RDPAC-HKAPI 关于在粤港澳大湾区“港澳药械通”下开展与医院、医疗卫生专业人士及患者的互动活动的指导意见

RDPAC-HKAPI Guidance on Interactions with Hospitals, HCPS and Patients under the Greater Bay Area “Hong Kong & Macau Registered Medicine Access to GBA Program”

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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)

香港科研制药联会

The Hong Kong Association of the Pharmaceutical Industry（HKAPI）

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1 引言 Introduction

粤港澳大湾区（简称“**大湾区**”）包括香港和澳门两个特别行政区，以及广东省九个城市（即广州、深圳、珠海、佛山、惠州、东莞、中山、江门和肇庆）。中国政府已将大湾区建设作为国家发展战略的重要组成部分，将大湾区建设视为国家经济创新发展的重要驱动力。

The Guangdong-Hong Kong-Macao Greater Bay Area (the “**Greater Bay Area**” or the “**GBA**”) comprises the two Special Administrative Regions of Hong Kong and Macao, and the nine municipalities in Guangdong Province (i.e., Guangzhou, Shenzhen, Zhuhai, Foshan, Huizhou, Dongguan, Zhongshan, Jiangmen and Zhaoqing). The Chinese government has made the development of the Greater Bay Area a key component of its national development strategy, and views it as an important driving force for the innovation-based growth of the country's economy.

在医疗卫生领域，中国政府一直积极推进在大湾区使用创新医药产品，提供优质医疗服务，造福大湾区居民。为此，2020 年 9 月 29 日，中央八部委联合发布了《粤港澳大湾区药品医疗器械监管创新发展工作方案》（“**《工作方案》**”）。《工作方案》设定了到 2035 年，建立完善的大湾区药品及医疗器械监管协调机制，为大湾区居民提供便利的药品及医疗器械产品及服务，打造大湾区医药产业科技创新平台的宏伟目标。

In the field of healthcare, the Chinese government has been actively promoting the use of innovative pharmaceutical products and the provision of high-quality medical services in the Greater Bay Area for the purpose of benefiting the residents in the Greater Bay Area. For this purpose, on September 29, 2020, *eight central government agencies jointly issued the Work Plan on Innovation & Development of the Supervision of Pharmaceutical and Medical Device Products in the Guangdong-Hong Kong-Macau Greater Bay Area* (《粤港澳大湾区药品医疗器械监管创新发展工作方案》; the “**Work Plan**”). The Work Plan sets the ambitious objectives of by 2035 establishing a GBA regulatory coordination mechanism for pharmaceutical and medical device products, making pharmaceutical and medical device products and services conveniently available to GBA residents, and establishing a GBA technology innovation platform for the healthcare industry.

作为《工作方案》的重要组成部分，八部委为大湾区内的一些指定医院（“**大湾区指定医院**”）开设了一条路径。通过该路径，大湾区指定医院在向广东省人民政府（“**广东省政府**”）提出临床用药需求申请并获得批准后，可合法采购未在中国内地获批但已在香港或澳门上市的临床急需药品，并将此类药品用于患者治疗（此类药品以下简称“**符合条件药品**”）。该路径称为“大湾区港澳药械通”。

As a key component of the Work Plan, the eight agencies have created a pathway by which certain designated hospitals in the Greater Bay Area (the “**GBA Designated Hospitals**”), after applying for and receiving the approval by the People’s Government of Guangdong Province (the “**Guangdong Provincial Government**”), may legally procure pharmaceutical products in urgent medical needs by patients that are not approved in Mainland China but are approved in Hong Kong or Macau, and use such pharmaceutical products for medical treatment of patients (such drugs, “**Eligible Drugs**”). This initiative is titled as the “Hong Kong & Macau Registered Medicine Access to GBA Program.”

