活动，其举办场地应有助于体现活动所包含的科学或教育性的主题、达到活动设定的目标。不得使用奢侈的

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 mark 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

场地或度假村举办活动。

为活动提供的点心和餐食，仅限于提供给活动参与者，消费水平应在合理且适当的范围内。

非因治疗需要，不得为不具备参与活动资格的随行人员（例如，配偶和子女）支付任何费用。

会议期间的住宿、餐饮、差旅等费用支出，应由会员单位直接向服务提供商支付。不得向参会人员给付现金，会员单位可通过官方银行账户向医务人员转账报销。但是参会人员在会议期间产生的与会议无关的差旅及交通费用不得予以报销。

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 and 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.

第二条 赞助

经所在医疗机构或上级主管部门书面批准，会员单位可以赞助医务人员参加活动，但应符合下列要求：

(一) 活动符合本准则第四章第一条要求；

(二) 给医务人员的赞助仅限于支付旅费、餐费、住宿和会议注册等会议过程中实际发生的费用，且应直接支付给服务提供商；

(三) 不得向医务人员支付误工费；

(四) 对医务人员的赞助不得以开具处方、购入药品或促销药品作为条件；

(五) 对医务人员的赞助不得意在影响药品采购等重大决策过程。

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 4.1 (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.

第三条 咨询和其他服务

医务人员可作为咨询专家为会员单位提供服务，例如主持会议、做报告或参加会议讨论、参与医学科学研究、临床试验或培训服务、参加上市后研究，会员单位应当保存并合理使用提供相关有偿服务的记录及报告。

会员单位在安排医务人员提供有偿服务的过程中，必须遵守下列要求：

(一) 必须在服务开始前与咨询专家达成书面协议，明确提供服务性质和支付服务费用范围；

(二) 咨询专家在提供具体服务前，已经清楚地确认了服务要求；

(三) 邀选咨询专家必须符合业务需求，负责邀选咨询专家和报告人的相关人员应当具备专业能力且充分评价相关医务人员是否符合要求；

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;

(四) 邀选的咨询专家人数不得超过工作所需合理人数；

(五) 不得以聘任咨询专家为名，诱导医务人员开具处方、推销某种药品；

(六) 不得通过聘请咨询专家，进行不正当利益输送，影响药品采购等重大决策过程；

(七) 给付咨询服务费必须合理反映咨询专家所提供的服务的市场价值；

(八) 与咨询专家或报告人会面场所和环境应当适宜，不得以各种名义的旅游给付财物以外的其他利益；

(九) 咨询服务费由企业代缴个人所得税，并以银行转账方式支付。

- 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.

第四条 娱乐

会员单位与医务人员的互动应旨在提供使患者受益的医学和 / 或科学信息的活动。

为确保以教育和信息交流为目的，避免出现不当行为，会员单位不应在交流活动中向医务人员提供任何形式的娱乐项目，诸如剧场门票、运动装备、休闲或假期旅行等，无论所提供的项目价值是否合理、医务人员是否作为活动发言人或咨询专家、娱乐项目是否为交流活动的附属项目，均不可以。

不得向参加交流活动的人员提供单独的娱乐或其他休闲或社会活动或支付任何形式的娱乐活动。

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.

第五条 礼品和其他赠品

不得(直接或间接通过诊所和医疗机构)向医务人员提供礼品(例如体育或娱乐的门票、电子产品、出于社交礼仪的礼物等)，也不得向医务人员提供现金、现金等价物(例如礼品卡)或个人服务。

推广辅助用品是为促进药品合理使用而提供的非现金物品。不得向医务人员提供与处方药推广相关的辅助用品。可以向非处方药相关医务人员提供低价、小量的促销辅助用品。

如果医疗设备价值适当、有助于改善医疗服务和患者护理，在获得医疗机构批准后，会员单位可向医疗机构提供此类医疗设备。会员单位不得擅自为医务人员提供医疗设备供其在医疗机构内使用。除非标明产品名称对于患者正确使用该医疗设备是必要的，否则赠送的医疗设备上不得标注产品名称。

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 direct-

ly 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 products' 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.

会员单位可以向医务人员提供信息或教育物品，用于患者或疾病教育，这些物品应仅用于教育目的且不具有独立价值。

向医务人员提供的信息或教育物品，可以标注公司名称，但不得标注产品名称，除非标注产品名称有助于患者正确使用。

提供给医务人员的书籍和杂志的价格应当在合理范围。其他信息或教育物品的价格也必须是在合理范围。

第六条 医学进修的资助

医学进修的首要目标是提升医学知识，因此，会员单位可以资助医务人员参加必要的医学进修，以利于医务人员更好的开展医疗服务。

会员单位应当就医学进修的资助金额制定客观的标准，确保资助项目为有益、高质量的教育项目，确保资金支持不是为了诱导医务人员开具处方或推荐特定药品或治疗手段。

会员单位为医学进修活动和项目提供的资助必须遵循公正、公平和客观的原则，活动设计应准许表达不同的理论和已认可的观点，活动必须提供有助于改善患者照护的医学、科学或其他信息。

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.

