RDPAC

RDPAC 数字医疗合规分项指南：与患者及患者组织的互动

RDPAC Digital Health Compliance Sub-Guidance: Interactions with Patients & Patient Organizations

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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 (RDPAC)

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引言 Introduction

RDPAC 认识到与患者和患者组织的互动对了解患者的经历与认知，帮助塑造并推动未来医疗发展，提高患者护理质量，造福个人及全社会具有重要意义。根据《RDPAC 数字医疗合规指南》（“《数字医疗指南》”）的原则，RDPAC 现发布本《数字医疗合规分项指南：与患者及患者组织的互动》（本“分项指南”），为会员公司设计并实施通过数字化渠道与患者（在适用的情况下包括护理人员）和患者组织的互动，提供不具约束力的指导。我们同时鼓励会员公司将本分项指南的一般原则用于线下场景中与患者和患者组织的互动。

The RDPAC recognizes the importance of interacting with patients and patient organizations to understand their experiences and knowledge to help shape and develop the future of healthcare, thereby improving the quality of patient care for the benefit of individuals and society as a whole. In accordance with the principles under the RDPAC Digital Health Compliance Guidance (the “Digital Health Guidance”), the RDPAC now issues this Digital Health Compliance Sub-Guidance: Interactions with Patients & Patient Organizations (this “Sub-Guidance”), aiming to serve as a non-binding resource for member companies when designing and implementing their interactions with patients (including caregivers where applicable) and patient organizations through digital channels. Member companies are also encouraged to use the general principles of this Sub-Guidance for interactions with patients and patient organizations that take place in off-line settings.

本分项指南应依据《数字医疗指南》进行解读，会员公司应始终遵守《RDPAC 行业行为准则（2022 年修订版）》（“《RDPAC 准则》”）开展相关活动。此外，在开展相关活动时，会员公司还必须遵守适用于这些活动的所有中国法律法规，包括但不限于药品管理、反不正当竞争、反贿赂与反腐败、广告和商业宣传、数据保护及药物警戒报告相关法律法规。

This Sub-Guidance should be read in accordance with the Digital Health Guidance, and member companies should conduct relevant activities always in accordance with the RDPAC Code of Practice 2022 (the “RDPAC Code”). In addition, when conducting relevant activities, member companies must comply with all the Chinese laws and regulations that are applicable to such activities, including without limitation laws and regulations on drug administration, anti-unfair competition, anti-bribery and anti-corruption, advertisement and commercial promotion, data protection and pharmacovigilance reporting.

为明确起见，本分项指南的侧重点是为临床研发过程之外与患者和患者组织的互动提供指导。对于临床研发过程中的互动，会员公司应主要从相关法律法规，而非本分项指南寻求指导。

For clarity, this Sub-Guidance is focused on interactions with patients and patient organizations outside of the clinical research and development process. For interactions within the clinical research and development process, member companies should seek guidance primarily from relevant laws and regulations, not this Sub-Guidance.

1 互动原则 Principles of Interaction

1. 非推广性质

会员公司必须按照专业及道德规范要求与患者和患者组织开展互动。会员公司不得利用此类互动宣传或推荐任何药品、医疗器械产品或医疗服务。会员公司不应利用此类互动不当影响患者的意见，或向患者输送不当利益。

会员公司应制定适当的控制措施，确保落实上述要求。

1. Non-promotional in nature

Member companies must conduct interactions with patients and patient organizations professionally and ethically. Member companies must not use such interactions to promote or recommend any pharmaceutical product, medical device product or medical service. Member companies should not use such interactions to unduly influence the opinions of patients, or to funnel improper benefits to patients.

Member companies should establish appropriate control measures to ensure the implementation of the above requirements.

