



**FOURTH ASIA PACIFIC
PHARMACEUTICAL
COMPLIANCE CONGRESS
AND BEST PRACTICES
FORUM
September 16 - 18, 2014**

**PRECONFERENCE: COMPLIANCE CONCERNS IN
NEGOTIATING, IMPLEMENTING AND MANAGING,
AUDITING AND MONITORING THIRD PARTY
RELATIONSHIPS IN THE ASIA PACIFIC REGION**

September 16, 2014

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Agenda

- Overview of Third Party Due Diligence Framework
- Identifying and Conducting Due Diligence on Third Party Intermediaries
- Negotiating with Third Parties to Include Enforceable Rights to Audit and Ongoing Monitoring
- Implementing and Managing Third Party Audit Rights and Ongoing Monitoring of Relationships
- Best Practices in Ongoing Auditing and Monitoring Third Party Relationships

Third Party Risks--Overview

- Nearly every multi-national pharmaceutical company does business using a combination of its own employees and third parties it hires to help perform essential tasks
- Companies routinely engage third party agents to assist in winning government contracts or to obtain permits to do business and perform services
- Third party agents also help companies comply with local law and regulations, and with the tasks of moving personnel and goods across borders
- In today's environment of heightened enforcement of anticorruption laws, they may expose a company to major liabilities if those third parties act corruptly in violation of applicable law

Third Party Risks--Overview

- Under the U.S. Foreign Corrupt Practices Act (FCPA), the U.K. Bribery Act, and many other anticorruption laws, a company may be held liable not only for the corrupt actions of its employees, but also a third party's actions when that third party acts on its behalf
- Companies can be held liable for the acts of third parties when they
 - Knew of the corrupt acts or
 - Showed willful blindness toward, deliberately ignored, or consciously disregarded suspicious actions or circumstances
- Many of the major corruption cases that have arisen around the world have involved the use of local third party consultants or advisers

Third Party Risks--Overview

- To reduce the risk of liability, pharmaceutical companies need to be vigilant in selecting and monitoring the third parties that act on their behalf
- To meet the expectations of governments world-wide, this means developing and implementing a rigorous third party due diligence procedure to properly identify, mitigate, and respond to the specific risks associated with the use of third parties
- Effective due diligence will help a company guard against having a third party acting corruptly, but it also will help mitigate any exposure if the third party nevertheless acts corruptly, contrary to the company's wishes

Third Party Risks--Overview

- Third-party corruption issues may arise in many diverse contexts
 - Regulatory third parties (e.g., licensing, permitting or product authorization)
 - Sales or tendering parties (e.g., distributors or tendering consultants)
 - Shipping third parties that assist in governmental processes (e.g., customs brokers, freight forwarders)
 - Professional services third parties assisting in governmental processes (e.g., lawyers, accountants, travel agencies securing visas)
 - Travel agents/event organisers in China
 - Event organisers in Indonesia
 - Lobbyists
 - Public relations, media, and marketing third parties assisting in governmental processes
 - Construction / Real estate third parties (e.g., environmental permitting consultants)
 - Payroll or collections third parties

Consider Key Questions Before Engaging a Third Party

- Is a third party really necessary?
- Will the third party interact with government officials on the company's behalf?
- Has the company already hired a third party that can handle the work?

Third Party Diligence--Risk Assessment

- To be effective, the third party framework should be based upon a risk assessment of how the company conducts business, how, when, where, and why it uses third parties, and how it supervises the work of those third parties
- The first step to implementing any due diligence review is a well considered cost/benefit analysis and risk assessment of the hiring, retention, and oversight of third parties
- A comprehensive risk assessment serves as the cornerstone of the design and operation of the third party due diligence review procedure, as it informs such key program design questions such as the scope, intensity, resources, organization and controls in the review

Which Third Parties Should be Assessed?

- The term “interaction” includes instances where a third party comes into contact with government officials such as:
 - Payments or transfer of money
 - Assisting with a government tender
 - Obtaining a regulatory opinion from or defending a company in a judicial forum
 - Presenting a border customs documents when crossing a border
 - Opening a truck or container for inspection at an international border
 - Seeking approval from a regulatory authority to sell a product
 - Obtaining a permit to use a public space for a marketing activity
 - Assisting with a government audit of a company facility
- The interaction may not always be immediately apparent or obvious

What Third Parties are “In Scope?”