在大湾区港澳药械通的支持指引下，跨国制药公司非常希望在中国政府的法律法规框架内，扩大其产品在大湾区的使用，加强大湾区医疗卫生专业人士的医学知识，以促进对患者的治疗水平，并为实现这一目标开展了实质性的活动。药品研制和开发工作委员会（“**RDPAC**”）及香港科研制药联会（“**HKAPI**”）很高兴看到各自会员公司开展此类活动，并致力于在这方面为各自会员公司提供必要支持与指导。

Under the auspices of the Hong Kong & Macau Registered Medicine Access to GBA Program, multinational pharmaceutical companies have developed strong interests in expanding the use of their products and strengthening the medical knowledge of healthcare professionals (“**HCPs**”) in the Greater Bay Area under the framework of the Chinese Government’s laws and regulations for the purpose of advancing medical treatment of patients, and have carried out substantial activities to achieve this objective. The R&D-based Pharmaceutical Association Committee (“**RDPAC**”) and the Hong Kong Association of the Pharmaceutical Industry (“**HKAPI**”) are glad to see such activities of their respective member companies, and are committed to providing necessary support and guidance to their member companies in this area.

在开展相关活动时，尤为重要的一项是关于向医疗卫生专业人士、医院、患者及其他利益相关方传播医学、科学和产品信息以及疾病教育信息的需求。RDPAC 和 HKAPI 认识到，在符合中国法律法规及医学伦理的前提下开展此类沟通活动，将对医疗界具有重要价值，同时也谨慎地注意到，如管理不当，此类活动也可能带来风险。因此，就这一重要问题，RDPAC 与 HKAPI 联合制定了本指导意见，为各自会员公司提供不具约束力的指导。

Among these activities, one particularly important one relates to the need for communications of medical, scientific and product information as well as disease education information to HCPs, hospitals and patients and other stakeholders. RDPAC and HKAPI recognize the value of such communications to the healthcare community if conducted in accordance with Chinese laws and regulations and medical ethics, and also are cautiously mindful of the risks of such activities if mismanaged. Therefore, RDPAC and HKAPI have jointly developed this document to provide non-binding guidance to their respective member companies in this important area.

会员公司在开展上述活动时，除参考本指导意见外，还应遵守《RDPAC 行业行为准则》及《HKAPI 行业行为准则》中规定的一般原则及相关规定。特别是在向医疗卫生专业人士传递药品推广信息时，会员公司必须遵守《RDPAC 行业行为准则》（2022 年修订版）第 4 条“推广信息的标准”中的规定。

It should be noted that when conducting such activities, in addition to this Guidance, member companies should also comply with the general principles and relevant provisions in the RDPAC Code of Practice and the HKAPI Code of Practice. Particularly, when communicating drug promotional information to HCPs, member companies must comply with requirements in Article 4 of the RDPAC Code of Practice 2022, i.e., “Standards of Promotional Information.”

需要进一步提醒会员公司注意的是，本指导意见只是对相关做法的一般性指导，会员公司可就本指导意见所载要求发布实施细则，也可根据各自公司的实际情况采用比本指导意见更为严格的规定。

It should be further noted that this Guidance only contains the general guidance on relevant practices, and that member companies have the freedom in issuing implementation details for requirements contained in this Guidance or adopting requirements stricter than those in this Guidance as they see appropriate in accordance with their companies’ respective situations.

2 适用范围 Scope of Application

本指导意见适用于会员公司根据大湾区港澳药械通开展的，与使用符合条件药品相关的以下几类活动：

(i) 与医院、医院管理人员及医疗卫生专业人士的互动；

(ii) 与患者个人及护理人员的互动；

(iii) 为开展上述互动与医学会、慈善组织及患者组织的合作；以及

(iv) 真实世界证据项目。

This Guidance applies to following types of activities of member companies under the Hong Kong & Macau Registered Medicine Access to GBA Program with respect to the use of Eligible Drugs:

(i) interactions with hospitals, hospital managers and HCPs;

(ii) interactions with individual patients and caregivers;

(iii) collaboration with medical associations, charitable organizations and patient organizations for the purpose of the above interactions; and

(iv) real-world evidence ("**RWE**") programs.