2. 科学、公正且客观的信息传播

会员公司可能有向患者和患者组织传播医学、科学和疾病信息的合理需要，以提高患者对疾病的认识，从而为患者提供更好的护理，并且，在相关活动可以促进实现上述目的的前提下，会员公司可开展此类信息传播活动。但会员公司不应以增加产品销量为直接目的开展此类活动。

为此，传播的信息必须科学、公正、全面、准确且不具有误导性，且不应以强调某一特定产品优越性的推广方式进行传播。

在任何情况下，会员公司均不应向患者和患者组织传播有关会员公司产品的超适应症用途的信息，不论该等信息是否具有推广性质。

2. Scientific, fair and objective information communication

Member companies may have a reasonable need to communicate medical, scientific and disease information to patients and patient organizations for the purpose of increasing their disease awareness so as to provide better patient care, and may conduct such activities as long as such activities may advance such purpose. Member companies should not conduct these activities for the direct purpose of increasing product sales.

For this purpose, information communicated must be scientific, fair and balanced, accurate and non-misleading, and should not be communicated in a promotional manner that emphasizes the superiority of a particular product.

Member companies should not, under any circumstances, communicate information, whether promotional or non-promotional, about off-label uses of their products to patients and patient organizations.

3. 服务报酬

制药公司和相关协会可根据具体情况、所需服务类型、所须经验及专长知识，聘请患者个人提供相关服务。对于此类服务，会员公司可根据该等患者的经验、专长知识及服务时间，向其支付服务报酬。此类聘请必须遵守适用于任何合约服务的一般原则：存在合法需求、根据服务的公平市场价值支付服务费、签署书面协议等。

3. Remuneration for services

Pharmaceutical companies and associations may engage the services of individual patients depending on the circumstances, type of service, experience and expertise required. For such services, member companies may renumerate such patients for the service they have provided based on their experience, expertise and time. Such engagements must be conducted on the basis of the general principles applicable to any contracted services: presence of a legitimate need, service fee payment based on the service's Fair Market Value ("FMV"), execution of a written agreement, etc.

4. 合理的招待

会员公司在与患者和患者组织互动时，可提供或支付相应的适当招待或招待费用，但前提是此类招待：

- 应附属于互动项目的主要目的；
- 仅提供给互动项目的参与者；且
- 根据当地标准判断，应当是中等适度且合理的招待。

在评估向患者提供招待是否适当时，会员公司应参考《RDPAC 准则》第 7.1.3、第 7.1.4、第 7.1.5 和第 7.6 条关于适当的地点和住宿、招待、娱乐和礼品限制的规定及其他相关规定，并在适当的情况下执行该等规定。

原则上，对于面向患者或患者组织的虚拟互动项目，会员公司不应提供或支付招待或招待费用，例如任何旅行、住宿、餐饮和茶点费。

4. Reasonable hospitalities

Member companies may provide or pay for hospitalities that are appropriate for the interactions with patients and patient organizations, provided that such hospitalities are:

- incidental to the primary purpose of the interaction program;
- provided only to participants in the interaction program; and
- moderate and reasonable by local standards.

Member companies should refer to Section 7.1.3, 7.1.4, 7.1.5 and 7.6 of the RDPAC Code regarding appropriate venue and accommodation, limits on hospitality, entertainment and gifts and other requirements when assessing the appropriateness of providing hospitalities to patients, and implement these requirements where appropriate.

In principle, for virtual interaction programs with patients or patient organizations, a member company should not provide or pay for hospitalities, such as any cost for travel, accommodation, meals and refreshments.

5. 患者互动项目：使患者受益

与患者或患者组织的任何互动的最终目的是为患者、医疗系统及全社会实现更好的医疗成果。因此，会员公司通过患者互动项目提供的任何患者支持（不论是经济还是实物支持）的目的，都应该是使患者受益，而非使医疗卫生专业人士或其他人受益。

5. Patient interaction programs: benefiting patients

The ultimate goal of any interaction with patients or patient organizations is to achieve better outcomes for patients, healthcare systems and the society as a whole. Therefore, any patient support, whether financial or in-kind, provided through member companies' patient interaction programs should be for the benefit of patients, not HCPs or others.

