RDPAC行业行为准则

（2017年修订版）

RDPAC Code of Practice 2017

中国外商投资企业协会药品研制和开发行业委员会

China Association of Enterprise with Foreign Investment R&D-Based Pharmaceutical Association Committee

主席致辞

尊敬的各位同仁：

作为制药行业的主要从业者，贵公司须遵守《RDPAC行业行为准则》，这一点非常重要。在我们行业与医疗卫生专业人士的互动以及我们的工作中保持诚信非常关键，这才可以确保我们的产品和治疗方案能以最高专业标准被研究并传递给患者。

本《行为准则》体现了我们制药行业在道德和专业方面的承诺。

本《行为准则》的基础是本委员会所属的国际制药企业协会联盟（IFPMA）的药品推广行为准则。本《行为准则》已经是其自1999年实施以来的第七版。

在《“健康中国2030”规划纲要》和《十三五规划纲要》中，中国政府将医疗保障和疾病预防作为中国发展最重要的目标之一。为确保科学进步可以惠及中国患者并提高他们的生活质量，我们制药行业的行为符合道德标准和合规要求非常关键。

我们相信，我们的一切活动都将患者放在第一位。责任、独立和透明是我们的核心准则。从根本上讲，我们必须始终有信心认为，处方决定的作出是以患者为中心，并符合道德标准。

Chairman’s Message

Dear Colleagues

As key players in the pharmaceutical industry it is important that your Company abides by the RDPAC Code of Practice. Integrity is an essential part of the interaction between our Industry and healthcare professionals and works towards ensuring that our products and therapeutical solutions are researched and delivered with the highest standards of practice.

This Code of Practice is the ethical and professional commitment of our industry.

The foundation of the Code is from the Code of Practice of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) to which RDPAC belongs. It is now in its 7th version, which started in 1999.

The Chinese government recognizes healthcare and disease prevention as one of the most important objectives for the development of China, as described in the “Healthy China 2030” and the “13th Five Year Plan”. That our Industry behaves in an ethical and compliant manner is essential so that scientific advancement reaches Chinese patients and contributes to the improvement of their quality of life.

We believe that patients are put first in all of our activities and that accountability, independence and transparency are our core principles. Fundamentally, there must always be confidence that prescription decisions are made on an ethical and patient-focused basis.

我们共同且独立地对本《行为准则》负责。

我信赖你们。

We are collectively and individually accountable to this Code of Practice.

I count on YOU.

Eric Bouteiller 主席

Chairman, RDPAC

2017年1月1日

1 January 2017

RDPAC行为准则（2017）

序言

医疗卫生专业人士与制药行业在多个关键领域内合作，以推动科学进步，为患者谋求最大福祉。RDPAC 与制药行业和医疗卫生专业机构共同努力，通过行业自律行为准则和指南在中国推进其相互间开展符合伦理准则的合作，确保合作的开展是合规的、适当的。尽管制药企业与医疗卫生专业人士之间的互动交流被广泛认为可为患者和社会带来裨益，以实际行动确保相关资助和经济往来是适当和有助于提高病患服务质量仍具有十分关键的重要。

RDPAC 行为准则（2015 年修订版）采纳 IFPMA 最新发布的、有关行业与医疗卫生专业人士间若干重要合作方式问题上的指导原则，如行业资助临床试验研究或医学继续教育；也融入了部分政府卫生主管部门最新颁布的规章的精神，如卫计委于 2013 年 12 月颁布的《加强医疗卫生行风建设九不准》。正如相关国际组织 2014 年 1 月签署的《病患组织、医疗卫生专业人士和制药行业间开展符合伦理准则合作的共识纲要》中所明确提出的，行业与医疗卫生专业人士开展合作的基本原则是：

一、患者至上

RDPAC Code of Practice (2017)

Preamble

Healthcare professionals and the pharmaceutical industry collaborate in many critical areas to support scientific advancement and serve the best interest of patients. RDPAC works with the pharmaceutical industry and healthcare professional organizations to promote ethical collaboration through self-regulatory codes of practice and guidelines in China, to help ensure that collaborations are ethical and appropriate. While collaboration and interaction between the member companies and healthcare professionals are widely acknowledged to be beneficial to patients and society, it is important to ensure that payments and other transfers of value involved therein are appropriate and lead to high quality patient care.

The RDPAC Code of Practice (2015) incorporates the most recent update of the IFPMA guidance on such critical areas of collaboration practices between Industry and healthcare professionals, such as Industry sponsorship to support clinical trials or CME, as well as principles of the newly issued ordinance from the Chinese health authority, such as the Nine Bans in Strengthening Ethics in the Healthcare Field (issued in December 2013 by the National Health & Family Planning Committee). As illustrated by the Consensus Framework for Ethical Collaboration between Patients Organizations, Healthcare Professionals and the Pharmaceutical Industry (issued in January 2014), the overarching principles governing such collaborations are:

(1) Put patients first;

二、维护符合伦理准则的科研和创新

(2) Support ethical research and innovation;

三、确保独立性和符合伦理准则的从业行为

(3) Ensure independence and ethical conduct; and

四、提高透明度和问责性

(4) Promote transparency and accountability.

作为全球制药行业的一员，RDPAC 致力于旨在推动造福患者和推动科学进步的信息共享，同时也着力防范在医疗卫生专业人士与会员企业之间开展互动交流可能存在的问题。

RDPAC joins the global pharmaceutical industry in our commitment to supporting information sharing that aims to benefit patients and foster scientific advancement, while ensuring that concerns about the legitimate relationship between healthcare professionals and companies are addressed.

本准则于 2017 年 1 月 1 日生效，并取代 2002 年版的 FRPIA 药品推广行为准则（第二版）及 2006 年版、2010 年版、2012 年版和 2015 年版 RDPAC 药品推广行为准则。

Effective 1 January, 2017, this Code of Practice replaces the FRPIA Code of Pharmaceutical Marketing Practices (2nd Edition, 2002), the RDPAC Code of Practice on the Promotion of Pharmaceutical Products (2006), (2010), (2012) and (2015).

IFPMA行为准则（2012）
序言

推进医学知识和改善全球公共卫生有赖于整个医学界在信息分享方面的互动交流－从研究人员到从业医师、护士到患者－而这些互动交流活动的关键就在于其道德上的正直性。从根本上讲，公众必须对医生开具处方这一行为是道德的和为患者着想的这一点充满信心。

这些互动交流中，政府、医疗卫生行业及患者对制药企业，无论其在世界任何地方经营，系以道德的和专业的方式从事经营活动是否有信心是极其重要的。而以高道德标准从业不仅应适用于药品推广活动，其应更广泛地适用于所有与医疗卫生行业的互动交流活动。这就是我们，国际制药企业协会联盟代表研发制药行业在最新修订的行为准则中所做的承诺。

该行为准则自1981作为行业在全球范围自律的基础性文件以来，一直随着新形势的要求而不断地更新和强化。2012年版行为准则将前一版对制药行业既已提出的高道德标准行为准则扩展适用于其与医疗卫生专业人士、医疗机构和患者组织的所有互动交流活动。

行为准则的成功不仅有赖于对准则制订的标准本身的遵守，还有赖于其是否具备完善的

Foreword of IFPMA Code of Practice 2012

Advancing medical knowledge and improving global public health depend on information-sharing interactions by the entire medical community - from researcher to attending physician and nurse to patient – and integrity is essential to these exchanges. Fundamentally, there must always be confidence that prescription decisions are made on an ethical and patient-focused basis.

In these interactions, it is essential that governments, the healthcare community and patients are confident that pharmaceutical companies, wherever they operate in the world, act in an ethical and professional manner. Such ethical practices should apply not only to the promotion of medicines but more broadly to all interactions with the healthcare community. This is the commitment that we, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) representing the research-based pharmaceutical industry, make in our recently-revised Code of Practice.

Since its initial adoption in 1981 as the foundation of a global self-regulatory approach, the Code has been regularly updated and strengthened to adapt to changing needs. The scope of the 2012 revision extends this already high standard of pharmaceutical industry practice beyond marketing practices to cover all interactions with healthcare professionals, medical institutions and patient organizations.

Success of the Code requires high awareness levels of both the standard itself as well as the established procedures for registering complaints. IFPMA member

投诉处理机制。国际制药企业联盟的成员公司致力于向其全部约一百三十万个雇员宣传本准则并提供全面的培训。在我行业承诺按最高道德标准从事经营活动的同时，我们亦鼓励诸如医生、药剂师、护士、学者、患者和消费者等在内的所有医疗卫生行业的相关人士都能意识到我们这一新的举措，并加入到按最高道德标准从业的队伍中来。

本着以患者的最大利益为根本的宗旨，我们对在所有的互动交流活动中应遵守诚信、求实和清晰准确的原则这一点负有道德义务。研发制药行业承诺其应在遵守最高道德标准从事经营活动的原则基础上对全球公共卫生事业做出积极贡献，而《国际制药企业协会联盟行为准则》就是践行这一承诺的范例。

Eduardo Pisani
总裁
国际制药企业协会联盟

companies are committed to informing all their 1.3 million employees about the Code as well as to providing thorough training. While our industry holds itself accountable to conduct business with the highest possible ethics, we encourage others – doctors, pharmacists, nurses, academicians, patients and consumers – to become aware of this new benchmark and to ensure equally high ethical practice throughout the healthcare sector.

Focused on serving the best interests of patients, we have a moral obligation to communicate and participate in all relationships with integrity, accuracy and clarity. The IFPMA Code of Practice is a tangible example of the research-based pharmaceutical industry's commitment to making a strong contribution to global public health while adhering to the highest standard of practice.

Eduardo Pisani
Director General
International Federation of Pharmaceutical Manufacturers and Associations
(IFPMA)

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IFPMA商业行为与推广伦理指导原则

国际制药企业协会联盟会员公司致力于医疗和生物制药研发事业，以为患者提供高品质的医疗服务。国际制药企业协会联盟所代表的制药企业应按高道德标准、并依照有关药品和医疗卫生的法律法规进行药品的推广、销售、和分销。

以下八项指导原则确定了国际制药企业协会联盟2011年版行为准则的基本规定和原则，适用于国际制药企业协会联盟的会员公司和其代理，以确保其与各利益相关方的互动交流行为是适当的。

1. 确保患者的医疗卫生保障与福祉是研发制药公司的最高目标和宗旨。

2. 研发制药公司应遵守相关药品主管部门对药品的质量、安全性有效性所制订的最高法定标准。

3. 研发制药公司与各利益相关方的互动交流活动在任何时候都必须是合乎高道德标准、正当、和专业的。会员公司不得支付或提供任何可能向对方施加不当影响的物品或服务。

4. 研发制药公司有责任提供有关其产品的准确、平衡、和有科学实证的信息。

IFPMA Guiding Principles on Ethical Conduct and Promotion

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) member companies engage in medical and biopharmaceutical research in order to benefit patients and support high-quality patient care. Pharmaceutical Companies, represented by IFPMA, 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 that inform the 2011 IFPMA Code of Practice which applies to the conduct of IFPMA Member Companies and their agents, to help ensure that their interactions with stakeholders are appropriate.

1. The health-care and well-being of patients is 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. 对药品的推广应当合乎高道德标准的，准确和平衡的，且不引起任何误解。推广材料中所记载的药品信息应当包含对相关药品的利益与风险的客观评价及正确的用药方法。

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. 研发制药公司应尊重患者的隐私与个人信息。

6. Pharmaceutical Companies will respect the privacy and personal information of patients.

7. 所有由研发制药公司组织或支持的临床试验和科学研究均应以探索可使患者受益和科学与医学进步的科学知识为其目的和宗旨。研发制药公司致力于使行业组织发起的患者临床试验越来越透明、公开。

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. 研发制药公司应严格遵守相关推广行为准则的条文及其内涵的价值观。为此，研发制药公司应确保其相关管理人员应接受充分的培训。

8. Pharmaceutical companies should adhere to applicable industry codes in both the spirit and the letter. To achieve this, pharmaceutical companies will ensure that all relevant personnel are appropriately trained.

