Mini Summit XI: Third Party Management, including Pre-evaluation, Due Diligence, Contracting, Monitoring and Payment

Shanghai

16:00 – 17:15

14 September, 2017

Disclaimer

Please note that the views and opinions that will be expressed during this panel are solely those of the presenters and do not reflect the official policy, position or views of their employers. Information has been gleaned from experiences in various settings as well as from open source data; thus, examples that may be discussed during this session are only examples and should not be attributed to any of their employers.

Introducing the panel

Redentor Romero, JD, Associate Director, Global Third Party Compliance Program, Takeda

Pharmaceuticals International; Former Regional Compliance Officer, Teva Pharmaceuticals; Former Regional Legal Counsel, AstraZeneca, Singapore

Yuet Ming Tham, JD, Partner, Sidley Austin LLP; Former Asia Pacific Regional Compliance Director, Pfizer; Former Deputy Public Prosecutor, Singapore, Hong Kong

Carol Wu, Director of Third Party Audit, Asia, Global Ethics & Compliance, GSK; Former Manager, Ethics & Compliance-China, Hospira; Former Senior Compliance Manager, AstraZeneca, Shanghai, China. Responsible for third party audit program for Asia Pacific

Andy Bender, MS, MBA, President and Founder, Polaris which is a QuintilesIMS company, New York, NY, USA (Moderator)

Topics to cover - Issues in third party relationships

•Introduction: why third parties have become relevant – Andy
- What is in scope – HCPs, Government officials

•Pre-evaluation: Due diligence process, covering the methodology and process – Redentor Romero

•Contracting process – Yuet Ming Tham
- Covering the legal framework around managing risks, and contractual implications

•Validation of risk and monitoring risks – Carol Wu

•Fair Market Value of payments – Andy Bender

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    c. Sales and marketing ops
    d. Finance
    e. Legal
    f. Other

Transparency reporting is putting scrutiny on interactions with third parties

Topic	Australia	Indonesia	Japan	Philippines	South Korea
Governing body / Industry	Medicines Australia / Pharma	Indonesia's Corruption Eradication Commission / Pharma and MedDevices	JPMA/JFDMA / Pharma and MedDevices	Food and Drug Administration Philippines / Pharma and MedDevices	Ministry of Health / Pharma and MedDevices
Enforcement	2015	November 2016	March 2012	February 2017	June 2017
Reportable recipients	-HCP report: HCPs registered to practice in Australia -HCO report: HCO is a not-for-profit organization -3rd parties report: HCPs registered to practice in Australia	HCPs & HCOs	-Report A: HCOs -Report B: HCOs -Report C: HCPs -Report D: HCPs & HCOs -Report E: HCPs & HCOs	HCPs	-HCPs are medical personnel, pharmacists …
Reportable Activities	-HCP report: AdBoard, speaker, consultant, market research -HCO report: grant, donation, sponsorship -3rd parties report: AdBoard, speaker, consultant, sponsorship	Sponsorships and any form of assistance and/or activities	-Report A: R&D -Report B: Donations -Report C: FFS -Report D: Congresses -Report E: Hospitality and Social Courtesy	Post Travel Meetings / Symposia	A: Samples B: Clinical Trials C: Post-Mark. Surv. D: Present. to 1 Institution E: Present. to Multiple Institutions F: Academic Conf. G: Price Discounts
Disclosure date	-HCP & 3rd parties report: within 4 months after each period: Nov to Apr, May to Oct -HCO report: before April 30th for the full previous year	no later than thirty days after receiving the sponsorship	Once a year, after the End of the fiscal period	List of HCPs must be submitted within the year	within three months after the end of the 2018 fiscal year
Consent / Pre publication	-HCP report: consent requested with a 6 weeks period for pre disclosure -HCO & 3rd parties report: no	No	Consent requested for reports A, B & C	No	No

Aggressive enforcement of anti-corruption laws by US and Chinese governements

The aggressive enforcement by the U.S. DOJ and SEC against corruption in China, coupled with China's increased domestic focus on prosecuting anti-corruption cases, creates a challenging environment for MNCs doing business in China

1.2016 was a record-breaking year for FCPA enforcement. In total, there were 27 corporate enforcement actions by the DOJ or SEC.

2.Even more striking is the fact that these actions can are dominated by one country and one industry: China and healthcare.

3.15 of the actions involved acts of bribery in China. The most common form of corrupt payment was the provision of gifts, travel, or entertainment to influence foreign officials.

