

RDPAC

与合同销售组织（CSO） 开展合作的合规指南

Compliance Guidance on Collaborations
with Contract Sales Organizations (CSO)

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使命宣言

Mission Statement

“合同销售组织”（“CSO”）是指与制药公司签订合同，通过开展市场营销、推广和其他活动，以促进该制药公司的药品产品销售的公司。CSO 可以是将药品经营作为其主营业务但同时提供药品推广服务的公司，也可以是没有药品经营业务仅提供药品推广服务的公司，或者制药公司（如 RDPAC 会员公司，或中国本土制药公司）。

RDPAC 注意到其会员公司在中国开展的 CSO 交易数量正在快速增长，尤其是会员公司作为药品持证人聘请 CSO 提供服务的情况。RDPAC 认可 CSO 交易在促进药品的成功商业化及扩大药品对患者的可及性方面可能创造的价值。与此同时，RDPAC 也清醒地认识到 CSO 活动可能带来的各种违法风险和医学伦理风险。特别是，根据中国法律和某些适用的外国法律（包括但不限于美国《反海外腐败法》），CSO 可能会被视为代表药品持证人推广药品，从而导致药品持证人可能会对 CSO 的贿赂行为承担责任¹。认识到药品持证人及其 CSO 之间的这一法律关系以及相关监管部门由此而产生的期待，《RDPAC 行业行为准则》明确规定其适用于“代表会员公司执行工作任务的分包商，如…外包的医药代表”²。现在，RDPAC 进一步采取措施，制定了本合规指南，旨在为会员公司提供原则性的、非约束性的指导，鼓励会员公司考虑和采取措施，以防止 CSO 业务中的不当行为（特别是贿

A “contract sales organization” (CSO) means a company that a pharmaceutical company contracts with to promote the sales of a drug product of this pharmaceutical company through the performance of marketing, promotional and other activities. CSO may be a company that has drug distribution as its primary business but also provides drug promotion services, a company that does not have a drug distribution business and provides drug promotion services only, or a pharmaceutical company such as an RDPAC member company or a domestic pharmaceutical company in China..

RDPAC has taken note of the fast-growing number of CSO transactions that its member companies have entered into in China, particularly those that its member companies are the drug owners that engage the services of CSOs. RDPAC recognizes the value that CSO transactions may create to the successful commercialization of drug products and the expansion of patients' access to drug products. At the same time, RDPAC is keenly aware of various legal violation risks and medical ethics risks that CSO activities may present. Particularly, under both Chinese laws and certain applicable foreign laws (including without limitation the U.S. Foreign Corrupt Practices Act), the CSO may be seen to promote drugs on behalf of the drug owner and therefore the drug owner may be held liable for bribery activities of the CSO.¹ Recognizing this legal relationship between a drug owner and its CSO and the resulted expectations from relevant regulatory authorities, the RDPAC Code of Practice has clearly stated that it applies to “subcontractors that carry out tasks on behalf of the company, such as ...contracted sales representatives.”² Now, RDPAC has further taken the

赂违法行为)。RDPAC 认识到 CSO 交易的复杂性及其交易条款的多样性，因此鼓励会员公司考虑其特定 CSO 交易的具体特点，以合理的灵活度理解并适用本指南的有关要求。除此之外，如果 CSO 使用其关联公司或分包商为会员公司开展 CSO 交易中的部分活动，我们鼓励会员公司将本文件的要求同样适用于该 CSO 的关联公司或分包商。

initiative in developing this document to provide high-level, non-binding guidance to its member companies on measures that they are encouraged to consider and take to prevent misconducts of CSOs, particularly bribery violations. RDPAC recognizes the complexity of CSO transactions and the diversity of their transaction terms, and therefore encourages member companies to interpret and apply relevant requirements in this document with reasonable flexibility by considering the specific features of their particular CSO transactions. In addition, if a CSO uses its affiliate or a subcontractor to carry out certain activities in the CSO transaction for a member company, the member company is encouraged to apply the requirements in this document equally to such entities as well..

