RDPAC

RDPAC 数字医疗合规指南

RDPAC Digital Health Compliance Guidance

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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

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使命宣言

Mission Statement

当今全球医疗卫生事业面临重重挑战，制药公司需采用创新工具提高疾病治疗质量，提升与医师的医学及科学交流的有效性，加强与患者及公众的信任关系。我们已看到制药公司正为此逐步加强在医疗卫生领域使用数字技术，并相信这一趋势将在未来多年保持强劲势头。

Today's global healthcare challenges require pharmaceutical companies to employ innovative tools to enhance the quality of disease treatment, upgrade the effectiveness of medical and scientific communications with physicians, and strengthen the trust-based ties with patients and the general public. For this purpose, we have seen the increasing use of digital technologies in the healthcare sector by pharmaceutical companies, and believe that such a trend will continue with strong momentum for the many years to come.

"数字医疗"一词没有固定定义，在通常理解中一般包括：（1）数字技术驱动的医疗解决方案，例如移动医疗（mHealth），以及可利用数字化数据的各类技术（例如，数据科学与人工智能（AI）技术），包括可穿戴设备及医疗器械独立软件（SaMD）；（2）远程医疗，即基于数据（包括通过电信系统传输的语音和图像、文件及其他信息等）实施医疗干预、提供诊疗决策与建议的远距离医疗活动；以及（3）使用数字技术提供健康与医疗卫生服务及相关信息，包括使用数字化工具与医疗卫生专业人士（HCP）及患者进行互动。

The term "digital health" does not have a fixed definition, and is commonly understood to include, among others: (i) digital-driven health solutions, such as mobile health (mHealth), and technologies that allow the utilization of digital data (e.g., data science and artificial intelligence (AI)), including wearables and software as a medical device (SaMD); (ii) telemedicine, i.e., practice of medicine over a distance, in which interventions, diagnostics and treatment decisions and recommendations are based on data, including voice and images, documents and other information transmitted through telecommunication systems; and (iii) the use of digital technology to deliver health and healthcare services and information, including using of digital tools in interactions with healthcare professionals (HCP) and patients.

为此，全球制药行业已制定了多项相关原则及指导文件，以供制药公司在考虑数字医疗技术应用时参考。上述原则及指导文件包括但不限于《生物制药行业数字医疗全球政策原则》（国际制药企业协会联盟（IFPMA）、日本制药企业协会（JPMA）与欧洲制药企业协会联盟（EFPIA）共同制定）、《社交媒体与数字化渠道指南联合说明》（IFPMA 与 EFPIA 共同制定）以及《教育活动及远程医疗行业支持指南联合说明》（IFPMA 与 EFPIA 共同制定）。

In this regard, the global pharmaceutical industry has formulated several principle and guidance documents for pharmaceutical companies when considering their application of digital health technologies, including but not limited to the Biopharmaceutical Industry's Global Policy Principles on Digital Health (co-authored by IFPMA, JPMA and EFPIA), the Joint Note for Guidance on Social Media and Digital Channels (co-authored by IFPMA and EFPIA), and the Joint Note for Guidance on Industry Support for Education and Access to Telemedicine (co-authored by IFPMA and EFPIA).

在中国，RDPAC 观察到数字化工具在与医疗卫生专业人士、患者以及公众等外部利益相关者进行广泛沟通交流中的应用。RDPAC 始终鼓励会员公司与这些外部利益相关者保持有效互动，提升医疗卫生专业人士的科学及医学知识与疾病治疗能力，以及提高患者和公众对疾病的认识及健康管理与疾病管理能力。

In China, RDPAC has observed the emergence of the use of digital tools in communications with external stakeholders, ranging from healthcare professionals to patients as well as the general public. RDPAC has always encouraged its member companies to maintain effective interactions with such external stakeholders, so as to advance the scientific and medical knowledge and disease treatment capabilities of HCPs, as well as the disease awareness knowledge and health management and disease management capabilities of patients and the general public at large.

在过去几年间，数字化工具的出现及广泛使用已使中国制药行业与医疗卫生专业人士及患者的互动模式发生了改变。这一改变大大提高了互动的覆盖面、效率和有效性，但同时也在法律及监管合规、内部控制、风险管理及医学伦理等方面给会员公司带来了挑战。

In the past few years, the emergence and wide use of digital tools has transformed the model of such interactions with HCPs and patients in the pharmaceutical industry in China. On one side, it has significantly increased the coverage, efficiency and effectiveness of the interactions. At the same time, it also has created challenges to member companies from the standpoints of legal and regulatory compliance, internal control, risk management as well as medical ethics.

