

RDPAC

# RDPAC行业行为准则 (2022年修订版) RDPAC Code of Practice 2022

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中国外商投资企业协会药品研制和开发工作委员会

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



## 主席致辞

### *Chairman's Message*



尊敬的各位同仁：

自从 1999 年成立之初，RDPAC 即始终将推动会员公司以最高道德与法律标准开展业务运营放在其使命的核心位置。当时，RDPAC 依据中国法律法规的规定，参照国际制药企业协会联盟（IFPMA）的行业准则，并考虑中国市场上的最佳实践做法，制定了第一版《RDPAC 药品推广行为准则》，并将遵守《行为准则》作为企业加入 RDPAC 的前提条件之一。

此后二十余年间，RDPAC 不断更新《行为准则》，以反映并适应外部环境的变化。最近一版的《行为准则》于 2019 年颁布实施，其不

Dear Colleagues,

Since its establishment in 1999, RDPAC has always put the task of promoting its member companies' operation of business activities in accordance with the highest ethical and legal standards at the center of its mission. At that time, RDPAC developed the first version of the RDPAC Code of Practice on the basis of the rules of Chinese laws and regulations, with reference to the Code of Practice of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), and in consideration of the best practices on the Chinese market. We also made the adherence with the Code of Practice as a precondition to any company's joining of RDPAC.

In the next more than 20 years that followed, RDPAC has kept updating the Code of Practice to reflect and to adapt to the changes of the external environment. The latest version of the Code of

但提出了新的合规标准，更向全部会员公司传递了 IFPMA 所倡导的共同价值观，即关怀、公平、尊重、诚实。我们努力引导会员公司通过践行这些共同价值观，塑造行业的道德和诚信文化，并以合规的方式开展各类业务活动以及与医疗行业各方之间的互动。

2019 年以来，中国的医药市场发生了重大的变化。中国政府持续推进医疗卫生体制改革，在很多领域推出了影响深远的新举措。这些新举措重新塑造了中国的医药市场，对医药公司的药品研发、上市与商业化带来了丰富的机遇，也带来了巨大的挑战。

为应对新的监管和市场环境，会员公司开展了多种商业创新。很多公司做出努力，通过各种数字化项目，依托各种基于互联网工具，提高对于医疗卫生专业人士和患者的服务水平。很多公司也在重新评估并积极探索对医疗卫生专业人士和患者提供医学、科学与产品支持的最佳做法，以及与各类医疗卫生组织开展医学、科学和产品教育合作的最佳模式，争取在中国医疗卫生体系中发挥更为重要和积极的作用。

Practice was issued in 2019, which not only raised new compliance standards, but also communicated to all member companies the collective core values advocated by IPFMA, i.e., care, fairness, respect and honesty. We endeavor to guide our member companies to foster a culture of ethics and integrity through the implementation of these collective core values, and to engage in all types of business activities and interactions with relevant healthcare stakeholders in a compliant way.

Since 2019, China's pharmaceutical market has undergone significant changes. The Chinese Government has continuously advanced its healthcare system reform, and put in place consequential, new measures in many areas. These new measures have reshaped China's pharmaceutical market, and brought about abundant new opportunities as well as enormous challenges to the drug development, approval and commercialization of pharmaceutical companies.

To respond to the new regulatory and market environment, member companies have launched many types of business innovations. Many companies have made efforts to raise the quality of the services to healthcare professionals and patients through a diversified portfolio of digital programs and Internet-based tools. Many companies are re-evaluating and exploring the best ways for providing medical, scientific and product support to healthcare professionals and patients as well as the best models for collaborating with various types of healthcare organizations on medical, scientific and product education, so as to play a more important and positive role in China's healthcare system.

尽管有这些重大变化，会员公司同时也在坚持很多的“不变”。首先，我们始终将患者利益放在所有业务活动的核心位置。我们的根本目标是使用我们的产品与技术，提高对患者的疾病治疗水平。我们坚持认为，患者的信任是制药企业声誉的基础，也是创新的必要条件；没有以道德为基础的商业决策，就没有真正的创新。其次，我们全力致力于提高中国医疗卫生专业人士的医学、科学与产品知识，认为这对于提高对中国患者的疾病治疗水平至关重要。同时，我们坚持以下原则，即任何与医疗卫生专业人士的互动，都应服务于其真实的医学需求，而不应用于影响其独立的医学判断。

基于以上精神，在过去几年间，会员公司在合规控制实践方面，一方面持续落实《行为准则》的要求，另一方面也做出了新的尝试，不断提高合规标准。为此之目的，RDPAC 更新了《行为准则》，以反映行业内商业实践和合规管控措施的发展，并向会员公司提供最新的、基于最佳实践的合规标准。

Despite these major developments, member companies at the same time have persisted with many "constants". First and foremost, we have always put patient's interests at the central position of all of our business activities. We have set our ultimate objective to be using our products and technology to advance the disease treatment for patients. We are steadfast in our belief that patient trust is the basis of our reputation and is essential for innovation, and that there is no true innovation without ethical decision-making. Secondly, we are fully committed to the advancement of the medical, scientific and product knowledge of Chinese healthcare professionals, which we believe is critically important to the enhancement of the disease treatment for Chinese patients. We also are unwaveringly loyal to the fundamental principle that any interaction with healthcare professionals must serve their bona fide medical needs, and must not be used to influence their independent medical judgement.

Guided by these spirits, in the past a few years, with regard to their compliance control practices, member companies have continued to implement the requirements of the Code of Practice, and also have made new endeavors to continuously raise their compliance standards. For this purpose, RDPAC has hereby updated the Code of Practice, so as to reflect the development of the business practices and compliance control measures of the industry, as well as to provide the latest, best practices-based compliance standards to its member companies.

我相信，会员公司均将严格执行本《行为准则》。我也相信，会员公司将继续坚守对中国患者和中国医疗卫生专业人士的承诺，以合规、透明的方式开展并增长在中国的业务，成为中国医疗卫生共同体重要的、负责的、做出积极贡献的一员！

I believe that member companies will implement this Code of Practice strictly. I also believe that member companies will continue to adhere to their commitment to Chinese patients and Chinese healthcare professionals, carry out and grow their business in China in a compliant and transparent manner, and act as an important, responsible and value-adding stakeholder of China's healthcare community!

**彭振科**

*Jean-Christophe Pointeau*

**RDPAC 主席**

*Chairman, RDPAC*

2022 年 09 月 30 日

September 30, 2022

# 《RDPAC 行业行为准则》 (2022 年修订版) 序言

*Foreword of RDPAC Code of  
Practice (2022 Revision)*

康韦  
Kang Wei

RDPAC 执行总裁  
RDPAC Managing Director



中国外商投资企业协会药品研制和开发工作委员会（RDPAC）成立于1999年，由45家具备研究开发能力的全球领先的跨国制药企业组成，隶属于商务部主管的中国外商投资企业协会。秉承“创新引领健康中国”的愿景，RDPAC始终致力于成为中国实现“健康中国2030”目标以及不断提高居民和患者生活质量的重要合作伙伴。

我们坚持“以患者为中心”的价值观，兼顾社会责任与行业发展，为中国不断提供高质量的创新医疗健康和产品和服务；我们为确保患者及时获得优质的创新药品而不懈努力；我们在药物研究和商业运营中保持诚信，遵循最高标准道德规范；我们支持中国建立可持续发展的医疗卫生体系，致力于为中国生物制药产业的发展做出积极的贡献。

Established in 1999, the R&D-Based Pharmaceutical Association Committee (RDPAC), made up of 45 leading multinational pharmaceutical companies with R&D capabilities, is a committee under the China Association of Enterprises with Foreign Investment (CAEFI), which in turn reports to the Ministry of Commerce of the People's Republic of China. With its vision of "Healthier China Through Innovation", RDPAC is committed to becoming an important partner of the Chinese Government as it works to achieve its goal of "Healthy China 2030", and to continuously improving the quality of life of the Chinese people.

We have always had a 'patient-centric' focus, taking into account both social responsibility and industry development, and continuously providing China with high-quality innovative healthcare products and services. We have always made an unrelenting effort to ensure that patients can access high-quality innovative drugs in a timely manner. We have always maintained integrity in drug research and business activities and adhered to the highest ethical and legal standards. And finally, we have always supported the building of a sustainable healthcare system in China and been committed to making a positive contribution to the development of China's biopharmaceutical industry.

创新是医药产业发展的 DNA。信任是声誉的基础，也是创新的必要条件。然而，没有道德决策，就谈不上信任，更没有真正的创新。RDPAC 作为国内最早开始重视医药合规的行业组织，一直致力于塑造行业的道德和诚信文化，引领医药行业行为准则的发展，筑牢医药行业可持续发展的基石。

作为全球制药企业协会体系的一员和积极参与者，RDPAC 在国际制药企业协会联盟 (International Federation of Pharmaceutical Manufacturers & Associations, IFPMA) 准则的基础上，根据中国法律、法规和政策，制定了 RDPAC 的行业行为准则，而且遵守 RDPAC 行为准则是所有会员公司的入会条件之一。除此之外，RDPAC 的国际合作伙伴还包括欧洲制药企业协会联盟、美国药品研发与制造企业协会、美国生物技术创新组织和日本制药企业协会。这让 RDPAC 在很多方面与全球制药企业协会保持同步，得以借鉴和学习医药行业最新国际经验，并将中国医药行业的可贵经验带到国际社会。

1999 年，RDPAC 推出中国医药行业首部《药品推广行为准则》。随后，在 2002 年、2007 年、2012 年、2015 年、2017 年和 2019 年，RDPAC 不断依照中国法律、法规和政策，结合国际制药企业协会准则，持续修订和推出新版的《行为准则》。

Innovation is in the DNA of the pharmaceutical industry and its ongoing development. A major requisite for innovation is integrity, which is also the foundation of reputation. However, without ethical decision-making, there is no integrity, let alone true innovation. As the first industry organization in China to attach great importance to pharmaceutical compliance, RDPAC has been dedicated to fostering a culture of ethics and integrity and to guiding the development of a code of practice for the pharmaceutical industry, at the same time as laying a solid foundation for the sustainable development of the industry.

As a member and an active player of the global pharmaceutical industry association system, RDPAC developed the RDPAC Code of Practice based on the Code of Practice of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and in accordance with Chinese laws, regulations, and policies. We have also made adherence to the Code of Practice a precondition for companies to join RDPAC. In addition, RDPAC's international partners include the European Federation of Pharmaceutical Industries and Associations (EFPIA), the Pharmaceutical Research and Manufacturers of America (PhRMA), the Biotechnology Innovation Organization (BIO) and the Japan Pharmaceutical Manufacturers Association (JPMA). Partnering with these organizations enables RDPAC to keep pace with global pharmaceutical developments across a wide range of areas, to draw on the latest international experience, and to bring the valuable experience of China's pharmaceutical industry to the international community.