3 指导原则 Guiding Principle

中国法律原则上仅准许经国家药品监督管理局（"**药监局**"）批准的药品在中国医院进行处方并用于治疗。大湾区港澳药械通相关政策（包括《工作方案》）设立了上述国家级监管规定的例外情形，使大湾区指定医院可合法采购符合条件药品用于医院的医疗救治，制药公司也因此可合法地与医院、医院管理人员及医疗卫生专业人士以及患者开展特定互动活动。

Chinese laws, in principle, only allow drugs that are approved by the National Medical Products Administration (the "**NMPA**") to be prescribed and used for treatment at hospitals in China. The relevant policies for the Hong Kong & Macau Registered Medicine Access to GBA Program (including the Work Plan) have created an exception to such national regulatory requirements, and made it legitimate for GBA Designated Hospitals to procure Eligible Drugs for medical treatment at the hospitals, and therefore for pharmaceutical companies to conduct certain interaction activities with the hospitals, hospital managers and HCPs, as well as patients.

然而，这种法律许可并不意味着上述互动活动没有界限限制。相反，大湾区港澳药械通有其明确的政策目标和监管要求。开展此类互动活动时，会员公司必须始终遵守这些监管要求，尊重这些政策目标，以确保其互动活动能够补充并支持中国政府对大湾区港澳药械通的政策导向，而不是与之相矛盾或相背离。

However, such legal permission does not mean that such interaction activities are without boundaries. Instead, the Hong Kong & Macau Registered Medicine Access to GBA Program has its clearly defined policy objectives and regulatory requirements. At all times when conducting such interaction activities, member companies must comply with these regulatory requirements and respect these policy objectives, so as to ensure that their interaction activities complement and support, not contradict or deviate from, the Chinese Government's policy directions for the Hong Kong & Macau Registered Medicine Access to GBA Program.

为此，RDPAC 和 HKAPI 提出以下一般原则，为会员公司开展与大湾区港澳药械通相关的活动提供指导。

For this purpose, RDPAC and HKAPI raise the following general principles to guide the activities of their member companies in connection with the Hong Kong & Macau Registered Medicine Access to GBA Program.

1. 促进患者医疗服务，禁止出于违反道德准则的目的滥用互动活动

《工作方案》明确规定，大湾区港澳药械通的宗旨是为“满足粤港澳大湾区居民用药用械需求”，“使粤港澳大湾区居民获得感、幸福感、安全感更加充实、更有保障、更可持续”。

因此，会员公司在根据大湾区港澳药械通开展的任何类型的互动活动时，均须以帮助医生安全且正确使用符合条件药品，为大湾区的患者带来最大的医疗利益为最终目标。

1. Advancement of Patient Care, No Abusive Use for Unethical Purposes

The Work Plan clearly provides that the Hong Kong & Macau Registered Medicine Access to GBA Program's purpose is "satisfying the needs of the residents in the Guangdong-Hong Kong-Macau Greater Bay Area for the use of pharmaceutical and medical device products" ("满足粤港澳大湾区居民用药用械需求") and "making the sense of gain, the sense of happiness and the sense of security of the residents in the Guangdong-Hong Kong-Macau Greater Bay Area more substantial, more secured and more sustainable" ("使粤港澳大湾区居民获得感、幸福感、安全感更加充实、更有保障、更可持续").

Therefore, for any type of interaction activities under the GBA Hong Kong-Macau Drug Program, member companies must be guided by the ultimate objective of helping physicians to use the Eligible Drugs in a safe and proper way and maximizing the medical treatment benefits for patients in the GBA area.

2. 不得对医疗卫生专业人士施加不当影响

会员公司应尊重医疗卫生专业人士的独立性，不得利用任何活动不当影响医疗卫生专业人士在以下方面的决定：是否将某种药品列入大湾区港澳药械通、为患者处方哪种药品、以及为患者采用何种治疗方案。

2. No Undue Influence on HCPs

Member companies should respect the independence of HCPs, and should not use any activity to unduly influence the HCPs' decisions in connection with whether to add a drug to the Hong Kong & Macau Registered Medicine Access to GBA Program, which drug to prescribe to patients, and what treatment plan to use for patients.

