Interpretation of the Compliance Guidance on Collaborations with Contract Sales Organizations

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Interpretation of the Compliance Guidance on Collaborations with Contract Sales Organizations

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China Association of Enterprise with Foreign Investment R&D-Based Pharmaceutical Association Committee (RDPAC) recently released the Compliance Guidance on Collaborations with Contract Sales Organizations (CSO) (hereinafter referred to as "Guidance"). It provides guidance on the services that CSOs provide to drug owners, as well as key compliance management measures for CSO activities.

Background

Though the CSO model creates distinguished value in commercialization of drug products and expansion their accessibility to patients, it also poses a variety of potential compliance risks. Against this backdrop, RDPAC has developed the Guidance, which advises pharmaceutical companies to consider and take steps to prevent misconducts in CSO transactions.

Highlights of the guidance

Activities and service types of CSOs

The Guidance lists out the various types of activities and services that CSOs may undertake and provide to drug owners.

CSO activities and services

*HCP: healthcare professionals

Key compliance management measures

While recognizing the bona fide value of these CSO activities and services, the Guidance puts forward 13 key measures to manage the potential risks and encourages companies to implement them accordingly.

- 1.Pre-engagement compliance due diligence

  In order to confirm that the CSO has the necessary registered business scope, internal resources and capabilities and an adequate internal compliance program for the contemplated activities and services, the pre-engagement compliance due diligence needs to cover at least, the compliance policies, internal control system, resources within the compliance function, the autonomy of the compliance function from its business team and its compliance management capabilities, the compliance awareness and commitment of the leadership team and the compliance awareness and past compliance performance of the relevant personnel that have the primary management responsibilities for the CSO transaction. At the same time, the compliance due diligence review should analyze the CSO's past performance under relevant laws and ensure that it will not repeat past violations. The due diligence enables pharmaceutical companies to understand the compliance and promotion business system of partnered CSO in advance and to manage the compliance risks through screening and evaluation process.

Case studies

To promote its mature products, a multinational pharmaceutical company considered selecting CSOs in various provinces for collaboration. Prior to signing the cooperation agreement, a compliance due diligence review was conducted on the CSOs. The due diligence covered the following aspects: basic information on the CSOs, industry experience and team structure, compliance function resources and management systems, process management for CSO activities, training, separate activity and expense management system, compliance monitoring, compliance and audit reports, non-compliance reporting hotline and penalty mechanisms and the compliance committee.

Based on the due diligence report, the pharmaceutical company specifically developed a project compliance manual for the potential CSO partners and included it in the CSO agreement to reduce compliance risks in subsequent cooperation.

- 2. Ongoing compliance enhancement program

  If the compliance due diligence review reveals that the CSO has significant compliance weakness, the companies may enter the CSO Agreement with the CSO after the it has fixed such weakness or alternatively, start the performance of the CSO Agreement on the condition that the CSO agrees to an ongoing compliance enhancement program, which should be completed before a specified point of time. If the CSO has effectively implemented the program and fully corrected its compliance weakness, the two parties may continue to perform the CSO Agreement, otherwise, the company should terminate the CSO Agreement.

- 3. Description of CSO services and activities

  The CSO Agreement should clearly describe the services and the activities that the CSO will provide to the companies are legally permissible under relevant laws.

- 4. Adequate compliance clauses

  The CSO Agreement should include the laws, regulations and compliance standards related to the services and give the company adequate power to monitor and audit the compliance performance of the CSOs.

- 5. Knowing the activities and misconducts of the CSO

  Pharmaceutical companies should require the CSOs to provide periodical reports that describe their activities, (to the extent feasible and necessary) expenses and substantified and suspected violations.

- 6. CSO service fees: Fair Market Value (FMV)

  The company 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 cost-plus mechanism and performance-based mechanism, or another one that may adequately achieve the purpose of the FMV principle.

Case studies

Prior to a CSO cooperation, a multinational pharmaceutical company conducted a benchmarking study on service fees.