4.9 of the actions involved life sciences companies (8 of which related to conduct in Asia).

5.Since 2011, either the DOJ or SEC has brought at least one FCPA enforcement action against a company in the healthcare sector.

Examples bribery scandals in China involving third parties in 2016

SciClone Pharmaceuticals, Inc.

February 4, 2016 | SEC

Location of Conduct: **China**
Amount of Fine: **$12.8 million**
Industry: **Healthcare**

Employees of SciClone's Chinese subsidiaries increased sales by providing improper payments, gifts, vacations, conference sponsorships, and other things of value to foreign officials, including HCPs. SciClone also hired a well-connected regulatory affairs specialist to facilitate a licensing application and arrange trips for foreign officials.

Novartis AG

March 23, 2016 | SEC

Location of Conduct: **China**
Amount of Fine: **$25 million**
Industry: **Healthcare**

Novartis' two Chinese subsidiaries provided things of value to Chinese officials, primarily HCPs, in order to influence those individuals and to increase sales. The things of value included gifts, travel, improper sightseeing, entertainment, and favors for families of HCPs. The subsidiaries used numerous third-party travel and event planning vendors to organize the entertainment and travel. Employees of one subsidiary also paid money to HCPs to collect medical data for studies that were never approved.

AstraZeneca PLC

August 30, 2016 | SEC

Location of Conduct: **China, Russia**
Amount of Fine: **$5.5 million**
Industry: **Healthcare**

The sales and marketing staff at two AstraZeneca subsidiaries authorized several schemes to make improper payments of gifts, speaker fees, travel, cash and other benefits to HCPs in order to reward or influence their purchases of AstraZeneca's pharmaceuticals. Also, its Chinese subsidiary made cash payments to local officials in order to avoid fines.

Nu Skin Enterprises, Inc.

September 20, 2016 | SEC

Location of Conduct: **China**
Amount of Fine: **$765,688**
Industry: **Healthcare**

Nu Skin's China subsidiary transferred RMB 1 million to a charity associated with a high-ranking Chinese Communist party official in order to avoid a potential fine from a provincial agency investigation.

GlaxoSmithKline plc

September 30, 2016 | SEC

Location of Conduct: **China**
Amount of Fine: **$20 million**
Industry: **Healthcare**

Two Chinese entities of GSK allegedly engaged in various transactions and schemes to transfer things of value to foreign officials in China, mainly HCPs, in order to increase sales of pharmaceutical products. The two Chinese entities provided gifts, improper travel and entertainment, shopping excursions, family and home visits, speaker fees, and cash. Chinese authorities also separately fined GSK nearly $500 million.

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Pre-evaluation: Due Diligence Process

Defining in-scope Third Party

- Current vs. New / Renewal Engagements
- Third Party Intermediaries vs. company-only interactions (e.g. lessee, office equipment)
- What about:
  - Low-value engagements – do you have a threshold?
  - HCPs with fee-for-service engagements
  - Medical Associations receiving sponsorships
  - Patient Organizations or Charitable Institutions receiving Grants or Donations

Identifying Third Parties for the DD Process

- Using systems to generate Customer and Vendor Master list for in-scope Third Parties with Current engagements
- Scrubbing the data for out-of-scope entities (e.g. employees, affiliates, postal service, inactive engagements)
- Identifying Business Sponsor responsibility for New and Renewal engagements (Procurement vs. Business)

Using a Third Party Questionnaire

- Simple, clear, relevant, limit possible answers to what will identify potential risk
- Accurate Translations
- Follow up Questions (local language)
- Who will review and identify red flags?

Pre-evaluation: Due Diligence Process

Risk Scoring Methodology and Level of Due Diligence

- Geographical Risk
- Nature of Engagement
- Value
- Conflict of Interest
- Terms of Payment

Due Diligence Reports

- Watch Lists; SOE/PEP; Adverse Media; Internet Searches; Litigation; Reputation Checks; Corporate Reports
- Local context
- User-friendly

Review and Approval Process

- Business vs. Compliance
- Central vs. Local
- Single Approval Flow vs. Business Sponsor-dependent Approval Flow
- Compliance-only Review vs. Multi-function-risk Review

Pre-evaluation: Due Diligence Process

Mitigating Action

- Anti-Corruption Contract Clauses
- Anti-Corruption Training
- Monitoring and Scheduled Audits
- Control Mechanisms

Documentation and Technology

- Internal vs Vendor
- Compliance-only vs. Multi-function
- User-friendly, task-oriented
- Ability to connect to other systems