3. 不得对患者施加不当影响

会员公司应尊重患者、护理人员及患者组织的独立性，不得利用任何活动不当影响患者或护理人员的用药决定或治疗决定。

3. No Undue Influence on Patients

Member companies should respect the independence of patients, caregivers and patient organizations, and should not use any activity to unduly influence the drug use decisions or medical treatment decisions of patients or caregivers.

4. 与医学会、慈善组织及患者组织的合作

我们鼓励会员公司，在根据大湾区港澳药械通开展与利益相关方互动时，与声誉良好且具备能力的医学会、慈善组织及患者组织合作。在合作过程中，会员公司应尊重这些实体的独立性，需特别注意的是，不得利用此类合作项目提高任何药品的销量或知名度，不当影响医疗卫生专业人士及患者的意见，或向医疗卫生专业人士输送不正当利益。

4. Collaboration with Medical Associations, Charitable Organizations and Patient Organizations

Member companies are encouraged to collaborate with reputable and capable medical associations, charitable organizations and patient organizations in connection with interactions with stakeholders under the Hong Kong & Macau Registered Medicine Access to GBA Program. In the course of such collaborations, member companies should respect the independence of these entities, and in particular should not use such collaboration projects to increase sales or recognition of a drug product, to unduly influence the opinions of HCPs and patients, or to funnel improper benefits to HCPs.

5. 不得面向公众开展药品推广

作为一项基本原则，会员公司不应向公众（即患者、护理人员及除医疗卫生专业人士以外的一般公众）传递药品信息，除非在特殊情况下有符合公众（特别是患者）利益的客观需要。会员公司在向公众传递药品信息时，应确保信息必须客观、中立且不具有推广性。

5. No Drug Promotion to the Public

As a general principle, member companies should not communicate drug product information to the public, i.e., patients, caregivers and the general public who are not HCPs, unless in exceptional cases where there is an objective need for the benefit of the public (particularly the patients). When member companies communicate such information to the public, they should ensure that the information must be objective, neutral and non-promotional.

4 互动场景；指导意见
Interaction Scenarios; Guidance

在本节中，我们列出了在大湾区港澳药械通的背景下与各利益相关方互动时最常出现的场景，并为每种场景提供了指导意见。

In this section, we have set forth the most frequently encountered scenarios for interactions with various stakeholders under the Hong Kong & Macau Registered Medicine Access to GBA Program, and provided guidance for each of the scenarios.

1. 向大湾区指定医院的医疗卫生专业人士传递医学及科学信息

在大湾区指定医院获广东省政府批准，可采购并使用符合条件药品后（符合条件药品的“**使用许可**”），会员公司可向大湾区指定医院的医疗卫生专业人士传递有助于安全、正确使用符合条件药品，以及与使用符合条件药品治疗患者相关的医学及科学信息。

不论大湾区指定医院是否已获得符合条件药品的使用许可，会员公司均可向医院的医疗卫生专业人士传递与符合条件药品相关的疾病的疾病认知信息。

1. Communication of Medical & Scientific Information to HCPs at GBA Designated Hospitals

After a GBA Designated Hospital has obtained the approval from the Guangdong Provincial Government to procure and use an Eligible Drug (the “**Use Approval**” for an Eligible Drug), member companies may communicate medical and scientific information to HCPs at GBA Designated Hospitals that is useful for the safe and proper use of the Eligible Drug and the treatment of patients using the Eligible Drug.

Whether or not a GBA Designated Hospital has obtained the Use Approval for an Eligible Drug, member companies may communicate disease awareness information to HCPs at the hospital for the disease associated with the Eligible Drug.