¹ RDPAC 认识到，除贿赂违法风险外，CSO 活动还可能带来其他方面的风险，包括但不限于反垄断、药品广告、药品推广（包括超适应症药品推广）、账簿和记录、商业秘密侵权、网络安全与个人信息保护、药物警戒合规等方面的风险。虽然本指南的关注重点是防范贿赂违法风险，但 RDPAC 提醒会员公司应采取措施，预防 CSO 活动可能在上述其他领域给会员公司带来的风险。

² 第 1.1 条，注释 1，第二段。

¹ RDPAC recognizes that, in addition to bribery violation risks, CSO activities may present risks in other areas, including without limitation antitrust, drug advertisement, drug promotion (including off-label drug promotion), books and records, infringement on trade secrets, cybersecurity and personal information protection, pharmacovigilance compliance. While this document has focused on the prevention of bribery violation risks, RDPAC reminds its member companies to take measures to prevent risks that CSO activities may present to them in these other areas.

² RArticle 1.1, Annotation 1, paragraph 2.



CSO 的活动

Activities of CSOs

根据交易特点，CSO 可以为药品持证人开展多种类型的活动，并向药品持证人提供多种类型的服务，主要包括：

- 向医疗卫生专业人士介绍产品；
- 为医疗卫生专业人士提供医学或科学教育；
- 向医疗卫生专业人士开展产品教育或培训；
- 疾病教育，无论是面向患者还是面向大众；
- 市场准入服务，特别是产品入院服务；以及
- 市场情报收集。

RDPAC 认可这些 CSO 活动和服务的真实价值，并鼓励会员公司实施本指南中的措施，以控制这些 CSO 活动和服务可能因管理不善而带来的风险。

Depending on the features of the transactions, CSOs may undertake various types of activities and provide various types of services to drug owners, primarily:

- Product detailing to healthcare professionals (HCPs);
- Medical or scientific education of HCPs;
- Product education or training of HCPs;
- Disease education, whether targeting patients or the general public;
- Market access services, particularly hospital listing services; and
- Gathering of market intelligence.

RDPAC recognizes the bona fide value of these CSO activities and services, and encourages member companies to implement the measures contained in this guidance to manage the risks of these CSO activities and services in case of mismanagement.



反贿赂合规管理的关键措施

Key Anti-bribery Compliance Management Measures

1. 签约前的合规尽职调查

在与 CSO 签订正式的、具有约束力的协议（“CSO 协议”）之前，会员公司应对 CSO 进行有效的合规尽职调查，该尽职调查的广度和深度需足以确认 CSO：

- 拥有开展所计划的活动的和服务所需的注册经营范围；
- 拥有开展所计划的活动的和服务所需的内部资源及能力；
- 拥有完善的内部合规管控。

为实现上述目的，该合规尽职调查应在适用于该 CSO 交易的前提下，至少涵盖 CSO 合规体系的以下方面：

- CSO 的合规政策及程序；
- CSO 执行合规规定的内控体系；
- CSO 合规部门人员和资源的充足度；
- CSO 合规部门相对于业务团队（特别是销售团队）的自主性；
- CSO 法律及合规部门的合规管理能力；

1. Pre-engagement compliance due diligence

Before entering into formal, binding agreements with CSOs (the “CSO Agreement”), member companies should conduct an effective compliance due diligence review on the CSO, and the review should have such a breadth and depth that are sufficient to ensure that the CSO:

- Has the necessary registered business scope for the contemplated activities and services;
- Has the needed internal resources and capabilities to conduct the contemplated activities and services;
- Has an adequate internal compliance program.