Third Party Types	Examples of Interactions
Regulatory Agents	<ul style="list-style-type: none">• Product registration agents• Vehicle licensing agents• Visa processors
Shipping Agents that Cross International Borders	<ul style="list-style-type: none">• Custom brokers• Freight forwarders• Transporters
Professional Services Assisting in Governmental Processes	<ul style="list-style-type: none">• Lawyers handling judicial proceedings• Accountants handling matters with tax authorities• Consultants securing visas and permits• Executive relocation companies relocating expats

What Third Parties are “In Scope?”(Cont’d)

Third Party Types	Examples of Interactions
Lobbyists	<ul style="list-style-type: none">• Consultants and law firms meeting with government officials to discuss legislative initiatives
Public Relations Companies	<ul style="list-style-type: none">• Securing permits for charitable events• Interacting with personnel and doctors at state-owned hospitals
Payroll or Collection Agents	<ul style="list-style-type: none">• Filing judicial or administrative complaints to demand payment
Charity Partners	<ul style="list-style-type: none">• Securing permits for charitable events• Interacting with personnel and doctors at state-owned hospitals
Errand Runners	<ul style="list-style-type: none">• Delivering and retrieving documentation, sometimes with power of attorney authority
Other	<ul style="list-style-type: none">• Security service providers• Product disposal services

What Third Parties are “In Scope?”(Cont’d)

- **Special Cases**
 - Regional or global services providers
 - Subcontractors
 - Individual government officials or an entity owned or controlled by an individual government official

What Third Parties are “Out of Scope?”

- Dependent on risk assessment and available resources
- Third party interacts with government officials on its own behalf and not on behalf of a company

Third Party Diligence

Heightened Review for Third Parties “In Scope”

- For those third parties “in scope,” a review should follow, both in vetting for suitability and risk signs and in overseeing their work
- Common elements that should be present in any effective procedure:
 - Ask preliminary questions on a variety of relevant issues, including, but not limited to, qualification to perform the work, staffing, level of experience, references, and company history. These responses are typically provided by the third party in a written questionnaire
 - Conduct reference checks with other parties with whom the third party conducts business
 - Conduct background search for news concerning the third party’s prior conduct, as well as the conduct of the third party’s owners, officers, directors, senior management, and those executives who are principally involved in the relationship with the company
 - Document results

Oversight and Administration of Due Diligence Program

- A successful third party due diligence procedure needs staff and resources to conduct the review and oversight
- Each company should consider a number of factors in deciding who actually conducts the review and administers the overall procedure, and each organization will have its own approach on these issues
- Relevant considerations include:
 - The type of business involved and how it operates, with considerations including size, complexity, lines of business, and decision makers
 - The extent to which a company is decentralized or centralized and the roles to be undertaken by headquarters versus regional and local operations
 - The role of the legal department at various phases of the development and oversight of third party relationships