2. 在符合条件药品获得使用许可后向大湾区指定医院的医疗卫生专业人士传递药品产品信息

在大湾区指定医院就某一符合条件药品获得使用许可后，该医院的医疗卫生专业人士对于获悉安全且正确地使用该药品的必要信息具有真实且客观的需要。为满足这种需要，会员公司可向大湾区指定医院的医疗卫生专业人士传递有助于安全、正确使用符合条件药品，以及与使用符合条件药品治疗患者相关的产品信息。会员公司可根据医疗卫生专业人士的要求，或在医疗卫生专业人士虽未提出要求，但会员公司认为开展上述沟通有客观需要时，与医疗卫生专业人开展上述沟通。

上述沟通必须以相关的符合条件药品在香港和 / 或澳门（视具体获批地而定）获得的药品批准信息为依据。

会员公司的代表在传递上述产品信息时，必须明确告知医疗卫生专业人士：（i）该药品在香港和 / 或澳门已获批，在中国内地尚未获批；（ii）该药品只能在已获得该药品的使用许可的大湾区指定医院使用。任何用于上述沟通的书面材料均须明确说明上述信息。

2. Communication of Drug Product Information to HCPs at GBA Designated Hospitals after an Eligible Drug’s Use Approval

After a GBA Designated Hospital has obtained the Use Approval for an Eligible Drug, the HCPs at the hospital will have a genuine, objective need for information that is necessary for their safe and proper use of the drug. To meet such need, member companies may communicate product information to HCPs at GBA Designated Hospitals for the Eligible Drug that is useful to the safe and proper use of the Eligible Drug and the treatment of patients using the Eligible Drug. Member companies may conduct such communication upon the request of the HCPs, or without the request of the HCPs when the companies see an objective need for such communication.

Such communication must be based on the approved drug information in Hong Kong and/or Macau for the Eligible Drug, wherever the drug is approved.

When communicating such product information, representatives of member companies must clearly inform the HCPs that: (i) the drug is approved in Hong Kong and/or Macau, and has not been approved in China; and (ii) the drug can be used only at GBA Designated Hospitals that have obtained the Use Approval for the drug. Any written materials used in such communication must bear statements clearly to such effect.

3. 在符合条件药品获得使用许可前向大湾区指定医院（包括医疗卫生专业人士）介绍药品产品信息

在大湾区指定医院获得某药品的使用许可前，医院（包括医院的医疗卫生专业人士）可能有了解该药品更多相关信息的客观需要，以便评估医院是否应就该药品申请使用许可，为患者提供更好的医疗服务。因此，会员公司可能有合理的需要向医院（包括医院的医疗卫生专业人士）介绍与该药品相关的产品信息，以介绍该药品的获益，并协助医院评估是否就该药品申请使用许可。

会员公司开展此类沟通活动时，必须谨慎从事，只有在满足以下所有条件的情况下，才能开展此类沟通活动：

(i) 相关药品已在香港或澳门获批，从而医院可申请该药品的使用许可；

(ii) 公司已进行评估并从其角度得出结论，认为相关药品可满足医院患者未获满足的医疗需求，从而促进患者治疗；

(iii) 公司介绍产品信息的首要考量因素必须是患者未获满足的医疗需求可得到满足，而不是提高产品销量；

(iv) 公司只可向大湾区指定医院的管理人员及医疗卫生专业人士介绍产品信息，而不可向其他医院的管理人员及医疗卫生专业人士介绍；且

(v) 相关信息必须公正、客观、准确、无误导性。

3. Introduction of Drug Product Information to GBA Designated Hospitals (Including HCPs) before the Drug's Use Approval

Before a GBA Designated Hospital has obtained the Use Approval for a drug, there may exist an objective need for the hospital (including its HCPs) to learn more information about the drug so as to assess whether the hospital shall seek the Use Approval for the drug so as to provide better patient care. For that reason, member companies may have a reasonable need to introduce product information to the hospital (including its HCPs) relating to a drug for the purpose of introducing the benefits of the drug and supporting the hospital to assess whether to seek Use Approval for the drug.

Member companies must conduct such communications carefully, and can do so only when the following conditions are all met:

(i) the drug is approved in Hong Kong or Macau and therefore the hospital may seek the Use Approval for the drug;

(ii) the company has performed an assessment and concluded that the drug, in its view, may meet unmet medical needs of patients at the hospital and therefore advance patient care;

(iii) the primary consideration of the company's information introduction must be meeting the unmet medical needs of patients, not increase of product sales;

(iv) the company can introduce the information to hospital managers and HCPs only at GBA Designated Hospitals, not other hospitals; and

(v) the information must be fair and balanced, and accurate and non-misleading.