因此，RDPAC 制定本指南，旨在为会员公司使用数字化工具与医疗卫生专业人士及患者进行的互动提供原则性的非约束性指导，以避免与法律及监管要求不一致，在最大程度上利用此类互动助益医疗卫生专业人士、提高患者福利，并保持最高的医学伦理标准。

Therefore, RDPAC has taken the initiative of developing this Guidance, aiming to provide high level non-binding guidance to member companies in connection with their use of digital tools in interactions with HCPs and patients, so as to prevent non-compliance with legal and regulatory requirements, to maximize the use of such interactions to the benefit of HCPs and the welfare of patients, and to maintain medical ethics at the highest level.

2 概述：与医疗卫生专业人士及患者互动过程中使用的数字化工具

Overview of Digital Tools Used in Interactions with HCPs and Patients

考虑到各种因素，RDPAC 会员公司在与医疗卫生专业人士及患者的互动过程中使用了多种不同的数字化工具。我们将在此第二部分描述 RDPAC 会员公司最常用的数字化工具，并将在第三部分提供合规指导。

RDPAC member companies, with consideration of various factors, have used different digital tools in their interactions with HCPs and patients. We will set forth, in this Part II, the most commonly used digital tools among RDPAC member companies, and will provide, in Part III, guidance on compliance.

1. 面向医疗卫生专业人士的虚拟医学教育活动

在此类活动中，会员公司通过自有数字平台或第三方业务合作伙伴运营的数字平台，向医疗卫生专业人士提供医学教育课程。这些课程大部分是直播课，有些是可重播的录播课。讲者通常是中国国内或国外的医疗卫生专业人士，听众也是医疗卫生专业人士。

1. Virtual medical education programs for HCPs

In these programs, member companies provide medical education programs to HCPs via digital platforms, whether platforms owned by themselves or operated by third-party business partners. Most of these programs are live broadcasts, with some programs using pre-recorded, repeatedly re-broadcast videos. The speakers are typically HCPs, whether in China or abroad, and the audience are HCPs as well.

2. 虚拟疾病认知 / 患者教育活动

在此类活动中，会员公司通过自有数字平台或第三方业务合作伙伴运营的数字平台向患者提供健康管理、疾病知识与疾病管理教育课程或科普。这些课程大部分是直播课，有些是可重播的录播课。讲者可能是医疗卫生专业人士、患者或会员公司员工，听众仅限于患者。

2. Virtual disease awareness/patient education programs

In these programs, member companies provide health management, disease awareness and disease management education programs to patients via digital platforms, whether platforms owned by themselves or operated by third-party business partners. Most of these programs are live broadcasts, with some programs using pre-recorded, repeatedly re-broadcast videos. The speakers may be HCPs, patients or company employees, and the audience are exclusively patients.

3. 医患互动数字平台

在此类活动中，会员公司提供自有的互动平台或第三方业务合作伙伴运营的互动平台，搭载在智能手机应用程序或微信小程序上（如“问答室”），医疗卫生专业人士可通过此平台为患者提供健康管理、疾病知识与疾病管理教育信息。在此类平台上，患者可向医疗卫生专业人士提出问题，医疗卫生专业人士可回答患者提问，但此类交流不应“越线”构成诊疗活动。

3. Digital HCP-patient interaction platforms

In these programs, member companies provide interactive platforms, either owned by themselves or operated by third-party business partners, on smartphone applications or WeChat mini-programs, such as “Q&A rooms,” for HCPs to provide health management, disease awareness and disease management education information to patients. On these platforms, patients ask questions to HCPs and HCPs provide answers, but such communications shall not “cross the line” and constitute diagnosis and treatment activities.

