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引言

Introduction

于 2023 年 6 月 30 日发布的《RDPAC 数字医疗合规指南》（“《数字医疗指南》”）为会员公司在与医疗卫生专业人士、患者及其他利益相关方的互动中使用数字化工具提供了高度概括、不具约束力的指导。根据《数字医疗指南》的原则，RDPAC 现发布本《RDPAC 数字医疗合规分项指南：与医疗卫生专业人士及医疗卫生组织的互动》（本“分项指南”），旨在为数字场景中医疗卫生专业人士及医疗卫生组织的互动提供具体指导。

本分项指南的目的是为会员公司提供不具约束力的指导，以供会员公司在考虑通过数字化渠道与医疗卫生专业人士及医疗卫生组织开展互动活动的合规问题时参考。本分项指南应依据《数字医疗指南》的精神，并始终遵守适用法律、法规、《RDPAC 行业行为准则（2022 年修订版）》（“《RDPAC 准则》”）的一般性原则及相关规定以及其他适用的行业标准进行解读。

还应注意的是，鉴于会员公司使用数字化工具的具体做法各不相同，本分项指南仅就某些相对广泛使用的做法提供一般性指导。会员公司可根据本分项指南所载原则，自行酌定适用于各类情景的实施细则，也可根据各自公司的具体考量，酌情采用比本分项指南更为严格的规定。

The RDPAC Digital Health Compliance Guidance (the “Digital Health Guidance”), published on June 30, 2023, provides high-level, non-binding guidance to member companies regarding the use of digital tools in their interactions with healthcare professionals (“HCPs”), patients and other stakeholders. In accordance with the principles under the Digital Health Guidance, the RDPAC now issues this RDPAC Digital Health Compliance Sub-Guidance: Interactions with HCPs & HCOs (this “Sub-Guidance”), aiming to provide specific guidance on interactions with HCPs and healthcare organizations (“HCOs”) in digital settings.

The purpose of this Sub-Guidance is to serve as a non-binding resource for member companies when considering their interaction activities with HCPs and HCOs through digital channels. This Sub-Guidance should be read in the spirit of the Digital Health Guidance and always in accordance with applicable laws, regulations, the general principles and relevant provisions of the RDPAC Code of Practice 2022 (the “RDPAC Code”) and other applicable industry standards.

It should also be noted that member companies have varying practices in the use of digital tools, and this Sub-Guidance only provides general guidance on certain relatively widely-used practices. Member companies have the freedom and discretion in determining the implementation details for various scenarios based on the principles contained in this Sub-Guidance, and in adopting more stringent requirements than those contained in this Sub-Guidance, as they deem appropriate in light of their companies’ specific considerations.

1

数字化渠道特有的合规考虑因素

Compliance Considerations Specific to Digital Channels

1. 数字化活动相关法规和规则

近年来，随着数字化工具在医药行业的兴起和广泛应用，中国政府制定了多项与数字化活动相关的法规和规则，例如与互联网诊疗、网售药品、互联网广告以及个人信息保护、数据安全和网络安全相关的法规和规则。会员公司在计划并实施涉及在数字场景中医疗卫生专业人士和医疗卫生组织进行互动的活动时，应严格遵守这些特定法规。

2. 第三方数字平台管理

会员公司在与医疗卫生专业人士和医疗卫生组织互动时，可能需要与各类第三方数字平台接触或合作，包括但不限于在线会议平台、社交媒体平台、健康管理平台、互联网医院、电商平台、电商零售药店等。

1. Specific regulations and rules relating to digital activities

With the emergence and wide use of digital tools in the pharmaceutical industry in recent years, the Chinese government has developed several regulations and rules related to digital activities, such as those related to Internet diagnosis and treatment, sale of medicines on the Internet, Internet advertising, as well as protection of personal information, data security and cybersecurity. Member companies should strictly adhere to these specific regulations when contemplating and implementing programs that involve interactions with HCPs and HCOs in digital settings.