To achieve the above objectives, such compliance due diligence review should, to the extent applicable to the particular CSO transaction, cover at least the following aspects of the CSO’s compliance system:

- The CSO’s compliance policies and procedures;
- The CSO’s internal control system that implements its compliance requirements;
- The sufficiency of the personnel and resources within the CSO’s compliance function;
- The autonomy of the CSO’s compliance function from its business team, particularly the sales team;
- The compliance management capabilities of the CSO’s legal and compliance functions;

- CSO 领导团队的合规意识及合规承诺；以及
- CSO 内部对本 CSO 项目承担主要管理责任的相关人员的合规意识及以往合规表现。

合规尽职调查应涵盖 CSO 遵守相关反贿赂法律的过往表现。如果调查结果显示 CSO 曾违反相关反贿赂法，会员公司应对该过往违法行为进行分析，以确定：

- CSO 的该等过往违法行为是否表明 CSO 存在任何系统性的合规缺陷，如费用报销中财务控制薄弱？如果是，CSO 是否已纠正了该缺陷？
- CSO 的该等过往违法行为与其计划开展的 CSO 活动是否有相关性？例如，如果该等过往违法行为与其计划开展的 CSO 活动涉及同一高级管理人员、同一销售主管、同一销售团队等，则可确定存在相关性。
- CSO 的该等过往违法行为与其计划开展的 CSO 活动是否性质上相同或相似？例如，如果该等过往违法行为与其计划开展的 CSO 活动均属于面向医疗卫生专业人士的小型教育项目或均属于零售渠道活动，则可确定具有相同或相似性质。

在考虑对上述问题的回答后，会员公司只有在认定 CSO 在开展当前交易中不会重复其过往违法行为的情况下，才能继续进行该 CSO 交易。

- The compliance awareness and commitment of the CSO's leadership team; and
- The compliance awareness and past compliance performance of the CSO's relevant personnel that have the primary management responsibilities for the CSO transaction.

The compliance due diligence review should cover the CSO's past performance under relevant anti-bribery laws. If the review reveals that the CSO has past violation of relevant anti-bribery laws, the member company should analyze such past violation to determine:

- Does the CSO's past violation indicate any systematic compliance weakness of the CSO, such as weak finance control over expense reimbursement? If yes, has the CSO fixed such weakness?
- Is the CSO's past violation relevant to its performance of the contemplated CSO activities? Such relevancy will be established if, for example, the wrong-doing activities in the past violation and the contemplated CSO activities involve the same senior manager, the same sales head, the same sales team, etc.
- Are the CSO's wrong-doing activities in the past violation and the contemplated CSO activities same or similar in nature? Such same or similar nature will be established if, for example, both the wrong-doing activities in the past violation and the contemplated CSO activities are small-sized HCP education programs, or retail channel activities.

The member company may proceed with the CSO transaction only if it, after considering the answers to the above questions, concludes that the CSO is unlikely to repeat its past violation during its performance of the CSO activities in the current transaction.

2. 持续性合规增强项目

如果合规尽职调查显示 CSO 存在重大合规缺陷，会员公司可以在 CSO 纠正该等缺陷后与之签订 CSO 协议并使用该 CSO 的服务。

作为替代方案，双方也可先行签订并开始履行 CSO 协议，但前提条件是：(i) CSO 同意开展持续性合规增强项目，该项目应在某个具体时间节点之前完成；(ii) 会员公司对 CSO 的项目实施情况进行审查和审计。如果 CSO 有效实施了该项目并在约定的期限前完全纠正了合规缺陷，则双方可继续履行 CSO 协议。但如果 CSO 未能有效实施项目并完全纠正其合规缺陷，会员公司应终止 CSO 协议。会员公司应注意，本段所述的替代方案仅是一种例外做法，并且在使用过程中应保持充分的审慎和谨慎。

3. 对 CSO 服务及活动的描述

CSO 协议应合理详细地逐项明确描述 CSO 将向会员公司提供的服务，以及 CSO 为提供这些服务将开展的活动。所有这些服务及活动均须为相关法律所允许。

2. Ongoing compliance enhancement program

If the compliance due diligence review reveals that the CSO has significant compliance weakness, the member company may enter into the CSO Agreement with the CSO and use the services of the CSO after the CSO has fixed such weakness.

