

Best Practices for Due Diligence & Audit of 3rd Parties

Outsourcing the task, not the risks

The rise of pharma outsourcing

- Using 3rd parties an important part of pharma business strategy, enabling cost savings and driving efficiencies
- Covers everything from R&D to production, marketing, PR and regulatory liaison
- Global R&D outsource market grew from USD11.4 billion in 2001 to around USD33.2 billion in 2010

Outsourcing the task, not the risks

Issues

- Some countries require you to find a local partner.
- Significant risks are driven by relationships with other entities e.g. service providers, business/JV partners:
- Controls for some risks are transferred to the 3rd party out of company's control (fraud, improper payments, poor controls)
- **New risks** are also created (shortages, supply chain disruption)
- Company's reputation is also linked to 3rd party's reputation and actions

Why is this an issue?

- No effective control over 3rd party's activities
- No effective training of their employees/vendors
- No effective process controls e.g. payment limits, approvals. Audit?

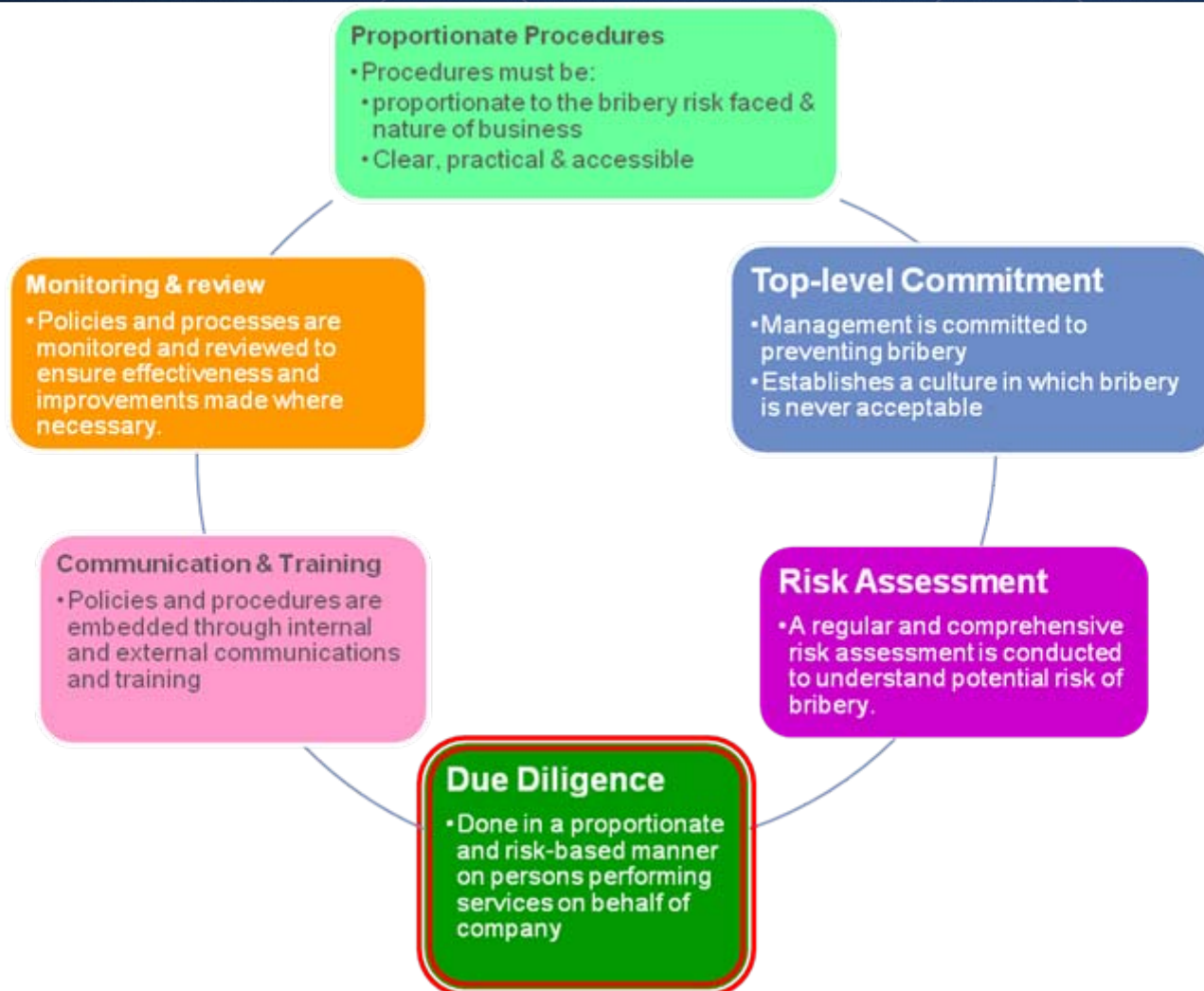
- Do you have sufficient information of 3rd party's reputation

- No effective control of 3rd party's vendors
- No control of 3rd party's production processes

You outsource the work -- not the liability

3rd party compliance is important

UKBA Guidance: 6 principles



Due diligence

- Identify the risks inherent in the engagement/3rd party relationship: bribery/corruption, off-label promotion, reputational, supply-side disruption etc.
- Establish high level principles: EG
 1. 100% screening above certain thresholds - no vendors who have a criminal history, are on government sanctions or watchlists. Lots of different software packages available...
 2. enhanced vigilance for or have directors/principles who are politically exposed persons (PEPs). Clearly justify & document why a vendor with PEPs was chosen – Independent sign offs.

Example of due diligence tool

3. Risk assessment and prioritisation: Not all vendors are the same
High risk 3rd parties include those that:
 - Liaise with government or regulatory authorities; or
 - Represent or act on behalf of the company, selling its products
 - Countries low on TI higher vigilance
 - High business volume = high potential disruption risk
 - “Mom and Pop” shops
4. Who owns and is accountable for 3rd party relationship?
Simplified approach works best.

Due diligence

Risk Database

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Person Entity Both

Name

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+ Region All Regions

+ PEP Category All PEP Categories

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Key considerations for due diligence

A standard approach to managing & documenting 3rd party due diligence & training

Senior management has oversight of program and issues are dealt with at the right level

Consistency

Reasonableness

Management oversight

Objectivity

- Risk-based, reasonable due diligence
 - Take into account country risk, size of deal, geography, nature of relationship
- All decisions are handled objectively separate from business owner to avoid inherent conflicts of interest

Right to audit

- Audit clause important to ensure that 3rd party is complying with their contractual obligations
- Should not be inadvertently lost, diluted or restricted e.g. being tied to pre-conditions related to “materiality”, volume, orders etc.
- Exercise your rights under those clauses. Danger of having clauses and not exercising audit rights
- Understand the issues faced by the 3rd party:
 - Give sufficient prior notice;
 - Agree on scope in advance;
 - Sign confidentiality/NDAs;
 - Restrict audit to activities directly related to engagement with you

What other measures?

- Annual certification by C level officer of their corporation
- Ask for a copy of their training materials
- Train their employees and get them to sign attendance sheets
- Have a compliance discussion with them as part of your performance appraisal of them
- Ask for their annual report and review any audit findings and what that potentially means for your relationship with them...

Questions?