In 1999, RDPAC issued the Code of Practice for Drug Promotion, the first of its kind in China's pharmaceutical industry. Subsequently, in 2002, 2007, 2012, 2015, 2017 and 2019, RDPAC released revised versions thereof that accorded with Chinese laws, regulations and policies and referenced the IFPMA Code of Practice.

2022年，RDPAC再次修订《行为准则》，于9月30日由45家会员公司投票批准了《RDPAC行业行为准则》（2022年修订版）。此修订版将于2023年4月1日生效。

二十多年以来，RDPAC不断修订《行为准则》，以反映国际医药行业协会的最新标准、国内法律、法规和政策的最新要求、以及国内医药行业商业实践和合规管控的前沿发展，向会员公司提供最新的和基于最佳实践的合规高标准。

《RDPAC行业行为准则》遵照多数同意的原则，由会员公司投票批准，对所有会员公司都具有强制性约束力。它反映了绝大多数在华跨国制药公司心目中的行业标准，也是众多会员公司遵循的最低行业标准，RDPAC会员公司内部的标准不得低于此标准。同时，RDPAC鼓励会员公司在此基础上制定和执行本公司更高的行为标准。

虽然《RDPAC行业行为准则》不适用于除RDPAC会员公司以外的医药企业，但由于它是国内首部医药行业行为准则，借鉴了国际行业组织准则的可贵经验，首次从行业的角度倡导医药企业合规经营，并制定了较高的行为标准，因此对我国医药行业产生了较大的积极影响。很多非RDPAC会员的医药企业自发地借鉴和参考《RDPAC行业行为准则》，而后来国内其他医药行业组织在制定伦理和合规规范时，都会借鉴和参考《RDPAC行业行为准则》。因此，《RDPAC行业行为准则》对国内医药行业行为规范具有独特的引领意义。

In 2022, RDPAC once again revised the Code of Practice. On September 30, the 45 member companies voted to approve the RDPAC Code of Practice (2022 Revision). This revision will take effect on April 1, 2023.

So, for more than two decades, RDPAC has been continuously revising the Code of Practice to reflect the latest standards of international pharmaceutical industry associations, the latest requirements of Chinese laws, regulations and policies, and the cutting-edge developments in business practices and compliance controls in China's pharmaceutical industry, providing member companies with the latest and highest standards of compliance based on best practice.

The RDPAC Code of Practice, approved by member companies under the principle of a majority vote, is mandatory and binding on all member companies. It represents the industry standard desired by the majority of multinational pharmaceutical companies in China, and the minimum industry standard to be followed by member companies. The in-house standards of RDPAC member companies must not be lower than this standard. At the same time, RDPAC encourages member companies to develop and implement their more stringent in-house codes of practice on this basis.

Although the RDPAC Code of Practice does not apply to non-RDPAC member companies, it has come to exert an overall positive influence on China's pharmaceutical industry. It was the first code of practice in China's pharmaceutical industry, with its appeal further strengthened by being a higher code of practice that has drawn on the experience of international industry associations, and which advocated compliant operation of pharmaceutical companies from an industry perspective for the first time. Indeed, many non-RDPAC member pharmaceutical companies have instinctively learned from the RDPAC Code of Practice by using it as a point of reference, as have Chinese pharmaceutical industry associations when developing ethical and compliant codes. Therefore, the RDPAC Code of Practice is of unique leading significance for the development of codes of practice in China's pharmaceutical industry.

在企业合规方面，近年来国家各项法律法规陆续出台，政策引领持续加强。比如，在政策引领方面，国资委分别于2018年和2022年制定了《中央企业合规管理指引（试行）》和《中央企业合规管理办法》，国家发改委等七部门于2018年联合发布了《企业境外经营合规管理指引》。

在医药合规方面，由于医药卫生和广大人民群众的安全感、幸福感、获得感息息相关，国家对医药行业的监管和合规要求也在不断提高。与此相应，我国医药行业合规建设整体上已经取得了较大发展，许多跨国药企持续加强内部合规管控，而广大医药企业对合规的重视、投入和建设也在不断进步。

制药行业的使命是通过对新药的发现、开发和市场化造福患者，解决未被满足的医药健康需求。遵循高标准的道德规范对于实现这一使命至关重要。秉承“以患者为中心”的使命，RDPAC衷心希望与行业伙伴和各相关方携手努力，为中国医药行业高质量可持续发展的蓬勃发展共同奋斗。

In recent years, China has issued various laws and regulations on corporate compliance, with policy guidance being continuously enhanced. For example, the State-owned Assets Supervision and Administration Commission of the State Council released the Guidance on Compliance Management for Central Stated-Owned Enterprises (Interim) in 2018 and the Measures for Compliance Management of Central Stated-Owned Enterprises in 2022; and seven departments, including the National Development and Reform Commission, jointly issued the Guidance on Compliance Management of Enterprises' Overseas Operations in 2018.

In terms of pharmaceutical industry compliance, given healthcare is so intimately tied to people's sense of security, well-being and inclusion, China has been constantly improving its regulatory and compliance requirements for the industry. At the same time, China's pharmaceutical industry has made great strides in compliance management, with many multinational pharmaceutical companies continuing to strengthen in-house compliance controls, and a large number of domestic pharmaceutical companies making continuous progress in compliance awareness, investment and management.

The mission of the pharmaceutical industry is to address unmet pharmaceutical and health needs through the discovery, development, and marketing of new drugs for the benefit of patients. Following high ethical standards is essential to achieving this mission. In adhering to its 'patient-centric' mission, RDPAC sincerely hopes to work together with industry partners and stakeholders to realize high-quality and sustainable development of China's pharmaceutical industry.

康韦  
Kang Wei

RDPAC 执行总裁  
RDPAC Managing Director

2022年09月30日  
September 30, 2022



# IFPMA 行为准则 (2019)

## 序言

*Foreword of IFPMA Code of  
Practice 2019*

以研发为基础的生物制药行业不同于其他行业，源于我们的产品发挥着延长和拯救生命的重要作用。鉴于我们业务的特性，社会对于这一行业有非常高的期待，在我们未达到期待时的批评也非常严厉。毫无疑问，这一行业在帮助改善全球健康方面为社会带来了巨大的价值，但我们也深刻的认识到，我们永远不能满足于现有的成就。行业的特性要求我们赢得并维持患者的信任，因此我们行业超过两百万的从业人员均秉承更高的标准。信任是我们行业的命脉。毫无疑问，关键的道德和安全价值观必须嵌入到这个高度监管的行业中。

如今，在这个变化越来越快、越来越相互关联的世界里，随着社会期望的提高，我们如何赢得和保持信任是至关重要的。信任是信誉的基础，是创新的基础。没有道德决策的指引就没有真正的创新。以正确的方式行事可以创造竞争优势，从而保障股东利益。道德的商业行为仍面临持续的挑战。在瞬息万变的环境里，几年前可以接受的商业惯例在今天可能已不再适用。因此，IFPMA 的使命是在更高的社会期待的基础上建立和推行整个行业的道德原则标准。

Our research-based biopharmaceutical industry is unlike any other – our products can prolong and save lives. Because of the very nature of our business, society's expectations of our industry are high and criticism is harsh when we do not meet these expectations. There is no doubt that this industry brings great value to society in helping to improve global health but we are deeply conscious we can never rest on our laurels. All who work in it, over two million employees, are properly held to higher standards than most because the very nature of our business requires us to win and retain patient trust. Trust is the life-blood of our industry. There is no doubt that the key values of ethics and safety must be embedded in this highly regulated industry.

Today, as societal expectations step up several gears within a world of ever faster, more and more interconnected change, how we earn and keep the trust is critical. Trust is the basis of reputation and essential for innovation. There is no true innovation without ethical decision making. Doing the right thing creates a competitive advantage and therefore increases shareholder value. Ethical business conduct remains a constant challenge. In a fast-changing world, what was acceptable business practice a few years ago may no longer be adequate today. Thus, IFPMA's mission which rests on the establishment and promotion of ethical principles for the industry as a whole, has to adapt to societal expectations of ever higher standards.

我们的行为准则于 1981 年首次起草，是所有行业中的首个行为准则文件。最初，关于药物疗效和副作用的正确信息传递是该准则的核心。如今，通过定期更新，关于合规的期望更加全面。经过几十年的更新和修订，该准则为临床研究、服务费、继续医学教育支持等制定出一个基于规则的合规框架。许多地方和区域协会以 IFPMA 准则作为其行为准则的指南。

在 2012 年完成的上一次准则修订中，它的范围从市场推广行为延伸出来，覆盖了与医疗卫生专业人士、医疗机构和患者组织的所有交往活动。

如今，在新的准则中，我们进一步提高了标准。我们在全球范围内禁止任何 IFPMA 会员公司以及所有 IFPMA 的相关区域或国内协会的会员公司提供礼品。新修订的准则更加凸显其原则导向的基础，力求体现对商业诚信的更深更广的认识。

Our Code of Practice was first drawn up in 1981, and it was the first one of its kind for any sector. Initially, correct information on the effects and side effects of medicines were at the core of the Code. Today, through periodic updates, expectations regarding compliance are much more comprehensive. Updated and revised over the decades, the Code sets out a rules-based compliance framework for clinical research, fees for services, support for continuing medical education, to name but a few. Many local and regional associations rely on the IFPMA Code as guidance for their own codes of conduct.

The last Code revision in 2012 saw its scope expanded beyond marketing practices to cover all interactions with healthcare professionals, medical institutions and patient organizations.

Now, with the new Code, we are setting the bar higher. We are placing a global ban on gifts for any company that is a member of IFPMA, and for all those firms that are members of our regional and national associations. This new revised Code is more principles-based and seeks to embody a deeper and broader appreciation of business integrity.

我们是否能够做到百分之百正确？不，我们正视犯错的可能性。有了这个新准则，我们重申我们的承诺，即在错误发生时采取行动。我们认真对待这些问题，因为在医疗领域中，信任是我们所做的一切的核心，这种信任是通过行动逐步建立起来的。一家公司的声誉可能在一夜之间一落千丈，也可能会导致整个行业的声誉受损。

在 IFPMA，我们通过会员公司及各国协会成员倡导诚信、道德和合规。全面实施修改后的新准则要做到言出必行，依监管行事。与所有事情一样，这是一项正在进行的工作，我相信还有更多的工作需要完成。但我们永远不会停止改进的步伐。

Do we and will we get it right 100 percent of the time? No, our member organizations are comprised of fallible human beings who make mistakes. With this new Code, we reaffirm our commitment to take action when mistakes occur. We take these matters seriously because in healthcare, trust is at the center of all we do, and that trust is built up over time by deeds. A company's reputation can vanish overnight, and in doing so, can tarnish the reputation of an entire industry.