Alternatively, the two parties may enter into the CSO Agreement and start the performance of the CSO Agreement on the condition that: (i) the CSO agrees to an ongoing compliance enhancement program, which should be completed before a specified point of time; and (ii) the member company reviews and audits the CSO's implementation of the program. If the CSO has effectively implemented the program and fully corrected its compliance weakness before the agreed time, the two parties may continue to perform the CSO Agreement. If the CSO however fails to effectively implement the program and fully correct its compliance weakness, the member company should terminate the CSO Agreement. It should be noted that member companies may use the alternative approach described in this paragraph on an exceptional basis only and with an abundance of prudence and caution.

3. Description of CSO services and activities

The CSO Agreement should clearly describe the services that the CSO will provide to the member companies, and the activities that the CSO will undertake to provide such services, in each case with reasonable details and in an item-by-item format. All such services and activities must be legally permissible under relevant laws.

4. 充分的合规条款

CSO 协议应规定 CSO 在履行 CSO 服务过程中须遵守中国和其他相关司法辖区的反贿赂法律、中国与医药代表管理有关的法律法规以及《RDPAC 行业行为准则》中的相关适用条款。

CSO 协议还应规定 CSO 在协议项下的活动所应遵守的合规标准。CSO 至少应当遵守其自身的合规政策和程序。此外，会员公司可要求 CSO 遵守会员公司的合规政策，并在适当且可行的情况下执行会员公司的合规程序。

CSO 协议应给予会员公司监察并审计 CSO 合规表现的充分权利。并且，CSO 协议应给予会员公司在 CSO 出现重大违反相关合规要求的情况时终止该协议的权利。

4. Adequate compliance clauses

The CSO Agreement should require that the CSO, for and during the performance of the CSO services, adhere to anti-bribery laws in China and other relevant jurisdictions, Chinese laws and regulations related to the management of medical representatives, and relevant clauses in the RDPAC Code to the extent applicable.

The CSO Agreement should also specify the compliance standards that the CSO should comply with for its activities under the agreement. At a minimum, the CSO should comply with its own compliance policies and procedures. In addition, the member company may require the CSO to comply with the member companies' compliance policies and, when appropriate and practical, procedures.

The CSO Agreement should give the member company adequate power to monitor and audit the compliance performance of the CSO. Also, the CSO Agreement should give the member company the power to terminate the agreement in case of the CSO's significant violations of relevant compliance requirements.

5. 了解 CSO 的活动和不当行为

会员公司应尽其最大合理努力，尽可能详细地了解 CSO 开展的与履行 CSO 协议有关的活动，包括 CSO 为这些活动所产生的费用支出。为此，会员公司应要求 CSO 以合理的频次提供定期报告，描述其开展的活动以及（如可行且有必要）费用支出，且该定期报告应包含合理详细的内容。

5. Knowing the activities and misconducts of the CSO

The member company should make reasonable best efforts to understand, with reasonable details, the activities that the CSO carries out in connection with its performance of the CSO Agreement, including the expenses that the CSO incurs for such activities. For this purpose, the member company should require the CSO to provide, at a reasonable frequency, periodical reports that describe its activities and (to the extent feasible and necessary) expenses, and such reports should contain reasonable details.

尤其是，会员公司应要求 CSO 报告其在开展合规监督过程中发现的和履行 CSO 协议有关的违反相关合规要求的情况，包括已证实的违规行为和怀疑的违规行为。

Particularly, the member company should require the CSO to report its violation of relevant compliance requirements in connection with its performance of the CSO Agreement that the CSO has identified during the course of its compliance monitoring, including both substantiated and suspected violations.

6. CSO 服务费：公允市场价值

会员公司应确保支付给 CSO 的服务费以 CSO 服务的公允市场价值为基础。在上述原则的指导下，会员公司应选择适当的机制来评估和计算服务费的公允市场价值。该机制可以是以下机制之一或其结合，或能够充分实现公允市场价值原则之目的的其他机制：

- 成本加成机制，即服务费包括 CSO 提供服务的成本，加上合理的利润率，利润率通常为成本的一定比例。使用该机制时，会员公司和 CSO 应明确描述服务的构成、每项服务的成本，以及服务的执行和完成标准。此外，在向 CSO 支付服务费之前，会员公司应根据预先设定的标准，核实服务的执行情况并确认服务完成。