不得以换取推荐使用药品或开具处方为目的，或者采用有悖伦理和影响、干预医务人员处方行为独立性的方式，向医务人员提供补助、奖学金、补贴、资助、咨询合同、教育等类似条件。

第七条 研究项目的资助

会员单位委托或支持医疗机构开展的临床评估、上市后监测项目、上市后研究，不应被曲解为推广行为。上述活动的进行不得包括不正当利益输送。

会员单位在资助研究项目时，不得直接资助医务人员个人开展研究。会员单位应与医疗机构(或发起研究的专业医学组织，例如医学会)签订合作协议，在协议中明确项目要求、项目负责人、预算安排、生效和终止条件、违约条款等内容。项目资金应从会员单位账户转入医疗机构账户或医学、科学协会账户，按照项目预算合理使用。

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.

第八条 当面沟通

会员单位的医药代表可以根据医务人员的日程和工作情况，在合适的时间（包括午餐时间）向医务人员展示药品信息。展示信息可以包括介绍产品相关的科学和医学知识、用药方法、不良反应的防范等，但不得过度宣传产品疗效。

医药代表进入医疗机构进行信息展示应确保遵守医疗机构的相关规定。

4.8 Communications in Medical Institutions

Pharmaceutical representatives of member companies are allowed to present drug information in appropriate time (including meal times) 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 compliant with relevant regulations of medical institutions.

第五章 样品

第一条 样品

为评估患者对治疗的耐受性，可以在销售前提供样品。样品的提供应当符合 GSP 的要求，通过有资质的配送渠道提供给医疗机构（而非医务人员个人），医疗机构应能控制样品的发放。

样品在合理使用时，可以成为帮助医务人员积累临床经验的重要工具。

会员单位可以免费向医务人员提供已获批准药品的样品，以改善患者症状。样品应当有（免费）样品标识，以便它们不被重新销售或者以其他方式滥用。提供样品的时机、数量和频率应当合理。

会员单位应使用有资质的第三方进行样品发放、配送，且样品的保管应当符合 GSP 要求。

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.

对于提供给医务人员的样品，包括由医药代表分发的样品，必须建立充分的问责体系。

会员单位不得将样品作为用于支付医疗服务费用和对开具处方的回馈，或者其他不适当行为的诱导。

第六章 企业责任

第一条 企业合规义务

会员单位应当建立合理的合规程序，审查和监控所有与药品推广相关的活动，以确保其符合国家相关法律、法规、规章以及全国性、地区性产业伦理准则。合规程序应当存档并提供给员工以进一步促进员工合规操作。

会员单位应当在监管部门指定的平台为其医药代表办理登记备案手续。

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.

第二条 医药代表的行为和培训

会员单位应当对其所有雇员，尤其是医药代表，开展相关法律、规章和行业伦理准则的培训，以确保其行为符合相关法律、法规的要求。会员单位还要针对医药代表开展产品特性、与医务人员正确沟通及如实撰写培训记录等专业培训，以确保他们对于本企业药品的科学和特定信息有充分的了解，并能够为有关人员提供准确、最新的药品信息。

会员单位应当定期对医药代表进行评估，以确保他们遵守公司的相关规定和行为规范。

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 Practice 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.

第七章 合规监督与违规制裁

第一条 合规监督

中国药促会应成立合规工作组，负责监督会员单位的合规相关活动，审查会员单位提交的年度合规报告。任何会员单位及个人、机构或组织，认为其他会员单位有违反伦理准则的行为，可以向中国药促会投诉并举证。中国药促会合规工作组可依据本伦理准则，要求被投诉会员单位做出解释并提供必要证据，以及提交自查报告。

第二条 违规制裁

一旦某会员单位被认定有违反本伦理准则的行为，中国药促会将视情况对其采取以下一种或几种行动：

(一) 将其违规行为收录在诚信档案中并予以公布；

7. Infringements, Complaints and Enforcement

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 compliant 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 Measures to Ensure and Enforce Compliance

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;

(二) 在会员大会上以“违反伦理准则自省”为主题做书面陈述报告，并保证将来不再违规；

(三) 开展中国药促会伦理准则的企业内部培训，包括聘用外部专家进行合规培训；

(四) 对屡次发生严重违规行为且无意改正的会员单位，经一半以上会员单位同意，中国药促会可取消该会员单位的会员资格。

第八章 附则

第一条 概念

在 PhIRDA 伦理准则中：

“药品”指的是用于预防、治疗、诊断人的疾病，有目的地调节人的生理机能并规定有适应症或者功能主治、用法和用量的物质，包括中药材、中药饮片、中成药、化学原料药及其制剂、抗生素、生化药品、放射性药品、血清、疫苗、血液制品和诊断药品等。

- 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 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.