At IFPMA, across our member companies and throughout our national member associations, we need to champion integrity, ethics, and compliance. Implementing the new and revised Code in full is about walking the talk, about earning our license to operate. As with all things, it is work in progress and I am sure more needs to be done. But we will never stop trying to improve.

*Thomas Cueni*  
*Director General, IFPMA*

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# IFPMA 核心理念

*IFPMA's Ethos*

国际制药企业协会联盟 (IFPMA) 的以研发为基础的生物制药会员公司致力于研发最新的药物和疫苗，按照药品和医疗保健的所有规章制度，以合乎道德的方式开发、推广、销售和分销这些产品。在此过程中，他们向医疗行业提供最新的科学和教育信息以提高其对患者可用的治疗方案的理解，并支持高质量的病患服务。

IFPMA 采取了新的方式，从基于规则的准则规定转变为基于诚信、价值观和原则的文化——最重要的是，还要获得患者的信任。核心理念塑造了以研发为基础的生物制药行业如何基于关怀、公平、尊重和诚实的核心价值观来维持信任，以符合不断变化的社会期望。这些核心理念有助于灌输道德和诚信的文化，以指导我们的商业行为以及 IFPMA 成员与医疗行业各方之间的互动。

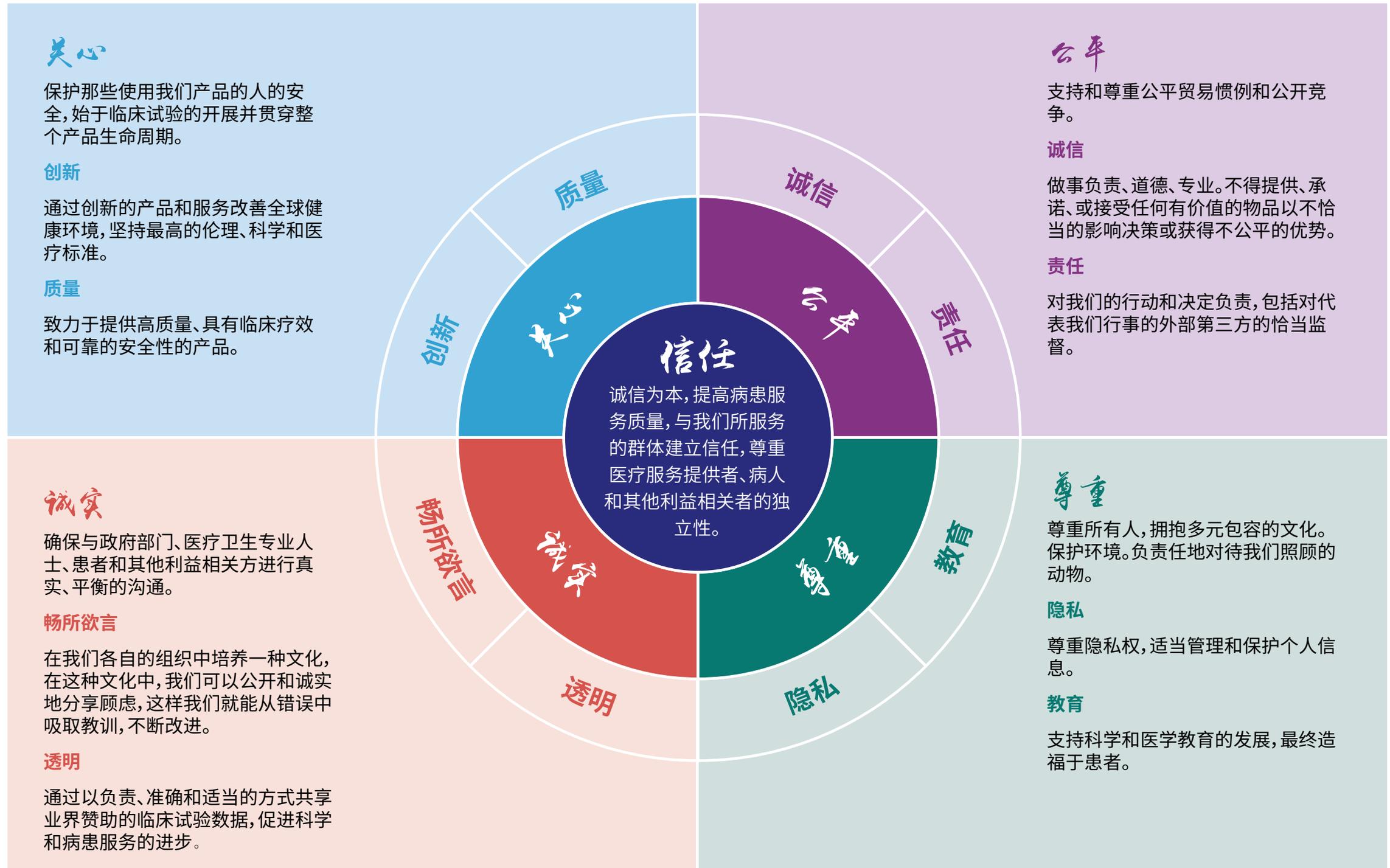
这些核心理念为 IFPMA 行为准则提供了支撑，并搭建了不论情况如何棘手时以诚信行事的框架。

R&D-based biopharmaceutical member companies of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) are responsible for the discovery of most new medicines and vaccines, which they go on to develop, promote, sell and distribute in an ethical manner and in accordance with all the rules and regulations for medicines and healthcare. In doing so, they provide the healthcare community with the latest scientific and educational information to improve understanding of treatment options available to patients and support high-quality patient care.

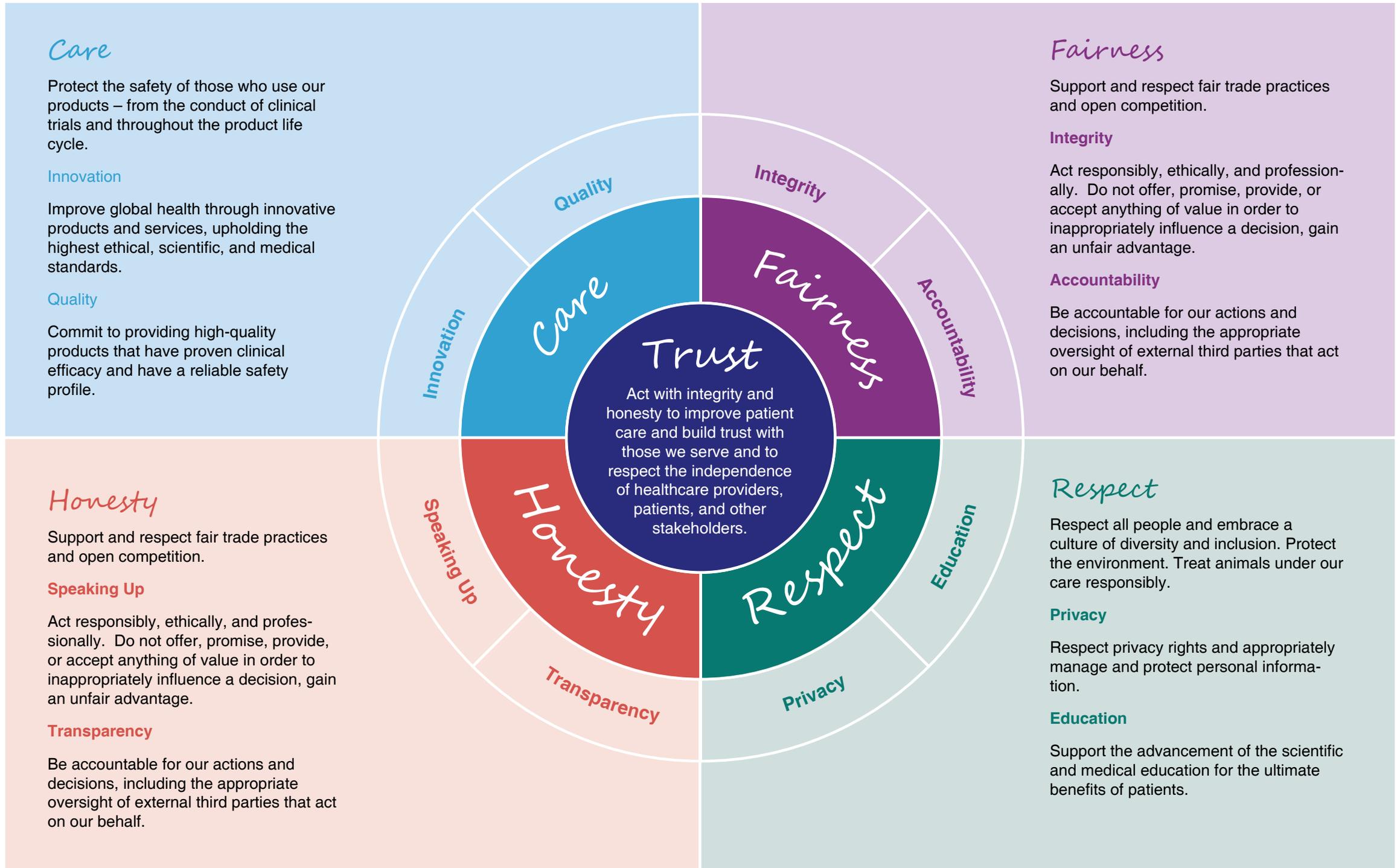
IFPMA has taken a new approach and moved from a Code based on rules to a culture grounded in integrity, values and principles – and, most importantly, patient trust. The Ethos is the foundation that shapes how the R&D based biopharmaceutical industry sustains trust based on the core values of care, fairness, respect and honesty in line with ever-changing society's expectations. The Ethos serves to instill a culture of ethics and integrity needed to guide our business behaviours and interactions between IFPMA members and the healthcare community.

The Ethos underpins the rules of the IFPMA Code of Practice and provides a framework to behave with integrity no matter how testing the circumstances.

# 我们的核心理念 - 建立信任的文化



# Our Ethos – Building a culture of trust



# RDPAC 行业行为准则 (2022 年修订版)

*RDPAC Code of Practice  
(2022)*

# 第一条 范围与定义

## 1.1 范围

RDPAC 行业行为准则（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、医疗卫生组织、患者组织和患者之间的医学互动交流，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 准则的规制范围之内。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、医疗卫生组织、患者组织和患者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，以及代表会员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（OTC）推广；

# Article 1 Scope and Definitions

## 1.1 Scope

The RDPAC Code of Practice (hereinafter also the "RDPAC Code") covers medical interactions with healthcare professionals, healthcare organizations, patient organizations and patients, 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, healthcare organizations, patient organizations and patients – 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 member company employees are covered by the Code, as well as subcontractors that carry out tasks on behalf of the member 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 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；
  - 某些特定形式的非推广类信息与活动；
  - 对医疗器械的推广。
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、及有关影响会员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。
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。
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。
- RDPAC鼓励会员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。
- Pricing or other trade terms for the supply of pharmaceutical products, including promotion and marketing of pharmaceutical products to commercial customers;
  - Certain types of non-promotional information or activities; and
  - Promotion of medical devices.
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 member 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 member company and its products is also not covered by the Code.
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. 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, member companies should respect the customer's role as a healthcare professional and, if applicable, comply with the requirements of the RDPAC Code.