RDPAC行为准则

（2017年修订版）

第一条 范围与定义

1.1 范围

RDPAC行为准则（以下也称“RDPAC准则”）的规范对象是会员公司与医疗卫生专业人士及医疗机构之间的医学互动交流活动，以及药品的推广活动。

注释1-5：

1. RDPAC准则适用于RDPAC会员公司。非RDPAC会员的制药公司不在RDPAC准则的规治范围之内。RDPAC鼓励非会员公司和其他需要向医疗卫生专业人士推广药品或服务、或需要与医疗卫生专业人士开展互动交流活动的组织都能遵守与RDPAC准则所规定药品推广及相关互动交流道德标准相类似的道德行为标准。

值得注意的是，RDPAC准则适用于所有会员公司的雇员，以及代表公司执行工作任务的分包商，如咨询公司或人员、外包的医药代表或公关公司或人员。

2. RDPAC准则不适用于下列活动：

- 直接针对一般公众所进行的处方药推广 (即DTC广告)；
- 直接针对消费者就自我诊疗药品进行的非处方药

RDPAC Code of Practice

(2017)

Article 1 Scope and Definitions

1.1 Scope

The RDPAC Code of Practice (hereinafter also the “RDPAC Code”) covers medical interactions with healthcare professionals, medical institutions, and the promotion of pharmaceutical products.

Annotation 1-5:

1. The RDPAC Code applies to RDPAC’s member companies. Pharmaceutical companies that are not members of RDPAC fall outside the reach of the RDPAC Code. RDPAC encourages such companies – and other organizations marketing healthcare products or services to healthcare professionals, or those having interactions with healthcare professionals, medical institutions - to follow ethical standards for promotion and interactions, similar to those set forth in the RDPAC Code.

It should be noted though that all relevant company employees are covered by the Code, as well as subcontractors that carry out tasks on behalf of the company, such as consultants, contracted sales representatives or PR agents.

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

- Promotion of prescription only pharmaceutical products directly to the general public (i.e. direct to consumer advertising);
- Promotion of self-medication products that are provided “over the-counter” (OTC) directly to consumers without

（OTC）推广；

prescription;

• 价格或其他有关药品供应的商务条款，包括：向商业性组织进行的药品推广和营销；

• Pricing or other trade terms for the supply of pharmaceutical products, including promotion and marketing of pharmaceutical products to commercial customers;

• 某些特定形式的非推广类信息与活动；

• Certain types of non-promotional information or activities; and

• 对医疗器械的推广。

• Promotion of medical devices.

3. 不适用RDPAC准则的非推广类信息可包括为回答针对某个药品的具体问题而进行的往来函件及其附随的非推广类信息资料。有关会员公司的非推广类的一般信息（如面向公司投资者及现有的或未来的员工提供的信息），包括财务数据、公司研发项目介绍、及有关影响公司及其产品的药事管理最新进展的讨论等，也不适用RDPAC准则。

3. Examples of non-promotional information that are not covered by the Code include correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product is not covered by the Code. Non-promotional, general information about companies (such as information directed to investors or to current/prospective employees), including financial data, descriptions of research and development program, and discussion of regulatory developments affecting the company and its products is also not covered by the Code.

4. RDPAC准则适用于向医疗卫生专业人士进行的非处方药的推广，而不适用于向消费者进行的非处方药的推广。

4. The RDPAC Code applies to the promotion of over-the-counter (OTC) products directed towards healthcare professionals. However, the promotion of OTC products to consumers falls outside the scope of this Code.

5. RDPAC准则适用于向既是有业务关系的商业性组织同时也是医疗卫生专业人士的主体进行的药品推广和营销，比如药剂师自有的药店。在与此类主体的往来中，会员公司应尊重和重视其作为医疗卫生专业人士的角色定位，并相应遵守RDPAC准则的要求。

5. The RDPAC Code applies to the promotion and marketing of pharmaceutical products to commercial customers who are also practicing healthcare professionals, such as a pharmacist who operates his/her own practice. In any dealings with such a customer, companies should respect the customer's role as a healthcare professional and, if applicable, comply with the requirements of the RDPAC Code.

RDPAC鼓励公司间的竞争并且不限制或规范向消费者供应药品的商业交易条款。

RDPAC encourages competition among companies, and the RDPAC Code does not restrain or regulate commercial trade terms for the supply of pharmaceutical products, to customers.

1.2 定义

1.2 Definitions

在RDPAC准则中：

For the purposes of the RDPAC Code:

- “药品”指根据《中华人民共和国药品管理法》第102条的规定用于预防、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。

- “pharmaceutical product” means, as set forth in Article 102 of the Drug Administration Law, any articles intended for use in the prevention, treatment or diagnosis of human diseases, or intended to effect the purposive regulation of human physiological functions, for which indications or major functions, usage and dosage are prescribed. They include raw traditional Chinese medicinal materials, traditional medicines prepared in ready-to-use forms, and other prepared Chinese medicines, medicinal chemicals and their preparations, antibiotics, biochemical medicines, radioactive drugs, serums, vaccines, blood products, diagnostic aids, etc.

- “推广”指由某会员公司通过各种方式——包括互联网，以促进其药品的处方、推荐、供应、用于病人或为病人自用等为目的的，针对医疗卫生专业人士所进行的或组织、赞助的任何行为或活动。

- “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.

- “医疗卫生专业人士”指医疗、牙科、药剂或护理领域中的专业人员，或其他任何在其专业活动中可能开具药品处方或推荐、采购、供应药品或将药品用于病人的人员。

- “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.

- “医疗机构”一般指由医疗专业人士组成的机构，或提供医疗服务、和/或进行医疗研究的机构。

- “medical institution” means typically an organization that is comprised of healthcare professionals and/or that provides healthcare or conducts healthcare research.

“医学互动交流”或“医学互动交流活动”是指会员公司向医疗机构、专业学

- “medical interaction” or “medical interaction programs” means events through which member

会及协会或医疗卫生专业人士提供、从其获得或与之交流医学和/或科学信息的活动。

- “会员公司”指依法在中国境外成立或组建、在中国境内有实质性投资或经营性投资并成为RDPAC会员公司的研发类制药企业，包括外商投资企业或其他由前述中国境外研发类制药企业在中国依法设立的机构。

companies provide, receive or exchange medical and/or scientific information to, from or with medical institutions, academic associations or healthcare professionals.

- “member company” means any R&D-based pharmaceutical company lawfully established or incorporated outside of China with substantial investment or operational interests in China that became a member of RDPAC, including a foreign-invested enterprise or other legal entity registered in China by such an overseas R&D-based pharmaceutical company.

第二条 医学互动交流活动的基本原则

2.1 医学互动交流活动的基本原则

会员公司与医疗卫生专业人士和其他利益相关人士开展医学互动交流活动的目的是造福患者和提高医疗水平。医学互动交流活动的重点应集中在向医疗卫生专业人士传达药品信息、提供科学及教育方面的资讯、以及支持医学研究和教育。

2.2医学互动交流活动的透明度

会员公司共同致力于合法前提下通过适当地公开与医疗机构、相关专业学会及协会、以及医疗卫生专业人士的医学互动交流活动，

Article 2 Basis of Medical Interaction Programs

2.1 Basis of Medical Interaction Programs

Medical interaction programs that member companies conduct in relation to healthcare professionals and other stakeholders are intended to benefit patients and to enhance the practice of medicine. Medical interaction programs should be focused on informing healthcare professionals about medicines, providing scientific and educational information and supporting medical research and education.

2.2 Transparency of Medical Interaction Programs

Member companies are committed to improving the transparency of medical interaction programs in relation to medical institutions, relevant academic associations and healthcare professionals through

逐步提高医学互动交流活动的透明度，提升监管机构以及公众对会员公司及整个行业的信任度。

appropriate disclosure of these programs on a legitimate basis, so as to earn more trust from regulatory bodies and the general public with regard to member companies and the industry as a whole.

对于由会员公司赞助的、与药品及其使用相关的材料，无论其性质是否属于推广，均应明示该材料系由某会员公司赞助。

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

对于由会员公司组织或赞助的医学互动交流活动，无论其性质是否属于推广，均应在合法前提下通过日程、条幅、海报或其他方式明示由某会员公司组织或赞助。会员公司不得对其学术活动作任何形式的隐藏或掩饰。如果会员公司赞助第三方组织的医学互动交流活动，则需在主办方知情并同意的情况下做出上述披露。

Medical interaction programs hosted or sponsored by member companies, whether promotional in nature or not, should clearly indicate by whom it has been hosted or sponsored, through agenda, banner, poster or other effective measures, under the premise that such disclosure will not breach laws and regulations. Academic activities should not in any way be concealed or disguised by member companies. If a member company sponsors medical interaction programs organized by a third party, the above disclosure should be made subject to the knowledge and consent of the organizer.

会员公司内部应有完整的记录和备案系统，通过合理清晰的分类，准确地记录有关医学互动交流活动涉及的费用、提供给医疗卫生专业人士的相关利益等。费用类别可包括但不限于捐赠、资助、赞助、会议费、讲课费、咨询费等。明确区分与医疗机构及医疗卫生专业人士互动产生的费用和内部员工费用。

Member companies should have a comprehensive internal recording and filing mechanism to accurately document, with reasonable and clear classifications, expenditures and benefits provided to healthcare professionals that are associated with medical interaction programs. The classifications of expenditures may include, without limitation, donation, grant, sponsorship, meeting expenses, speaker fees, consultancy fees, etc. There should be clear separation between expenditures associated with interaction with medical institutions and healthcare professionals and those for internal expenses for employees.

医学互动交流活动的开展须以医疗卫生专业人士的知情同意为前提。尤其针对电子邮件推送、社交媒体等线上互动活动，应确保获得相关的知情同意并授权后，再开展相关活动。

Medical interaction programs should be premised on the informed consent of healthcare professionals. In particular, for online interactions through push email, social media, etc., the informed consent and appropriate authorization should be obtained prior to the commencement of relevant activities.

注释6：

6. 当公司以资助或其他方式安排将其推广材料刊登在有相关资质的纸质或电子媒体上，这些推广材料不得有使人误解其为独立的编者评论之嫌。

Annotation 6:

6. Where a company finances or otherwise secures or arranges the publication of promotional material in qualified paper or electronic media, such promotional material must not resemble independent editorial matter.

第三条 药品获得上市许可之前的信息交流及在药品标明的适用范围之外使用药品

Article 3 Pre-Approval Communications and Off-Label Use

会员公司在其药品获得中国药品主管部门颁发的上市（生产或进口）许可之前，不得从事为在中国上市使用该药品而进行的推广活动。

No pharmaceutical product shall be promoted for use in China until the requisite approval for marketing for such use has been given by the CFDA.

上述规定不应影响科学界及公众对科学和医学发展动态的充分知情权。它既不限制对药品的科学信息作充分适当的沟通，包括通过专业的科学或大众媒体以及在专业的科学交流会议上公布有关药品的科研结果，也不限制应相关法律、法规、准则或规章的要求或号召向利益相关人士和其他人公开披露药品信息。

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 any applicable laws, regulations, codes, or rules.

注释7：

7. 会员公司在药品获得上市许可前，或就药品说明书之外的信息与医疗卫生专业人士的互动交流，无论以口头或书面形式进行，均应由会员公司医学专业人员进行或在医学专业人员的监督下进行。

对药品获得上市许可之前信息交流的禁止并不妨碍在遵守各项法律法规和行政规章的前提下开展的药品慈善使用项目。会员公司应努力确保有关药品慈善使用项目的信息交流活动不演变为某个未获得上市许可的药品的推广活动。

Annotation 7:

7. Pre-approval or off-label communication with healthcare professionals, whether in verbal or written form, should be conducted by or under the supervision of medical experts of the Companies.

The prohibition of pre-approval promotion does not prevent compassionate use programs which must of course comply with all applicable laws, regulations and administrative rules. Care should be taken to ensure that communications for a compassionate use program are not, in effect, advertisements for an unlicensed medicine or use.

第四条 药品推广信息的标准

4.1 药品信息的一致性

药品信息推广应与中国药品主管部门批准的药品信息相一致。在遵守药品信息推广应与中国药品主管部门批准的药品信息相一致的要求同时，中国的医疗卫生专业人士应及时获得在世界其他国家传播的药品信息。

Article 4 Standards of Promotional Information

4.1 Consistency of Product Information

Promotion should not be inconsistent with pharmaceutical product information approved by the CFDA. Respecting the requirement that promotion should be consistent with the label and approved uses by the CFDA, Chinese healthcare professionals should have access to similar data to those being authorized for communication in other countries of the world.

注释8：

8. 会员公司应根据中国药品行政法律法规的要求或在其他适当的情况下提供与其在其他国家所提供的信息相同的主要产品信息（如：药品使用禁忌及警示、预防措施、副作用和剂量等）。

Annotation 8:

8. Where necessary or appropriate within the context of Chinese regulatory requirements, companies should provide the same core product information (such as contraindications, warnings, precautions, side effects and dosage) as it provides in other countries.