2. Management of third-party digital platforms

In their interactions with HCPs and HCOs, member companies may need to engage or collaborate with various third-party digital platforms, including but not limited to, online conference platforms, social media platforms, health management platforms, Internet hospitals, e-commerce platforms, e-commerce retail pharmacies, etc.

会员公司应妥善管理因使用此类平台而产生的合规风险。特别是在与第三方数字平台接触或合作时，会员公司应适当评估相关合作项目的合规及执行风险，并在此基础上对第三方数字平台以及该平台在项目中使用的主要分包商及服务商进行充分、有效的合作前尽职调查。我们建议此类尽职调查应至少涵盖相关实体的注册状态及资质、既往受处罚及负面新闻报道情况、其合规控制体系的有效性、其是否同意在适用的情况下遵守会员公司的合规标准及要求，以及其是否同意在需要时配合会员公司的合规监控及审计。对于可能参与向医疗卫生专业人士付款的第三方数字平台（例如互联网医院、电商零售药店等），我们鼓励会员公司对此类第三方数字平台向医疗卫生专业人士支付报酬的模式进行尽职调查，尤其应关注此类模式是否可能会对医疗卫生专业人士的处方决定产生不当影响。

会员公司可出于对相关数据进行合理分析和利用之目的与各类数字平台（包括但不限于互联网医院、电商平台、网上药店等）进行合作。但是，会员公司不得出于不正当商业目的收集任何药品处方量数据。

此外，会员公司应考虑制定健全的合规监控及基于风险的审计计划，对第三方数字平台进行有效监控及审计。

Member companies should properly manage the compliance risks arising from using such platforms. Particularly, when engaging or collaborating with third-party digital platforms, member companies should properly assess the compliance and execution risks of the program, and on that basis perform an adequate and effective pre-collaboration due diligence review on the third-party digital platform as well as the key subcontractors and vendors that such platform uses for the program. It is recommended that such due diligence review should cover, at a minimum, the relevant entities' registration status and qualifications, past penalties and negative press reports, the effectiveness of their compliance control system, whether they agree to comply with the member company's compliance standards and requirements when applicable, and whether they agree to cooperate with the member company's compliance monitoring and auditing when needed. With respect to third-party digital platforms that may be involved in making payments to HCPs (e.g., Internet hospitals, e-commerce retail pharmacies, etc.), member companies are encouraged to conduct due diligence on such third-party digital platform's HCP compensation models, with a particular focus on such models' potential undue influence on HCP prescribing decisions.

Member companies may cooperate with various digital platforms, including but not limited to Internet hospitals, e-commerce platforms, online pharmacies, etc., for the purpose of conducting reasonable data analysis and utilization. However, member companies are not allowed to collect any drug prescription amount data for unjustifiable commercial purposes.

In addition, member companies should consider developing a robust compliance monitoring and risk-based audit plan for third-party digital platforms, and conduct effective monitoring and audits accordingly.

3. 信息安全、数据隐私和网络安全技术

会员公司通过数字化渠道与医疗卫生专业人士互动时，可能会有收集医疗卫生专业人士的个人信息合法且合理的需要，例如用于用户注册和身份验证等目的。在开展此类活动之前，会员公司应考虑相关数字平台的资质和技术标准，及其对适用的法律法规的遵守情况。在处理从医疗卫生专业人士收集的个人信息时，会员公司应遵守适用的数据保护及隐私保护法律法规，以及各类国家标准及指导原则。

特别是，如果会员公司对医疗卫生专业人士个人信息的使用将涉及医疗卫生专业人士的用户画像，则用户画像的使用不应识别到特定个人，除非是为实现个人信息主体已提供特别授权和同意的使用目的所必需。会员公司不得使用用户画像推送药品广告或其他商业广告。

我们建议会员公司在使用数字平台（例如举行虚拟会议）时，实施相关流程对与会者身份属于医疗卫生专业人士或非医疗卫生专业人士进行确认。对于第三方活动，会员公司应考虑与活动主办者（例如医疗卫生组织）合作，尽合理努力确保只有医疗卫生专业人士才能访问活动资料（尤其是包含药品信息的资料）。

3. Information security, data privacy and cybersecurity technology

When interacting with HCPs through digital channels, member companies may have legitimate and reasonable needs to collect personal information from HCPs for purposes such as user registration and identification authentication. Before performing such activities, member companies should consider the qualification and technical standards of the digital platforms and their compliance with applicable laws and regulations. When processing personal information collected from HCPs, member companies should comply with applicable data protection and privacy laws and regulations, as well as various national standards and guidelines.