RDPAC encourages competition among member 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

在 RDPAC 准则中：

- “药品”指根据《中华人民共和国药品管理法》第2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、化学药和生物制品等。
- “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。
- “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。
- “医疗卫生组织”指在医疗卫生领域从事任何专业活动的组织，包括但不限于：(i) 医疗机构；(ii) 医学协会、医师协会和医院协会；(iii) 行业协会；以及 (iv) 慈善基金会。

## 1.2 Definitions

For the purposes of the RDPAC Code:

- "pharmaceutical product" means, as set forth in Article 2 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 traditional Chinese medicines, chemical drugs, biologic products, etc.
- "promotion" means any activity undertaken, organized or sponsored by a member company which is directed at healthcare professionals to promote the prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s) through all methods of communications, including the internet.
- "healthcare professional" means any member of the medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, recommend, purchase, supply, or administer a pharmaceutical product.
- "healthcare organization" means an organization that performs any professional activities in the healthcare area, including without limitation: (i) medical institutions; (ii) medical associations, physician societies, and hospital associations; (iii) industry associations; and (iv) charitable foundations.

- “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，例如公立医院、私立医院和互联网医院。
- “医学互动交流”或“医学互动交流项目”是指会员公司向医疗机构、专业学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。
- “患者组织”指主要代表患者、他们的家人和 / 或护理人员的利益和需求的非营利机构。
- “讲者项目”指由会员公司组织的、由医疗卫生专业人士就药品或医疗器械产品或任何医学或科学知识向医疗卫生专业人士参会者发表演讲或进行演示的活动。
- "medical institution" means typically an organization that is comprised of healthcare professionals and/ or that provides healthcare or conducts healthcare research, e.g., public hospitals, private hospitals, and Internet hospitals.
- "medical interaction" or "medical interaction programs" means events through which member 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.
- "patient organization" means a not-for-profit institution that primarily represents the interests and needs of patients, their families and/or caregivers.
- "speaker program" means a program organized by a member company at which a healthcare professional makes a speech or presentation to healthcare professional attendees about a drug or medical device product or any medical or scientific knowledge.



## 第二条 医学互动交流项目 的基本原则

### 2.1 医学互动交流项目的基本原则

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项目的目的是造福患者和提高医疗水平。医学互动交流项目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 医学互动交流项目的透明度

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

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。

## 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 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.

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项目，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项目，则需在主办方知情并同意的情况下做出上述披露。

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项目涉及的费用、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。明确区分与医疗卫生组织及医疗卫生专业人士互动产生的费用和内部员工费用。

医学互动交流项目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 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.

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 healthcare organizations and healthcare professionals and those for internal expenses for employees.

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. 当会员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 member 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**

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。

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。

### **Article 3 Pre-Approval Communications and Off-Label Use**

No pharmaceutical product should be promoted for use in China until the requisite approval for marketing (manufacturing or importing) for such use has been given by the NMPA.

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。

## 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。

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 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 member companies.

The prohibition of pre-approval communication 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, promotions for an unlicensed medicine or use.

## Article 4 Standards of Promotional Information

### 4.1 Consistency of Product Information

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

Annotation 8:

8. Where necessary or appropriate within the context of Chinese regulatory requirements, member 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、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。

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。

## 4.2 Accurate and Not Misleading

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

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

药品推广信息应能通过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适当的药品信息。

注释 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。在可以进行比较式表述的情况下，比较式表述不应引起误解。

### 4.3 Substantiation

Promotion should be capable of substantiation either by reference to the approved labeling or by scientific evidence. Such evidence should be made available on request to healthcare professionals. Member 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.

Annotation 10:

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。

## 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 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 should 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项目

### 7.1 医学互动交流项目

#### 7.1.1 涉及出国的医学互动交流项目

会员公司不得组织或赞助医疗卫生专业人士赴其本国以外参加医学互动交流项目（包括支持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（2019）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医疗卫生专业人士赴其本国以外参加医学互动交流项目；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其本国以外，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

## Article 7 Medical Interaction Programs with Healthcare Professionals

### 7.1 Medical Interaction Programs

#### 7.1.1 Medical Interaction Programs Involving Foreign Travel

No member company may organize or sponsor a medical interaction program for healthcare professionals (including supporting 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 2019, 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 member 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) 作为有关活动主题的相关资源或专家均在医疗卫生专业人士本国以外

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项目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项目时，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。该指南的具体内容请见本准则附件一，或参考在 IFPMA 官网发布 / 更新的该指南文件 (<https://www.ifpma.org/resources/publications/>)。

### 7.1.2 医学互动交流项目中的药品推广信息

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参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，大多数讲者和参会者应来自会议所在国以外的其他国家；

(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, member 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, or refer to the Guidance posted and updated on IFPMA Website (<https://www.ifpma.org/resources/publications/>) .

### 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;

- 尚未在会议所在国注册的药品推广材料（不包括本准则第 7.6.2 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。
- Promotional material (excluding promotional aids as described in Article 7.6.2) 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

医学互动交流项目举办的地点应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项目。在选择医学互动交流项目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。

### 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. Member 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.

## 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、度假酒店、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，或参考在 IFPMA 官网发布 / 更新的该指南文件 (<https://www.ifpma.org/resources/publications/>)。

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，会员公司应当确保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。

## 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, or refer to the Guidance posted and updated on IFPMA Website (<https://www.ifpma.org/resources/publications/>).

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 限制

附属于医学互动交流项目的招待仅可提供给：

- 医学互动交流项目的参会者。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项目的招待应限于：(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项目期间相匹配，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。

### 7.1.4 Limits

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

- 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.

## 禁止津贴

会员公司不得就参加医学互动交流项目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“中等适度和合理的”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，须得到会员公司总经理或其特别授权的代理人的批准和认可。

### 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娱乐、休闲和社交活动。会员公司在组织医学互动交流项目时，可以向参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、在互动交流举办地播放的背景音乐或进行的本地表演。

## 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 member company.

### 7.1.5 Entertainment

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

Annotation 15:

15. Member 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, member 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 member 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.

## 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 支持

会员公司仅可出于满足医疗卫生专业人士未获满足的医学、科学或产品知识需求之目的，为医疗卫生专业人士参加医学互动交流项目提供支持，提供支持应满足以下条件：

- (a) 有关医学互动交流项目符合本准则第 7.1 条关于招待活动的规定；
- (b) 对医疗卫生专业人士的参会支持只限于对旅行、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，或直接将支持资金转入其账户；并且

## Annotation 16:

16. Member companies 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 Support

Member companies may provide support to healthcare professionals for attending medical interaction programs only for the purpose of satisfying such healthcare professionals' unmet needs for medical, scientific or product knowledge, on the condition that such providing of support should meet the following requirements:

- (a) The medical interaction program complies with the requirements in this Code as described in 7.1;
- (b) Support 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 member company make any payment or transfer any support fund directly to a healthcare professional or a hospital department; and

(e) 会员公司不得以医疗卫生专业人士对药品的处方、使用、推荐、推广、医院准入或医院采购的已有的或可能有的有利决定，作为对其提供参会支持的前提条件或考量因素。

### 7.2.1 直接支持个人医疗卫生专业人士

“直接支持个人医疗卫生专业人士”或“直接支持”是指会员公司在向医疗卫生专业人士提供参加医疗卫生组织所主办的医学互动交流项目的支持时：(i) 选择参会的医疗卫生专业人士；或(ii) 在已知悉某医疗卫生专业人士的身份的情况下，支付该医疗卫生专业人士的参会费用。

会员公司在开展直接支持时须遵循以下基本原则：

(a) 会员公司应根据行业通行合规做法，建立关于可以被支持对象的适当标准；

(e) A member company should not use healthcare professionals' past or potential favorable decision in connection with the prescription, use, recommendation, promotion, hospital access or hospital procurement of pharmaceutical products as a precondition to or consideration factor for providing support to such healthcare professionals.

### 7.2.1 Direct Support to Individual Healthcare Professionals

"Direct support to individual healthcare professionals" or "direct support" means those arrangements in which a member company, when providing support to healthcare professionals for them to attend medical interaction programs organized by healthcare organizations: (i) selects the healthcare professional attendees; or (ii) pays the fees for a healthcare professional's attendance in the medical interaction program when it already knows the identity of the healthcare professional.

Member companies should adhere to the following basic principles when conducting direct supports:

(a) the member company should establish proper criteria on who may receive the support that are in line with prevailing industry compliance practices;

(b) 会员公司在选择参加医学互动交流项目的医疗卫生专业人士时，其销售职能部门可以发挥有限的、协助或辅助性质的作用（如推荐参会者），但不发挥任何决定性作用；

(c) 如果会员公司明知医疗卫生专业人士接受和使用直接支持会违反其所任职医疗机构的内部规章，则不应提供直接支持；以及

(d) 会员公司应对直接支持设定适当的标准，以避免其被认为是不当行为的可能性，并应在设定标准时考虑至少以下因素：(i) 对每名医疗卫生专业人士开展直接支持的频率的合理水平；及 (ii) 对每个医学互动交流项目，获得直接支持的医疗卫生专业人士的总人数的合理水平。

(b) when the member company selects healthcare professionals to attend the medical interaction program, its sales function may play limited role that is facilitating or auxiliary in nature (such as recommending the attendees), but may not play any decision-making role;

(c) if the member company expressly knows that a healthcare professional, by receiving and using the direct support, will violate the internal rules of his/her employer medical institution, it may not provide the direct support; and

(d) the member company should develop proper criteria for direct supports so as to avoid the perception of impropriety, and shall take into account at least the following factors when developing such criteria: (i) for a healthcare professional, the reasonable frequency of direct supports; and (ii) for each medical interaction program, the reasonable total number of healthcare professionals that may receive direct supports.

### 7.3 服务费

医疗卫生专业人士通常作为顾问提供以下服务：

- 作为医学互动交流项目的讲者和 / 或主持人；

### 7.3 Fees for Services

Healthcare professionals are typically engaged as consultants and advisors for services such as:

- Lecturing at and/or chairing of medical interaction programs;

- 参与付费的医学或科学研究、临床试验或培训；
- 在专家小组会议中提供咨询服务。

会员公司在对上述服务作安排时，须确保其安排满足以下条件：

#### 服务协议

- (a) 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。
- (b) 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。

#### 医疗卫生专业人士的选择及管理

- (a) 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。

- involvement in medical/scientific studies, clinical trials or training services;
- Consulting in advisory board meetings.