4. 向没有获得相关药品使用许可的医院（包括医疗卫生专业人士）介绍药品产品信息

如果某医院，因不是大湾区指定医院，而无法获得某药品的使用许可，或某医院是大湾区指定医院，但尚未获得某药品的使用许可，该医院的医疗卫生专业人士亦可能有了解该药品相关信息的客观需要，以便从患者的最佳利益出发进行评估，是否应将患者转介至已获得该药品使用许可的大湾区指定医院（“**符合条件的大湾区指定医院**”），使相关患者获得最佳治疗。因此，会员公司可能有向此类医院的医疗卫生专业人士介绍相关产品信息的合理需要，使这些医疗卫生专业人士了解在符合条件的大湾区指定医院已获得使用许可的相关药品。

会员公司开展此类沟通活动时，必须谨慎从事，我们建议，在可行的情况下，会员公司在开展此类沟通活动前，应首先进行相关评估，并得出相关药品可满足医院患者未获满足的医疗需求的结论。

此外，只有在满足以下所有条件的情况下，会员公司才能开展此类沟通活动：

(i) 符合条件的大湾区指定医院已获得相关药品的使用许可；

4. Introduction of Drug Product Information to Hospitals (Including HCPs) Not Having the Use Approval of the Drug

If a hospital is not a GBA Designated Hospital and therefore cannot receive Use Approval for a drug, or if a hospital is a GBA Designated Hospital but has not obtained the Use Approval for a drug, there may exist an objective need for the HCPs at the hospital to learn information about the drug so as to assess whether, in the patients' best interests, the HCPs shall refer the patient to a GBA Designated Hospital that has obtained the Use Approval for the drug (an "**Eligible GBA Designated Hospital**") so that the patient will receive the best medical treatment. For that reason, member companies may have a reasonable need to introduce product information to the HCPs at the hospital relating to a drug that has received Use Approval at an Eligible GBA Designated Hospital.

Member companies must conduct such communications carefully, and we recommend that prior to such communications, when feasible, member companies should perform an assessment and conclude that the drug may meet unmet medical needs of patients at the hospital.

In addition, member companies may conduct such communication only when the following conditions are all met:

(i) the drug has received Use Approval at an Eligible GBA Designated Hospital;

(ii) 公司介绍产品信息的首要考量因素必须是为医疗卫生专业人士作出以下决定提供支持：是否应将相关患者转介至符合条件的大湾区指定医院，以满足患者未获满足的医疗需求，而不是增加产品销量；

(iii) 公司只可向医院的医疗卫生专业人士介绍产品信息，不可向其他人员介绍；

(iv) 公司只可向大湾区内医院的医疗卫生专业人士介绍产品信息，不可向大湾区之外的医院介绍；且

(v) 相关信息必须公正、客观、准确、无误导性。

(ii) the primary consideration of the company's information introduction must be supporting the HCPs' decision on whether to refer the patient to the Eligible GBA Designated Hospital so as to meet the unmet medical needs of patients, not increase of product sales;

(iii) the company can introduce the information to HCPs at the hospital only, not other personnel;

(iv) the company can introduce the information to HCPs at hospitals in the Greater Bay Area, not hospitals outside the GBA; and

(v) the information must be fair and balanced, and accurate and non-misleading.