4. 与互联网医院的合作

与互联网医院的合作形式多种多样，典型合作形式包括：

- 会员公司介绍医疗卫生专业人士在互联网医院执业；
- 会员公司向互联网医院的患者提供患者教育信息；
- 会员公司向在互联网医院接受处方的患者提供产品折扣（如优惠券）；及
- 会员公司与互联网医院合作，收集并分析经适当处理的患者治疗数据。

4. Collaboration with Internet hospitals

Collaboration with Internet hospitals take a variety of forms, and typical forms include:

- member companies introduce HCPs to practice at Internet hospitals;
- member companies provide patient education information to patients on Internet hospitals;
- member companies provide product discounts (such as coupons) to patients who receive prescriptions at Internet hospitals; and
- member companies collaborate with Internet hospitals to collect and analyze properly processed patient treatment data.

5. 与电商零售药店的合作

与电商零售药店的合作形式多种多样，典型合作形式包括：

- 电商零售药店向患者提供产品折扣，通常由会员公司提供相应补贴；
- 会员公司与电商零售药店合作，在电商药店提供患者教育视频；及
- 会员公司与电商零售药店合作，在电商药店展示会员公司药品。

5. Collaboration with e-commerce retail pharmacies

Collaboration with e-commerce retail pharmacies take a variety of forms, and typical forms include:

- e-commerce retail pharmacies provide product discounts to patients, usually with subsidy by member companies;
- Member companies and e-commerce retail pharmacies collaborate to provide patient education videos on e-commerce pharmacy stores; and
- member companies and e-commerce retail pharmacies collaborate to display drug products of the member companies on e-commerce pharmacy stores.

6. 运营数字医疗产品

一些会员公司设计、开发并运营数字医疗产品（DTx），并向患者提供该等产品。此类数字医疗产品可能注册为医疗器械或不注册，可能与会员公司的药品联用或不联用。此类数字医疗产品通常在互联网医院使用或处方。对此应关注的重点是，鉴于外资公司从事此类活动会受到相关限制，会员公司需考虑其运营此类数字医疗产品是否需要获得增值电信业务经营许可证和 / 或互联网内容提供商（ICP）许可证。[1]

6. Operating digital therapeutic products

Some member companies design, develop and operate digital therapeutic products (DTx), and provide such DTx products to patients. Such DTx products may be registered as medical devices, or not, and may be used in combination with the companies' pharmaceutical products, or not. In frequent cases, such DTx products are used or prescribed on Internet hospitals. Importantly, given relevant restrictions on foreign companies' involvement in such activities, member companies need to consider whether they need to obtain the Value-Added Telecom Service (VATS) License (增值电信业务经营许可证) and/or the Internet Content Provider (ICP) License (ICP 许可) for the operation of such DTx products. [1]

[1] An ICP License is in nature one type of VATS License, although in practice it is typically regulated separately.
ICP 许可在性质上是增值电信业务经营许可证的一种类型，虽然在现实中通常进行单独监管。

7. 使用社交媒体工具

“社交媒体工具”包括微博、微信和抖音等。会员公司会在各类项目中使用社交媒体工具，例如：

- 发布与其药品相关的文章或视频，如新产品发布、药物研发进展等；
- 发布与其药品项目相关的文章或视频，如患者援助项目（PAP）、保险项目等；及
- 直接或间接发布以公众或患者为受众的有关健康管理、疾病知识与疾病管理的文章或视频（统称为“患者教育资料”）。

7. Use of social media tools

“Social media tools” include, among others, Weibo, WeChat and Douyin. Member companies use social media tools in a variety of programs, such as:

- publish articles or videos about their drugs, such as launch of new products, drug development progress, etc.;
- publish articles or videos about their drugs’ programs, such as patient assistance programs (PAP), insurance programs, etc.; and
- publish, directly or indirectly, articles or videos on health management, disease awareness and disease management that target the general public or patients (collectively, “Patient Education Materials”).

3 指导原则
Guiding Principles

RDPAC 强调会员公司在使用数字化工具时，应遵守 RDPAC 行业行为准则（2022 年修订版）的全部相关适用条款。

RDPAC 鼓励会员公司根据适用的法律法规、监管要求以及医学伦理准则，在与医疗卫生专业人士及患者的互动中，探索使用数字化工具，提升医疗卫生专业人士的医学知识及患者福利。同时，RDPAC 认识到，任何滥用数字化工具的行为均可能产生法律、监管及道德风险，因此 RDPAC 提出以下指导原则，并要求会员公司在使用数字化工具时认真考虑这些原则。

RDPAC stresses that member companies, when using digital tools, shall comply with relevant sections of the RDPAC Code of Practice 2022 whenever applicable.