The arrangements which cover these genuine services must, to the extent relevant to the particular arrangement, fulfill all the following criteria:

#### Contracting of Legitimate Services

- (a) The legitimate need for the services must be clearly identified and documented in advance.
- (b) A written contract or agreement must be in place prior to commencement of the services, specifying the nature of the services to be provided and the basis for payment of those services.

#### Selection and Governance of Consultants

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

(b) 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、医学知识、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。

#### 公平市场价值及服务费管理

(a) 向医疗卫生专业人士支付服务费或报销的标准须合理并符合公平市场价格标准。

(b) 此外，各会员公司应制定其对每个医疗卫生专业人士所支付的服务费上限。例如向每个医疗卫生专业人士所支付的年度讲课费次数上限、金额上限，以及会员公司服务次数的年度上限等。

(b) The selection of healthcare professionals must be exclusively based on objective criteria, including but not limited to education, knowledge, expertise and experience in a particular therapeutic area, etc., which should be directly related to the justifiable purpose for the needed service. The selection of any healthcare professional must be validated prior to commencement of the service by functions that have the requisite skills and are fully independent from the sales function, so as to ensure that the above objective criteria are met and the above justifiable purpose is achieved.

#### Fair Market Value and Compensation Governance

(a) Any compensation or reimbursement made to a healthcare professional in conjunction with any service should be reasonable and based on fair market value.

(b) Additionally, each member company must establish caps on service fees to be paid to each healthcare professionals, such as the caps on the number and amount of speaker fee payments to each healthcare professional per year, the number of services to the member company per year, etc.

(c) 下列限制特别适用于仅在会员公司提供讲者培训后发生的讲课服务：原则上，当讲者与其他参会人员来自于同一科室时，禁止支付讲课费。

### 禁止性原则

- 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；
- 收集处方信息不属于向医疗卫生专业人士付费的合法服务；
- 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。

#### 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，会员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。

IFPMA 提供了《关于服务费的指南说明》，请参考在 IFPMA 官网发布 / 更新的该指南说明 (<https://www.ifpma.org/resources/publications/>)。

(c) The following limitation applies specifically to lecturing, which should occur only after member company-provided speaker training: in general, any fee-for-service, where the speaker and all participants come from the same department of a hospital, is forbidden.

### Prohibitions of Note

- The hiring of any healthcare professional must not be an inducement to prescribe, recommend, purchase, supply, and/or administer any medicine.
- Collection of prescribing data is not a legitimate service warranting compensation to healthcare professionals.
- Payments of fee-for-service cannot be made in cash or with cash equivalents.

#### Annotation 17:

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

IFPMA provides Note for Guidance on Fees for Services, please find this Guidance posted and updated on IFPMA Website (<https://www.ifpma.org/resources/publications/>).

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 should follow the code of practice for the market research industry (*ICC/ESOMAR INTERNATIONAL CODE ON MARKET AND SOCIAL RESEARCH.*)

## 7.4 讲者项目

## 7.4 Speaker Programs

### 7.4.1 讲者项目的目的

### 7.4.1 Purpose of Speaker Programs

会员公司仅可出于以下目的组织讲者项目：向医疗卫生专业人士参会者提供真实的产品、医学或科学知识，且医疗卫生专业人士参会者对于上述知识有客观和合理的学习需要，以提高他们的医学知识或疾病治疗能力。

Member companies may organize speaker programs only for the purpose of providing bona fide product, medical or scientific knowledge to the healthcare professional attendees that the healthcare professional attendees have an objective and reasonable need to learn for the advancement of their medical knowledge or their capabilities for disease treatment.

会员公司不得以任何不合法或不道德的目的组织讲者项目，无论这种不合法或不道德的目的是全部还是部分的目的，例如为医疗卫生专业人士演讲者创造获得报酬的机会或不正当影响医疗卫生专业人士参会者的医疗判断。

Member companies may not organize speaker programs for any illegal or unethical purpose, such as creating an opportunity for the healthcare professional speaker to receive remuneration or unduly influencing the medical judgement of the healthcare professional attendees, whether such illegal or unethical purpose is the entire or partial purpose of the program.

### 7.4.2 选择医疗卫生专业人士讲者

会员公司可以聘请医疗卫生专业人士作为讲者项目的讲者，以向参会者进行教育或信息沟通。

### 7.4.3 对参会者的要求

会员公司应采取适当措施，确保参会者应仅限为对于了解会员公司药物的有关收益、风险和适当使用及相关疾病状态有独立的、真实的学习需求的人群。

此外，会员公司应考虑采取适当措施，避免任何人不合理、不必要地重复参加多次内容相同或基本相同的讲者项目。

## 7.5 演示材料的审阅

在满足以下条件的前提下，会员公司可以审阅讲者将使用的演示材料：

### 7.4.2 Selection of Healthcare Professional Speakers

Member companies may engage healthcare professionals as speakers for speaker programs to educate and inform the attendees.

### 7.4.3 Requirements on Attendees

Member companies should take appropriate measures to ensure that the attendees are limited to those who have an independent, bona fide educational need to receive information about the benefits, risks and appropriate use of the member company's medicines and related disease states.

In addition, member companies should consider taking appropriate measures to prevent unreasonably and unnecessarily repeated attendance by any person in multiple speaker programs that have the same or substantially the same contents.

## 7.5 Review of Presentation Materials

Member companies may review the presentation materials that the speaker will use, on the condition that such review should meet the following requirements:

- (a) 会员公司应仅出于恰当且必须的目的审阅材料，例如确保：(i) 材料中的产品和医疗信息是公平、客观、准确和正确的；(ii) 材料不存在虚假或误导性宣传、药品广告或医疗广告的不合理风险；(iii) 材料不包含任何中国法律法规不允许的标签外信息；并且
- (b) 会员公司不应将此类审阅用作影响讲者或参会者的独立判断的工具。

## 7.6 礼品及其他

本部分所涉及各类被允许提供的物品，均不得以对某药品的处方、推荐、采购、供应、使用或推广等义务作为条件。

- (a) the member company should review the materials only for proper and necessary purposes, such as ensuring: (i) the product and medical information in the materials is fair, objective, accurate and correct; (ii) the materials do not carry unreasonable risk of false or misleading promotion, drug advertisement, or medical treatment advertisement; and (iii) the materials do not contain any off-label information that is not allowed by Chinese law or regulation; and
- (b) the member company should not use such review as a tool to influence the independent judgement of the speaker or attendees.

## 7.6 Gifts and Other Items

Items in this Article, where permissible, must never constitute an inducement to prescribe, recommend, purchase, supply, administer or promote a pharmaceutical product.

### 7.6.1 禁止提供礼品

会员公司不应向医疗卫生专业人士提供（无论是直接提供或是通过诊所和机构提供）个人礼品（如：体育或娱乐项目的入场券，社交或风俗礼品等）。禁止提供现金、现金替代物或者个人服务。个人服务包括任何与医疗卫生专业人士的职业无关、仅医疗卫生专业人士个人获益的服务。

### 7.6.2 推广辅助用品

推广辅助用品是指用于药品推广的非现金价值物品（不包括第5条和第6条中的推广资料）。

禁止向医疗卫生专业人士提供用于处方药推广的推广辅助用品。

在会员公司自办会议或第三方会议中，在满足“最小价值”及“最少数量”的前提下可以提供仅带有会员公司标识的笔和记事本。

禁止提供的推广辅助用品包括便利贴、鼠标垫、日历等。

### 7.6.1 Prohibition of Gifts

Gifts for the personal benefit (such as sporting or entertainment tickets, social courtesy gifts, etc.) of healthcare professionals (either directly or through clinics and institutions) are prohibited. Providing or offering cash, cash equivalents or personal services is also prohibited. For these purposes, personal services are any type of service unrelated to the healthcare professional's profession and that only confer a personal benefit to the healthcare professional.

### 7.6.2 Promotional Aids

A promotional aid is a non-monetary item given for a promotional purpose (which does not include promotional materials as defined in art. 5 and 6).

Providing or offering them to healthcare professionals in relation to the promotion of prescription-only medicines is prohibited.

Pens and notepads can be provided to healthcare professionals in the context of member company organized or third-party events as long as they are member company branded only, of minimal value and quantity for the purpose of the event.

Examples of banned promotional aids include sticky notes, mouse pads, calendars, etc.

在满足“最小价值”及“最少数量”的前提下，会员公司仅可在推广非处方药品时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。

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。

### **7.6.3 为提高医疗及病患服务的医用物品**

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、且有助于其实现医疗和病患服务的医用物品。

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。

医用物品可以带有会员公司名称而不可带有产品名称，除非产品名称对于患者正确使用该医用物品而言是必须的。

Promotional aids of minimal value and quantity may be provided or offered to healthcare professionals solely for the promotion of over-the-counter medicines if such promotional aids are relevant to the practice of the healthcare professionals.

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

### **7.6.3 Items of Medical Utility to Enhance the Provision of Medical Services and Patient Care**

Items of medical utility may be offered or provided by member companies if such items are of modest value, do not offset routine business practices, and are beneficial to enhancing the provision of medical services and patient care.

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

Items of medical utility can include the member company name, but must not be product branded, unless the product's name is essential for the correct use of the item by the patient.

应由医疗卫生专业人士或其雇主自行承担费用的日常执业工作物品包括听诊器、手术手套，血压计和针头等。

单个医用物品的价值不得超过人民币 500 元。

#### **7.6.4 为提高病患服务的信息及教育物品**

会员公司可向医疗卫生专业人士提供帮助其或其患者学习疾病及其治疗手段的信息或教育物品，前提是这类物品主要用于教育目的且不具有额外价值。

向医疗卫生专业人士提供的信息及教育物品可带有会员公司名称而不可带有产品名称，除非产品名称对于患者正确使用该医用物品而言是必须的。

书籍和订阅的费用必须合理。其他信息或教育物品的价值应当适度。

Items such as stethoscopes, surgical gloves, blood pressure monitors and needles are examples of routine business expenses, and they are expected to be supplied by the healthcare professionals themselves or their employers.

Value cannot exceed five hundred (500) RMB per item.

#### **7.6.4 Informational & Educational Items that Enhance Patient Care**

Informational or educational items provided to healthcare professionals for their education or for the education of patients on disease and its treatments may be offered by member companies provided that the items are primarily for educational purposes and do not have independent value.

Informational and educational items provided to healthcare professionals can include the member company name, but must not be product branded, unless the product's name is essential for the correct use of the item by the patient.