Particularly, if the use of HCP personal information by member companies involves HCPs' user portrait, such use of user portrait should not identify specific individuals, except to the extent necessary to achieve the purpose of the use for which the personal information subject has provided specific authorization and consent. Member companies should not use user portrait to deliver drug advertisements or other commercial advertisements.

When using digital platforms (e.g., conducting virtual meetings), member companies are recommended to implement a process to confirm participants' status as HCPs or non-HCPs. For third-party events, member companies should consider working with the event owner (e.g., an HCO) to make reasonable efforts to restrict access to event materials (particularly materials containing drug information) to HCPs only.

2

具体场景指导

Specific Scenario Guidance

1. 面向医疗卫生专业人士的虚拟医学教育活动

会员公司可支持医疗卫生专业人士参加公司组织的虚拟项目和第三方主办的医疗卫生专业人士活动。会员公司可根据医疗卫生专业人士的专业知识、资质、经验及教育需求，考量项目 / 活动对医疗卫生专业人士个人的价值，从而作出是否支持医疗卫生专业人士参加此类活动的决定。

原则上，对于第三方组织的虚拟医学互动项目，会员公司对医疗卫生专业人士参加此类项目的支持一般应仅限于承担项目注册费，提供的支持不应涵盖任何差旅、住宿及餐饮费。

此外，我们鼓励会员公司确保制定相关流程，对公司组织的虚拟项目的参与者的身份进行验证。

任何向医疗卫生专业人士支付的、与其在线提供讲者服务相关的讲者费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。

1. Virtual medical interaction programs with HCPs

Member companies may support HCPs to attend virtual company-organized programs and third-party HCP events. Member companies may make decisions on HCP attendance support on the basis of the value of the programs/events to individual HCPs depending on their expertise, qualifications, experience, and educational needs.

In principle, for virtual medical interaction programs organized by third-parties, a member company's support of HCP attendance should typically be limited to program registration fees only, and should not include any cost for travel, accommodation and meals.

In addition, member companies are encouraged to ensure that a process is in place to conduct identification authentication on attendees for company-organized virtual programs.

Any payment of speaker fees to HCPs in connection with online speaking services should comply with the Fair Market Value ("FMV") principle, and member companies should establish an appropriate FMV mechanism.

2. 数字化医患互动项目

数字化医患互动项目可以采取多种形式，例如虚拟患者教育项目以及移动应用程序或微信小程序上的虚拟“问答室”。不论采取何种形式开展数字化医患互动项目，会员公司均应确保此类互动内容公平、全面且中立，仅限于非推广性质的科学和疾病认知内容，且互动不会造成医患关系中的利益冲突风险。与患者分享信息不应构成诊疗活动，不应以推广产品为目的，也不应包括可能会不当影响患者用药及治疗决定的产品相关信息。

会员公司应确保参与医患互动项目的医疗卫生专业人士具备与项目主题相关的适当资质、知识及经验，并熟悉在线互动的技术和形式。向医疗卫生专业人士支付的任何服务费均必须基于医疗卫生专业人士提供的真实且合法的服务，并符合公平市场价值原则。

为确保医疗卫生专业人士与患者之间的交流不构成非法诊疗活动，会员公司应考虑采取适当的方法监控交流互动内容，例如标准化下拉式短语回复和禁用自由文本回复。

2. Digital HCP-patient interaction programs

Digital HCP-patient interaction programs can take various forms, such as virtual patient education programs and virtual "Q&A rooms" on mobile apps or WeChat mini-programs. Regardless of the form of digital HCP-patient interaction programs, member companies should ensure that the content of such interaction is fair, balanced and neutral, and is limited to non-promotional scientific and disease awareness content, and the interactions do not pose a risk of conflict of interest in the HCP-patient relationship. Information sharing with patients should not constitute diagnosis and treatment activities, should not be product promotion driven and should not include product-related information that could inappropriately influence patients' drug use and medical treatment decisions.