4.2 准确和不误导

推广信息应当清楚、易理解、准确、客观、

4.2 Accurate and Not Misleading

Promotional information should be clear, legible,

公正、和高度完整，足以使受众能就有关药品的治疗价值形成自己的观点。药品推广信息应以对所有相关证据所作的最新评估为依据，并清楚地记载相关证据事实。推广信息不应通过曲解、夸大、过分强调、忽视、或其他方式误导相对人。推广者应尽最大努力避免使推广信息出现内容上的模糊不清。在给出绝对的和无所不包的论断时应十分谨慎，其必须以充分的论证和实证为基础。一般应避免使用诸如“安全”、“无副作用”之类的描述性用语，如需使用也须有充分的科学论证。

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.

注释9：

9. 对医学和科学文献或对个人交流文件的摘录应忠实于原文（法规和规章要求对原文进行改编和修订的除外，在此情况下应清楚显示所作的改编和修订），并准确地注明出处。对文献的摘录不应曲解作者的真实意图或文献所记载的研究工作的重要性。

Annotation 9:

9. 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 regulations or administrative rules, 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.

4.3 实证

4.3 Substantiation

药品推广信息应能通过对已经批准的药品说明书或科学证据的引用而得到证实。当医疗卫生专业人士要求提供上述实证资料时，推广者应向其提供。会员公司应客观对待要求获取有关药品信息的善意请求，并应根据不同查询者的具体情况提供充分和适当的药品信息。

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.

注释10：

Annotation 10:

10. 对两种不同药品的比较式表述仅可针对有对应性和可比性的内容进行，且应加以充分的实证。比较式表述应尽量不引起误解。

10. Any comparison made between different pharmaceutical products should be based on relevant and comparable aspects of the products and be capable of substantiation. Comparative claims, where possible, should not be misleading.

第五条　印刷推广材料

在遵守中国法律、法规各项规定的前提下，所有印刷推广材料均须清晰易懂，并包括以下必备内容：

(a) 药品名称（通常为药品的商品名）；

(b) 药物活性成份（应尽可能地使用经批准的名称）；

(c) 制药公司或药品代理公司的名称及地址；

(d) 推广材料制作的日期；

(e) 处方信息概要，包括已经批准的一项或多项适应症、用法用量，以及对禁忌症提示和副作用的简要说明。

Article 5　Printed Promotional Materials

Subject to additional requirements under the Chinese laws and regulations, all printed promotional materials must be legible and include:

(a) the name of the product (normally the brand name);

(b) the active ingredients, using approved names where they exist;

(c) the name and address of the pharmaceutical company or its agent responsible for marketing the product;

(d) date of production of the material;

(e) “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.

注释11：

11. 科学或医学文章的翻印本在单独使用时不构成“药品推广材料”，因其非由制药公司制作；但如果将它们连同由制药公司制作的其他文件一起发送到医疗卫生专业人士手中，则这些翻印本就转变为药品推广材料。一旦某个推广材料中提及或者包含了科学或医学的论文或研究报告，或这些

Annotation 11:

11. Reprints of scientific and medical articles, when used as standalone documents, are not developed by pharmaceutical companies and as such cannot be considered as promotional materials. If, however, they are proactively presented to a healthcare professional together, with other, company-originated documents, they then become promotional materials. In all cases, where promotion refers to, includes, or

论文报告与推广材料一起被发送给相对人时，推广人均应对论文或报告的出处作清楚说明。对任何选自于某论文或研究报告、并被包含在推广材料中，或与推广材料一起被发送给相对人的非文字信息（包括图表、示图、照片或者表格等）的翻印，推广人均须清楚地注明出处，且翻印应忠实于原文。

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 promotional materials should clearly indicate the source of the artwork and be faithfully reproduced.

第六条　电子版推广材料，包括音像制品

电子版推广材料应遵守与印刷形式推广材料相同的各项要求。就与药品有关的网页而言：

(a) 制药公司的名称以及推广所针对的受众应一目了然；

(b) 推广内容应适合于其所针对的受众；

(c) 其制作（内容、链接等）对其所针对的受众而言应适当、清晰；

(d) 针对中国市场的信息应符合中国法律法规的各项规定。

Article 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:

(a) the identity of the pharmaceutical company and of the intended audience should be readily apparent;

(b) the content should be appropriate for the intended audience;

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

(d) information specific to China should comply with all the Chinese laws and regulations.

第七条　与医疗卫生专业人士的医学互动交流活动

7.1 医学互动交流活动

Article 7　Medical Interaction Programs with Healthcare Professionals

7.1 Medical Interaction Programs

7.1.1 涉及出国的医学互动交流活动

会员公司不得组织或赞助医疗卫生专业人士赴境外参加医学互动交流活动（包括赞助个人参加满足如下第7.2条所述条件的活动），除非满足IFPMA行为准则（2012）以及IFPMA关于赞助互动交流活动的指南说明（以下称“IFPMA赞助指南”）所提供的原则和要求。

注释12：

12. 会员公司只可在理由充分的情况下组织或赞助医疗卫生专业人士赴其本国以外或境外参加医学互动交流活动；所谓“理由充分”是指：

(a) 有关活动所邀请的大部分医疗卫生专业人士都来自境外，且出于会议行程及安全的考虑，在境外举办该活动更为合理；或者

(b) 作为有关活动主题的相关资源或专家均在境外

RDPAC准则所指的“本国”是指相关医疗卫生专业人士执业的国家。

此外，会员公司在评价医学互动交流活动地点或场所的适当性时，或者在决定是否赞助医学会等第三方组织的医学互动交流活动时，或者在审查会议官方宣传材料和网站时，应按照IFPMA赞助指南所提供的标准进行评价。指南的具体内容请见本准则附件一。

7.1.1 Medical Interaction Programs Involving Foreign Travel

No company may organize or sponsor a medical interaction program for healthcare professionals (including sponsoring individuals to attend such a medical interaction program as described in Article 7.2) that takes place outside of their home country unless the principles and requirements set by the IFPMA Code of Practice 2012, as well as the IFPMA Note for Guidance on Sponsorship of Events and Meetings (hereinafter “IFPMA Guidance on Sponsorship”) are satisfied.

Annotation 12:

12. A company can only organize medical interaction programs involving foreign travel if it is justified, i.e.:

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

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

Under the RDPAC Code, the home country of a healthcare professional is the country in which he/she practices.

Also, Companies should refer to the Criteria set by the IFPMA Guidance on Sponsorship when assessing the appropriateness of the Location of a medical interaction program, or the Venue of a medical interaction program, or when deciding whether to support a medical interaction program organized by a third party such as a medical society, or when reviewing the Official meeting materials and websites of a medical interaction program. For details see

IFPMA Guidance on Sponsorship in Appendix I of this Code.

7.1.2 医学互动交流活动中的药品推广信息

药品推广者可在国际科学大会或座谈会上通过展台或直接分发给与会者的方式推广某个/些尚未在会议所在国获得上市许可、或虽获得上市许可但许可的内容和条件与其他国家有所不同的药品，但还须同时满足以下几项条件：

- 会议所在国法律允许进行此种推广活动。
- 会议本身应当是真正意义上的国际科学会议，大多数讲者和与会者应来自会议所在国以外的其他国家；
- 尚未在会议所在国注册的药品推广材料（不包括本准则第7.5.2中的推广辅助用品）应包含该药品已在哪些国家获得上市许可的适当说明，同时清楚声明该药品尚未在会议所在国获得上市许可；
- 如药品推广材料中包含在会议所在国之外的其他国家批准的药品处方信息（适应症、警告等），则推广材料应清楚声明该药品在全球各国所获得的上市许可的内容和条件有所不同。

7.1.2 Promotional Information at Medical Interaction Programs

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 meeting 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 meeting with a significant proportion of the speakers and attendees from countries other than the country where the meeting 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 meeting 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 meeting takes place but where the product is also registered, should be accompanied by an explanatory statement indicating that registration conditions differ internationally.

7.1.3 适当的地点/住宿

医学互动交流活动举办的地点应适当且以有助于实现其科学、教育及会议本身的目的为宗旨。会员公司应避免选择名胜或铺张奢侈的地点举办医学互动交流活动。在选择医学互动交流活动的适当地点时还应遵守本准则第7条及IFPMA赞助指南相关原则和要求。

注释13：

13. 会员公司应谨慎选择会议的举办地，以尽量减少参会者的旅行，并避免造成铺张奢侈的公众形象，避免选择与奢侈的娱乐活动相关联的场所，如SPA、温泉、度假、滑雪、高尔夫、赌博、邮轮等。IFPMA赞助指南所提供的其他原则和要求详见本准则附件一。

会员公司可提供/负担与会议相匹配的交通，但应避免可能造成铺张奢侈公众开形象的交通服务。

除此之外，会员公司可以为参会的医疗卫生专业人士支付包括房费和房费所包含的税金、符合RDPAC准则标准的合理餐费、茶点及合理的互联网使用费等在内的食宿费用，但不得支付其他的酒店服务费，如私人用酒吧账单、电影、洗衣、电话及酒店其他服务费用。旅行费用的支付可包括地面交通费及其税金和参会者本人的旅行保险费。此外，会员公司应确保当为参会的医疗卫生专业人士所购买的车、船、机票等不被挪作私用。

7.1.4 限制

附属于医学互动交流活动的招待仅可提供给：

7.1.3 Appropriate Venue and Accommodation

All medical interaction programs must be held in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the medical interaction program. Companies must avoid using renowned or extravagant venues. The additional requirements set forth in Article 7 of this Code, as well as the IFPMA Guidance on Sponsorship also apply accordingly.

Annotation 13:

13. Member companies should select meeting venues discreetly to minimize travel and avoid public perception of extravagance. Theme-venues associated with leisure activities, such as spa, hot spring, holiday resort, ski, golf, gambling, cruise ships, etc., should be avoided. For details of other principles and requirements see IFPMA Guidance on Sponsorship in Appendix I of this Code.

Member companies may provide/pay for transportations that are appropriate for the meeting destination, but should avoid transportation services that may have public perception of extravagance.

In addition to the above, member companies are allowed to cover room charges, including taxes, appropriate meals and refreshments within Code limit, and reasonable internet service, but not incidentals such as personal bar bills, movies, laundry, telephone and other business services. Travel costs may include ground transportation, taxes and travel insurance for the meeting participant. Also when issuing tickets to healthcare professionals, it has to be ensured that they are not misused.

7.1.4 Limits

Hospitalities incidental to the main purpose of the medical interaction program can only be provided:

- 医学互动交流活动的参会者。会员公司不得支付应邀参会的医疗卫生专业人士的随行客人的任何费用；且

- 用于招待的支出按当地标准应当是中等适度和合理的。一般而言，招待的费用不应超过参会者通常的自付费用标准。

可提供的附属于医学互动交流活动的招待应限于：（1）场地和住宿，（2）交通，（3）餐饮和小食。

招待时间

招待需与医学互动交流活动期间相匹配，任何明显不合理地早于或晚于活动时间的招待费用均不应承担。

禁止津贴

会员公司不得就参加医学互动交流活动向医疗卫生专业人士（包括讲者和参会者）承担或支付任何形式的津贴（如按天支付的补助），或对其差旅时间或未能工作时间的补偿。

注释14：

14.本条规定的“中等水平的和合理的”应解释为每人每餐不超过人民币300元。在极少数特殊情况下需超出上述用餐标准的，须得到公司总经理或其特别授权的代理人的批准和认可。

- exclusively to participants of the medical interaction program. Member companies should not pay for any costs associated with individuals accompanying invited healthcare professionals; and

- if they are moderate and reasonable as judged by local standards. As a general rule, the hospitality provided should not exceed what participants would normally pay for themselves.

The hospitality incidental to the medical interaction program should be limited to: (1) venue and accommodation, (2) transportation, (3) meals and refreshments.

Hospitality Period

The hospitality should be appropriate and consistent with the period of the medical interaction program, i.e., any hospitality which apparently is unreasonably earlier or later than the program period cannot be provided or paid by member companies.

Prohibition of Allowance

Member companies are not allowed to bear or pay any allowance (such as per diem) to healthcare professionals, both speakers and attendees, for their attendance of a medical interaction program, or to bear or pay any compensation for their travel time or lost working hours.

Annotation 14:

14. “Moderate and reasonable” hereunder should be interpreted as not more than three hundred (300) RMB per person per meal, with exceptions for rare occasions which must be supported by appropriate approval and justification

by the GM or GM-delegate(s) of the company.