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

## 第八条 样品

### 8.1 样品

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。

### 8.2 有效控制和责任落实

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制，包括对样品的分发、交付、验收。

## Article 8 Samples

### 8.1 Samples

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 third party. Samples should be marked as such so that they cannot be resold or otherwise misused.

### 8.2 Control and Accountability

Member companies should have adequate systems of control and accountability for samples provided to healthcare professionals through medical institutions including for distribution, delivery and acceptance of samples.



## 第九条 临床研究和透明度

### 9.1 透明度

会员公司致力于提高由其参与主办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。

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。

## Article 9 Clinical Research and Transparency

### 9.1 Transparency

Member 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.

Member 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

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。

注释 18:

18. 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。

## 9.2 Distinct from Promotion

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

Annotation 18:

18. 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). Corresponding fees paid to healthcare professionals in the Studies must be reasonable and commensurate with the effort made by the healthcare professionals.

## 第十条 与医疗卫生组织的 互动

会员公司提供财务资助给医疗卫生组织时须遵循以下基本原则：

- (a) 提供给有一定声誉的机构(而非个人或医疗机构科室)；
- (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) 应在提供支持前完成尽职调查。

## Article 10 Interactions with Healthcare Organizations

In general, member company may provide financial support to healthcare organizations 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 should be paid directly to the organization receiving the support ; and
- (e) Due diligence should be completed before such support is provided.

## 10.1 资助

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

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。

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

- (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。
- (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。单纯对会员公司支持的致谢（例如，在非推广性的字段中体现会员公司名称或展现会员公司标识）不被认定为利益回报。

## 10.1 Grants

Member companies may give financial support/grant to healthcare organizations to support their independent activities, including but not limited to medical education activities, scientific research etc.

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.

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

- (a) Objectives and expected results of such activity/project should be clearly defined in the agreement to be entered into by both parties.
- (b) The member company should not receive any direct benefit in return, such as services, naming right, etc.. A mere recognition for such support, such as disclosing the member company's identity or displaying the member 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。

(d) 会员公司应建立适当的机制, 以审核并批准每项资助, 如建立一个由相关职能部门的代表组成的委员会 (应至少包括医学部和法律 / 合规部的代表)。

(e) 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。

**10.2 赞助** (会员公司与医疗卫生组织共同合作的活动 / 项目不在此范围)

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卫生组织, 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:

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

(d) The member company should establish a proper mechanism to review and approve each Grant, such as establishing a committee consisting of representatives from relevant functions (with representatives at least from Medical and Legal/ Compliance).

(e) 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 Sponsorship** (Activities/projects through collaboration between healthcare organizations and member companies are not included in this section)

Member companies may give financial or non-financial support to healthcare organizations 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) 赞助应基于公开的商业邀请函/招商函；
- (b) 会员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。

### 10.2.1 独家赞助

对于医疗卫生组织主办的医学互动交流项目，在特定情况下，独家赞助可能是合理且适当的。会员公司在遵守以下原则的前提下，可以向此类项目提供独家赞助：

- (a) 作为一项基本原则，会员公司应对此类受到其独家赞助的项目实施有效的合规管控，且在现实可执行的前提下（即除非接受赞助的医疗卫生组织不予配合），合规管控标准（如讲者选择标准、讲课费标准、第三方供应商管理标准等）应等同于或基本等同于其对自办项目所适用的标准。

- (a) The sponsorship should be based on an open invitation letter;
- (b) The member 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.

### 10.2.1 Sole Sponsorship

For medical interaction programs organized by healthcare organizations, in certain instances, sole sponsorships may be reasonable and appropriate. Member companies may provide sole sponsorships to such programs if they adhere to the following principles:

- (a) As an underlying principle, the member company should implement effective compliance control on these programs with sole sponsorships, and to the extent practicable (i.e., unless the sponsored healthcare organization refuses to cooperate), the compliance control criteria (such as speaker selection criteria, speaker fee criteria, third-party vendor management criteria, etc.) should be the same with, or substantially the same with, the criteria for their self-organized programs.

- (b) 会员公司对医疗卫生组织主办的医学互动交流项目提供独家赞助，应有充分、必要且合理的理由，并且应与活动的客观特征一致而不矛盾。
- (c) 会员公司应充分尊重医疗卫生组织主办方的中立性和独立性，不得以独家赞助为工具，影响医疗卫生组织主办方在赞助项目的目标、组织和执行方面的中立性和独立性。
- (d) 只有在以下情况下，提供赞助的会员公司才可以就该赞助项目向医疗卫生组织主办方提供某些医疗或学术支持或后勤协助：(i) 医疗卫生组织主办方对此类支持或协助有客观需要；(ii) 会员公司对赞助项目的关键设计不具有任何类型的决策权，如项目主题和内容、演讲者、参会者等。
- (e) 会员公司应建立内部控制机制，以确保以上合规要求得到有效执行。

- (b) The member company should provide sole sponsorship to medical interaction programs hosted by healthcare organizations only if there is an adequate, necessary and reasonable justification, and having only one sponsor is consistent, not contradictory, with the objective features of the programs.
- (c) The member company should fully respect the neutrality and independence of the healthcare organization organizer, and should not use the sole sponsorship as a tool to influence the neutrality and independence of the healthcare organization organizer with respect to the objective, organization and operation of the sponsored program.
- (d) The sponsoring member company may provide certain medical or academic support or logistical assistance to the healthcare organization organizer with respect to the sponsored program only if: (i) there is an objective need by the healthcare organization organizer for such support or assistance; and (ii) the sponsoring member company does not exercise any type of decision-making right with respect to the program's key design, such as program topics and content, speakers, attendees, etc.
- (e) The member company should establish an internal control mechanism to ensure the effective implementation of the above compliance requirements.

此外，作为一项总体性原则，对于一个医学互动交流项目，一家会员公司所提供的赞助金额在项目总赞助金额中的比例越高，则其对该项目的合规管控责任就越高，该会员公司相应地应考虑使用更接近于适用于独家赞助项目的标准对该项目开展合规管控，特别是当该会员公司对于某医学互动交流项目的赞助金额达到项目总赞助金额的50%或以上时。

### **10.3 对医疗卫生组织的尽职调查**

在向医疗卫生组织提供任何赞助、捐赠或资助之前，会员公司应对医疗卫生组织进行适当的尽职调查，以确定医疗卫生组织是否是此类赞助、捐赠或资助的合适接受者。

In addition, as a general principle, for a particular medical interaction program, when a member company's sponsorship accounts for a larger percentage of the total sponsorship that the program receives, the member company's obligation for the compliance control for the program will become higher, and accordingly the member company should consider using criteria more comparable with those for sole sponsorship programs for compliance control on such program, in particular when the sponsorship paid by the member company for a certain medical interaction program accounts for 50% or more of the total sponsorship that the program receives.

### **10.3 Due Diligence on Healthcare Organizations**

Before providing any sponsorship, donation or grant to a healthcare organization, member companies should perform proper due diligence on the healthcare organization, so as to determine whether the healthcare organization is an appropriate recipient for such sponsorship, donation or grant.

为此目的，会员公司应：

- (a) 制定有关此类尽职调查的正式程序；
- (b) 以合理的详细程度规定尽职调查的标准；
- (c) 按照相关程序进行尽职调查；
- (d) 在以下情况下更新尽职调查 (i) 应以预先定义的频率定期更新； (ii) 如有任何事件发生并表明医疗卫生组织存在任何潜在不合规活动或任何不合规风险，应随时更新；
- (e) 妥善处理尽职调查中发现的问题，并实施适当的风险管控措施；以及
- (f) 保留相关的尽职调查记录。

## 10.4 专家咨询会议

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：

For this purpose, member companies should:

- (a) develop formal procedures for such due diligence;
- (b) set forth the criteria for the due diligence in reasonable details;
- (c) perform such due diligence in accordance with relevant procedures;
- (d) renew the due diligence: (i) periodically with a pre-defined frequency; and (ii) at any time when any incident emerges that indicates any potential non-compliance activities or any non-compliance risks of the healthcare organization;
- (e) address issues identified in the due diligence properly, and implement appropriate risk mitigation measures; and
- (f) retain relevant due diligence records.

## 10.4 Advisory Board Meetings

Advisory Board Meetings (ABMs) are non-promotional events and are intended to seek advices or insights from healthcare professional 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
- Scientific: Medical/Clinical Development/Health Economy;
- 市场领域：产品策略 / 定位 / 品牌核心信息
- Marketing: Product Strategy/Positioning/Brand Key Messaging; or
- 若在以上未提及的领域举办专家咨询会议，应该得到会员公司指定的委员会或者管理层的特批
- ABMs involving areas not mentioned above should have special approval from the committee designated by or the management of the member 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 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，应确保能够对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参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。
  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会员公司指定的委员会或者管理层的特批。
  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。
  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。
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. Internal participation – Internal participants of ABMs should take an active role that is clearly defined, and passive participation should be kept at 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. 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. 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.

## 第十一条 与患者组织的互动

### 11.1 范围

制药行业与患者组织有许多共同利益。与患者组织的所有互动都必须符合道德规范。必须尊重患者组织的独立性。

### 11.2 参与声明

在与患者组织合作时，会员公司必须确保从一开始就明确会员公司的参与和参与的性质。任何会员公司不得要求成为患者组织或其任何项目的独家资助者。

### 11.3 书面文件

向患者组织提供财务支持或实物捐助的会员公司必须有书面文件，说明支持的性质，包括任何活动的目的及其资助。

## Article 11 Interactions with Patient Organizations

### 11.1 Scope

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

### 11.2 Declaration of Involvement

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

### 11.3 Written Documentation

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

## 11.4 活动

会员公司可以为患者组织会议提供财务支持，前提是会议主要目的具备专业性、教育性和科学性的性质，或以其他方式支持患者组织的使命。当会员公司为患者组织召开会议时，会员公司必须确保场地和位置合适并有利于信息交流。此外，会员公司提供的任何餐饮或茶点在当地标准下都必须是适度的。

## 11.4 Events

Member companies may provide financial support for patient organization meetings, provided that the primary purpose of the meeting is professional, educational, and scientific in nature, or otherwise supports the mission of the patient organization. When member companies hold meetings for patient organizations, member companies must ensure that the venue and location is appropriate and conducive to informational communication. In addition, any meals or refreshments provided by a member company must be modest as judged by local standards.



## 第十二条 对医学继续教育的支持

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。

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，并参考在 IFPMA 官网发布 / 更新的关于医学继续教育的指南说明 (<https://www.ifpma.org/resources/publications/>)。

## Article 12 Support for Continuing Medical Education

Continuing medical education (CME) helps ensure that healthcare professionals obtain the latest and most accurate information and insights on therapeutic areas and related interventions that are critical to the improvement of patient care and overall enhancement of the healthcare system. The primary purpose of CME must be the enhancement of medical knowledge and therefore, only for such purpose, will financial support from member companies be appropriate.