5. 向患者及护理人员传递疾病认知信息

会员公司可直接或与患者组织合作，向大湾区内患者及护理人员传递疾病认知信息，包括与符合条件药品的适应症相关的信息。会员公司在开展此类沟通活动时，应尊重患者及护理人员的独立性，不得利用任何活动不正当地影响患者或护理人员的用药决定或治疗决定。为此，如果患者、护理人员或公众个人希望就个人医疗事项获得相关信息或建议，应直接向大湾区内有相关资质的医疗卫生专业人士提出。

5. Communication of Disease Awareness Information to Patients and Caregivers

Member companies may communicate disease awareness information to patients and caregivers in the Greater Bay Area region, including information relating to diseases that Eligible Drugs are indicated for, either directly or with collaboration with patient organizations. When conducting such communication activities, member companies should respect the independence of patients and caregivers, and should not use any activity to unduly influence the drug use decisions or medical treatment decisions of patients or caregivers. For this purpose, request from patients, caregivers or individual members of the public for information or advice on personal medical matters should be directed to qualified HCPs within the GBA.

6. 患者支持项目

会员公司可直接或与合格的医疗组织、慈善组织、患者组织或其他类型的主体合作，针对符合条件药品，开展各类患者支持项目，例如药品成本补贴项目、药品样品项目等。作为一项基本原则，会员公司只能在指定医院获得相关药品的使用许可后，才能在这些指定医院内开展此类项目。

会员公司开展患者支持项目时，应遵守以下要求：

(i) 患者支持项目的目的必须是降低患者的用药成本、促进患者利益，而不是为了推广药品、提高药品的知名度等其他目的；

(ii) 患者应该是可合法获得符合条件药品处方的患者；且

(iii) 会员公司应遵守中国适用的监管规定，包括但不限于药品经营监管规定（如适用）。

6. Patient Support Programs

Member companies may conduct various types of Patient Support Programs ("**PSP**") for Eligible Drugs, such as drug cost subsidy programs, drug sample programs, etc., either directly or in collaboration with qualified medical organizations, charitable organizations, patient organizations or entities of other types. As a general principle, member companies may conduct such programs only within the Designated Hospitals after such hospitals have obtained Use Approval for the drug.

When conducting such PSPs, member companies should satisfy the following requirements:

(i) the objective of the PSPs must be reducing the drug use cost of the patients and advancing the benefits of the patients, not any other objective such as promotion of the drug, increase of the drug's recognition, etc.;

(ii) the patients should be those that may legitimately receive the prescription of the Eligible Drugs; and

(iii) member companies should comply with applicable regulatory requirements in China, including without limitation drug distribution requirements (if applicable).

7. 使用内部员工开展大湾区港澳药械通互动活动

在开展上述互动活动时，会员公司必须确保相关员工具备开展此类活动所需的知识及专长。

会员公司可以使用其香港或澳门关联公司的员工开展此类活动，但前提是，这些员工开展此类活动，符合中国法律法规，包括但不限于与医药代表备案相关的法规（如适用）。

7. Use of Internal Employees for GBA Hong Kong-Macau Drug Program Interactions

When conducting the interaction activities listed above, member companies must ensure that relevant employees possess the necessary knowledge and expertise for such activities.

Member companies may use the employees in their Hong Kong or Macau affiliates for such activities, but only if such activities of these employees comply with Chinese laws and regulations, including without limitation regulations relating to the registration of medical representatives (if applicable).

8. 科学、医学及产品材料的制作

在开展上述互动活动的过程中，会员公司可能需要制作科学、医学或产品材料。会员公司在制作此类材料时，应遵守以下要求:

(i) 材料必须以简体中文提供（不论是只提供中文或与英文等其他语言一起提供）；

(ii) 相关材料信息必须与该药品在香港和 / 或澳门（视具体获批地而定）获得的药品批准信息一致；且

(iii) 会员公司必须建立并实施适当且健全的制度，对此类材料进行审批和管理。

8. Development of Scientific, Medical and Product Materials

During the course of conducting the interaction activities listed above, member companies may need to develop scientific, medical or product materials. When doing so, member companies should satisfy the following requirements:

(i) the materials must be in simplified Chinese (whether Chinese only or with another language such as English);

(ii) the information must be consistent with the drug approval information in Hong Kong and/or Macau, wherever the drug is approved; and

(iii) member companies must establish and implement an appropriate and robust system to review, approve and manage such materials.