Member companies should ensure that HCPs participating in HCP-patient interaction programs have appropriate qualifications, knowledge, and experience with the subject matter of the program, and are familiar with the technology and format of online interactions. Any payment of service fees to HCPs must be based on HCPs' genuine and legitimate services and comply with the FMV principle.

To ensure that communications between HCPs and patients do not constitute unlawful diagnosis and treatment activities, member companies should consider implementing appropriate methods to monitor the content of interactions, such as standardized drop-down response phrases and prohibition of free text responses.

在开展数字化医患互动项目时，会员公司还应确保遵守不良事件收集及报告义务，并可事先对医疗卫生专业人士进行充分的培训，使其了解如何正确收集并处理不良事件信息。

3. 与相关协会的数字化互动项目

与相关协会的数字化互动项目可以采取多种形式，例如合作开发数字化患者护理系统，供医疗卫生专业人士用于患者管理。此类项目的目的及重点应该是向医疗卫生专业人士提供科学或教育信息，以加强对患者的护理，和 / 或通过提供疾病或护理知识使患者受益。会员公司不应将数字化项目作为工具，不当影响医疗卫生专业人士的处方决定。

为确保遵守上述原则，会员公司应制定适当的内部控制及管理措施，我们建议这些措施应涵盖：以合规方式收集医疗卫生专业人士或患者信息，使用合格的第三方和第三方管理，以及记录留存规定。会员公司应对合作协会进行适当的尽职调查和审计。此外，我们鼓励会员公司要求合作协会在聘用第三方服务商之前，首先完成对该等服务商的尽职调查，并要求合作协会对其聘用的第三方服务商进行监控和审计。为核实付款情况，会员公司可考虑要求合作协会提供与第三方服务商的费用结算报告及付款证明发票。

When carrying out digital HCP-patient interaction programs, member companies should also ensure their compliance with adverse event (“AE”) collection and reporting obligations, and may organize adequate prior trainings to HCPs on the proper collection and handling of AE information.

3. Interaction with associations on digital programs

Digital interaction programs with associations may take various forms, such as co-development of a digital patient care system that could be used by HCPs for patient management. The purpose and focus of digital interaction programs with associations should be to provide scientific or educational information to HCPs for the enhancement of patient care, and/or to benefit patients through the provision of disease or care knowledge. Member companies should not use the digital program as a tool to unduly influence the prescription decisions of HCPs.

To ensure compliance with the above principles, member companies should have appropriate controls and governance in place, which is recommended to cover compliant collection of HCP or patient information, use of qualified third-parties and third-party management, and record retention requirements. Member companies should perform proper due diligence and audits on the collaborating associations. In addition, member companies are encouraged to require collaborating associations to conduct due diligence on the third-party vendors used by the associations before engagement, and require the associations to conduct monitoring and audit on third-party vendors that they engage. For payment verification purposes, member companies may consider requiring associations to provide fee settlement reports and supporting invoices with their third-party vendors.