7.1.5 娱乐

会员公司不应提供或支付任何娱乐活动或其他休闲及社交活动。

注释15：

15. 应无例外地禁止会员公司向医疗卫生专业人士和其他利益相关方提供或支付娱乐、休闲和社交活动。会员公司在组织医学互动交流活动时,可以向与会者提供附属于活动的合理餐饮和小食。此外，会员公司可以以工作餐形式，与医疗卫生专业人士进行以医学、科学和教育为主题的医学互动交流。会员公司不得向参会者提供音乐会或娱乐节目的入场券或支付任何形式的娱乐活动，但可以提供非由会员公司支付的、在互动交流活动举办地播放的背景音乐或进行的本地表演。

注释16：

16.会员公司不应在任何推广活动中组织“幸运抽奖”类的活动，或在第三方组织的抽奖活动中为奖品支付费用；但可以在药品推广活动现场进行的有奖问答或竞猜活动中提供RDPAC准则规定的推广辅助用品。

7.2 赞助

在满足以下条件的前提下会员公司可赞助医疗卫生专业人士参加医学互动交流活动：

(a) 有关医学互动交流活动符合本准则第7.1

7.1.5 Entertainment

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

Annotation 15:

15. Companies are prohibited, with no exceptions, from providing entertainment, leisure and social activities to healthcare professionals and other stakeholders. When a member company organizes a medical interaction program, reasonable meals and refreshments incidental to the main purpose of the program may be provided. Besides, companies may conduct medical interactions with healthcare professionals on medical, scientific and educational topics in the form of working meals. 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 member company, this may be permitted.

Annotation 16:

16. A member company should not organize lucky draw in any promotional activities or pay for prizes in any lucky draw organized by third parties . Promotional aids may be provided as prize for on-site Q&A contests during the promotional activities, subject to the provisions on promotional aids set by the Code.

7.2 Sponsorship

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

(a) The medical interaction program complies with

条关于招待活动的规定；

(b) 对医疗卫生专业人士的参会赞助只限于对旅行、餐费、住宿及会议注册费的支付；

(c) 对医疗卫生专业人士的参会时间不得作任何补偿；

(d) 在任何情况下会员公司均不得向医疗卫生专业人士或医院科室直接支付任何款项，或直接将赞助资金转入其账户；并且

(e) 对医疗卫生专业人士任何参会赞助不得以其对某药品的处方、推荐、采购、供应、使用或推广等义务为条件。

the requirements in this Code as described in 7.1;

(b) Sponsorship to healthcare professionals is limited to the payment of travel, meals, accommodation and registration fees;

(c) No payments are made to compensate healthcare professionals for time spent in attending the program;

(d) Under no circumstance should a Company make any payment or transfer any sponsorship fund directly to a healthcare professional or a hospital department; and

(e) 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.

7.3 服务费

医疗卫生专业人士可以应聘作为医学互动交流活动的讲者和/或主持人，参与付费的医学或科学研究、临床试验或培训、专家小组会议、及市场调查等服务。会员公司在对上述咨询类和其他服务作安排时，须确保其安排满足以下条件：

7.3 Fees for Services

Healthcare professionals may be engaged as consultants and advisors for services such as speaking at and/or chairing medical interaction programs, 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) 会员公司一般不应通过医疗卫生专业人士收集和提供患者的病例和处方信息，也不应对此付费；

(a) Companies generally should not employ nor pay for any healthcare professionals to collect or provide such information as patient case or prescription data.

(b) 会员公司在任何情况下不应以现金或现金替代物支付本条下的服务费；

(b) under no circumstance should a Company make payment for the Service hereunder in cash or cash equivalents.

(c) 双方须在开始提供服务之前签订有关服务内容和服务费计费依据的书面协议；

(c) 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.

(d) 在开始提供服务之前须确定并记录需要有关服务的正当理由；

(d) a legitimate need for the services must be clearly identified and documented in advance.

(e) 对相关医疗卫生专业人士的遴选标准须与上述正当理由直接相关，且所确定的人选须具备必要的资质；

(e) 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.

(f) 所聘医疗卫生专业人士的人数不得超过实现服务目的所需要的合理人数；

(f) the number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need.

(g) 对所聘医疗卫生专业人士的选择必须完全基于客观标准，包括但不限于所受教育、专业技能、某治疗领域的经验以及技能等等，并且须与所需服务的正当理由直接相关。所聘医疗卫生专业人士的选择必须在服务提供前经过具备相应技能并且独立于销售职能的部门的专业验证，以确保其满足上述客观标准并能实现上述正当理由。

(g) the selection of consultants must be exclusively based on objective criteria, including but not limited to education, knowledge, expertise and experience in a particular therapeutic area, etc., which shall be directly related to the identified need of the services. The selection of consultants must be validated prior to commencement of the services by departments with sufficient expertise and full independency from sales function, in order to evaluate whether the consultant satisfies the above objective criteria. and is able to fulfill the identified need

(h) 任何因医疗卫生专业人士提供的演讲服务而支付的报酬或补偿（以下统称“讲课费”）金额应当合理且基于公平市场价。会员公司应各自分别、独立地制订其对每个医疗卫生专业人士所支付的年度讲课费金额上限。会员公司还应就如何选择和聘用演讲者制订公司政策，包括应在对演讲者进行适当培训后方可聘用，以及在一定时间内对某个特定演讲者的聘用次数予以合理限定等；

(h) any compensation or reimbursement made to a healthcare professional in conjunction with a speaking arrangement should be reasonable and based on fair market value. Each company should, individually and independently, cap the total amount of annual compensation it will pay to an individual healthcare professional in connection with all speaking arrangements. Each company also should develop policies addressing the appropriate use of speakers, including utilization of speakers after training and the appropriate number of engagements for any particular speaker over time.

(i) 不得以聘用医疗卫生专业人士提供相关服务作为诱导其开具处方、推荐、采购、供应和/或使用任何药品的条件；

(i) 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.

(j) 所支付的服务费标准须合理并符合公平市场价格标准。

(j) the compensation for the services must be reasonable and reflect the fair market value of the services provided. And,

注释17：

17. 当会员公司聘用医疗卫生专业人士在会议中担当讲者时，公司对医疗卫生专业人士的补偿可包含其实际支出的旅行和住宿费。

Annotation 17:

17. When a healthcare professional is employed by a company to speak at a meeting, the company may reimburse the healthcare professional his/her out of pocket expenses including travel and accommodation as part of the compensation arrangements.

上述有关现金支付与合同的要求不适用于某些由企业独立的市场调研部门所领导的市场调研项目。对于这种市场调研项目应该遵循市场调研行业的行为守则。*（ICC/ESOMAR INTERNATIONAL CODE ON MARKET AND SOCIAL RESEARCH.）*

The above restrictions on cash payments and contracting requirements are not applicable to certain market research projects that are led by independent Market Research Department/function of the member company. Those market research projects shall follow the code of conduct for the market research industry *(ICC/ESOMAR INTERNATIONAL CODE ON MARKET AND SOCIAL RESEARCH.*

7.4 礼品及其他

7.4 Gifts and Other Items

7.4.1 禁止提供现金及个人礼品

会员公司不应向医疗卫生专业人士提供现金或者现金替代物（如：礼品券）、抽奖，也不应向其提供用于个人目的的礼品（如：风俗礼品，体育或娱乐项目的入场券，电子产品等）。

7.4.1 Prohibition of Cash & Personal Gift

Payments in cash or cash equivalents (such as gift certificate) and lucky draw must not be provided or offered to healthcare professionals. Gifts for the personal benefit of healthcare professionals (such as cultural gifts, sporting or entertainment tickets, electronics items, etc.) must not be provided or offered.

7.4.2 推广辅助用品

在满足“最小价值”及“最少数量”的前提下，会员公司可以向医疗专业卫生人士提供与其执业工作相关的推广辅助用品。

注释18：

18. 推广辅助用品是指用于药品推广的非现金价值物品。推广辅助用品只能提供给准则第1.2条中定义的医疗卫生专业人士。推广辅助用品须与相关医疗卫生专业人士的执业工作相关，且须满足最小价值和最少数量的要求。举例而言，推广辅助用品可以是非贵重的笔或记事薄。仅与医疗卫生专业人士个人有利的用品如音乐光盘、绘画或精装食品等是不允许作为推广辅助用品的。药品推广的文字资料如药品信息说明、活页、手册等等不构成准则第7.5.2所指的推广辅助用品。

本条规定的“最小价值”应解释为每件物品的价值不得超过人民币100元。

7.4.2 Promotional Aids

Promotional aids of minimal value and quantity may be provided or offered to healthcare professionals if relevant to the practice of the healthcare professional.

Annotation 18:

18. A promotional aid is a non-monetary item given for a promotional purpose. Promotional aids can only be given to healthcare professionals as defined in Article 1.2 of the RDPAC Code of Practice. Promotional aids must be related to the work of the recipient healthcare professionals and should be of minimal value and quantity. Possible examples include inexpensive pens and notepads. Promotional items intended for the personal benefit of the healthcare professional, such as music CDs, paintings or food baskets are not acceptable. Promotional literature such as detail aids, leave-behind pieces, booklets, etc. are not considered to be promotional aids as meant in Article 7.5.2.

“Minimal value” hereunder should be interpreted as not more than one hundred (100) RMB in value per item.

7.4.3 医用物品

在符合中国法律法规各规定的前提下，会员公司可向医疗卫生专业人士提供价值适度、不超出日常执业工作范围、且有助于其实现

7.4.3 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

医疗和病患服务的医用物品。

business practices and are beneficial to enhancing the provision of medical services and patient care.

注释19：

Annotation 19:

19. 医用物品可包括实验室陈列的解剖模型或医学书籍，因其均有助于实现病患利益。DVD或CD播放器则禁止被称为医用物品。即使单个医用物品符合要求，对医用物品的提供也只能偶尔为之。

19. Items envisaged as being items of medical utility might include an anatomical model for use in an examination room, or medical textbooks, as both primarily involve a patient benefit. A DVD or CD player however would not be permissible. Items should not be offered on more than an occasional basis, even if each individual item is appropriate.

会员公司可以科学教育为目的偶尔向医疗卫生专业人士提供有限数量且每件不超过人民币500元的医学书籍、杂志或期刊（包括网上期刊的订阅）、解剖模型、图例等。在提供此类物品时不得提供或使用预先付费的购书券、购书卡等代金券。

Companies may provide limited medical textbooks/journals/magazines (including e-journal subscriptions), anatomical models and diagrams of less than five hundred (500) RMB per item on an infrequent basis to healthcare professionals for educational purposes. No pre-paid coupon or purchase card is allowed for the purpose of this provision.

第八条 样品

Article 8 Samples

8.1 样品

8.1 Samples

根据中国法律、法规，为使医疗卫生专业人士充分了解相关药品的知识以便更好地服务于病患，会员公司应该直接把限量样品提供给医疗机构，并使用有资质的第三方进行样品递送。所有样品均应被清楚标注，以防止其被转卖或以其他方式被滥用。

In accordance with Chinese laws and regulations, in order to enhance patient care, samples of a pharmaceutical product with a limited quantity should be supplied directly to medical institutions for the purpose of familiarization of healthcare professionals with the product, and should be delivered through a qualified 3rd party. Samples should be marked as such so that they cannot be resold or otherwise misused.

8.2 有效控制和责任落实

8.2 Control and Accountability

会员公司应对通过医疗机构提供给医疗卫生专业人士的样品建立有效的控制和责任机

Companies should have adequate systems of control and accountability for samples provided to healthcare professionals through medical institutions including

制，包括对样品的分发、交付、验收。

distribution, delivery and acceptance of samples.

第九条 临床研究和透明度

Article 9 Clinical Research and Transparency

9.1 透明度

9.1 Transparency

会员公司致力于提高由其参与支持的临床试验的透明度，并意识到使执业医师、患者和其他人可从公开渠道获得临床试验信息符合公共健康的最大利益。而对此类信息的公布又必须严格保护个人隐私、知识产权、契约利益，并遵守现行专利法的立法、行政及司法理论与实践。

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.

会员公司应依照由国际制药企业协会联盟、欧洲制药企业协会联盟、日本制药企业协会、及美国药品研发与制造商协会共同发布的《通过临床试验注册平台与数据库公开临床试验信息的联合声明（2009）》，以及《在科学文献中公开临床试验结果的联合声明（2010）》公开临床试验的信息。

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 与推广行为的区别

9.2 Distinct from Promotion

所有对人体进行的科学研究均须有正当的科学目的。对人体进行的科学研究，包括临床试验和观察性试验，均不得成为隐藏或掩饰的药品推广活动。

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

注释20：

20. 临床评估、药品上市后监测、药品临床反应、及药品获得上市许可后的评估等（以下统称“临床研究”）均须以科学和教育为目的，而不得作为一种隐藏或掩饰的药品推广活动。当前述临床研究需要以样本量来计算统计学的把握度时，应以实现临床研究的目标为宗旨对样本量做适度的规划，使其不过度超出恰当的统计学把握度、且系基于主要终点指标计算出的样本量。会员公司为此类临床研究而支付给医疗卫生专业人士的报酬应当是合理的，且应与医疗卫生专业人士付出的劳务成正比。

Annotation 20:

20. Clinical assessments, post-marketing surveillance, experience programs and post-authorization studies (collectively "Studies") must be conducted for scientific or educational purpose and not as a disguised form of promotion. When sample size is required for the power calculation in the Studies, the sample size should be planned appropriately to achieve the Study objectives, and should not unduly exceed the number that is calculated to allow statistical power for the primary endpoint(s). Fees paid to healthcare professionals must be reasonable and commensurate with the effort made by the healthcare professionals.