6. 无诊疗活动

作为一般原则，会员公司在与患者互动时不应开展任何诊断或治疗活动。如果会员公司收到患者或公众寻求关于诊断或治疗信息的问询，会员公司必须始终建议患者向医疗卫生专业人士咨询，以获取进一步信息。

6. No diagnosis and treatment activities

As a general principle, member companies should not engage in diagnostic or treatment activities when interacting with patients. When a member company receives inquiries from patients or the general public seeking information relating to diagnosis or treatment, the company must always advise the patients to consult a healthcare professional (HCP) for further information.

7. 独立性及隐私

会员公司应在诚信及相互尊重、患者自愿参与和完全透明的基础上与患者和患者组织开展互动。会员公司不应利用此类互动干扰医患关系。

患者和患者组织的独立性必须受到尊重。《RDPAC 准则》规定，“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”。我们鼓励会员公司避免造成只有一家公司为患者组织主办的项目提供全部资金支持的情况。

会员公司应尊重患者的隐私权，妥善管理并保护个人信息。患者隐私和患者医疗信息的保密性至关重要，应根据适用的法律法规予以保护。

7. Independence and privacy

Member companies should conduct interactions with patients and patient organizations on the basis of integrity and mutual respect, the patients' voluntary participation, and full transparency. Member companies should not use such interactions to interfere with the physician-patient relationship.

The independence of patients and patient organizations must be respected. The RDPAC Code provides that "no member company may require that it be the sole funder of the patient organization or any of its programs". Member companies are encouraged to avoid situations where only one company provides all financial support to a program organized by a patient organization.

Member companies should respect the privacy rights of patients, and appropriately manage and protect personal information. Patient privacy and the confidentiality of patient medical information are paramount, and should be protected in accordance with applicable laws and regulations.

8. 患者安全；履行药物警戒义务

患者互动项目的架构应确保通过药物警戒程序和控制措施维护患者安全。在与患者和患者组织开展互动活动时，会员公司必须确保遵守适用的法律法规中关于药物警戒责任的规定。

8. Patient safety; fulfilment of pharmacovigilance obligations

Patient interaction programs should be structured to ensure that patient safety is maintained through pharmacovigilance procedures and controls. When conducting interaction activities with patients and patient organizations, member companies must ensure compliance with pharmacovigilance-related responsibilities as set forth in applicable laws and regulations.

2 具体场景指导

Specific Scenario Guidance

1. 面向患者的虚拟互动项目

会员公司可组织虚拟患者互动项目，或支持第三方的虚拟患者项目。这些项目可包括通过数字化平台为患者提供健康管理、疾病认知、疾病筛查、疾病预防和疾病管理教育。在任何情况下，这些项目的目的都不应是宣传特定的药品、医疗器械产品或医疗服务。

1. Virtual interaction programs with patients

Member companies may organize virtual patient interaction programs, or support third-parties' virtual patient events. These programs may include health management, disease awareness, disease screening, disease prevention and disease management education to patients via digital platforms. In all circumstances, the purpose of these programs should not be to promote a specific pharmaceutical product, medical device product, or medical service.

会员公司和相关协会可在患者互动项目中聘请患者作为讲者或专题讨论组成员，向他们支付适当报酬，并为其承担合理的相关费用。会员公司和相关协会还可聘请患者提供咨询及顾问服务，包括邀请其参加顾问会议或市场调研项目。

会员公司可根据患者的经验，决定是否聘请特定患者作为分享病例的讲者，但分享的信息不应包括对特定产品的宣传或认可。任何向患者支付的、与其在线提供讲者服务相关的讲者费均应符合公平市场价值原则，且会员公司应建立适当的公平市场价值评估机制。