Toolkit

- Ongoing Training and Guidance for Business Sponsors and Approvers
- Resources (Communication Templates; Training Slides)
- FAQs

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Third party contract

- **Compliance requirements**
  - **Anti-Corruption laws**
    - FCPA
    - Bribery Act
    - OECD Convention
    - Local Anti-Corruption laws
    - Industry Codes
  - **Compliance program**
    - Compliance policies
    - Employee training

Third party contract

- **Compliance requirements**
  - **Audit rights**
  - **Notification of non-compliance/investigation**
  - **Indemnity**
  - **Assistance during investigation (who pays for disbursements?)**
  - **Record keeping**
  - **Certification**

Third party contract

- **Agents or Sub-distributors of Third Party**
  - **Written agreements**
  - **DD of agents and sub-distributors**
  - **Approval and termination of agents or sub-distributors**
  - **Training of agents or sub-distributors.**
  - **Notification of non-compliance/investigation**
  - **Audit of agents or sub-distributors**
  - **Certification**

Third party contract

- **Other Issues**
  - **Governing law**
  - **Dispute Resolution**
  - **Termination**

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What Makes an Effective Monitoring

APPROPRIATE

Exercise due professional care

Be objective

Demonstrate the Company Values

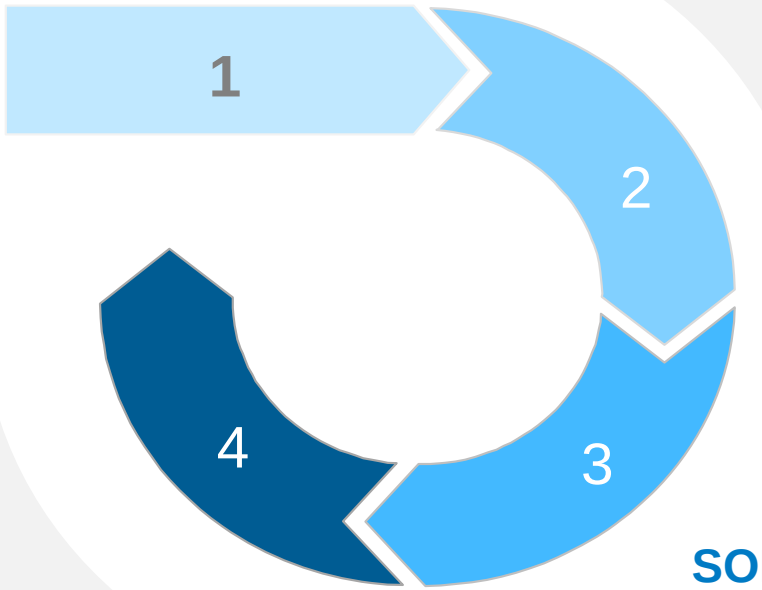
PROPORTIONATE

Focus on key activities and controls

Areas with limited in-process controls

Risk based approach

Perform with sufficient regularity



DOCUMENTED

Plan and document the approach

Record and retain the results (as appropriate)

SOLUTION FOCUSED

Gather and act on knowledge through the process

Focus on the outcome

Turn results into action

Key Success Factor for Implementing Monitoring

- Top management support & attention
- Limits your third party pool
- Invest on technology vs. Take follow up actions
- Back to basic – easy start for management monitoring
- Resources: internal vs. external
- Global program vs. Local focus
- Enterprise thinking to bring additional value (e.g., operation efficiency)
- Benchmarking & well balance btw. Monitoring and Audit