第十条　与医疗机构的互动

会员公司提供财务资助给医疗机构时须遵循以下基本原则：

(a) 提供给有一定声誉的机构（而非个人或科室）；

(b) 财务资助需有一个明确的、合法的目的;

(c) 双方须签署书面协议以提高资金流转和记录的透明性，从而进一步确保资金被用于约定好的用途;

(d) 要求把资金直接支付给接受资助或赞助的机构;

(e) 高度鼓励在提供支持前进行尽职调查

Article 10 Interaction with Medical Institutions

In general, member company may provide financial support to medical institutions in accordance with the following requirements:

(a) The recipient should be a reputable organization, not an individual or a department/section of the medical institution);

(b) There should be a clearly identified, legitimate purpose for the financial support;

(c) A written agreement is required to be in place between the two parties to enhance the transparency of fund transfer and documentations, and to further ensure the fund will be used for the agreed purpose;

(d) The support shall be paid directly to the organization receiving the support ; and

(e) Due diligence is highly recommended before such support is provided.

10.1资助

10.1 Grants

会员公司可提供财务资助给医疗机构进行独立的活动，包括但不限于医学教育或科学研究等。

Member companies may give financial support to medical institutions to support their independent activities, including but not limit to medical education activities, scientific research etc.

提供资助的目的是帮助医疗卫生专业人士掌握疾病治疗领域和相关干预方法的最准确的医疗信息和观点，这对改善病患服务、提升医疗卫生专业人士的诊疗知识，整体提升医疗卫生系统的服务水平极为重要。

The purpose of Grant should be to help healthcare professionals obtain the most accurate medical information and insights on therapeutic areas and related interventions, which are critical to the improvement of patient care, enhancement of healthcare professionals' medical knowledge and overall enhancement of the healthcare system.

会员公司可以提供财务资助给医疗机构进行独立的医学教育或科学研究，且须遵守以下规定：

Member companies may give financial support to medical/health institution to support their independent medical education activities or scientific research, subject to the following requirements:

(a) 双方签署的协议内容包括该活动/项目的目标和预期结果;

(a) Objectives and expected results of such activity/project should be clearly defined in the agreement to be entered into by both parties;

(b) 会员公司不得获取任何直接的利益作为回报，如服务、冠名授权等。单纯对公司支持的致谢（例如，在非推广性的字段中体现公司名称或展现公司标识）不被认定为利益回报。

(b) Member Companies should not receive any direct benefit in return, such as services, naming right, etc. . A mere recognition for such support, such as disclosing the company's identity or displaying the company's logo in a non-promotional context will not be considered as a benefit in return.

(c) 该活动/项目应遵守本准则第7.1条的规定。

(c) Such activity/project should comply with the requirements described in Section 7.1 of this Code ;

(d) 会员公司应建立健全适当的审核程序，如建立一个由不同职能部门成员组成（包括医学部和法律合规部成员）的委员会，审

(d) Member Companies shall establish a robust review process to review and approve each Grant, e.g. establishing a committee consisting of

核并批准每项资助。

业务部门不能引导资助审核和审批流程，且不能成为唯一或最终决定资助行为的人。业务部门可以作为联络人提出资助需求，或在活动执行过程中提供协助。

members from various functions, including Medial and Legal/Compliance.

Business functions must not lead the review/approval process for the Grant and must not be the only or ultimate decision maker to give a Grant. Business functions may act as a "liaison" to request the Grant , or to assist the activity /project in execution.

10.2 商业赞助（会员公司与医疗机构共同合作的活动/项目不在此范围）

10.2 Commercial Sponsorship (Activities/projects collaborated by medial institutions and member companies are not included in this section)

会员公司可以为了双方共同利益并促进合法商业目的提供财务支持或非财务支持给医疗机构，如推广会员公司的形象、品牌或产品。提供此类赞助须遵循以下规定：

Member companies may give financial or non-financial support to medical institutions for mutual benefits and to advance legitimate business purposes, e.g. to promote image, brands or products of the member companies, subject to the following requirements:

(a) 商业赞助应基于公开的商业邀请函/招商函

(a) The sponsorship should be based on an open invitation letter;

(b) 公司获得直接的利益（如冠名授权、会员权利、广告权利等）并在支持文件中明示。此支持的回报须与市场公允价值相符。

(b) Company will receive a direct benefit in return (naming right, membership rights, advertisement rights etc.) which is clearly defined in supporting documents. The return of such support must reflect the fair market value of the benefits received.

10.3 专家咨询会议

10.3 Advisory Board Meetings

专家咨询会议是非推广性质的活动，其目的是对以下领域所涉及的一系列特定的问题向医疗卫生专业领域的KOLs寻求建议或独特的见解：

Advisory Board Meetings (ABMs) are non-promotional events and are intended to seek advices or insights from HCP KOLs for a set of specific questions typically in the following areas:

- 科学领域： – 医学 / 临床开发 / 卫生经济学
- 市场领域：产品策略 / 定位 / 品牌核心信息
- 若在以上未提及的领域举办专家咨询会议，应该得到公司指定的委员会或者管理层的特批

- Scientific: Medical/Clinical Development/Health Economy;
- Marketing: Product Strategy/Positioning/Brand Key Messaging; or
- ABMs in areas not mentioned above should have special approval from the committee designated by or the management of the company

所有的专家咨询会议都应该有特定的管控措施，同时销售团队不得组织专家咨询会议，从而确保该活动不带有任何推广目的。管控措施应该遵循以下几个原则：

Member companies should set up specific control measures for all ABMs, and sales functions should not be allowed to organize ABMs so as to avoid any promotional nature attached to ABM. The s control measures should be in line with the following principles:

1. 频率：专家咨询会议的召开频率应根据其非推广性质的特性有所限制，并具备合理理由，区域性的专家咨询会议需谨慎举办。

1. Frequency – frequency of ABMs should be limited and justified to reflect its non-promotional nature, while regional ABMs should be held with caution.

2. 参会者的选择：参会者的资质与经验须与专家咨询会议的目标相符。

2. Selection of participants – The qualification and experience of participants should be appropriate for the intended objectives of the ABMs.

3. 专家咨询会议的KOL参会者人数，应能够确保能够既定会议目标进行充分和高质量的讨论，并避免因参会者过多而导致部分与会者的有效参与度过低。专家咨询会议的讨论环节应至少占会议时长的一半以上。

3. The number of KOL participants in ABMs should be appropriate in order to allow an adequate and quality discussion around the intended objectives, and to avoid low level of effective participation by some due to the large number of participants. Discussion sections in ABMs must be at least 50% of the total length of AMBs.

4. 内部参会者 – 专家咨询会议的内部参会人员应该在会议中承担明确具体的积极角色，被动参会者应该控制在最低限度。来自

4. Internal participation – Internal participants of ABMs should take an active role that is clearly defined , and passive participation should be kept at

市场部或市场准入部的同事，以被动参会的形式参加非商业性质的专家咨询会议必须得到公司指定的委员会或者管理层的特批。

the minimum. Passive participation by marketing or market access functions in non-commercial ABMs must be subject to special approval from the committee designated by or the management of the member company

5. 合同、报酬、及审核 – 专家咨询委员会参会者应签署相关服务协议，支付的报酬必须合理。

5. Contract, compensation, and review – A service agreement with each of the ABMs participants should be signed, and compensation for the ABM participants must be reasonable .

6. 会议结论及文件存档 – 组织者应负责对专家咨询委员会会议进行妥善记录（包括准备工作及后续跟进计划）及保存专家咨询委员会的会议结论。

6. Outcome and documentation – Organizers should be responsible for properly producing meeting minutes of the ABMs (including preparation work and follow-up actions), and keeping record of the outcomes of the ABMs. t

第十一条 对医学继续教育的支持

Article 11 Support for Continuing Medical Education

医学继续教育可帮助医疗卫生专业人士掌握有关疾病和相关治疗手段的最新、最准确的信息和观点，这对改善病患服务、提升医疗卫生服务水平是极为重要的。继续教育的主要目的应当是提升医学知识，会员公司仅在此目的下提供的资金支持才是正当的。

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.

如会员公司向医学继续教育活动和项目提供教学材料时，这些材料必须公平、全面、客观，其在设置上应允许不同理论和公认观点的表达。会员公司提供的教学材料应包含有助于提升病患福利的医学、科学或其他信

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

息。

会员公司支持医学继续教育还须遵守本准则第七条的规定。

care.

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

第十二条 公司程序与职责分配

12.1 程序

会员公司应建立健全适当的程序以确保其对相关法律和准则的遵守，并应以合法合规为目的对相关程序的实施和内容进行审查与监控。

12.2 培训

会员公司还应确保相关雇员接受与其职责相适应的培训。

12.3 药品推广材料的审批

会员公司应配备一名有足够知识与相应资格的雇员负责审批公司的药品推广材料，或是指定一名高级职员在具备足够资质的科研人员的指导下负责审批公司的药品推广材料。

Article 12 Company Procedures and Responsibilities

12.1 Procedures

Companies should establish and maintain appropriate procedures to ensure compliance with relevant codes and applicable laws 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.

第十三条 对准则的违反、投诉与准则的执行

Article 13Infringement, Complaints, and Enforcement

RDPAC鼓励会员公司就违反本准则的行为提出善意投诉。具体的投诉及对投诉的处理程序详见本准则附件二即《投诉及争议解决规程》。

Genuine complaints relating to infringements of the RDPAC Code are encouraged. Detailed procedures for complaints and the handling of complaints are set out in the RDPAC Complaint and Dispute Resolution Procedure (Appendix II).

附件一

IFPMA 关于赞助医药互动交流活动的指南说明

引言

作为研发制药行业的代表，国际制药商协会联合会即 IFPMA 的一项重点工作始终是推动医疗知识进步和提高全球公共卫生水平。医疗卫生专业人士和制药行业之间的合作极为重要，确保患者能够获取其所需药物、医疗卫生专业人士能够获得关于疾病和药物的最新、最全面的信息。IFPMA 会员始终致力于开展医药互动交流活动，以期为医疗卫生专业人士提供科学信息和教育内容，提高其医学知识与经验水平。上述这些活动可以各种不同的方式和媒介开展。

《IFPMA 行为准则》为行业在全球的业务实践设立了标准，包括关于符合商业道德高标准的行为及药品推广的指导原则，以及向医疗卫生专业人士推广药品、或与医疗卫生专业人士和其他利益相关方之间进行互动交流时应当符合的要求。制药行业为各种地方性、全国性及国际性会议提供多种类型的赞助，包括赞助医疗卫生专业人士出席会议、向组织活动的医学会提供赞助、租赁展览场地、向演讲人支付服务费等。制药企业参与赞助的方式也多种多样，包括在地方医院或

Appendix I

IFPMA Note for Guidance on Sponsorship of Events and Meetings

Introduction

Advancing medical knowledge and improving global public health remains a priority for the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) representing the research-based pharmaceutical industry. Collaborations between healthcare professionals and the pharmaceutical industry are essential and ensure that patients have access to the medicines they need and that healthcare professionals have up-to-date comprehensive information about the diseases they treat and the medicines they prescribe. IFPMA members remain committed to activities that provide scientific and educational content to healthcare professionals and advance their medical knowledge and expertise. These activities may take place through various means and media.