RDPAC encourages member companies to explore the use of digital tools in interactions with HCPs and patients in accordance with applicable laws and regulations, regulatory requirements, as well as medical ethics rules, so as to advance the medical knowledge of HCPs and the welfare of patients. At the same time, acknowledging the legal, regulatory and ethical risks that may arise out of any misuse of such digital tools, RDPAC raises the following guiding principles, and requests member companies to consider them carefully in their use of digital tools.

1. 信息应公平且平衡

通过数字化工具传达的所有信息均须公平且平衡，能够反映该信息相关标的事项的各个关键方面。对于任何标的事项，会员公司不得隐瞒重要信息，或以对其业务有利的不公平方式夸大某些信息。

1. Fair and balanced information

All information communicated via digital tools must be fair and balanced, representing all key aspects of the subject matter that the information relates to. On any subject matter, member companies shall not conceal important information or exaggerate certain information in a way that is unfairly advantageous to its business.

2. 无虚假或误导性宣传

通过数字化工具向医疗卫生专业人士及患者传达的所有信息均可能构成中国《反不正当竞争法》中所指的“商业宣传”，因此不得虚假或有误导性。会员公司必须采取适当措施审核此类信息，确保信息真实、准确且无误导性。

2. No false or misleading promotion

All information communicated via digital tools to HCPs and patients may constitute “commercial promotion” referenced by China’s Anti-unfair Competition Law, and therefore shall not be false or misleading. Member companies must take appropriate measures to review and approve such information to ensure that the information is true, accurate, and non-misleading.

3. 不做超说明书推广；对说明书外科学交流实施健全的管理

会员公司在任何情况下均不得通过任何数字平台，对其药品进行超说明书推广。

会员公司可以通过数字平台沟通交流与超说明书用药有关的科学及医学信息，但前提是会员公司需建立并实施充分且健全的体系，以审核并管理此类信息。特别是，此类信息不能带有推广性质，且只能服务于提升医疗卫生专业人士科学及医学知识的目的。

3. No off-label promotion; robust management of off-label scientific communication

Member companies shall not conduct off-label promotion of their drugs in any circumstance through any digital platform.

Member companies may communicate scientific and medical information about the off-label use of drugs through digital platforms, but only on the condition that member companies establish and implement an adequate and robust system to review, approve and manage such information. Particularly, such information must be non-promotional, and serve exclusively the purpose of the advancement of scientific and medical knowledge of HCPs.

4. 不得发布非法药品、医疗器械及医疗广告

会员公司不得使用其数字平台发布直接面向消费者的（DTC）处方药广告。会员公司还应注意，非处方药、医疗器械及医疗广告必须在获得相关监管机构的批准后才能发布，通过数字平台发布也不例外。因此，会员公司必须建立并实施充分且健全的体系，

4. No illegal drug, device and medical treatment advertisement

Member companies shall not use their digital platforms to publish direct to consumer (DTC) advertisements for prescription drugs. They should also note that advertisements for OTC drugs, medical devices and medical treatments must be approved by relevant regulatory authorities before being published, and

以对通过数字化工具传播的信息进行审核，确保任何此类信息均不构成非法药品广告、医疗器械广告或医疗广告。

- **案例分析**：某制药公司向明星及网络博主（即所谓的“影响者”）提供产品信息和资金资助，请他们在社交媒体平台上发布视频。视频中，“影响者”会作为患者出现，介绍产品的功效。执法部门可能会质疑此类视频，认为其内容是未经批准的药品广告并予以处罚。

the digital platforms are not an exemption to such principles. Therefore, member companies must establish and implement adequate and robust review of the information communicated via digital tools to ensure that no information constitutes illegal drug advertisement, medical device advertisement or medical treatment advertisement.

- **Case study:** a pharmaceutical company provides product information and financial funding to celebrities and Internet bloggers (so called “influencers”) for them to publish videos on social media platforms. In such videos, the “influencers” will, with the appearance of patients, introduce the efficacy of the product. Enforcement authorities may challenge this kind of video as an unapproved drug advertisement and impose penalties.