6. CSO service fees: Fair Market Value

Member companies should ensure that the service fees paid to CSOs are based on the Fair Market Value (FMV) of the CSOs' services. Guided by this principle, member companies should choose the appropriate mechanism for the evaluation and calculation of the FMV for the service fees, which may be one or the combination of the following, or another mechanism that may adequately achieve the purpose of the FMV principle:

- Cost-plus mechanism, i.e., the service fees consist of the cost of the services that the CSO provides, plus a reasonable profit margin which is typically a certain percentage of such cost. When using this mechanism, the member company and the CSO should clearly describe the composition of the services, the cost of each service, and the criteria for the performance and completion of the services. In addition, the member company should verify the performance of the services and confirm the completion of the services in accordance with pre-set criteria before making payment of service fees to the CSO.

- 基于绩效的机制，即基于特定绩效指标（通常是量化指标）的完成情况计算服务费。使用该机制时，会员公司应通过服务成本评估、公平谈判以及参考行业基准等综合手段，确定服务费的公允市场价值。会员公司还应评估服务费计算方法对 CSO 行为的影响，以尽量减少绩效指标对 CSO 为促进销售而开展不当推广活动的激励作用。

- Performance-based mechanism, i.e., the service fees are calculated on the basis of the achievement of certain performance indicators (typically quantitative indicators). When using this mechanism, the member company should determine the FMV of the service fees through a combination of tools, such as service cost evaluation, arms-length negotiation, and industry benchmarking. The member company also should evaluate the impact of the service fee calculation method on the behaviors of the CSO to minimize the effect of the performance indicators in incentivizing the CSO to conduct improper promotional activities for the purpose of boosting sales.

7. 会计处理；账簿和记录

会员公司和 CSO 均应按照中国法律和适用的外国法律，对 CSO 交易中产生的所有费用进行准确的会计处理，并为 CSO 的活动和费用创建并维持准确的账簿和记录。如果 CSO 是会员公司的经销商且会员公司以产品折让或折扣的形式向该 CSO 支付服务费，则会员公司应特别注意上述会计合规要求。

7. Accounting treatment; books and records

Both the member companies and the CSOs should maintain accurate accounting treatment for all expenses incurred in the CSO transactions and create and maintain accurate books and records for the CSO activities and expenses, in both cases in compliance with Chinese laws and applicable foreign laws. Member companies should pay particular attention to this accounting requirement when the CSO is a distributor of the member company and the member company pays service fees to the distributor CSO in the form of product rebate or discount.

8. 单独的活动和支出管理系统

根据中国法律和适用的外国法律，在满足特定条件的情况下，制药公司可能要对 CSO 根据 CSO 协议为制药公司利益开展的

8. Separate activity and expense management system

Under both Chinese laws and applicable foreign laws, when certain conditions are met, a pharmaceutical company may be held liable for the activities that its

活动以及该 CSO 为此产生的费用承担责任。因此，会员公司应尽合理最大努力，确保在需要时能够审查或审计 CSO 的该等活动或费用。

为此，会员公司应鼓励 CSO 使用单独或专用的系统记录其为会员公司开展的服务活动，以及为这些服务活动承担的费用（即与 CSO 推广自身或其他公司药品的活动和费用分开记录），以便会员公司可以单独审查或审计这些活动或费用。如果 CSO 能实施某种替代解决方案以达到相同或类似效果，则也可接受，如 CSO 对其系统中记录的为会员公司开展的活动或承担的费用添加标签。会员公司在选择 CSO 的过程中，应该优先考虑能够满足上述要求的 CSO。

9. 合规培训

会员公司应确保对 CSO 进行适当培训，使其了解适用于 CSO 活动的合规要求。原则上，此类培训应至少每年一次。

此类培训可采取多种形式，包括：（i）由会员公司提供培训；（ii）由 CSO 开展培训；以及（iii）由第三方开展培训。此类培训应至少涵盖以下主题：（i）中国法律规定；（ii）适用的外国法律规定；（iii）CSO 协议规定的合规要求，包括但不限于《RDPAC 行业行为准则》的相关要求。

CSO has performed for its interest pursuant to the CSO Agreement, as well as the expenses that the CSO has incurred for such purpose. Therefore, member companies should make reasonable best efforts to ensure that they will be able to review or audit such activities or expenses of the CSO if they need to do so.