The IFPMA Code of Practice sets global standards for industry business practices and includes guiding principles of ethical conduct and promotion as well as requirements for the promotion of medicines to health professionals and interactions with healthcare professionals and other stakeholders. The pharmaceutical industry provides various types of support for a wide range of local, national, and international meetings including sponsorship of healthcare professionals' attendance, provision of grants to medical societies organizing events, hiring of exhibition space, provision of speakers etc. The

诊所举办其公司会议，或在由医学会组织的国际会议中举办卫星研讨会。《IFPMA 行为准则》第 7 条（互动交流活动与会议）对这些活动进行了规定。此类活动的主要目的应当在于其教育价值，而不在于其举办的地点、场所、款待、或举办时间等因素。活动地点和场所的选择必须恰当、有助于达到教育目的、且标准适度。在决定是否赞助某项会议时，应考虑教育项目、总费用、会场设施、地点的合理性、听众来源、招待能力，某些情况下还需考虑安保等因素。在做此类安排时应始终考量公众可能对其产生的印象。制药企业应尽可能清晰地记录其决定赞助或举办某会议的理由，这对合规将大有帮助。就会议安排而言，各协会会员的行为准则和企业会员的内部政策及流程通常比《IFPMA 行为准则》更具规范性。

involvement of pharmaceutical companies also varies and includes arranging its own meetings such as in a local hospital or a clinic to running a satellite symposium at an international meeting organized by a medical society. These activities are covered by Article 7 (Events and Meetings) of the IFPMA Code. The prime reason for attending such meetings should be the educational value and not other factors such as the location, venue, hospitality or timing of the meeting. The choice of location and venue must be appropriate, conducive to the educational objectives and modest. In determining whether to support an event consideration should be given to the educational program, overall cost, facilities offered by the venue, justification for the location, nature of the audience, hospitality and for certain situations, security arrangements. The impression given by all the arrangements should be kept in mind. Pharmaceutical companies might find it helpful to clearly document the reasons as to why they decide to support or run a meeting. Member Associations' codes and member companies' policies and procedures are often even more prescriptive than the IFPMA Code in relation to arrangements for meetings.

本指南说明的目的是对《IFPMA 行为准则》的相关规定提供更全面的说明。为此，本指南说明旨在：

The purpose of this document is to provide more information in relation to relevant requirements of the IFPMA Code of Practice. In this respect, the guidance intends to:

- 对于由制药企业或第三方如医学会等团体组织的会议，在考量会议地点和场所是否适当时，帮助所有利益相关方，包括制药企业、协会会员、其他国内行业协会、医学会、第三方会议组织方等确定其应考虑
- assist all stakeholders, including pharmaceutical companies, member associations, other national trade associations, medical societies, third party event organizers, etc., in the factors to consider when determining whether locations and venues are appropriate, for meetings organized by

的因素；且

- 在制药企业对其自行举办的会议或其参与赞助的由其他团体（如医学会）举办的活动（包括赞助专家演讲、资助医疗卫生专业人士参会、或其他类型的帮助，如提供赞助、租借展览场地等）是否适当进行评价时提供方向性指导。

pharmaceutical companies or third parties such as medical societies and

- provide direction for pharmaceutical companies in the process of assessing the appropriateness of their own meetings and their involvement in supporting meetings organized by others, such as medical societies, (e.g. by sponsorship of expert speakers, paying for healthcare professionals to attend or other type of assistance such as providing a grant, renting exhibition space, etc.).

1. 评价互动交流活动的地点是否适当时应考虑的标准（非穷尽式列举）：

- 所选地点应位于或邻近公认的科学或商业中心的城镇，便于目标听众抵达；
- 所选地点不应主要以其旅游或休闲设施闻名遐迩；
- 所选地点和会议场所不应成为互动交流活动的主要卖点，也不能对外造成此种印象；
- 互动交流活动的时间不应与在当地举办的本地或国际知名体育赛事或文艺演出相重合，也不宜紧接在此类活动的前后；
- 所选地点对于互动交流活动旨在覆盖的地理范围而言应是适当的（如欧洲的学术会议不应在欧洲以外的地点举办）。

1. Criteria to consider when assessing the appropriateness of the Location of an Event (non-exhaustive)

- The geographical location is in or near a city or town which is a recognized scientific or business center and is easily accessible for the intended audience;
- The location should not be primarily known for its touristic or recreational offering;
- The location and venue should not be the main attraction of the event or be perceived as such;
- The time of the event should not coincide with local or internationally recognized sporting or cultural events taking place in the same location, at the same time and preferably not just before or just after the meeting;
- The location is appropriate in respect to the geographical scope of the event (e.g. a European congress should not take place outside of Europe).

注：一般而言，首都和省会城市以及其他被视为商业中心的大都市都是合理和适当的会议地点。一个完全由本地医疗卫生专业人士参加的互动交流活动和一个区域性或国际性的互动交流活动在判断地点是否适当时也会有所不同。此外，如有令人信服的确凿理由证明某地点确为互动交流活动中的项目所需，如该地区有相关专家，或有相关研发或生产设施等，则活动项目也可成为选择该地点的理由。

Note: Capital cities and other large metropolitan cities considered to be commercial hubs are likely to be reasonable and appropriate locations for meetings. The appropriateness of a location may be assessed differently for strictly local events attended by local healthcare professionals as opposed to regional or international events. The program for an event may justify a particular location if there are valid and cogent reasons for that location such as the availability of relevant expertise, for example, research or manufacturing facilities.

2. 评价互动交流活动场所是否适当时应考虑的标准（非穷尽式列举）：

- 所选场所应有助于实现会议的科学和教育目的；
- 所选场所应配备必要的商业与技术设施，具有举办会议及接待与会者的能力；
- 会议设施应仅对与会者开放；
- 如会议地点兼具科学或商业中心和旅游胜地双重特性，则会议场所应选择在远离主要旅游景点的区域，这点很重要；
- 所选会议场所不应为著名的娱乐、体育、休闲或度假设施和场所（如高尔夫俱乐部、疗养温泉、海滩/河岸/湖岸景点或赌场等）；
- 对于所选会议地点而言，会议场所应

2. Criteria to consider when assessing the appropriateness of a Venue of an Event (non-exhaustive)

- The venue is conducive to the scientific and educational purpose of the meeting;
- The venue has the necessary business and technical facilities to accommodate the meeting and its participants;
- The meeting facilities should only be accessible to intended audience;
- In the case of cities which are both major scientific or business centers and locations highly desirable for tourists, it is important to select venues which are away from the main tourist spots;
- The venue must not be renowned for its entertainment, sports, leisure or vacation facilities (e.g. golf club, health spas, Beach /River/ Lake side locations or casino);
- The venue provides safe & secure

能提供安全可靠的住宿条件；

accommodation when considering the chosen location;

- 即使与其他场所相比费用相对低廉，所选场所也不应奢华（对奢华与否的判断可参考诸如国家旅游部门排名和/或旅行社平均的排名等标准）。

- The venue must not be lavish even if the cost is low compared to other venues. (e.g. ranking by the tourism department of the country and/or the average ranking by travel agencies can help with this assessment).

3. <u>决定是否赞助医学会等第三方组织的互动交流活动时应考量的标准（非穷尽式列举）</u>：

3. <u>Criteria to consider when deciding whether to support an event organized by a third party such as a medical society (non-exhaustive):</u>

a. 关于科学项目（《IFPMA 行为准则》第 7.1.1 条）

a. Scientific Program (Article 7.1.1 of the IFPMA Code)

如果对以下问题的答案均为“否”，则制药企业应在作出赞助决定之前考虑获取更多信息或建议修改赞助条件。

If the answer to any of the questions below is ‘no’, then pharmaceutical companies should consider obtaining further information or suggesting amendments before agreeing to any involvement with the meeting.

- 在会议开始足够长的时间之前能否从组织方的网站上查询到该科学项目？

- Is the scientific program available on the event organizer’s website well in advance of the meeting?

- 科学项目的时间是否占据互动交流活动的全部日程安排，以及基本上占满其中每天的工作时间？

- Does the scientific program cover the whole duration of the event with content generally filling the business hours each day?

- 该项目内容是否有具有足够的科学性，且系针对参会听众制订？

- Is the program content scientifically grounded and adapted to the targeted audience?

b. 关于娱乐、休闲活动、餐饮（《IFPMA 行为准则》第 7.1.5 条和第 7.1.6 条）

b. Entertainment, leisure activities, meals (Articles 7.1.5 and 7.1.6 of the IFPMA Code)

如果对以下问题的答案均为“是”，则制药企业应在作出赞助决定之前考虑获取更多信息或建议修改赞助条件。

If the answer to any of the questions below is ‘yes’, then pharmaceutical companies should consider obtaining further information or suggesting amendments before agreeing to any involvement with the meeting.

- 在互动交流活动之前、之中或之后是否安排了附属的娱乐（例如观光或休闲活动）？活动期间是否安排了不合理的或需要频繁外出的餐饮？
- Is any entertainment (such as sightseeing tours or leisure activities) organized in connection with the event either before, during or after it? Is there unreasonable or frequent traveling for meals during the event?
- 餐饮是否安排在旅游景点或文化遗产/文化旅游区？
- Are meals arranged in tourist or heritage/cultural attractions?
- 该项目在宣传上是否有看似奢华的描述（例如欢迎香槟酒会、庆祝晚宴等）？
- Are any of the descriptions on the program such that they appear to be excessive (e.g. champagne reception, gala dinner, etc.)?

c. 关于随行客人（《IFPMA 行为准则》第 7.3 条）

c. Accompanying Persons (Article 7.3 of the IFPMA Code)

若该项目提及与会医疗卫生专业人士的随行人员/客人，则应考虑以下问题：

If the program mentions accompanying persons/guests of the healthcare professional attendees, consider the following:

- 随行人员/客人是否需要支付全部合理费用，且不会获得任何形式的补贴？
- Are they required to pay the full reasonable costs which are not subsidized in any way?
- 医疗卫生专业人士是否预计应参加学术会议，而不是被鼓励参加任何为随行人员安排的活动？
- Are healthcare professionals expected to participate in the meeting rather than encouraged to join any program for accompanying persons?
- 是否明确地不鼓励与会者提前到达或推迟离开？
- Is it clear that attendees are not being encouraged to arrive before the meeting starts or stay on after it ends?

如果对以上问题的答案均为“否”，则制药

If the answer to any of the questions above is ‘no’,

企业应在作出赞助决定之前考虑获取更多信息或建议修改赞助条件。

then pharmaceutical companies should consider obtaining further information or suggesting amendments before agreeing to any involvement with the meeting.

4. <u>其他应考虑的标准——官方会议材料和网站</u>

4. <u>Other criteria to consider – Official meeting materials and websites</u>

会议的宣传描述通常是衡量一个会议的地点、场所和其他安排是否适当的重要指标。类似活动的举办地位于"世界著名度假胜地",或"毗邻美丽的海滩"等宣传语通常表明，该会议的举办并非主要出于教育目的，所选会议地点和场所可能不适当。此时可考虑以下几个问题：

The description of the meeting is often an indicator of whether the location/venue and other arrangements are appropriate. Language about the event being located at "world renowned resort" with "beautiful beaches nearby" or other similar language is an indicator that the prime purpose may not be educational and the location/venue may not be appropriate. The following questions could be considered:

- 网站宣传是否仅关注会议的教育目的，还是宣传旅游安排或款待作为会议的卖点？
- Does the website focus purely on the educational merit of the meeting or does it promote tourism or hospitality as one of its attractions?
- 网站宣传是否提及会议举办前或举办后的其他活动内容？
- Does the website mention pre or post event activities?
- 网站宣传中的会议赞助商为何？是医学会等专业机构，还是当地的旅游部门？
- Who is mentioned as a supporter of the event? Is it medical societies, or similar, or the local tourist board, etc.?

除上述信息外，所选会议场所的网站信息也能进一步说明该地点和场所的适当性。

In addition, information on the proposed venue's website may give a further indication of the suitability of the location/venue.

现有工具与资源

Existing Tools and Resources

除《IFPMA 行为准则》、各国协会准则、及企业规章外，目前还有以下工具和资源可帮助会员企业决定其是否赞助某一特定的互动

In addition to the IFPMA Code, national and company codes, there are a number of existing tools and resources to assist companies in deciding whether

交流活动：

- **西班牙制药行业协会大会评价平台** http://www.codigofarmaindustria.es
- **欧洲制药工业协会联盟的 e4ethics 平台** http://www.efpia-e4ethics.eu
- **欧洲医疗科技行业协会大会评价平台** http://www.ethicalmedtech.eu/

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or not to support a specific event.