8. Miscellaneous

8.1 Definitions

For the purpose of the PhIRDA Code of Practice: “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 prepara-

“会员单位”是指中国医药创新促进会会员单位。

“推广”是指由会员单位实施、组织或举办，通过一定媒介和形式直接或者间接地向医务人员或公众，意在推广其医疗产品的处方、建议、供应、或消费的商业活动。

“医务人员”是指经过考核和卫生行政部门批准和承认，取得相应资格及职业证书的，就职于医疗机构，从事中医、西医、卫生防疫、药剂、护理、妇幼保健等医疗技术活动，在专业活动中可能开具处方、建议用药、出售、供应药品或给患者用药的各级各类卫生技术人员。

tions, 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.

“患者组织”是指主要代表患者及其家属和 / 或看护人员的利益和需求的典型的非营利机构。

“医疗机构”是指依据《医疗机构管理条例》和《医疗机构管理条例实施细则》的规定，经登记取得《医疗机构执业许可证》，由医务人员组成的机构，包括从事疾病诊断、治疗活动的医院、卫生院、疗养院、门诊部、诊所、卫生所（室）以及急救站。

“医药代表”是指代表作为药品上市许可持有人的会员单位从事药品信息传递、沟通、反馈的专业人员。

第二条 生效

本伦理准则将于 2018 年 9 月 18 日对会员单位生效。

“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 Practice will enter into force at September 18, 2018 for member companies of PhIRDA

附件:

违规投诉程序

第一条 合规工作组

中国医药创新促进会秘书处下设合规工作组，合规工作组在秘书处领导下开展会员单位的合规监查及处理违规投诉工作。

合规工作组职责包括：(1) 核实投诉；(2) 调节争议双方；(3) 协助合规专业委员会进行合规裁决；(4) 执行合规专业委员会的裁决。

合规工作组应就争议处理程序的公正性、透明性及公开性向中国药促会秘书处汇报。

Appendix

The Procedure of Code Complaints

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.

第二条 合规专业委员会

中国药促会合规专业委员会由来自会员单位的合规、法律事务等有关部门负责人以及外部专家、学者组成。

第三条 违规投诉

投诉人应以书面形式提出投诉。投诉书中应包括下列内容：

(1) 提出投诉的会员单位或其他人(统称“投诉人”)的机构、身份信息，并应列明完整的通讯地址信息，包括联络用的传真号码及电邮地址。

(2) 涉嫌违反本伦理准则规定的会员单位的机构、身份信息(统称“被投诉人”)，涉嫌违规行为的发生日期以及涉事产品名称(如有)。

(3) 对于涉嫌违反本伦理准则规定的活动或行为的清晰描述，相关证明材料(包括书面或印刷材料)，并应标明被投诉人违反本伦理准则的具体条款。

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.

- A 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@phrda.com

- (4) 投诉人所在机构的负责人(总经理及以上人员)签字。

所有投诉均应通过如下地址或者电邮将投诉书送交中国药促会：

地址: 中国医药创新促进会秘书处
北京市东城区东直门南大街 5 号
中青旅大厦 601
邮编: 100007
电子邮件: phirda@phrda.com

第四条 投诉的核实

中国药促会合规工作组收到投诉书后，应对投诉书所陈述内容进行以下核实：

- (1) 被投诉人确为中国药促会会员；
- (2) 提交争议事宜系非恶意投诉、属真实、客观发生事宜；
- (3) 投诉行为确为违反本伦理准则规定的行为；
- (4) 处理投诉所需的相关证据及信息充分。
- (5) 投诉申请已由投诉人所在机构负责人做出书面证实。

4. Complaint Validation

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

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

第五条 投诉的驳回

若投诉人未能证明争议行为违反本伦理准则规定，中国药促会将对相关投诉予以驳回。对于完全或主要基于追求经济利益的投诉请求，中国药促会应予驳回。

第六条 告知被投诉人

中国药促会合规工作组应在完成投诉核实工作后十个工作日内，按照被投诉人在中国药促会登记的邮寄地址或者电邮地址信息，将书面投诉副本连同所有证明材料及信息一并发送给被投诉人，并确认被投诉人收到以上材料。

5. Dismissal of a Complaint

Where a Complaint fails to establish a *prima facie* case for a breach of the PhIRDA Code of Practice, 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.