The benchmarking analysis included dimensions such as product characteristics, CSO agreement structures, fee rates and payment methods, assessment of service fee settlements, cost structure and profit margins of the CSO. This analysis aimed to assess the value and compliance risks associated with the collaboration model and to establish a suitable mechanism to calculate the FMV of CSO service fees.

- 7. Accounting treatment; books and records

  The two parties should maintain accurate accounting treatment for all expenses incurred in the CSO transactions and accurate books and records.

- 8. Separate activity and expense management system

  The companies should encourage CSOs to use a separate or dedicated system to record their service activities and expenses for their separate review or audit purpose.

- 9. Compliance training

  In principle, compliance training for CSOs should be conducted at least once a year. It is encouraged to make exams mandatory and required such CSO personnel to pass the exams before starting to carry out CSO services and activities and maintain the training records properly.

- 10. Effective compliance oversight mechanism

  The company and the CSO may establish a dedicated Joint Compliance Committee for the CSO transaction or create a special, compliance-focused task force within similar oversight body to discuss and review the CSO's compliance performance and any encountered compliance incidence on a regular basis.

Case studies

In the agreement signed with a CSO, a multinational pharmaceutical company stipulated the establishment of a joint compliance committee as part of the management coordination mechanism. The agreement specified the committee's purpose, responsibilities, composition and authority, as well as the meeting content and frequency.

During the formal cooperation, regular joint compliance committee meetings allowed for timely discussion and decision-making on compliance events and potential risks within the CSO project.

- 11. Monitoring and auditing

  The company should monitor and audit the service activities in connection with the CSO Agreement through CSO activity report, inspection of the CSO representatives' activities (with or without advance notice), review and evaluation of CSO expenses, interview of CSO's personnel and on-site audit. This would ensure the effectiveness of the CSO's internal compliance control, identify the CSO's compliance violations and risks (if any) and implement necessary corrective actions. The drug owner may directly conduct such monitoring and audit activities or dedicate the audit to the CSOs or a third party to get the relevant reports.

Case studies

In the cooperation agreement signed with a CSO, a multinational pharmaceutical company stipulated that all expenses related to CSO activities for the company must be accurately recorded and kept in a separate account. It also clarified the company's rights to monitor and audit CSO projects, requiring CSOs to retain program-related documents and actively cooperate with audits.

Following the initial collaboration, the company engaged a third party to conduct a professional compliance review of the CSO activities and related expenses, issuing recommendations for improvement to mitigate future compliance risks in the program.

- 12. Non-compliance reporting mechanism

  The company should set up a reporting mechanism, a non-compliance reporting hotline (email or telephone), for the relevant personnel to report the potential or real non-compliance CSO activities.

- 13. Remediation and termination

  If the non-compliant activities or risks are severe and demonstrate the CSO's inability to implement the agreed compliance control system, the company should terminate the CSO Agreement. If the non-compliant activities or risks are not severe and are remediable, the 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 company should terminate the CSO Agreement to lower its compliance risk.

EY team has in-depth insights and rich experience in the pharmaceutical industry and CSO transaction practice. The team provides end-to-end services to CSO cooperation from plan design to implementation, fair value benchmarking, due diligence and compliance review and improvement.

For more information, please contact us:

Felix Fei

Life Sciences and Healthcare Segment Leader
Managing Partner, Assurance, China Central
Ernst & Young Hua Ming LLP
felix.fei@cn.ey.com

Ronald Wang

Executive Director, Consulting
Ernst & Young (China) Advisory Limited
ronald.wang@cn.ey.com

Sharry Wu

Life Sciences and Healthcare Segment Leader
Managing Partner, Management Consulting
Ernst & Young (China) Advisory Limited
sharry.wu@cn.ey.com

Fay Cheng

Manager, Consulting
Ernst & Young (China) Advisory Limited
fay.f.cheng@cn.ey.com

Michelle Yan

Partner, Consulting
Ernst & Young (China) Advisory Limited
michelle-xx.yan@cn.ey.com

Eve Wu

Senior Consultant, Consulting
Ernst & Young (China) Advisory Limited
eve.yl.wu@cn.ey.com

Jeffrey Yu

Partner, Consulting
Ernst & Young (China) Advisory Limited
jeffrey.yu@cn.ey.com

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