For this purpose, member companies should encourage CSOs to use a separate or dedicated system to record their service activities for the member company, and also their expenses incurred for such service activities (i.e., separate from the CSO's activities and expenses for the promotion of its own drugs, or drugs of other companies), so that the member company can separately review or audit such activities or expenses. If the CSO can implement an alternative solution to achieve same or similar results, such alternative solution is acceptable as well, such as the CSO adding tags to activities or expenses recorded in its system that are for the member company. Member companies should give preferential consideration to CSOs that can meet the above requirement during the CSO selection process.

9. Compliance training

Member companies should ensure that the CSO is properly trained on the compliance requirements applicable to its CSO activities. In principle, such training should be conducted at least once a year.

Such trainings may take various forms, including: (i) training provided by the member company; (ii) training conducted by the CSO; and (iii) training conducted by a third party. Such trainings should cover topics of, at a minimum: (i) legal requirements of Chinese laws; (ii) legal requirements of foreign laws, to the extent applicable; and (iii) compliance requirements specified in the CSO Agreement, including without limitation relevant RDPAC Code requirements.

除此之外，我们鼓励会员公司组织对开展 CSO 服务和活动的 CSO 人员进行合规考试，包括但不限于 CSO 的医药代表团队，且将此考试作为强制要求，要求该等 CSO 人员在开展 CSO 服务和活动前应通过考试。

最后，会员公司应要求 CSO 创建并妥善保管培训记录，并在会员公司提出要求时将该记录提供给会员公司查阅。

In addition, member companies are encouraged to organize compliance exams for CSO's personnel who carry out the CSO services and activities, including without limitation the CSO's medical representatives team, and make such exams mandatory and require such CSO personnel to pass the exams before starting to carry out CSO services and activities.

Lastly, member companies should require the CSO to create and maintain the training records properly, and to make them available to the member company for review when requested.

10. 有效的合规监督机制

会员公司应为 CSO 交易建立有效的合规监督机制。为此，会员公司与 CSO 可为 CSO 交易成立一个专门的联合合规委员会，或在联合指导委员会（或其他类似监督机构）内部为 CSO 交易设立一个主要负责合规监督的工作组。会员公司和 CSO 应利用该合规监督机制，定期讨论并评估 CSO 的合规表现及遇到的任何合规事件，并作出与合规相关的关键决策。会员公司应该确保该合规监督机制有足够的权力来开展上述监督活动。

10. Effective compliance oversight mechanism

Member companies should set up an effective compliance oversight mechanism for the CSO transaction. For this purpose, member companies and the CSO may establish a dedicated Joint Compliance Committee for the CSO transaction, or create a special, compliance-focused task force within the Joint Steering Committee (or another, similar oversight body) for the CSO transaction. Member companies and the CSO should use such compliance oversight mechanism to discuss and review, on a regular basis, the CSO's compliance performance and any encountered compliance incidence, and make key compliance-related decisions. Member companies should ensure that such compliance oversight mechanism is adequately empowered to perform the above activities.

11. 监督与审计

会员公司应监督并审计 CSO 开展的与履行 CSO 协议有关的服务活动，以评估 CSO 合规内控的有效性，识别 CSO 的合规违规行为和风险（如有），并且实施必要的整改措施。为此，会员公司可使用以下一种或多种方法：

- 审阅 CSO 的活动报告；
- 在事先通知或不事先通知的情况下，检查 CSO 代表的活动；
- 审查并评测 CSO 的开支；
- 对 CSO 人员进行访谈；及
- 现场审计。