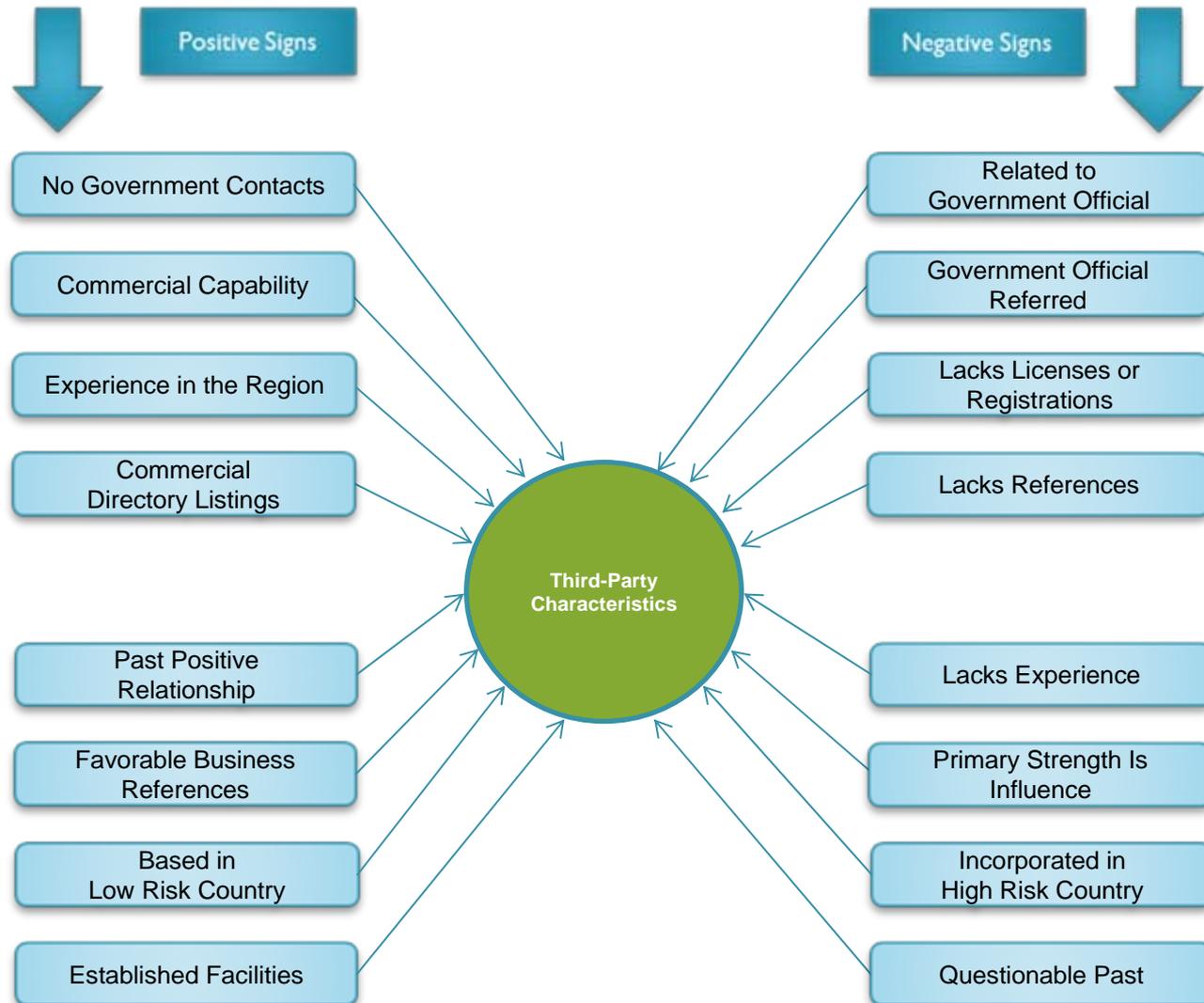
Oversight and Administration of Due Diligence Program

- To be effective, a review procedure must have:
 - built-in mechanisms to ensure consistency of review across the company
 - a mechanism to create and maintain a complete review “file” to document the work undertaken and resolution of any warning signs
 - appropriate oversight of program operation by senior management regardless of how decentralized a review procedure operates