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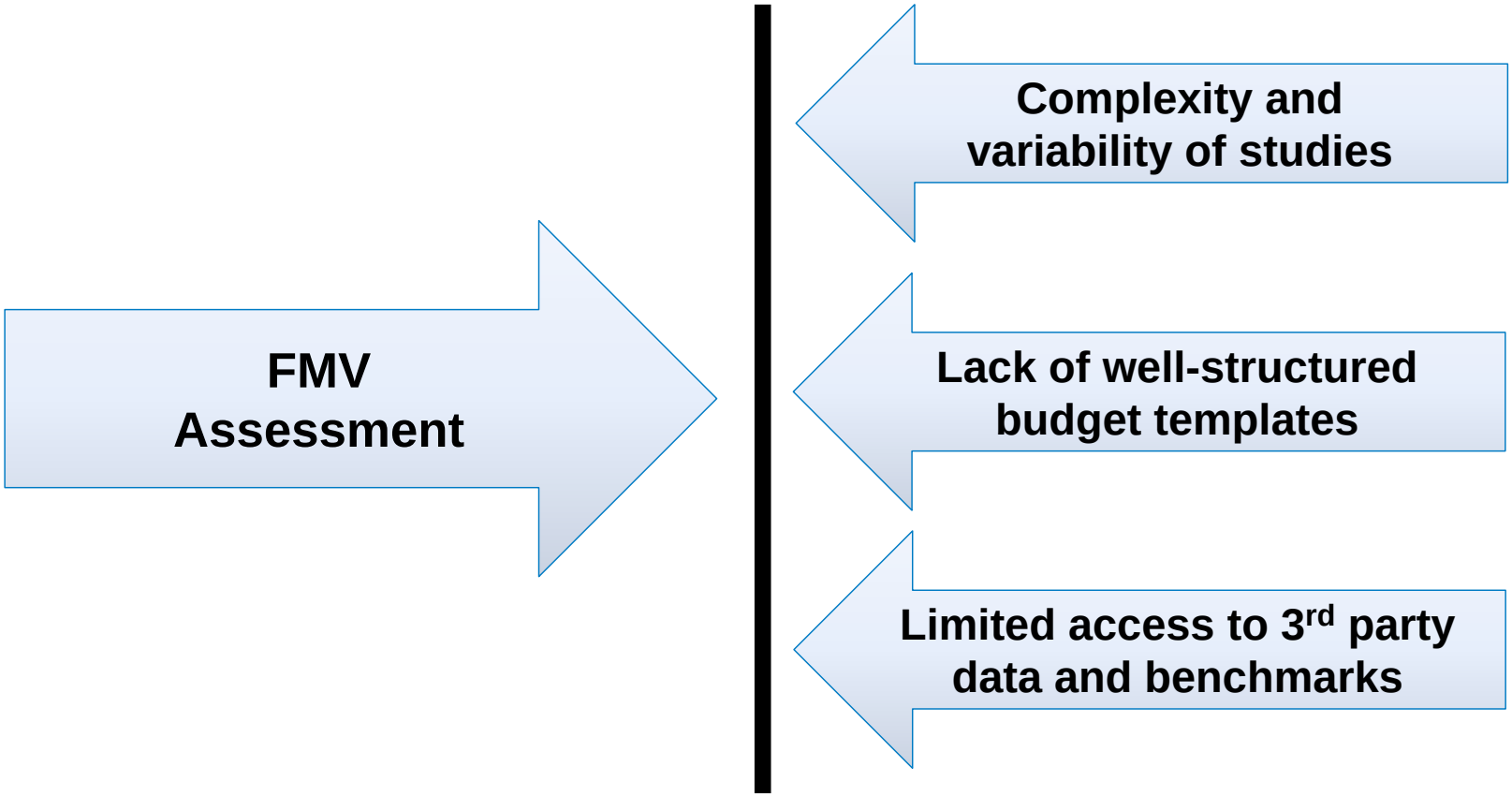
Overview of Health Care Organization Interaction and the common risks

Risks

- Payments to HCOs above normal & customary charges or Fair Market Value, may be perceived as:
  - Improper influence on product sales inducement
  - Selective publication of study results
  - Patient selection and endpoint analysis/classification in trials
- High Value and Solo Sponsorship program are with highest risk, might required details budget assessment

Fair market value is an important element of defenses under most kickback / anti-bribery statutes

Determining FMV for Third Parties can be very challenging



Internal process and benchmarking capability to benchmark contracts has been effective

Methodology

- Define 3-6 different program/ contract types and define a budget for each program
- Collect submission process and forms for each program type
  - Standard information about each program
  - Standard budget template breaking down the budget so that line items can be compared and benchmarked
  - Additional key metrics to allow benchmarking (number of impressions, HCPs, etc) to develop ratios
- Benchmarking will streamline the review and approval, by focusing review on only those relatively expensive fee requests

Benchmarking

- Two sets of benchmarks:
  - Benchmark budget line items
  - Develop ratio benchmarks – costs per HCP or patient to determine whether overall budget is in line
- Use market pricing for benchmarking where available:
  - Use historical data if market prices are not available
- Develop price metrics and benchmarks to benchmark on a line item basis
- Regular updating of benchmark values, will improve metric quality
- To manage volume companies are starting to automate

Costs should be assessed for allocability, reasonableness, and consistency. Clear documentation of all critical steps of the review process