5. 不得对医疗卫生专业人士处方进行不当影响

会员公司不得借助数字化工具上的活动，不当影响医疗卫生专业人士的处方决定。

特别是，会员公司在与互联网医院合作时，应对互联网医院向医疗卫生专业人士支付报酬的模式及做法进行有效的尽职调查。会员公司如发现互联网医院可能会利用合作项目（特别是利用会员公司的参与、资源、资金或支持）不当影响医疗卫生专业人士的处方决定，则不得与其开展合作。

会员公司与零售药店或零售药店药师合作或使用其服务的，不得利用数字化工具开展的活动不当影响药师向患者推荐药品的决定。

5. No undue influence on HCP prescriptions

Member companies shall not use activities on digital tools to unduly influence the prescription decisions of HCPs.

Particularly, when collaborating with Internet hospitals, member companies shall perform effective due diligence on the Internet hospitals’ model and practices in connection with compensation to HCPs, and shall not conduct the collaboration in case of findings that the Internet hospital may use the collaboration program (particularly the participation, resources, funding or support by the member company) to unduly influence the prescription decisions of HCPs.

If member companies collaborate with or use the services of retail pharmacies or retail pharmacists, they shall not use activities on digital tools to unduly influence the decisions of the retail pharmacists when recommending drugs to patients.

- **案例分析**：某制药公司与某互联网医院开展全面合作。在合作中，公司员工介绍医疗卫生专业人士到该互联网医院执业。作为对该活动的回报，该互联网医院向公司承诺，对于这些医疗卫生专业人士开出的公司药品处方，该互联网医院将向这些医疗卫生专业人士提供额外的服务费。中国执法部门极有可能将此类安排视为互联网医院对医疗卫生专业人士的商业贿赂。此外还有一个风险，即美国《海外反腐败法》（FCPA）的执法部门可能认为此类安排是向医疗卫生专业人士的贿赂，且公司应对该贿赂付款承担部分责任。

- **Case study**: a pharmaceutical company has a comprehensive collaboration with an Internet hospital. As part of the collaboration, the employees of the company introduce HCPs to practice at the Internet hospital. In return for such activities, the Internet hospital promises to the company that they will give extra service fees to the HCPs for their prescription of the drug of this company. There is a substantial possibility that Chinese enforcement authorities view such an arrangement to be commercial bribery to HCPs by the Internet hospital, and there is also a risk that U.S. enforcement authorities of the Foreign Corrupt Practices Act (FCPA) view such arrangement to be corrupt payment to HCPs and that the company be partially liable for such corrupt payments

6. 不得对患者的用药决定及治疗决定进行不当影响

会员公司在使用数字化工具开展活动的过程中，应当尊重患者的独立判断，不得利用任何活动不当影响患者的用药决定或治疗决定。

- **案例分析**：某制药公司与某药品零售公司旗舰店开展合作项目。通过该项目，该制药公司向该旗舰店付费发布患者教育视频。该旗舰店在其网页上发布这些视频，视频大力宣传该公司某款药品的治疗优势，并提及一些缺乏依据的关于某竞争药品的药物警戒事件，暗示该竞争药品的疗效可疑。此类视频可能会造成不当影响患者用药决定的效果。

6. No undue influence on patient's drug use and medical treatment decisions

Member companies, when performing activities on digital tools, shall respect the independent judgement of patients, and shall not use any activity to unduly influence the drug use decisions or medical treatment decisions of patients.

- **Case study**: a pharmaceutical company has a collaboration project with the flagship store of a drug retail company . Through the project, the company pays the flagship store to post patient education videos on its webpage, and the videos strongly advocate the treatment advantages of a drug of the company and also insinuate doubts about the efficacy of a competing drug by mentioning certain unfounded PV incidences of the competing drug. Such videos may have an effect of unduly influencing the patients' drug use decisions.

7. 支付服务费

如果会员公司就任何人士（尤其是医疗卫生专业人士）通过数字化工具提供的服务向其支付服务费，则在付费前，会员公司应确保医疗卫生专业人士已按预先商定的条款提供了相应服务，且付费金额必须符合公允市场价值（FMV）原则。会员公司应确保，其直接或通过任何第三方间接向医疗卫生专业人士支付的任何付款，均不得用于奖励或诱导医疗卫生专业人士的药品处方行为，或以其他不当方式影响其用药意见或建议。

7. Payment of service fees

If a member company pays any person, particularly an HCP, service fees for such person's services conducted via a digital tool, the member company shall ensure that the HCP has performed the services in accordance with pre-agreed terms before making the service fee payments, and the amount of the payment must comply with the Fair Market Value (FMV) principle. Member companies shall ensure that any payment to HCPs, either directly or indirectly through any third parties, must not be a reward or inducement for the HCPs' drug prescription behavior, or otherwise unduly influence their drug use advice or recommendation.