患者可自行决定是否参加此类项目，会员公司不应选择参加此类项目的患者或干预患者的参与决定或治疗决定。一般而言，在虚拟患者互动项目中，会员公司不应提供或支付任何形式的招待或礼品。

此外，会员公司应确保患者互动项目中的交流内容（例如在线问答或在线健康问卷）不构成非法诊疗活动。会员公司应采用适当的方法实现这一目的，例如标准化短语回复和禁用评论弹幕。

Member companies and associations may engage patients as speakers or panelists in patient interaction programs, remunerate them properly, and to bear associated expenses that are reasonable. Member companies and associations may also engage patients to provide consulting and advisory services, including through participation in advisory meetings or market research projects.

Member companies may make decisions on engaging specific patients as speakers for case sharing on the basis of their experience, but such sharing should not include promotion or endorsement of a specific product. Any payment of speaker fees to patients in connection with online speaking services should comply with the FMV principle, and member companies should establish an appropriate FMV mechanism.

Patients may voluntarily decide on whether to participate in these programs, and member companies should not select the patient attendees or interfere with the participation decisions or treatment decisions of individual patients. For virtual patient interaction programs, as a general rule, member companies should not provide or pay for hospitalities or gifts of any kind.

In addition, member companies should ensure that communications in patient interaction programs (e.g., online Q&A or online health questionnaires) do not constitute unlawful diagnosis and treatment activities. Member companies should implement appropriate methods to achieve this purpose, such as standardized response phrases and prohibitions on pop-up comments.

2. 与患者组织的数字化互动项目

《RDPAC 准则》第 11 条的规定适用于与患者组织的互动，该条规定为会员公司提供了应遵守的最低标准。

在数字化场景中，与患者组织的数字化互动项目可以采取多种形式，例如合作开发可供患者用于健康管理的数字化健康管理系统。此类项目的目的及重点应该是分享知识，促进患者组织达成其使命。

为确保患者组织的独立性及对患者组织使命的适当支持，在开展相关数字化互动项目前，会员公司应对该项目进行全面的风险评估，并对合作患者组织进行适当的尽职调查。在评估为患者组织数字化项目提供支持是否适当时，会员公司应参考《RDPAC 准则》第 10 条中规定的原则，并在相关情况下适用这些原则。

2. Interaction with patient organizations on digital programs

Interactions with patient organizations are governed by Article 11 of the RDPAC Code, which has provided the minimum standards for member companies.

In digital scenarios, digital interaction programs with patient organizations may take various forms, such as co-development of a digital health management system that patients may use for health management. The purpose and focus of such interaction programs with patient organizations should be to enable knowledge sharing and to advance the mission of patient groups.

To ensure the independence of the patient organization and appropriate support of the organization's mission, member companies should conduct an overall risk-based assessment of the program and perform appropriate due diligence on the collaborating patient organization prior to carrying out a digital interaction program. Member companies should refer to Section 10 of the RDPAC Code when assessing the appropriateness of supporting digital patient organization programs and apply those principles where relevant.

3. 远程医疗；远程药物递送

会员公司可与互联网医院合作开展远程医疗项目，与电商平台和电商零售药店合作开展远程药物递送项目。在这些项目中，会员公司可与患者进行特定互动或沟通，例如协助患者登记、向患者提供相关购药信息等。

3. Telemedicine; remote drug delivery

Member companies may collaborate with Internet hospitals for telemedicine programs, and with e-commerce platforms and e-commerce retail pharmacies for remote drug delivery programs. In connection with these programs, member companies may conduct certain interactions or communications with patients, such as assisting with patient registration, providing patients with relevant drug-purchase information, etc.