- **Farmaindustria Congress Assessment Platform** http://www.codigofarmaindustria.es
- **EFPIA's e4ethics platform** - http://www.efpia-e4ethics.eu
- **EUCOMED Congress Assessment Platform** - http://www.ethicalmedtech.eu/

Issue Date: November 2014

附件二

投诉及纠纷解决程序

（经执行委员会核准，本程序自 2015 年 7 月 22 日起正式生效）

1.一般规定

1.1中国外商投资企业协会药品研制及开发行业委员会（简称“RDPAC”）的各会员公司（简称“各会员公司”或“各公司”）继续对 RDPAC《行业准则》（简称“行业行为准则”或者“准则”）的内容及其执行进行充分的讨论及协商。如果在讨论及协商过程中出现任何争议，RDPAC 鼓励各会员公司就任何违反 RDPAC 行业行为准则的行为提交相应真实的投诉报告（简称“投诉”）。

1.2本投诉及纠纷解决程序（简称“本程序”）及行业行为准则所规定的相应处理流程适用于所有会员公司；同时，对于会员公司中遵循本行业行为准则精神且善意履行职责的任何职工，经总经理书面核准，亦予以适用。

1.3RDPAC 应确保其网站中包含与本行业行为准则有关的信息，以及与本行业行为准则所规定的投诉申请规定有关的信息，构建一个供各会员公司就如何进行行业自律进行建设性沟通、交流，以及就各会员公司有关准则的良好合规实践进行分享、学习的平台。

Appendix II

Complaint and Dispute Resolution Procedure

(Effective on 22 July 2015 by Approval of the Executive Committee)

1. General Provisions

1.1 RDPAC member companies (“Member Companies” or “Companies”) continue to have robust discussion and dialogue about the RDPAC Code of Practice (“Code of Practice”, or “Code”) and its enforcement among and between themselves. In the event that disagreement emerges from such discussion or dialogue, RDPAC encourages genuine reports of complaint (“Complaint”) from its Member Companies regarding any breach of the RDPAC Code of Practice.

1.2 This Complaint and Dispute Resolution Procedure (also this “Procedure”) and the proceedings thereunder are open to each and all Member Companies, including, upon written approval of the General Manager, their employees acting in good faith and in the spirit of the Code.

1.3 RDPAC should ensure that its website contains information about the Code as well as the Procedure to file a complaint under the Code, in order to create a forum for constructive communication of Industry’s self-regulation and to exchange Code compliance best practices among the Member Companies.

1.4RDPAC 应确保本程序所规定的处罚措施的力度与违规行为的性质相称，相关处罚措施应具有震慑效果，并应将性质相同的屡次违规与不同性质的多次违规加以区分对待。同时，RDPAC 亦应确保，投诉的处理过程以及处罚的执行过程应当符合本程序的规定；同时，在处理投诉及执行处罚的过程中，其具体实施方式应当符合数据保护/保密法律法规、竞争法律法规及其他相关法律、法规及行政规章的相应规定。

1.4 RDPAC should ensure that sanctions imposed hereunder are proportionate to the nature of the infringement, have a deterrent effect and take account of repeated offences of a similar nature or patterns of different offences. RDPAC also ensures that the processing of Complaints as well as the enforcement of the sanctions comply with this Procedure, and conducted in a manner consistent with applicable data/confidentiality protection, competition and other applicable laws, regulations, and administrative rules.

1.5所有会员公司，签署确认《RDPAC 成员协议》后即视为承认遵守 RDPAC 的管理规则、行业行为准则、本程序以及本程序所规定的具体处罚措施等内容。本程序规定的所有规则及原则对 RDPAC 的所有会员公司均具有约束力。

1.5 Each Member Company, by accepting the Membership Agreement of RDPAC commits to abide by the governing rules, the Code of Practice, this Procedure, as well as the sanctions imposed hereunder by RDPAC. The rules and principles hereunder provided are binding upon each and all Member Companies of RDPAC.

1.6RDPAC 应在中华人民共和国法律、法规及行政规章许可的范围内，提高各会员公司对于行业行为准则的了解及认知程度，并推动各会员公司开展培训课程，包括向各会员公司提供有关如何避免违规的指南，避免后者违反或违背行业行为准则的相关规定。同时，RDPAC 鼓励各会员公司在由 RDPAC 组织的定期会议中或者通过国际药品制造商协会联合会（简称“IFPMA”）的伦理和商业道德委员会（简称“eBIC”），分享各自关于行业行为准则的合规实践经验。

1.6 RDPAC should, within applicable PRC laws, regulations and administrative rules, facilitate the Member Companies’ awareness and education programs of the RDPAC Code of Practice, including by providing guidance to companies in order to prevent breaches or violations thereof. Member Companies are encouraged to share their implementation practices of the Code of Practice through regular meetings organized by RDPAC as well as through the IFPMA’s eBIC (Ethnics & Business Integrity Committee).

1.7RDPAC 办公室将制备有关其所承担的 RDPAC 行业行为准则实施、制定及执行工作的各年的报告，并将该等报告递交至执行委员会。该报告书应当对如下内容进行总则：

1) 各会员公司将行业行为准则并入至各自标准操作规程（SOP）的实际情况以及各会员公司对于行业行为准则的实施情况；

2) 相关投诉处理及处理结果的总体情况；

3) RDPAC 办公室针对行业行为准则的培训及教学情况，以及合规实践经验分享情况；

4) 前一年度行业行为准则实施方面所取得的改进。

1.7 RDPAC Office will prepare, and provide to the Executive Committee an annual report summarizing the work undertaken by it in connection with the implementation, development and enforcement of the RDPAC Code of Practice during the year, which should summarize.

1) Incorporation of the Code into its company SOP as well as implementation thereof by the Member Company;

2) The Complaints processed and the general outcome thereof, if applicable;

3) The training or education of the Code as well as the sharing of best practices conducted or organized by the RDPAC Office regarding the Code of Practice;

4) Any improvement of the Code enforcement achieved during the past year.

2.准则管理

2.1 管理机构

RDPAC 的内部规章所规定的 RDPAC 执行委员会（该机构英文简称“EC”）是行业行为准则实施机制的管理机构。执行委员会应当遵守 RDPAC 管理规则所规定的相关决策程序，特别是关于会议法定人数、保密以及利益冲突等方面的规定，例如，对于会员公司之间发生的争议，执行委员会在进行决策时，对与争议会员公司存有从属关系的执行委员会成员应予排除在外，不得参与。

2.Code Administration

2.1 Management Body

The Executive Committee of RDPAC as defined by the RDPAC Bylaw (also the “EC”) should serve as the management body of the Code enforcement mechanism, abiding by the same decision-making procedure provided by the Governing Rules of RDPAC, including in particular the rules regarding quorum, confidentiality, and conflict of interest; e.g. the EC member(s) whose Company is a Party to the dispute should be excluded from the decision-making process.

2.2 秘书处

1) 执行委员会应根据本程序的规定，将处理投诉的具体权力授权于本程序秘书处（以下简称“秘书处”，秘书处由RDPAC 的常务理事及法律顾问组成）。除对第 6.1 条所规定的审理委员会成员的选任工作进行监督以外，执行委员会对于针对依据本程序提交的任何投诉的所有审理工作，均不得参与干涉。

2) 秘书处的职责包括：（1）进行投诉核实；（2）适当时主持争议双方之间的调解；（3）协助审理委员会进行审理工作；以及（4）协助执行或者执行审理委员会的裁决。

3) 秘书处应对争议处理程序的公正性、透明性及公开性向执行委员会进行汇报。

3.投诉及核实

3.1 提出投诉。所有人投诉人均应以书面形式提起投诉，投诉申请中应包含如下内容：

1) 提出投诉的会员公司（简称“投诉人”）的身份信息，并应列明完整的通讯地址信息，包括联络沟通用的传真号码及电邮地址。如投诉人请求对其身份信息进行保密的，则相应身份信息除向秘书处、被投诉人（定义见下文第 3.1.2 条）及审理委员会进行披露以外，

2.2 Secretariat Office

1) The EC should delegate the details of handing a Complaint in light of this Procedure to the Secretariat Office of this Procedure (hereinafter also “Office”, which consists of the Managing Director and the General Counsel of RDPAC), and should not, except for monitoring the designation of the Hearing Panel as defined in Section 6.1, participate in the adjudication of any individual Complaint submitted hereunder.

2) The responsibilities of the Secretariat Office include to (i) conduct Complaint validation; (ii) preside over mediation between the two Parties, where applicable; (iii) facilitate the Hearing Panel with its adjudication; and (iv) facilitate/conduct execution of Panel decisions.

3) Office should report to the EC on the integrity, transparency and openness of the proceedings.

3. Complaints & Validation

3.1 Filing a Complaint. All Complaints must be in writing and include the following contents:

1) The identity of the complaining Member Company ("Complainant"), with full mailing address including fax number and email address for correspondence. On request of the Complainant, its identity should be kept confidential to any party other than the Office, the Respondent (as defined in Section 3.1.2) below) and the Hearing Panel.

不得向其他任何人披露。

2) 涉嫌违反行业行为准则规定的会员公司的身份信息（简称“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）。

2) 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.

3) 对于涉嫌违反本行业行为准则规定的活动或行为的清晰描述（包括任何书面或印刷材料）；任何相关证明材料，并应列明被投诉人违反的具体行业行为准则条款。

3) 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.

4) 由做出投诉的公司的总经理针对投诉内容出具的书面批准或证实材料。

4) An endorsement or verification of the Complaint in writing by the General Manager of the complaining Company.

3.2 地址信息。所有投诉均应通过如下实体地址或者电邮地址送交至 RDPAC：

RDPAC 常务理事和/或法律顾问收

中国北京市朝阳区东三环北路 8 号亮马河大厦 1 号办公楼 506 室

邮编：100004

电邮地址：complaint@rdpac.org

3.2 Addresses. Any Complaint hereunder should be sent to either the physical address or the email address of RDPAC as set forth below:

Executive Director and/or General Counsel, RDPAC

Office Bldg 1, Rm 506, Landmark Tower

No. 8 Dongsanhuanbei Rd., Chaoyang District

Beijing 100004, PR China

Email: complaint@rdpac.org

3.3 投诉核实。

收到投诉后，秘书处应对投诉书中所陈述的内容进行核实，确保：

3.3 Complaint Validation.

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

1) 投诉人及被投诉人均为 RDPAC 的会员

1) both the Complainant and the Respondent are

公司；

Member Companies of RDPAC;

2) 提交的争议事宜系由投诉人善意提交的真实、客观事宜；

2) it appears to be a genuine matter submitted in good faith;

3) 争议行为可被认定为违反行业行为准则规定的行为；

3) the complained behavior can be identified as violation or breach of the Code;

4) 处理投诉所需的相关证据及信息充分；

4) there is sufficient evidence or information to enable the Complaint to be processed;

5) 投诉申请已由投诉人的总经理进行了书面证实。

5) the Complaint has been verified in writing by the GM of the Complainant.

3.4 投诉驳回。投诉人未能初步证明争议行为违反 RDPAC 行业行为准则规定，其相关投诉将依据行业行为准则之规定予以驳回。另外，对于完全或主要追求经济利益的投诉请求，秘书处应予驳回。

3.4 Dismissal of a Complaint. Where a Complaint fails to establish a prima facie case for a breach of the RDPAC 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.

3.5 时限。对于投诉请求的核实工作，秘书处应在收到投诉请求后的五（5）个工作日内完成。随后，秘书处应在完成投诉核实工作后的五（5）个工作日内，按照被投诉人在 RDPAC 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至被投诉人的总经理处。

3.5 Timeline. The validation of the Complaint hereunder should be completed within five (5) working days upon receipt of a Complaint. The Office 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 RDPAC, within five (5) working days upon validation of the Complaint.

4.答复

4. **Response**

4.1 被投诉人应在收到由秘书处发出的书面投诉后的十五（15）个工作日内，对投诉进行答复（简称“答复”）。在将

4.1 The Respondent should respond to the Complaint ("Response") within fifteen (15) working days of its receipt of the Complaint from the Office. After

书面投诉副本及证明材料发给投诉人以后，秘书处应同被投诉人的总经理进行联系，敦促后者在上述期限内对争议事宜予以澄清和/或对投诉人进行答复。

sending the Complaint and supporting evidence, the Office 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.

4.2 秘书处应在收到答复后的五（5）个工作日内，将其转交至投诉人。

4.2 Response received by Office should be forwarded to the Complainant within five (5) working days upon receipt of the same.

4.3 如果被投诉人回复承认争议所涉活动或行为违反了行业行为准则的规定的话，应以书面形式作出承认，并列明被投诉人为纠正或补救该违规行为而已实施或计划实施的具体行为。投诉人应在收到承认回复后的五（5）个工作日内，通过书面回复秘书处的方式，选择（a）是否撤回投诉，或者（b）不予接受被投诉人提议的补救措施。如果投诉人未能在上述五（5）个工作日的期限内通知秘书处是否选择撤回投诉的，则该投诉视为予以撤回。

4.3 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, within five (5) working days upon receipt of the acknowledgement, choose to, through written reply to the Office, (a) withdraw the Complaint or (b) refuse to accept the remedial actions proposed by the Respondent. If the Complainant fails to inform the Office whether it chooses to withdraw the Complaint within the above five (5) working day period, the Complaint will be deemed withdrawn.