会员公司应根据 CSO 交易的特点，选择使用以下任何一种适当的合规监督与审计机制：

- 会员公司直接开展该监督和审计活动；
- 由 CSO 开展该监督和审计活动，并向会员公司报告监督和审计结果；及
- 由合格的第三方开展该监督和审计活动，并向会员公司报告其发现。

对于上述第二和第三种机制，会员公司应审查并确认该 CSO 或第三方的监督和审计能力。

11. Monitoring and auditing

Member companies should monitor and audit the service activities of CSO companies in connection with the performance of the CSO Agreement, so as to assess the effectiveness of the CSO's internal compliance control and also to identify the CSO's compliance violations and risks (if any) and implement necessary corrective actions. For this purpose, member companies may use one or the combination of the following methods:

- Review of the activity report of the CSO;
- Inspection of the CSO representatives' activities, with or without advance notice;
- Review and testing of expenses of the CSO;
- Interview of CSO's personnel; and
- On-site audit.

Member companies should, depending on the features of the CSO transaction, choose the appropriate mechanism for the compliance monitoring and audit, which may be one of the following:

- the member company directly conducts such monitoring and audit activities;
- the CSO conducts such monitoring and audit activities, and reports its findings to the member company; and
- a competent third party conducts such monitoring and audit activities, and reports its findings to the member company.

In case of the second and third mechanisms above, the member company should review and confirm the monitoring and audit capabilities of the CSO or the third party.

12. 违规举报；热线

会员公司应建立一个举报机制，以便 CSO 人员或会员公司人员可适当地向会员公司报告 CSO 的任何潜在或实际的违规活动。

为此，我们鼓励会员公司为 CSO 交易设立违规举报热线（可以是电子邮件或电话，不论是作为专用热线或整体热线系统的附加功能）。会员公司应将该热线提供给会员公司人员及 CSO 人员，并向这些人员广泛告知该热线的存在。

12. Non-compliance reporting; hotline

Member companies should set up a mechanism so that any non-compliant activities of the CSO, whether potential or real, can be properly reported to them, whether by the CSO personnel or the member company personnel.

For this purpose, member companies are encouraged to set up a non-compliance reporting hotline for the CSO transaction (whether an email hotline, or a telephone hotline; whether a dedicated hotline, or as an added function of the overall hotline system). Member companies should make the hotline available to personnel of both the member company and the CSO, and also make the existence of the hotline widely known to such personnel.

13. 补救；终止

如果会员公司发现 CSO 有任何违规活动或违规风险，会员公司应根据该活动或风险的特征，采取以下两种行动之一：

- 如果违规活动或违规风险严重，表明 CSO 无能力实施双方约定的合规控制制度，会员公司应终止 CSO 协议；以及
- 如果违规活动或违规风险不严重且可以补救，会员公司应与 CSO 合作制定并实施补救方案。如果 CSO 未能完全执行该补救方案以实现其预设目标，会员公司应终止 CSO 协议。

13. Remediation; termination

If member companies have discovered any non-compliant activities or risks of such of the CSO, they should, depending on the features of such activities or risks, take one of the following two types of actions:

- If the non-compliant activities or risks are severe and demonstrate the CSO's inability to implement the agreed compliance control system, the member company should terminate the CSO Agreement; and
- If the non-compliant activities or risks are not severe and are remediable, the member company should work with the CSO to develop and implement a remediation plan. If the CSO cannot fully implement the remediation plan to achieve its pre-set objectives, the member company should terminate the CSO Agreement.

RDPAC 会员公司

(更新日期: 2024 年 9 月)

雅培	益普生
艾伯维	强生
艾尔建美学	协和麒麟
爱而开	利奥制药
安进	灵北
爱施健	美纳里尼
安斯泰来	默克
阿斯利康	默沙东
拜耳	萌蒂
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	平安盐野义
第一三共	罗氏
卫材	赛诺菲
礼来	参天制药
爱的发制药	施维雅
辉凌医药	住友制药
匈牙利吉瑞大药厂	武田
吉利德科学	梯瓦制药
葛兰素史克	优时比制药
赫尔森	赞邦

RDPAC Member Companies

(Updated in September 2024)

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