4. 与互联网医院的互动

我们建议会员公司在与互联网医院开展任何互动项目前，对整个项目进行全面评估，评估应涵盖：项目目的、招募或聘请医疗卫生专业人士参与该项目的理由（如适用）、根据该项目向医疗卫生专业人士转移价值的情况、是否存在任何反垄断或不正当竞争问题、是否存在对医疗卫生专业人士或参与该项目的患者产生不当影响的风险，以及是否存在通过互联网医院平台对疾病和 / 或产品相关内容进行不当宣传或广告的风险。

特别是，为有效管理反腐败 / 反贿赂风险，我们鼓励会员公司在开展互动项目前，对互联网医院进行背景调查、法律与合规尽职调查及业务尽职调查。我们建议尽职调查的重点是互联网医院的业务模式及盈利模式，以及互联网医院向医疗卫生专业人士支付报酬的模式，包括相关做法。一般情况下，互联网医院可就医疗卫生专业人士提供的真实、合法服务，例如在线诊疗、在线健康管理、在线咨询等，向医疗卫生专业人士支付符合公平市场价值原则的服务费。但原则上，不论是在会员公司的互动项目中或其他项目中，如果某互联网医院在确定应支付给医疗卫生专业人士的服务费时，完全或部分以医疗卫生专业人士的药品处方量为依据，则会员公司不应与该互联网医院合作。

4. Interaction with Internet hospitals

Prior to commencing any interaction program with Internet hospitals, member companies are recommended to conduct a thorough evaluation of the entire program, including an assessment of the purpose of the initiative, the rationale for recruiting or involving HCPs (if applicable), the transfer of value to HCPs under the program, any antitrust or unfair competition issues, the risk of undue influence on HCPs or patients of the program and the risk of improper promotion or advertising of the disease and/or product-related content on such platforms.

In particular, to effectively manage anti-corruption/anti-bribery risks, before carrying out the interaction program, a member company is encouraged to conduct background check, legal and compliance due diligence review and business due diligence review on the Internet hospital. It is recommended that such due diligence review focuses on the business model and profit model of the Internet hospital, as well as the Internet hospital's HCP compensation model including relevant practices. Generally, Internet hospitals can pay HCPs for their genuine and legitimate services, such as online diagnosis and treatment, online health management, online consultation, etc., in compliance with the FMV principle. In principle, a member company should not collaborate with an Internet hospital that uses drug prescription amount, either fully or partially, when determining the service fees to be paid to HCPs, whether within the member company's interaction program or in other programs.

5. 与电商平台及电商零售药店的互动

同样，我们鼓励会员公司在与电商平台和 / 或电商零售药店开展任何互动项目前，对拟议项目进行全面评估和审评，尤其应注意价格控制风险以及关联医院及药店之间的跨渠道干预风险。

此外，由于电商平台及电商零售药店可能会与患者和公众有实质直接互动，在评估具体互动项目时，会员公司应特别注意将在电商渠道上发布的材料。特别是，我们建议会员公司审查电商平台和 / 或电商零售药店编制的材料，确保互联网零售药店发布的材料中不含有超适应症信息，不具有虚假或误导性，且不属于非法药品、医疗器械或医疗广告。

5. Interaction with e-commerce platforms and e-commerce retail pharmacies

Similarly, prior to commencing any interaction program with e-commerce platforms and/or e-commerce retail pharmacies, member companies are encouraged to conduct a thorough evaluation and assessment of the proposed program, paying particular attention to price control risk and the risk of cross-channel interference among affiliated hospitals and pharmacies.

In addition, because e-commerce platforms and retail pharmacies may have substantial direct interactions with patients and the general public, when evaluating a specific interaction program, member companies should pay particular attention to the materials that will be posted on e-commerce channels. In particular, member companies are recommended to review the materials developed by the e-commerce platforms and/or retail pharmacies to ensure that information contained in materials posted on online retail pharmacies does not contain off-label information, is not false or misleading and is not illegal drug, device or medical treatment advertisement.