第七条 投诉答复

被投诉人应在收到由中国药促会合规工作组发出的书面投诉副本后二十个工作日内，对投诉事项进行答复。若被投诉人逾期未与答复或未说明不能答复的理由，合规工作组应要求被投诉人尽快就争议事宜予以澄清或说明。

中国药促会合规工作组应在收到被投诉人答复后，尽早将其答复转交投诉人。

如果被投诉人承认争议所涉活动或行为违反了本伦理准则规定，被投诉人应以书面形式予以承认，并列明为纠正或补救该违规行为而已实施或计划实施的措施。投诉人应在收到承认回复后十个工作日内，以书面形式通知中国药促会合规工作组投诉人的主张：(1) 撤回投诉，(2) 不接受被投诉人提议的补救措施。如果投诉人未能在规定期限内通知中国药促会表

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

明主张，中国药促会则视为投诉撤回。

如果被投诉人主张争议所涉活动或行为并未违反本准则的规定，应以书面形式作出否认答复，并在答复中应列明理由和支持证据。

第八条 调解

如果被投诉人对投诉内容予以否认，而投诉人对于被投诉人提议的补救措施不予接受决定，合规工作组应在接到投诉人和被投诉人否认答复后二十个工作日内（以接受上述较晚回复时间为准），召集并主持争议双方的调解或协商活动。

fails to inform the PhIRDA whether it chooses to withdraw the Complaint, the Complaint will be deemed withdrawn.

Where the Respondent insist 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.

如果争议双方未能通过调解达成一致，合规工作组应将该争议提交合规专业委员会进行裁决。

第九条 裁决

合规专业委员会以裁决专家组形式，对经调解未能达成一致的争议进行裁决。裁决专家组由三名成员组成，投诉人和被投诉人可以分别从合规专业委员会委员名单中指定一名裁决专家，并共同指定一名委员担任专家组组长。如果投诉与被投诉双方未能就组长人选达成一致，则由合规工作组指定一名委员担任裁决专家组组长。裁决专家组成员应向合规工作组提交利益冲突声明，说明其与投诉人和被投诉人不存在利益冲突。

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.

裁决专家组应对投诉内容以及所有相关证明材料或信息进行审查并依此作出相应裁决。裁决专家组应在裁决书中明确说明，该裁决所依据的事实、推理论证过程、最终结论以及相应的处罚措施。对于违规方所作出的处罚决定，裁决专家组还应在裁决书中列明要求违规方履行相应处罚的时限。

裁决书经裁决专家组 3 名专家签字确认并予公布后，即具有终局效力并对争议双方具有约束力。

如果专家组裁决被投诉人确有违规行为，裁决过程中产生的费用由被投诉人承担；如果裁决被投诉人行为并未违规，裁决过程中产生的费用则由投诉人承担。

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 compliant 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 claimed activity or practice is not in breach of the Code, the Complainant should undertake cost and expenses incurred.

第十条 处罚

对于有违规行为的会员单位，除要求其立即终止违规行为之外，还可以对其采取以下一种或几种处罚措施：

（一）将其违规行为收录在诚信档案中并予以公布；

（二）在会员大会上以“违反伦理准则自省”为主题做书面陈述报告，说明违规行为和纠正 / 补救措施，并保证将来不再发生违规行为；

（三）开展中国药促会伦理准则的企业内部培训，包括聘用专业人士进行合规培训；

（四）对屡次发生严重违规行为且无意改正的会员单位，经一半以上会员单位的同意，中国药促会可取消该会员单位的会员资格。

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.

第十一条 公布结果

如果裁决专家组裁决认为被投诉人的确发生违规行为，中国药促会应在其网站上公布该裁决书摘要。摘要披露信息包括：违规企业名称，违规行为的主要事实，涉事产品名称，采取的处罚措施。

如果裁决专家组裁决认为被投诉人行为并未违规，中国药促会也应在其网站上公布该裁决书摘要。摘要披露信息应包括争议的主要事实，但不应提及投诉人、被投诉人和产品名称。

中国药促会应向被投诉人提供公布摘要的副本。

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.

第十二条 监督执行

合规工作组应与违规会员单位保持联系，核实其确已终止违规行为，督促其采取纠正补救措施，并开展对本伦理准则的内部培训。

对于屡次发生严重违规行为且无意改正的会员单位，由秘书处在会员大会上组织会员单位投票，如能获得一半以上会员单位同意，可取消该会员单位的会员资格。

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.