在开展远程医疗或远程药物递送项目前，会员公司应对拟议项目进行全面评估和审评，尤其应注意是否存在对患者的治疗或医疗决定产生不当影响的风险，及项目中使用的材料是否会造成广告及宣传风险。

此外，会员公司还应采取适当措施，确保患者的保密权和数据完整性不受损害。为此，此类项目须征得患者的适当知情同意，确保以清晰易懂的方式向患者充分解释有关远程医疗或远程药物递送项目的所有必要信息，包括项目的运作方式、局限性、可供选择的适当替代方案、隐私保护、可能发生的技术故障及其潜在后果等。

Prior to initiating telemedicine or remote drug delivery programs, member companies should conduct a thorough evaluation and assessment of the proposed program, paying particular attention to the risk of undue influence on patients' treatment or medical decisions, as well as the advertising and promotional risk of materials to be used in such programs.

In addition, member companies should take appropriate measures to ensure that patient confidentiality and data integrity are not compromised. In this regard, proper informed consent by patients is required, which should ensure that all necessary information regarding the telemedicine or remote drug delivery programs be explained fully to the patient in a clear and understandable manner, including how the program works, its limitations, suitable alternatives available, privacy protection, the possibility of technological failure and its potential consequence, etc.

4. 患者支持项目；患者援助项目

会员公司提供的患者支持项目和患者援助项目（统称“患者项目”）可能会存在很大差异，主要取决于涉及的产品、疗法、疾病状态的性质以及适用的法律、法规和行为准则的相关规定。患者项目（不论是传统项目或数字化项目）的目的可能包括疾病管理教育、健康指导、药品说明及协助家庭用药等。

4. Patient support programs; patient assistance programs

Patient support programs and patient assistance programs (collectively "Patient Programs") offered by member companies may have significant variances depending on the nature of involved products, therapies, disease states, and requirements of applicable laws, regulations and codes of practice. A Patient Program, whether traditional or digital, may serve the purposes of, among others, disease management education, wellbeing advice, pharmaceutical product instructions, assisting with home administration of the pharmaceutical product, etc.

会员公司在设计并实施患者项目时应考虑以下原则：

- 患者项目不应用于向包括患者在内的公众推广药品，也不得含有对医疗卫生专业人士的任何形式的诱导，使其处方任何药品。

- 患者项目不得干扰医患关系。患者项目的任何内容或组成部分均不应损害医疗卫生专业人士和患者的独立治疗选择或医疗决定。

- 患者项目应根据患者的需求设计。会员公司应通过征求患者群体意见等方式，适当评估并确认患者对项目的需求。

- 会员公司应为患者项目制定明确合理的患者入组标准，并应在项目实施期间，将这些标准告知相关医疗卫生专业人士和利益相关方。

- 在聘请第三方服务提供商或医疗卫生专业人士为患者项目提供服务时，会员公司应确保受聘方具备必要的资质。

- 患者的保密权及隐私权应始终受到保护，在任何可能收集、使用或转移患者数据的情形中，均应采取适当的隐私保护措施。

Member companies should take into consideration the following principles when designing and implementing Patient Programs:

- The Patient Program should not be used to promote pharmaceutical products to the general public, including patients, and also may not include any type of inducement for HCPs to prescribe any pharmaceutical product.

- The Patient Program must not interfere with the HCP-patient relationship. Any component or part of the Patient Program should not compromise independent treatment choices or medical decision of HCPs and patients.

- The Patient Program should be designed on basis of the needs of the patients. Member companies should properly assess and confirm the patient needs for the programs through means such as soliciting comments from the patient community.

- Member companies should establish clear and reasonable patient enrollment criteria for the Patient Program. Those criteria should be communicated to HCPs and stakeholders for the duration of the program.

- When engaging third party services providers or HCPs to provide services for a Patient Program, member companies should ensure that they have the necessary qualification.

- Patient confidentiality and privacy should be maintained at all times, and adequate privacy practices should be exercised in connection with any potential collection, use or transfer of patient data.

- 患者项目应通过药物警戒程序和控制措施，在架构上确保维护患者安全。

- Patient Programs should be structured to ensure that patient safety is maintained through pharmacovigilance procedures and controls.