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

Member companies must also follow Article 7 of the RDPAC Code where applicable, and refer to the Note for Guidance on Continuing Medical Education posted and updated on IFPMA Website (<https://www.ifpma.org/resources/publications/>).

## 第十三条 公司程序与 职责分配

### 13.1 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。

### 13.2 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。

### 13.3 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会员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会员公司的药品推广材料。

## Article 13 Company Procedures and Responsibilities

### 13.1 Procedures

Member 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.

### 13.2 Training

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

### 13.3 Responsibilities for Approving Promotional Communications

Each member company should designate an employee with sufficient knowledge and appropriate qualifications to be responsible for approving all promotional communications. Alternatively, the member company may designate a senior employee to take such responsibility under the guidance from adequately qualified scientific personnel.

## 第十四条 对准则的违反、投 诉与准则的执行

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三即《投诉及争议解决规程》。

## Article 14 Infringement, Complaints, and Enforcement

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 III).



# 附件

*Appendix*

## 附件一

## IFPMA 关于赞助医药互动交流活动的指南说明

来源 IFPMA 官网 (<http://www.ifpma.org/>)

### 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，以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。

## Appendix 1

## IFPMA Note for Guidance on Sponsorship of Events and Meetings

From: IFPMA Website (<http://www.ifpma.org/>)

### 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.

《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，包括资助医疗卫生专业人士的医学教育、向组织活动的医学会提供赞助、租赁展览场地、向演讲人支付服务等。制药企业参与医学教育的方式也多种多样，包括举办其公司会议，或支持其他人主办的会议。《IFPMA 行为准则》第 7 条（互动交流与会议）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

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 funding to assist in the medical education of healthcare professionals, provision of sponsorship agreements to medical societies organizing events, hiring of exhibition space, support of speakers etc. Pharmaceutical companies are involved in the medical education through company specific meetings, and also by supporting meetings organized by other parties. These activities are covered by Article 7 (Events and Meetings) of the IFPMA Code. The 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 overall impression given by all the various arrangements should be kept in mind. Pharmaceutical companies might find it helpful to clearly document the reasons as to why

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。

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：

- 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。

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.

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:

- 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 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；
- 所选地点应尽量减少参会者的旅行并将安全因素纳入考量；
- 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的**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 aim to minimize travel for the attendees and take security considerations into account;
- 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—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，或有相关研发设施等，则活动项目也可成为选择该地点的理由。

## 2. 评价互动交流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参会者的能力；
- 会议设施（包括展览场地）应仅对参会者开放；
- 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；

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 facilities.

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

- The venue must be 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 including exhibition 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;

- 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，会议场所应能提供安全可靠的住宿条件；
- 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）。

### 3. 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）：

下列原则适用于所有第三方组织者（如医学会，药师或医师群体）。

IFPMA 并不针对第三方是否可以为成员或其他医疗卫生专业人士组织包含娱乐的活动，和 / 或在以休闲设施闻名的场所举办活动，和 / 或没有可信的科学项目安排等问题做出决定。

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

### 3. Criteria to consider when deciding the company level support of an event organized by a third party such as a medical society (non-exhaustive):

The principles below apply to all third party organizers (e.g. medical society, groups of pharmacies or physicians).

It is not for IFPMA to decide whether third parties can organize events for their members and other healthcare professionals that include entertainment, and/or take place in sumptuous locations known for leisure facilities, and/or do not have credible scientific program.

但是，如果制药企业考虑提供任何形式的财务资助（如资助医疗卫生专业人士参会，支持会议的举办，租借展览场地）时，应当考虑下列问题。

a. 关于科学项目（《IFPMA 行为准则》第 7.1.1 条）

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获取更多信息或建议修改赞助条件。

- 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？
- 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？
- 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？

If, however, pharmaceutical companies consider providing a financial contribution whatever the format (e.g. supporting healthcare professionals' participation, supporting the organization of the event, renting a booth), the following questions should be considered.

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

If the answer to any of the questions below is 'no', then pharmaceutical companies should obtain further information or suggest amendments before agreeing to any involvement with the meeting.

- Is the scientific program available on the event organizer's website well in advance of the meeting?
- Does the scientific program cover the whole duration of the event with content generally filling the business hours each day?
- 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)

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获取更多信息或建议修改赞助条件。

- 在互动交流之前、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? 如果安排了休闲活动, 是否安排在日间大会期间?
- 餐饮是否安排在旅游景点或文化遗产 / 文化旅游区?
- 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)?
- 是否期望获得公司对休闲娱乐等活动的资助?
- 如果安排了休闲娱乐活动, 是否由参会人员承担此类费用?

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

If the answer to any of the questions below is 'yes', then pharmaceutical companies should obtain further information or suggest amendments before agreeing to any involvement with the meeting.

- Is any entertainment (such as sightseeing tours or leisure activities) organized in connection with the event before, during or after it? Is there unreasonable or frequent traveling for meals during the event? If there is leisure activity, is it planned in the daytime during the congress?
- Are meals arranged in tourist or heritage/ cultural attractions?
- Are any of the descriptions on the program such that they appear to be excessive (e.g. champagne reception, gala dinner, etc.)?
- Is there an expectation that sponsoring companies fund such activities?
- If there is leisure activity, are they self-funded by the participants?

c. 关于随行客人 (《IFPMA 行为准则》第 7.3 条)

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。

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：

- 随行人员 / 客人是否需要支付全部费用（且不会获得制药行业提供的任何形式的补贴）？
- 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？
- 是否明确地不鼓励参会者提前到达或推迟离开？

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

If the answer to any of the questions below is 'no', then pharmaceutical companies should obtain further information or suggest amendments before agreeing to any involvement with the meeting.

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

- Are they required to pay the full costs incurred by their participation (that is not subsidized by the pharmaceutical industry in any way)?
- Are healthcare professionals expected to participate in the meeting rather than encouraged to join any program for accompanying persons?
- Is it clear that attendees are not being encouraged to arrive before the meeting starts or stay on after it ends?

#### 4. 其他应考虑的标准——官方会议材料和网站

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：

- 其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？
- 其宣传是否提及会议举办前或举办后的其他活动内容？
- 是否提及对参会人员提供的个人服务？
- 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？

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。

#### 4. Other criteria to consider – Official meeting materials and websites

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:

- Is the focus purely on the educational merit of the meeting or does it promote tourism or hospitality as one of its attractions?
- Are pre- or post-event activities mentioned?
- Are there references to personal services provided to attendees?
- Who is mentioned as a supporter of the event? Is it medical societies, or similar, or the local tourist board, etc.?

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

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交流活

- 欧洲制药工业协会联盟的 e4ethics 平台 <http://www.efpia-e4ethics.eu>
- MedTech 大会评估平台 <http://www.ethicalmedtech.eu/>
- 西班牙制药行业协会大会评价平台 <http://www.codigofarmaindustria.es>
- IPCAA 医疗大会指南 <http://www.ipcaa.org>

## Existing Tools and Resources

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 or not to support a specific event.

- EFPIA's e4ethics platform  
- <http://www.efpia-e4ethics.eu>
- MedTech Congress Assessment Platform  
- <http://www.ethicalmedtech.eu/>
- Farmaindustria Congress Assessment Platform  
- <http://www.codigofarmaindustria.es>
- IPCAA Congress Healthcare Guideline  
- <http://www.ipcaa.org>



## 附件二

# IFPMA 关于服务费 的指南说明

来源 IFPMA 官网 (<http://www.ifpma.org/>)

## 引言

制药企业可以向医疗卫生专业人士等人员支付对其产品或业务相关事项提出专业意见的服务费。

《IFPMA 行为准则》第 7.4 条介绍了服务费的支付条件，其中包括该服务需求的正当理由以及服务前必须签订书面合同的要求。可付费的服务包括多种形式，例如 作为医学互动交流项目的讲者和 / 或主持人，参与付费的医学或科学研究、临床试验或培训，在专家小组会议中提供咨询服务，参与市场调研等。如果提供服务费，应明确表示这是对此类工作和建议所支付的报酬。服务费必须与所付出的劳务以及接受者的专业地位相符。《IFPMA 行为准则》第 7.4 条要求服务费必须合理，并反映所提供服务的公平市场价值。应考虑每个参与者所在国家的实践。

## Appendix II

# IFPMA Note for Guidance on Fees for Services

From: IFPMA Website (<http://www.ifpma.org/>)

## Introduction

Pharmaceutical companies can compensate healthcare professionals and others for advice on subjects relevant to their products or business. Payment of fees for services are covered in Article 7.4 of the IFPMA Code of Practice including the requirement for a legitimate need for the service and that a written contract be agreed in advance. Fees for services include many activities such as speaking at and/or chairing meetings and events, involvement in medical/scientific studies, clinical trials or training services, participation in advisory board meetings, participation in market research. If a fee for service is offered it should be made clear that it is a payment for such work and advice. Fees for services must be commensurate with the time and effort involved and the professional status of the recipients. Article 7.4 of the IFPMA Code requires that compensation must be reasonable and reflect the fair market value of the services provided. Account should be taken of the country of practice of each participant.

## 实用指南 - 考查要点

IFPMA 认为，以下要点有助于确保服务费用安排符合其所要求的标准，并且相关信息可用于评估建议。考查要点反映了在公司须对投诉作出回应的情况下可能需要哪些信息。

对以下问题的回答应该为“是”：

- 1 参与者所获报酬是否不超过“公平市场价值”？
- 2 如果产品 / 适应症未获得许可，公司是否确信没有推广该产品 / 适应症？
- 3 所有涉及服务活动费的人员（工作人员、第三方、参与者）是否都清楚需求和预期产出？
- 4 安排（如场地、茶点、旅行和合同）是否合适？
- 5 是否有涉及利益冲突时的管理机制？
- 6 一年内的聘用次数和向个人支付的总报酬是否合理？

## Practical Guidance – points to consider

The IFPMA considers that the following points are helpful to ensure that fee for service arrangements meet the required standards and that the relevant information is available to those assessing proposals. The points to consider reflect what information might be required in the event that a company has to respond to a complaint.

The answers to the following questions should be 'yes':

- 1 Are the participants being paid no more than 'fair market value'?
- 2 If the product/indication is unlicensed, is the company confident that there is no promotion of that medicine/indication?
- 3 Are all those involved with the fee for service activity (staff, third parties, participants) clear on the need for it and expected output?
- 4 Are the arrangements (such as venue, refreshments, travel, and contract) appropriate?
- 5 Are there arrangements to manage any conflicts of interest?
- 6 Are the number of engagements and total compensation paid to an individual in one year reasonable?