会员公司应考虑数字化活动的独特特征，设计并落实充分且健全的系统，以跟踪并核验医疗卫生专业人士的数字化活动。

- **案例分析**：某制药公司就医疗卫生专业人士在抖音上开展的疾病知识教育活动支付服务费，该服务费按小时计算的服务费率高于线下活动的服务费率。该公司进行了全面的公允市场价值评估，并认为医疗卫生专业人士需要付出更多努力来完成相关服务，例如出镜、参与脚本和视频制作以及在社交媒体账号上发布内容，因此较高的费率具有合理性。这种健全的付费前公允市场价值分析机制值得高度推荐。

Member companies shall design and implement an adequate and robust system to track and verify the digital activities of the HCPs by taking into account the unique features of digital activities.

- **Case study**: a pharmaceutical company pays HCPs service fees for disease awareness education activities on Douyin, and the service fees, when calculated on an hourly rate basis, are higher than those for off-line activities. The company performed a thorough FMV assessment, and believes such higher rate is justifiable because the HCPs need to put in more efforts to complete the relevant services, such as appearing on camera, participating in script and video production, and publishing the contents on social media accounts. Such a robust pre-payment FMV mechanism is highly recommended.

8. 数据收集

会员公司可能需要通过数字化工具收集某些数据，如用药数据、患者数量数据、医师治疗数据等。在收集此类数据时，会员公司必须确保：

- 此类数据收集符合所有中国法律法规的规定；
- 会员公司不得出于不正当的商业目的收集医师、临床治疗科室或医院已处方的药品的数量信息；

8. Collection of data

Member companies may have a need to collect certain data via digital tools, such as drug use data, patient amount data, physician medical treatment data, etc. When collecting such data, member companies must ensure that:

- such data collection meets all legal and regulatory requirements in China;
- member companies shall not collect data on the amount of drugs prescribed by a physician, a clinical treatment department, or a hospital for unjustifiable commercial purposes;

- 数据的收集符合“数据量最小化”原则，即会员公司必须将数据收集限制在与实现预期目的直接相关且必要的范围内；且

- 会员公司不得为收集任何数据向医疗机构及医疗机构的任何工作人员（特别是医疗卫生专业人士）付费，除非该医疗机构或工作人员需要为收集这些数据开展实质性活动。

➢ **案例分析**：某制药公司从医疗卫生专业人士处收集“新患者人数数据”，并就医疗卫生专业人士提供这些数据向其支付一定的费用。然而，后来经调查发现：（1）这些医疗卫生专业人士无需为生成这些数据开展任何实质性活动；（2）该公司自称收集这些数据是为了“管理产品生产计划”，但这些数据似乎不具有实现该目的价值；且（3）这些数据由该公司的销售团队使用，从未传送给生产团队。因此，这一数据收集活动似乎缺乏真实目的，且有滥用为向医疗卫生专业人士输送款项的风险。

- such data collection complies with the “data minimization” principle, i.e., member companies must limit the collection of data to what is directly relevant and necessary to accomplish the intended purpose; and

- member companies shall not pay medical institutions and any person working at medical institutions (particularly HCPs) for the collection of any data, except in cases in which such medical institutions or persons need to perform substantive activities for the collection of such data.

➢ **Case study:** a pharmaceutical company collects “new patient number data” from HCPs, and pays HCPs certain fees for providing such data. However, it was later discovered that: (i) the HCPs did not need to carry out any substantive activity to generate such data; (ii) the company collects such data for the self-claimed purpose of “managing product manufacturing plans,” but the data do not appear to have the value for such purpose; and (iii) the company’s Sales team uses such data, and never transfers the data to the manufacturing team. Therefore, this data collection activity does not appear to have a genuine purpose, and has the risk of being misused to funnel payment to HCPs.