5.调解

5. **Mediation**

5.1 如果被投诉人对投诉内容予以否认的，或者未能在上述规定时间内进行答复的，或者投诉人对于被投诉人作出的、表明具体补救措施或补救措施方案的答复不予接受的，秘书处应在投诉人和秘书处均收到被投诉人的否认回复后，或者被投诉人在上述第 4.1 条规定的十五（15）个工作日期限内未能作出答

5.1 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, Office should preside over mediation or consultation between the two Parties within fifteen (15) working days of receipt by both the Complainant and the Office, whichever is later, of Respondent’s denial, or its failure to respond by end of the fifteen (15)

复，或者投诉人作出不予接受的决定（以上述较晚时间为准）后的十五（15）个工作日内，召集并主持争议双方的调解或协商活动。

working days as stipulated in Section 4.1 above, or Complainant's refusal to accept the Response.

5.2 如果争议双方在上述 15 个工作日的期限内未能通过调解达成一致，秘书处应依据下文第 6 条的规定将该争议提交至审理委员会进行审理。

5.2 Upon failure of any agreement from the mediation between the Parties within the above fifteen (15) working day's timeline, Office should then submit the Complaint for Panel Review in light of Article 6 hereunder.

6. 委员会审理

6. Panel Review

6.1 审理委员会

6.1 Hearing Panel

1) 对于上述未能通过调解达成一致的争议，应依据本程序第 6.5 条之规定成立由三（3）位专家组成的审理委员会（简称“审理委员会”），对相关争议进行审理。

1) Upon failure of any agreement from the mediation as prescribed above, a hearing panel ("Hearing Panel") consisting of three (3) panelists should be formed to review the Complaint in light of Section 6.5 of this Procedure.

2) 对于审理委员会在审理过程中产生的所有成本及费用，应由违规方及 RDPAC 秘书处分担。

2) The cost and expenses incurred from the Panel review should be undertaken evenly by the offending Company and RDPAC Office.

6.2 专家组

6.2 Panel Pool

1) RDPAC 拥有由十（10）至十五（15）名专家组成的专家组，包括律师事务所或者会计师事务所的合伙人或者是由会员公司聘请并得到执行委员会认可的知名学者。同时，会员公司（主要是 RDPAC 法律及合规工作组，英文简称“WG”）每年会根据 WG 的反馈情况

1) RDPAC maintains a Panel Pool of ten (10) to fifteen (15) Panelists, consisting of partners from law firms and accounting firms, or of renowned scholars selected by the Member Companies and confirmed by the EC, and should be subject to review by the Member Companies (mainly the Legal and Compliance Working Group of RDPAC, or the "WG") every one (1) year based

对专家组进行审核。

on the feedback of the WG.

2) 除非秘书处决定给予例外，专家组成员在其专业领域至少拥有 8 年专业经验，且在业内享有良好的声誉；同时，对在争议解决方面拥有两（2）年以上相关经验的，优先考虑。

2) Unless waived by Office at its discretion, Panelists must have a minimum of eight (8) years of professional experience in the relative field, good reputation in his/her professional community, and preferably two (2) years of experience in dispute resolution.

6.3 专家指定

6.3 Appointment of Panelists

1) 在收到秘书处发出的关于指定专家的通知后，争议双方应分别从专家组中指定一名专家，并在收到上述指定通知后的五（5）个工作日内将该人选告知秘书处。同时，争议双方在分别指定专家之后，应在其第一次指定完成之后的五（5）个工作日内共同从专家组指定一位委员会主席（简称“主席”）并将该主席人选告知秘书处。

1) Upon receipt of notice from the Office for Panel appointment, each Party should appoint one (1) Panelist from the Panel Pool and notify the same to the Office within five (5) working days of the said notice from the Office. Upon the appointment of the said Panelist by each Party, the two Parties should then jointly appoint the Chairman of the Panel (or the “Chairman”) from the Panel Pool, and inform their appointment to the Office, within another five (5) working days of their first appointment of a Panelist.

2) 如果争议双方未能就主席人选达成一致意见，秘书处应组织争议双方进行协商，并应在协商开始后的五（5）个工作日内促使争议双方达成一致意见，推选出主席。

2) In case the two Parties cannot reach an agreement on the appointment of the Chairman, Office should facilitate a consultation between the two Parties till they can agree on the appointment of the Chairman, within five (5) working days of the commencement of the said consultation.

3) 如果争议双方经过上述协商过程仍未就主席人选达成一致意见的，秘书处应在争议双方未能指定主席后的十（10）个工作日内，根据投诉性质并对潜在利益冲突进行合理评估的基础上，为争议双方指定一名专家组成员或者非专家组

3) In the event the two Parties disagree on the appointment of the Chairman even with the Office’s facilitation, Office may then nominate an expert from either in or outside of the Panel Pool, based on the nature of the Complaint and a reasonable assessment of potential conflict of interest, for the two Parties to appoint as the

成员担任主席。

Chairman, in ten (10) working days upon failure of the appointment of the Chairman by the Parties.

6.4 指定的接受及确认

6.4 Acceptance and Confirmation of Appointment

1) 在收到争议方发出的指定通知后，被指定的专家应提供一份由其事务所出具的接受函，并在接受函中声明如下内容：（1）专家接受相关指定；以及（2）该指定符合其所在事务所关于利益冲突的规定以及《国际律师协会（IBA）关于国际仲裁中利益冲突问题的指导意见》的规定，具体内容请查看此链接：http://www.ibanet.org/Publications/publications_IBA_guides_and_free_materials.aspx。

1) Upon notification of his/her appointment by the Parties, each Panelist should present a Letter of Acceptance from his/her Firm, stating 1) the Panelist's acceptance of the appointment, and 2) that the appointment complies with Firm's policy on conflict of interest, as well as the IBA Guidelines on Conflict of Interest in International Arbitration, as available at the link here: http://www.ibanet.org/Publications/publications_IBA_guides_and_free_materials.aspx.

2) 除非争议一方因正当理由请求撤销另一方指定的专家的，执行委员会应在相关专家或主席确认接受争议方的指定后的五（5）个工作日内对相关指定情况进行确认。上述“正当理由”是指接受指定的专家或其所属事务所与争议事项存在利益冲突的情形。如发生特殊事宜，则秘书处应通知被指定的专家，并告知指定方重新进行指定。

2) Subject to request for withdrawal for cause by the other Party, the appointment of the Panelists and the Chairman should be confirmed by the EC within five (5) working days of their acceptance of the appointment by the Parties. The "cause" herein referred will need to be instances of specific conflict with the appointed Panelist or his/her Firm, in which case Office will notify the appointed Panelist and the appointing Party for re-appointment.

6.5 委员会裁决

6.5 Panel Decision

1) 审理委员会应在执行委员会对相关专家的指定情况进行确认之后的三十（30）个工作日内，对投诉内容连同所有相关证明材料或信息进行审查并依此作出相应裁决（简称“委员会裁决”或“裁

1) The Hearing Panel should review the Complaint together with all the supporting evidence and information, and thereupon come up with a decision ("Panel Decision" or "Decision") within thirty (30) working days as from the EC confirmation of the Panelists.

决”）。

2) 依据争议内容及争议解决的难易程度，委员会主席可在委员会审理期限（30天）的基础上，另行准予最多不超过十五（15）个工作日的延长期限。

2) Depending on the complexity of the dispute and its resolution, the Chairman may grant an extension of the above thirty (30) day timeline for Panel review for no more than fifteen (15) working days.

3) 根据具体情况，审理委员会应在委员会裁决中明确说明，该裁决所依据的事实情况、推理论证过程以及据此作出的相关结论，同时，还应包括相应的处罚内容（详细内容，请见下文第 7 条）。对于针对违规方所作出的处罚决定，审理委员会应在裁决中列明违规方履行相应处罚内容的具体时间要求。

3) The Hearing 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 (as defined in further detail in Section 7 below). The timeline for the offending Company to take any of the sanctioned actions should also be stated in the Decision, where applicable.

4) 委员会裁决经 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。

4) The Panel Decision, once issued and signed by all three (3) Panelists, should be final and binding on both Parties.

7.处罚

7. Sanctions

7.1 如果争议一方的行为经过上述处理程序被确认为违规的，委员会有权依据该违规行为的严重程度以及违规方对于纠正/补救该违规行为的意愿程度，对违规方处以下述一项或者多项处罚。

7.1 In the event that a breach is established pursuant to the proceedings hereunder, the Panel may impose one or more of the following sanctions on the Offending Company, depending on the severity of the breach of the Code as well as the Offending Company’s willingness to correct/remedy its breaching conduct.

1) 违规公司的总经理应出具一份由其签字确认的书面声明，承诺立即停止相关争议行为，并采取对违规行为进行纠正/补救的措施或者措施方案。

1) A written and signed statement by the GM of the Offending Company committing to an immediate cessation of the practice in question, as well as actions taken or to be taken to correct/ remedy the breaching conduct;

2) 违规情况较为轻微的，应对侵权公司处以 20000-30000 人民币的处罚。该处罚款项应在委员会作出裁决后的十（10）天内交付至秘书处，秘书处在收到该处罚款项时，应在收据上标注（“违约金”）字样。对于该类处罚款项，RDPAC 只可将其用于行业行为准则的培训及执行之目的。

2) In case of a minor breach, a fine of RMB 20,000 – RMB 30,000 may be imposed on the Offending Company, which should be paid to Office within ten (10) days of the Panel Decision and marked as “damage” (违约金) on the receipt thereof by the Office. RDPAC should use the money collected hereunder only for Code education and enforcement purposes.

3) 对于严重违规行为或者屡次违规行为，可对违规公司处以中止会员资格六（6）至二十四（24）个月的处罚。同时，可要求违规公司（由合规主管所代表）聘请第三方审核人员依据 RDPAC 行业行为准则的规定对违规公司的标准操作规程进行审查，该审查过程应在委员会作出裁决后的最多九十（90）天内完成。

3) In case of serious or repeated breach, suspension of membership for six (6) to twenty four (24) months may be imposed on the Offending Company. Meanwhile, the Offending Company (represented by its Compliance Officer) may be required to employ a 3rd Party auditor to review its Company SOP in light of the RDPAC Code of Practice, which process should last no more than ninety (90) days as from the date of the Panel Decision.

4) 如违规行为极为恶劣且违规方无意对违规行为进行纠正或补救的，秘书处应制备一份包含相关违规行为内容及相应处罚措施的书面报告，并将该报告发送至违规公司的总部。

4) In case of an egregious breach and lack of intention to correct or remedy the wrongdoing on the part of the Offending Company, a written report of the breach and the sanctions imposed should be prepared by the Office and notified the same to the Headquarter of the Offending Company.

7.2 同时，如果违规方对于委员会裁决或者在依照本程序实施的处理过程中所作出的任何其他通知未能及时进行答复的，经执行委员会确认后，秘书处可将相关违规行为内容、具体处罚决定以及违规方未能及时进行答复的情况制成报告，发送至违规方的公司总部。

7.2 Also, should the Offending Company fail to respond to the Panel decision or any other notification during the process of the Procedure hereunder, Office may, upon confirmation with the EC, notify the report of the breach and the sanctions imposed, as well as Offending Company’s failure to respond to the Procedure hereunder to the Headquarter of

the Offending Company.

7.3 本程序的实施及执行应当遵循第 6.4（1）条载明的《国际律师协会（IBA）关于国际仲裁中利益冲突问题的指导意见》中保密条款及利益冲突条款的规定。

7.3 The implementation and execution of the Procedure hereunder should comply with the rules of confidentiality and conflict of interest as provided in the IBA Guidelines as referred to in Article 6.4 (1).

完结

End

附件三

RDPAC 会员公司
（更新日期：2015 年 9 月）

雅培
艾伯维
艾尔建
安进
安斯泰来
阿斯利康
百特
拜耳医药保健
勃林格殷格翰
百时美施贵宝
新基医药
凯西
中外制药
卫材
礼来
费森尤斯卡比
爱的发制药
匈牙利吉瑞大药厂
赫尔森
益普生
协和发酵麒麟
利奥制药
灵北
美纳里尼
默克雪兰诺
默沙东
萌蒂制药
诺华
诺和诺德
辉瑞
罗氏
赛诺菲
施维雅
住友
武田
优时比制药
西安杨森
赞邦

Appendix III

RDPAC member companies
(Updated on Sep 2015)

Abbott
AbbVie
Allergan
Amgen
Astellas
AstraZeneca
Baxter
Bayer HealthCare
Boehringer Ingelheim
Bristol Myers Squibb
Celgene
Chiesi
Chugai
Eisai
Eli Lilly
Fresenius Kabi
Ethypharm
Gedeon Richter
Helsinn
Ipsen
Kyowa Kirin
LEO Pharma China
Lundbeck
Menarini
Merck Serono
MSD
Mundipharma
Novartis
Novo Nordisk
Pfizer
Roche
Sanofi
Servier
Sumitomo
Takeda
UCB
Xian-Janssen
Zambon