## 实用指南 – 专家咨询会议额外的考查要点

涉及服务费的活动类型之一是专家咨询会议，制药企业在必要时可通过专家咨询会议了解公司尚不知晓答案的合法商业问题。

专家咨询会议必须符合《IFPMA 行为准则》第 7 条有关会议的要求，包括会议应当在有助于实现业务目的的恰当地点召开，且用于招待的支出按当地标准应当是中等适度和合理的。

专家咨询会议应满足正当性要求，会议参与者的选择和数量应经过独立审查；应仅根据其专业知识进行选择参与者，以便他们能够对会议的目的和预期结果做出有意义的贡献。应限制参会者的人数以确保能够对既定会议目标进行充分和高质量的讨论，而不应由受邀者的参加意愿决定。会议日程应安排足够的讨论时间，并且必须侧重于获得

## Practical Guidance – additional points to consider for advisory boards

One example of a fee for service activity is advisory boards which are used by the pharmaceutical industry when necessary to answer legitimate business questions to which the company does not already know the answer.

Advisory board meetings must meet the requirements for meetings in Article 7 of the IFPMA Code including that the meeting is held in an appropriate venue conducive to the business purpose of the meeting and that hospitality is moderate and reasonable as judged by local standards.

To be considered a legitimate advisory board the choice and number of participants should stand up to independent scrutiny; each participant should be chosen according to their expertise only, such that they will be able to contribute meaningfully to the purpose and expected outcomes of the meeting. The number of participants should be limited so as to allow active participation by all and should not be driven by the invitees' willingness to attend. The agenda should allow adequate time for discussion and must focus on gaining advice. The number of meetings and the number

建议。会议次数和每次会议的参加人数应根据需要来决定，即两者均应严格限制为不超过达到规定目标所需的数量。除非有合理理由，否则应避免就同一议题召开多次专家咨询会议。公司应确定是否举行以及何时举行专家咨询会议。专家咨询会议的会议邀请应说明会议的目的、预期的咨询角色和所需工作量。

专家咨询会议的内容应仅与当前事项相关。仅当为满足规定目标必须对特定药物的临床数据进行讨论时，方可在专家咨询会议上进行此类讨论。否则这类会议可能被视为该药物的变相推广或对未经许可的药物或适应症的推广。

应保留会议记录，列出会议目的、参会者和会议结果。会议报告和结论只能与对专家咨询会议结果有合法权益的人员分享。

of participants at each should be dictated by need i.e. both should be strictly limited to no more than the number required to achieve the stated objective. Multiple advisory boards on the same topic should be avoided unless a clear need can be demonstrated. Companies should determine if and when advisory board meetings are required. Invitations to participate in an advisory board meeting should state the purpose of the meeting, the expected advisory role and the amount of work to be undertaken.

The content of advisory board meetings should relate solely to the matter in hand. Discussion of clinical data about a particular medicine should only take place at an advisory board if such discussion is essential to meet the stated objective. To do otherwise might risk the meeting being viewed as disguised promotion for that medicine or promotion of an unlicensed medicine or indication.

A record of the meeting should be prepared, to include the meeting's objectives, attendees and outcomes. The meeting report and conclusions should only be shared with those who have a legitimate interest in the outcomes of the advisory board.

除上述要点外，IFPMA 认为以下要点有助于确保专家咨询会议符合要求。对以下问题的回答应该为“是”：

- 7 公司是否有合法的需寻求解答的商业问题？
- 8 专家咨询会议是否是最合适的信息获取方式？
- 9 公司是否完全和独立确定了其对专家咨询会议的需求？
- 10 参会代表 / 会议的数量是否严格限于回答问题所需的数量？
- 11 每位参与者是否具备相关的专业知识，能够对会议的目的和预期产出作出有意义的贡献？
- 12 参与者人数是否受限，以便所有人能够积极参与？
- 13 会议日程是否有充分的讨论时间？大部分时间是否用于获取参与者的反馈？

In addition to the points above, the IFPMA considers that the following points are helpful to ensure that advisory boards meet the required standards. The answers to the following questions should be 'yes':

- 7 Does the company have a legitimate unanswered business question?
- 8 Is an advisory board the most appropriate way of obtaining the information?
- 9 Has the company wholly and solely determined its need for the advisory board?
- 10 Is the number of delegates/meetings strictly limited to that required to answer the question?
- 11 Does every participant have the relevant expertise to contribute meaningfully to the purpose and expected output of the meeting?
- 12 Is the number of participants limited so as to allow active participation by all?
- 13 Does the agenda allow adequate time for discussion? Is a significant majority of the time spent on feedback from the participants?

14 会议邀请是否明确说明会议目的、预期的咨询角色和所需工作量？

15 计划向参与者展示的资料是否与其在回答业务问题中的作用相关？

公司应确保考虑以下问题：

16 这些信息是否可以通过其他方式获得？

17 是否期望参与者做任何准备工作？

18 如何选择参与者？

19 公司中的哪些成员或哪些成员代表公司参加会议？他们的出席是否合理？他们是否有明确的角色？公司员工 / 其他人与参与者的比例是否合理？

14 Does the invitation to participate clearly state the purpose of the meeting, the expected advisory role and the amount of work to be undertaken?

15 Are intended presentations to participants relevant to their role in answering the business question?

Companies should ensure that the following questions are also considered:

16 Could the information be obtained any other way?

17 Are the participants expected to do any preparatory work?

18 How were the participants selected?

19 Who from, or on behalf of, the company is attending? Can their attendance be justified? Do they have a defined role and is the ratio of company employees/others to participants reasonable?

- 20 会议结果如何记录？结论 / 建议报告将有何用途？
- 20 How are the outcomes documented? What use will be made of the conclusions / recommendations report?
- 21 当同一药物 / 治疗领域的专家咨询会议已召开时，再次召开此类会议是否有明确的理由？
- 21 When advisory boards for the same medicine/therapy area have already taken place are there clear reasons for another one?
- 22 将与参与者进行哪些后续跟进工作？如果进行了后续跟进工作，考虑到专家咨询会议的非推广性质，这些工作是否适当？
- 22 What follow-up, if any, is to be undertaken with participants? If so, is this appropriate given the non-promotional nature of advisory boards?



## 附件三

## 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工作委员会（简称“RDPAC”）的各会员公司（简称“会员公司”）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。

## Appendix III

## 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") 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 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，以及就会员公司有关准则的良好合规实践进行分享、学习的平台。
- 1.4 RDPAC 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。
- 1.5 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。
- 1.3 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.
- 1.4 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 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.

1.6 RDPAC 应在中华人民共和国法律、法规及行政规章许可的范围内，提高会员公司对于行业行为准则的了解及认知程度，并推动会员公司开展培训课程，包括向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。

1.7 RDPAC 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) 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；

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).

1.7 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) 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。

## 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。

- 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. 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。

## 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. 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，不得向其其他人披露。
- 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）。
- 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. 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.
- 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) 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:

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

RDPAC 常务理事和 / 或法律顾问收

Executive Director and/or General Counsel,  
RDPAC

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

Office Bldg 1, Rm 506, Landmark Tower

No. 8 Dongsanhuanbei Rd., Chaoyang District

邮编: 100004

Beijing 100004, PR China

电邮地址: complaint@rdpac.org

Email: complaint@rdpac.org

3.3 投诉核实。

3.3 Complaint Validation.

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:

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均为 RDPAC 的会员公司;
- 2) 提交的争议事宜系由投诉人善意提交的真实、客观事宜;
- 3) 争议行为可被认定为违反行业行为准则规定的行为;

- 1) both the Complainant and the Respondent are Member Companies of RDPAC;
- 2) it appears to be a genuine matter submitted in good faith;
- 3) the complained behavior can be identified as violation or breach of the Code;

- 4) 处理投诉所需的相关证据及信息充分；
- 5) 投诉申请已由投诉人的总经理进行了书面证实。

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。

3.5 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。

- 4) there is sufficient evidence or information to enable the Complaint to be processed;
- 5) the Complaint has been verified in writing by the GM of the Complainant.

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 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

- 4.1 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。
- 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。
- 4.3 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話，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. Response

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

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

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. Mediation

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

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

### 6.1 审理委员会

- 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。
- 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。

### 6.2 专家组

- 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 的反馈情况对专家组进行审核。
- 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。

## 6. Panel Review

### 6.1 Hearing Panel

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

### 6.2 Panel Pool

- 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 on the feedback of the WG.
- 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

- 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。
- 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。
- 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成员担任主席。

### 6.3 Appointment of Panelists

- 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) 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) 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 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

- 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：<https://www.ibanet.org/resources>。
- 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。

## 6.4 Acceptance and Confirmation of Appointment

- 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: <https://www.ibanet.org/resources>
- 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

- 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。
- 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。
- 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。

## 6.5 Panel Decision

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

## 7. 处罚

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。

- 1) 违规方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。
- 2) 违规情况较为轻微的，应对违规方处以 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。

## 7. Sanctions

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) 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) 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，可对违规方处以中止会员资格六（6）至二十四（24）个月的处罚。同时，可要求违规方（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方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。
- 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方的总部。

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。

- 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) 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 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。

完结

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).

End



## 附件四

**RDPAC 会员公司**

(更新日期: 2023 年 3 月)

雅培	赫尔森
艾伯维	益普生
艾尔建	杨森
爱而开	协和麒麟
安进	利奥制药
爱施健	灵北
阿斯泰来	美纳里尼
阿斯利康	默克
百特	默沙东
拜耳医药保健	萌蒂中国
渤健	诺华
勃林格殷格翰	诺和诺德
百时美施贵宝	欧加隆
凯西	辉瑞
中外制药	罗氏
第一三共	赛诺菲
卫材	参天制药
礼来	施维雅
爱的发制药	住友
辉凌医药	武田
匈牙利吉瑞大药厂	梯瓦制药
吉利德	优时比制药
葛兰素史克	赞邦

*Appendix IV***RDPAC Member Companies****(Updated in March 2023)**

Abbott	Helsinn
AbbVie	Ipsen
Allergan	Janssen
ALK	Kyowa Kirin
Amgen	LEO Pharma China
Aspen	Lundbeck
Astellas	Menarini
AstraZeneca	Merck
Baxter	MSD
Bayer HealthCare	Mundipharma
Biogen	Novartis
Boehringer Ingelheim	Novo Nordisk
Bristol Myers Squibb	Organon
Chiesi	Pfizer
Chugai	Roche
Daiichi Sankyo	Sanofi Aventis
Eisai	Santen
Eli Lilly	Servier
Ethypharm	Sumitomo
Ferring	Takeda
Gedeon Richter	Teva
Gilead	UCB
GlaxoSmithKline	Zambon







## **R&D-based Pharmaceutical Association Committee (RDPAC)**

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