9. 履行药物警戒义务

药物警戒制度，是药品监管过程中保障公众健康的重要工具，因此也是患者医疗服务不可或缺的组成部分。制药公司是药品的“所有者”，因此，对确保采取必要的药物警戒措施，遵守适用的药物警戒监管规定，负有首要责任。

会员公司在根据本指导意见开展互动活动时，必须确保遵守适用法律法规中关于药物警戒责任的规定。会员公司有责任：

(i) 持续监测大湾区药品产品的药物警戒数据，并对与产品风险相关的所有信息进行科学评估；

(ii) 向主管部门提交准确且可核验的药物不良反应数据；

(iii) 与主管部门有效沟通可能影响相关药品获益 / 风险平衡的任何信息；并且

(iv) 更新产品信息，以反映与药物警戒相关的科学及医学相关知识的最新发展，并在必要时，获得监管部门对此类更新信息（包括对产品标签及说明书的修订）的批准，并向医疗卫生专业人士传达相关信息。

9. Fulfilment of Pharmacovigilance Obligations

Pharmacovigilance (“PV”) systems are important tools in the regulatory process for pharmaceutical products to safeguard public health, and therefore an integral component of patient healthcare. Pharmaceutical companies are the “owners” of a pharmaceutical product and as such are primarily responsible for ensuring that necessary PV actions are taken to comply with applicable PV regulatory requirements.

When conducting interaction activities under this Guidance, member companies must ensure compliance with PV-related responsibilities as set forth in applicable laws and regulations. Member companies are responsible for:

(i) Continuous monitoring of PV data and scientific evaluation of all information on the risks of the drug product in the Greater Bay Area;

(ii) Submission of accurate and verifiable data on adverse drug reactions (ADRs) to competent authorities;

(iii) Effective communication with competent authorities on any information that may impact the benefit/risk balance of relevant pharmaceutical products; and

(iv) Update of product information to reflect development of relevant PV related scientific and medical knowledge and – when required – obtaining of regulatory approval for such updates (including revisions to product labels and inserts), and communication of relevant information to HCPs.

10. 使用真实世界证据支持监管决策

“真实世界证据”是指通过分析真实世界数据（即从各种信息来源定期收集的，与患者健康状况和 / 或提供医疗健康服务相关的数据）而得出的有关医疗产品的使用情况及其潜在获益或风险的临床证据。在过去十年中，真实世界证据的价值在中国得到了越来越多的认可。自 2019 年以来，国家药监局和药品审评中心（“**药审中心**”）发布了多份关于真实世界证据的指南，为如何使用真实世界证据，促进并加快药品的研发与审批提供了指导。

鉴于以上情况，会员公司在大湾区开展真实世界证据项目，以及使用真实世界证据支持药品在药监局的注册申请时，应遵守药监局及药审中心发布的相关法规及指导意见，包括不良事件监测与报告的程序及要求。

此外，会员公司还必须确保，真实世界证据项目必须具有清晰且真实的医学目的，必须以此种目的为主要驱动力开展此类项目，不得以真实世界证据项目为手段，通过向医疗卫生专业人士支付经济利益，对医疗卫生专业人士施加不当影响（特别是医疗卫生专业人士的处方决定）。

10. Use of Real-World Evidence to Support Regulatory Decisions

“Real-world evidence” (“**RWE**”) is the clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of real-world data (“**RWD**”, i.e., data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources). Over the past decade, RWE has been increasingly recognized for its value in China. Since 2019, the NMPA and the Center for Drug Evaluation (“**CDE**”) have published several RWE-related guidelines, through which the two agencies provided guidance on how to use RWE to facilitate and expedite the development and approval of drugs.

In light of the above, when conducting RWE programs in the Greater Bay Area and using RWE to support drug registrations with the NMPA, member companies should comply with relevant regulations and guidelines issued by the NMPA and the CDE, including procedures and requirements on adverse event monitoring and reporting.

In addition, member companies must ensure that RWE programs must have clear and genuine medical purpose and must be primarily driven by such purpose, and must not use RWE programs as a means to exert undue influence on HCPs (particularly their prescribing decisions) by paying financial benefits to them.

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 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

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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