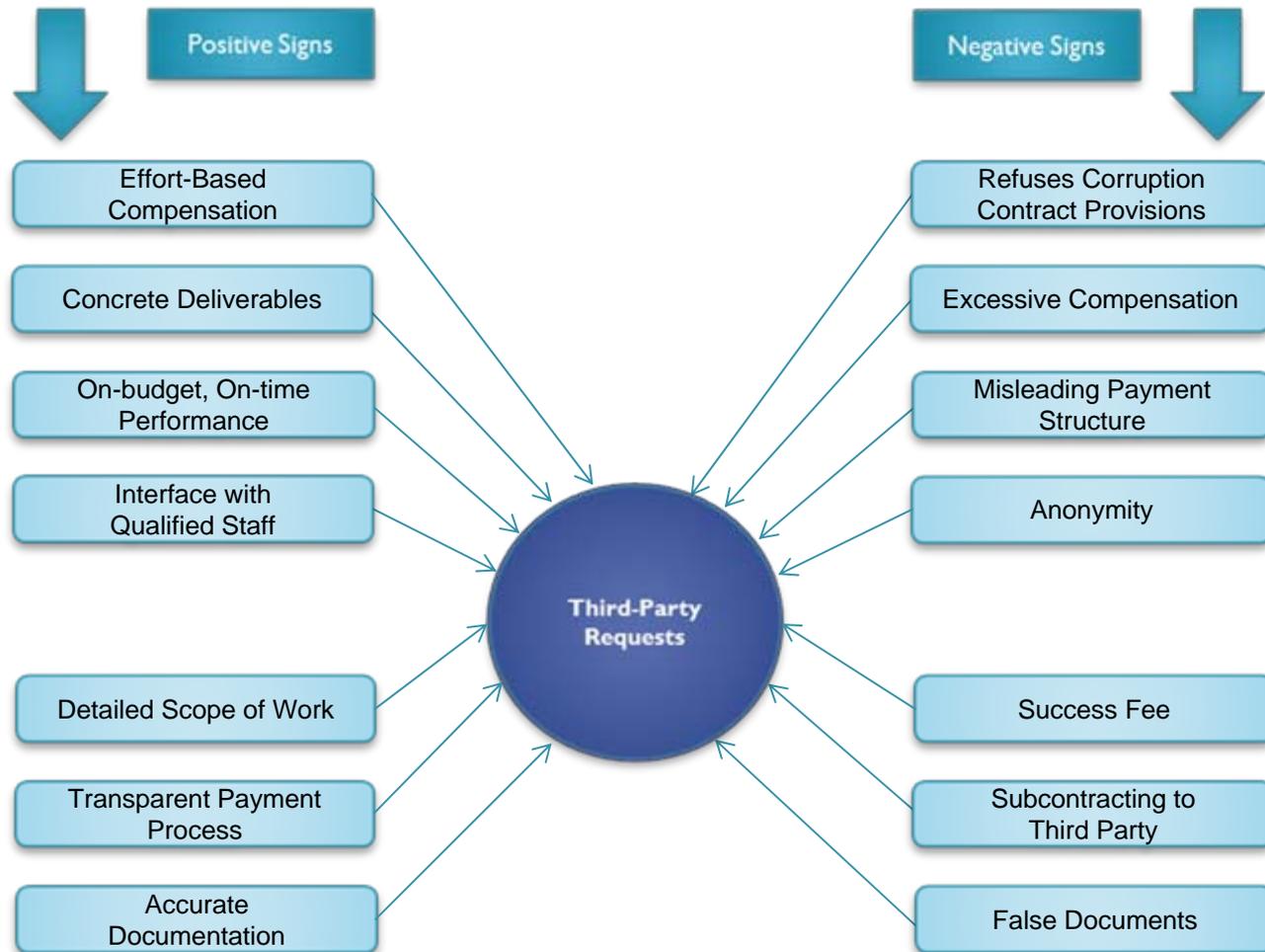
Addressing Warning Signs

- During any review, be alert for the classic warning signs of corruption, such as excessive requests for compensation, substantial amounts sought in advance, payments going to third parties subcontractors, payment only upon “success,” or involvement of government officials in the company or its operations
- If there are still questions or unresolved warning signs, leave open the option of a further review with additional follow up questions and due diligence review relating to actual or possible problems
- If warning signs cannot be resolved, decline to begin a relationship with a new third party or terminate its relationship with an existing third party
- Companies may seek to address potential warning signs -- if possible and prudent -- through enhanced reporting, more training, a more robust compliance program for the third party, anti-corruption contract clauses, more auditing, ongoing monitoring, and/or other risk mitigation strategies