6. 运营数字医疗产品

数字医疗产品 (DTx) 是用于预防、管理及治疗健康问题的软件类产品。此类产品受限于一系列特定的监管注册要求。数字医疗产品可在互联网医院使用或处方，或通过电商平台购买。会员公司应确保数字医疗产品的经销与推广符合《药品经营质量管理规范》(GSP) 相关法律法规、医院准入规则以及电商平台上传与下载规则。会员公司应对其数字医疗产品的任何推广活动或推广材料进行仔细审查，确保符合宣传和广告相关法律、法规以及公司内部政策及标准操作程序。

7. 使用社交媒体工具

作为一般原则，会员公司应对由会员公司或代表会员公司行事的第三方发起、冠名和 / 或赞助的，通过数字化渠道（包括社交媒体）传播的所有内容负责。会员公司不得利用社交媒体或数字化渠道（例如网站、网络研讨会、播客、博客、微信官方账号、微博账号等）对药品进行不当宣传或发布广告。因此，会员公司应考虑建立并实施适当、健全的审查机制，确保在社交媒体或数字化渠道上发布的内容均真实、无误导、全面、及时、准确，且符合药品宣传及广告法律、法规及指导原则的规定。

6. Operating digital therapeutic (DTx) products

Digital therapeutics ("DTx") are software-based products for the prevention, management and treatment of health conditions. They are subject to a set of specific regulatory registration requirements. DTx products may be used or prescribed on Internet hospitals, or purchased through e-commerce platforms. Member companies should ensure that the distribution and promotion of DTx products are in compliance with GSP-related laws and regulations, hospital listing rules, and e-commerce platform upload and download rules. Any promotional activities or promotional materials for the DTx products should be carefully reviewed by member companies to ensure compliance with promotion and advertising laws, regulations and company policies and SOPs.

7. Use of social media tools

As a general principle, member companies are responsible for all content disseminated via digital channels including social media, when the content is initiated, branded, and/or sponsored by the member company or a third party acting on its behalf. A member company must not use social media or digital channels (e.g., websites, webinars, podcasts, blogs, WeChat official account, Weibo account, etc.) to engage in improper promotion or advertising of pharmaceutical products. Therefore, member companies should consider establishing and implementing an adequate and robust review mechanism to ensure content published on social media or digital channels is truthful, non-misleading, balanced, current, and accurate, and complies with the provisions of the laws, regulations and guidelines on the promotion and advertising of pharmaceutical products.

作为利用社交媒体的一类新型数字化项目，会员公司可与某一领域或行业的媒体人物（“网红”）或特定问题专家（“数字平台意见领袖”）合作。由于网红和数字平台意见领袖有能力接触到大量受众，会员公司可以聘请他们提供顾问及咨询服务，包括创建、共同创建并发布数字化内容。

会员公司与网红及数字平台意见领袖合作时，须对合作项目进行仔细评估，包括评估对医疗卫生专业人士、医疗卫生组织、患者及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广告的风险。

此外，我们建议会员公司仔细评估与网红及数字平台意见领袖（包括医疗卫生专业人士及非医疗卫生专业人士）签订的合同，确保此类人士提供的服务是善意服务或满足合法需求，并且向他们提供的任何补偿或报酬都是适当且合理的，不会构成不当影响或利益冲突的风险。因此，我们鼓励会员公司制定根据公平市场价值计算网红和数字平台意见领袖的服务费费率的方法，以确保付费的透明度及一致性。

As a new type of digital program using social media, member companies may collaborate with online influencers who are media figures within an area or sector, or digital opinion leaders who are experts on specific issues. Because of their capabilities of reaching to a large group of audience, member companies may engage online influencers and digital opinion leaders as consultants and advisors for services, including creation and co-creation and posting of digital content.

Engaging with online Influencers and digital opinion leaders requires careful evaluation, including assessment of the risks of undue influence on HCPs, HCOs, patients and the general public, and risks that such digital content could be perceived as improper promotion or illegal advertisement of pharmaceutical products.

In addition, member companies are recommended to carefully assess engagements with online influencers and digital opinion leaders (both HCPs and non-HCPs) to ensure that the services provided constitute bona fide services or serve a legitimate need and that any compensation or remuneration provided to them is appropriate and reasonable and would not pose a risk of undue influence or conflict of interest. In this regard, member companies are encouraged to establish a methodology for calculating FMV rates for online influencers and digital opinion leaders to ensure transparency and consistency.



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
阿斯泰来	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



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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