5. 与数字平台意见领袖的合作

近年来，随着中国数字营销和短视频行业的蓬勃发展，出现了一类新型数字化项目，在此类项目中，制药及医疗公司与网红和数字平台意见领袖（包括患者）在社交媒体平台上（例如微信、微博、抖音、知乎等）合作开发并分享内容。

与网红和数字平台意见领袖合作，尤其是与患者合作，须谨慎评估。会员公司应仔细评估此类项目对患者和公众产生不当影响的风险，以及此类数字化内容可能被视为不当宣传或非法药品、医疗或医疗机构广告的风险。

作为一般原则，患者文章或视频中的内容应属于个人经历分享或疾病知识教育，而不是对任何特定药品的推荐或宣传。鉴于以上要求，我们鼓励会员公司制定相关程序，对将由患者在社交媒体平台上发布的内容进行发布前审查。

5. Collaboration with digital opinion leaders

In recent years, because of the booming of digital marketing and short-form video industry in China, a new type of digital program has emerged, where pharmaceutical and healthcare companies work with online influencers and digital opinion leaders (including patients) in content development and sharing on social media platforms (such as WeChat, Weibo, Douyin, Zhihu, etc.).

Engaging online influencers and digital opinion leaders, particularly engaging patients, requires careful evaluation. Member companies should carefully assess the risks of undue influence on patients and the general public, as well as the risk that such digital content could be perceived as improper promotion or illegal advertising of pharmaceutical products, medical treatments, or medical institutions.

As a general principle, the content of patients' articles or videos should be personal story sharing or disease knowledge education, rather than recommending or promoting any specific pharmaceutical products. In consideration of the above requirements, member companies are encouraged to establish a procedure to review the contents that will be used by the patients before publishing such contents on social media platforms.

此外，向网红或数字平台意见领袖支付的任何款项必须是对其提供的真实服务的报酬，且支付额必须符合公平市场价值原则。

In addition, any payment to such online influencers or digital opinion leaders must be compensation for their genuine services, and the amount of the payment must comply with the FMV principle.

6. 遵守药物警戒规定

药物警戒制度是医疗服务及合理用药不可或缺的重要组成部分。为确保医疗卫生专业人士、患者和其他利益相关方正确报告不良事件，会员公司应根据其产品、其产品的患者群体及医疗卫生专业人士群体的特点，开发不良事件报告数字化解决方案。

在开展数字化患者互动活动时，会员公司应确保遵守适用的法律法规中规定的不良事件的收集和报告义务。为此，会员公司应向医疗卫生专业人士和患者提供关于药物警戒原则、报告程序、及时报告的重要意义以及如何使用会员公司的数字化不良事件报告系统的适当教育及培训。

6. Pharmacovigilance compliance

Pharmacovigilance system is an essential component of healthcare and reasonable use of pharmaceutical products. To ensure proper reporting of adverse events by HCPs, patients and other stakeholders, member companies should develop digital solutions for adverse event reporting that correspond to the features of their products and their products' patient groups and HCP groups.

When conducting digital patient interaction activities, member companies should ensure compliance with adverse event collection and reporting obligations as set forth in applicable laws and regulations. To achieve this goal, member companies should provide appropriate education and training to HCPs and patients on pharmacovigilance principles, reporting procedures, the importance of timely reporting, as well as how to use the companies' digital adverse event reporting system.

附件
Appendix

RDPAC 会员公司
（更新日期：2023 年 3 月）

雅培	赫尔森
艾伯维	益普生
艾尔建美学	杨森
爱而开	协和麒麟
安进	利奥制药
爱施健	灵北
安斯泰来	美纳里尼
阿斯利康	默克
百特	默沙东
拜耳	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	住友制药
辉凌医药	武田
匈牙利吉瑞大药厂	梯瓦制药
吉利德科学	优时比制药
葛兰素史克	赞邦

RDPAC Member Companies

(Updated in March 2023)

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

RDPAC

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 (RDPAC)

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