9. 隐私保护

如果会员公司从中国收集任何个人信息，特别是医疗卫生专业人士及患者的个人信息，则必须严格遵守中国的《个人信息保护法》及其他相关法律法规。

- 会员公司应建立并实施适当的隐私合规计划，以确保遵守有关通知与同意、数据共享及转移、个人信息保护影响评估、安全事件管理等方面的规定。
- 会员公司应尊重数据主体对其个人信息的权利，例如查阅、复制、更正、补充或删除其个人信息的权利。
- 会员公司应在组织及技术层面采取适当措施，确保满足上述要求。

9. Protection of privacy

Member companies must strictly comply with China's Personal Information Protection Law and other relevant laws and regulations if they collect personal information of any person in China, particularly HCPs and patients.

- Member companies shall establish and implement appropriate privacy compliance programs to ensure compliance with requirements regarding notification and consent, sharing and transfers of data, personal information protection impact assessments, management of security incidents, etc.
- Member companies shall respect the rights of the data subjects with respect to their personal information, e.g., right to access, copy, correct, supplement or delete their personal information.
- Member companies shall adopt appropriate organizational and technical measures to ensure the satisfaction of the above requirements.

10. 遵守网络安全要求；数据跨境传输

会员公司在收集和处理数据过程中必须严格遵守中国的《网络安全法》及其他相关法律法规。

- 会员公司应采取适当的网络安全保护措施，监测并报告网络漏洞及安全事件，根据安全等级保护制度对其信息系统及数字化工具的安全级别进行评估及分级，并遵守其他相关规定。

10. Compliance with cybersecurity requirements; cross-border transfer of data

Member companies must strictly comply with China's Cybersecurity Law and other relevant laws and regulations when collecting and processing data.

- Member companies shall, among others, adopt appropriate measures to safeguard cybersecurity, monitor and report network vulnerabilities and security incidents, and assess and grade the security levels of its information systems and digital tools in accordance with the Multi-Level Protection Scheme.

- 会员公司向境外传输数据前，应根据适用的数据安全法律及个人信息保护法律进行自我评估，并采取适用的数据跨境传输的路径（即政府安全评估、个人信息保护认证或标准合同等）。

- Before transferring data overseas, member companies shall conduct a self-assessment in accordance with applicable data security and personal information protection laws, and use one of the permitted transfer mechanisms (i.e., governmental security assessment, personal information protection certification, or standard contract) as applicable.

11. 数字记录的保留

会员公司应为开展数字化活动期间生成的数字记录建立并实施充分且健全的记录保留内部程序，并根据该程序保留这些数字记录。该等数字记录应包含足够详细的信息，以使会员公司能够对相关数字化活动进行有效审查及审计，特别是关于医疗卫生专业人士在该等数字化活动中履行的服务的准确性及真实性。

11. Retention of digital records

Member companies shall establish and implement adequate and robust internal procedures governing the retention of digital records generated during the performance of the digital activities, and retain such digital records accordingly. Such digital records shall contain sufficient details that would enable member companies to perform effective review and audit of the digital activities, particularly on the veracity and authenticity of the HCP services performed in such digital activities.

12. 对供应商或业务合作伙伴的适当管理

会员公司在数字化活动中使用供应商或与业务合作伙伴开展合作的，其应对相关供应商或业务合作伙伴实施有效管控，以确保相关供应商或业务合作伙伴遵守本指南的适用要求。作为一项指导原则，会员公司不得利用供应商或业务合作伙伴规避本指南中适用于会员公司的任何要求，或达到规避效果。

12. Proper management of vendors or business partners

If member companies use vendors or collaborate with business partners in digital activities, they shall implement effective management and control of such vendors or business partners to ensure that they comply with the requirements in this Guidance to the extent applicable. As a guiding principle, member companies shall not use vendors or business partners for the purpose of or with the effect of circumventing any requirements in this Guidance that are applicable to the member companies.

4 专题指南
Subject Matter Guidelines

如果会员公司认为某一特定形式的数字化活动（包括本指南第二部分所述的活动）具有高法律风险或监管合规风险，RDPAC将针对该类数字化活动制定专题指南，为管理并降低相关法律风险及监管合规风险提供具体指导。

If member companies find that any form of digital activities, including those described in Part II of this Guidance, carries any high legal or regulatory compliance risks, RDPAC will develop subject matter guidelines on such forms of digital activities to provide specific guidance on the management and mitigation of legal and regulatory risks.

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	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 China
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	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 Enterprises with Foreign Investment
R&D-based Pharmaceutical Association Committee

CAEFI

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