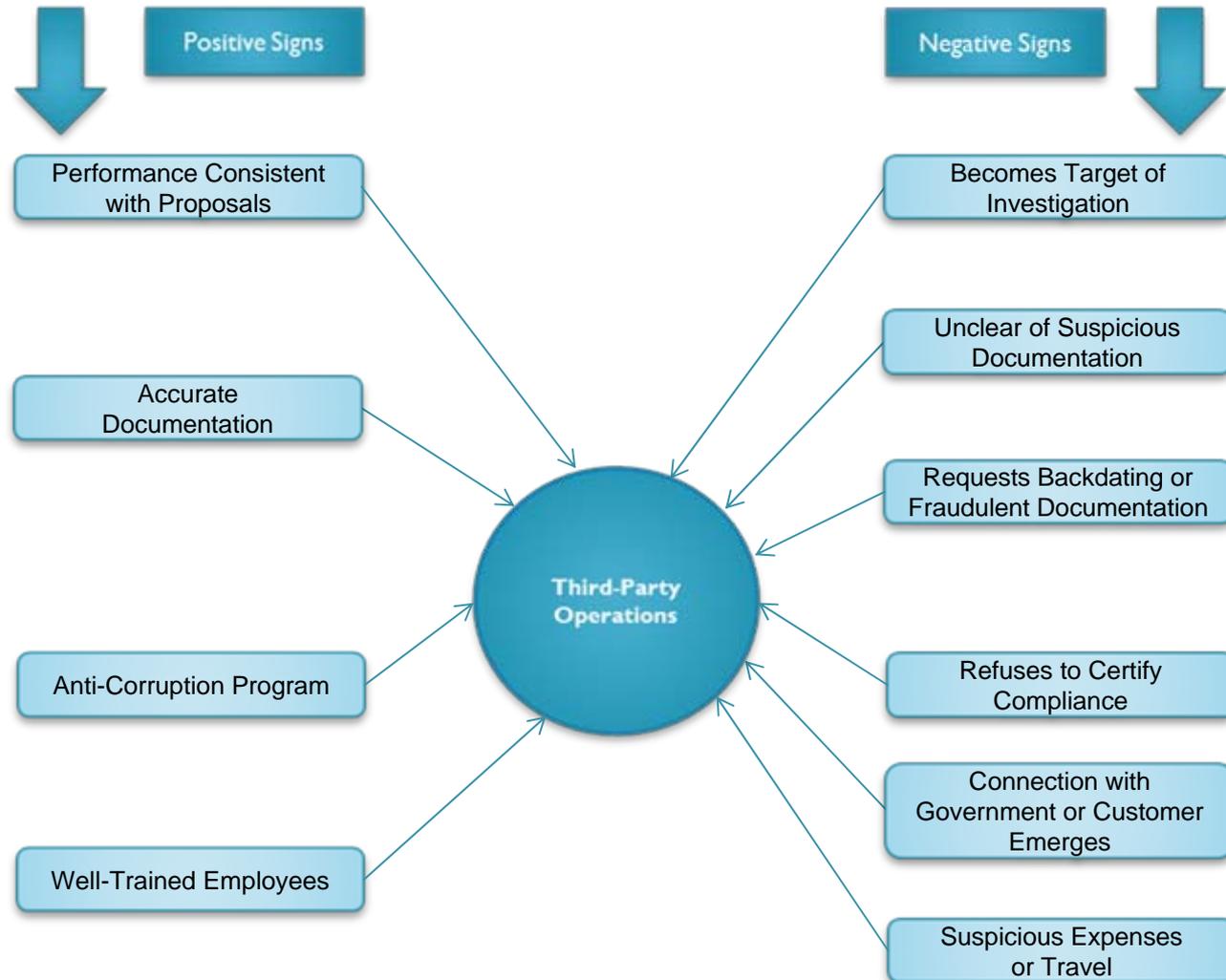
Warning Signs on Third Parties



Warning Signs on Third Parties



Warning Signs on Third Parties



Warning Signs on Third Parties



Dealing with Third Party Risks

- Standard Contractual Provisions
 - Model contractual language with anti-corruption representations and warranties
 - Payment restrictions (check/wire only; no third-party payees or countries)
 - Finite contract term (1-2 years)
 - Right to terminate and indemnification
 - Audit rights
- Annual Certifications
 - Not a foreign official or affiliated or related to a foreign official
 - Abide by anti-corruption laws, including local laws
 - Has not previously engaged in questionable conduct and will not in the future
 - Is prohibited from making improper payments
- Periodic Audits

Training and Communications with Third Parties

- Annual and Periodic Compliance Trainings (Compliance Forums) on
 - Code of Conduct
 - Responsible Business Practices
 - Interactions with Government Officials
- Whistleblowing Hotlines
 - Provide Company Hotline Number as an avenue for third parties to raise concerns if they received questionable requests from employees
 - Make Compliance Officer's contact details available to third parties
- Annual Compliance Certification of Third Parties – Online/Offline
- Compliance Best Practices Sharing
 - Share potential improvement areas identified from audits of other third parties

Monitoring and Auditing Third Parties

- Include a systematic and consistent way to monitor, audit, and review third party relationships
- Monitoring may be built into a company's internal controls through its finance function (i.e., a reconciliation of expenses and reimbursement claims against contractually required documentation and supporting documentation)
- Designation of internal person as the point of contact with the third party to manage the relationship between the company and the third party
- Establish a written audit plan based on a reasonable sample of third parties, that considers the nature of the third parties' activities, and the risks inherent in specific countries or regions where corruption risks with the use of third parties are greater
- Implement best practices identified from other third parties
- Taking audit learnings from the same class of third parties

Monitoring and Auditing Third Parties

- Where there are many third parties, there is a need to maximise the audit resources efficiently
- Use data analytics to identify which third parties to audit
- Need to identify the questions that are important to your compliance efforts (e.g., payments to government contractors, payments made above a certain threshold to a newly on-board/long term vendor or an expense category)
- Enforcing the company's rights
- Third party should be informed what to expect from a formal audit so expectations are set at the beginning of the relationship
- Conduct third-party review or a full third-party audit (i.e., a wider and deeper scope including interviews with key principals, data analytics and transaction review)
- Perform periodic risk assessment of third parties after audit
- Recommend next steps for monitoring relationship with third party



Questions?