Advanced topics in anti-corruption compliance programs

Time: 16.30 – 17.45 pm
Date: May 16, 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

Keith Korenchuk, JD, MPH, is partner at Arnold & Porter, Washington DC, USA

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Agenda for today

Emerging Market Challenges (Keith)	**1630 – 1700**
ABAC, Third Party Due diligence (Daniel)	**17:00 – 17:30**
Fair market value (Geert)	**17:00 – 17:45**

Emerging Markets: Managing Risk

- You are the new compliance officer from headquarters on a site visit to Indonesia
- As part of your review of HCP sponsorships, you find that commercial remains in control of this process, contrary to the global policies. In particular:
  - Commercial identifies the "list" of invitees
  - When the list is identified and delivered to medical, there is extensive contact with medical throughout the approval process to as one interviewee put it, "to make sure we get the right result"
  - Commercial asks the HCPs if they would like to attend the meetings as a "guest" of the Company
  - There is no request from the HCP for the sponsorship, either in writing or noted in the records
  - Commercial conducts all interactions with the HCPs from making them aware of the sponsorship, to notifying them on the invitation, to arranging for logistics, to attending the meeting to coordinate event planning and travel logistics to the HCPs
  - Commercial tracks HCP attendance at the meeting, using a CRM process that lists the "investment" in the HCP and evaluates the HCP as "advocate," neutral," or "adverse," and assesses what is needed to move HCPs to a higher category, or to maintain "advocate" loyalty status
- When you meet with the GM to review these findings she states: "We have local cultural expectations here and long standing partnerships with our HCPs. We don't see the need to apply global rules when we conduct business on a local basis and local regulators don't ever enforce local law. I suggest you leave us alone as Western ideas don't work here"
- How do you respond?

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ABAC Third Party Due Diligence

- Some Facts
- Regulatory Expectations
- Complexity/Issues at Hand
- Approach
- Due Diligence Renewals

ABAC Third Party Due Diligence

Some Facts

- Bribery and corruption risks are a worldwide concern
  - Can destabilize the health and sustainability of a company
  - Can harm reputation and can result in severe fines and criminal proceedings

- 2016 with highest number of ABAC enforcement actions
  - Record number of corporate FCPA resolutions and the collection of a record in total fines and penalties ($2.43 billion)
  - Increasing number of prosecutions in China; bribes to Chinese Public Officials were the most likely penalized

- In many jurisdictions companies can be liable for criminal offences

  Liability may arise in a number of ways including through:
  - The acts of its officers or employees
  - The acts of its agent
  - The acts of its related companies or **Business Partners/Third Parties**

- Huge majority of reported US FCPA cases involved Third Parties

ABAC Third Party Due Diligence

Regulatory Expectations

- Refraining from third party due diligence is not an option
  - Several examples of prosecutions and convictions although no actual knowledge of doubtful payments, but would have been with sufficient due diligence

- Performing appropriate/risk based due diligence is expected
  - DOJ Evaluation of Corp. Compliance Programs Check List (2017), UK SFO Bribery Act Guidance, Joint Guidance for Medical Device and Diagnostics Companies on Ethical Third Party Sales and Marketing Intermediary (SMI) Relationship

ABAC Third Party Due Diligence

Complexity/Issues at Hand

- Pure volume of Third Parties engaged by large multinational companies can be overwhelming
- Understanding your risks in general and specific
- Understanding how the business works (all the markets and jurisdictions before conducting any assessments of Third Parties)
- Designing Compliance programs that actually detect and manage risk with Business Partners
- Identifying and expressing the value and purpose of a risk-based approach to managing Third Party due diligence
  Identify the right stakeholders to participate in the development and roll-out

ABAC Third Party Due Diligence

Approach

- Third Party Data
  - Collect Third party data and define type and purpose of the business relationship
- Risk assessment and Third Party risk profiles
  - Key is to select only risk factors that are relevant and carried out in the company's business process (country Third Party is located/service is provided, business volume, type of service, compensation structure, interaction with Public Officials)
  - Third Party onboarding questionnaire
- Due Diligence
  - Type of service provided, shareholder/management identification, relationship with Public Officials, use of other 3rd parties, conflict of interest, past Compliance issues
- Red flags
  - Address and resolve red flags
  - Remedy (training, contract revisions/clauses etc.) or walk away
- Continuous monitoring
  - Regularly re-assess and monitor existing Third Parties and expect profile changes

ABAC Third Party Due Diligence

Due Diligence Renewals (1/2)

- Regulatory expectations
  - DOJ Evaluation of Corp. Compliance Programs (2017) Check List:
    Due Diligence renewals are not mentioned per se, but there needs to be greater focus on analytics and not just collecting the data but actually looking at it
  - UK SFO Bribery Act Guidance (similar to SEC/DOJ)
  - Joint Guidance for Medical Device and Diagnostics Companies on Ethical Third Party Sales and Marketing Intermediary (SMI) Relationship
    "Establish a risk-based pre-engagement and renewal due diligence program..."

- Advices on risk-based renewal program (1/2)

  Ongoing Risk Assessment + Need for Due Diligence = Need for Due Diligence Renewal Program
  - Where to start? (Company's risk profile, company's geographic risk, company's business risk, changes since the initial process (changes in management, Corporate structure or product), Business need or any other factors) → Start somewhere
  - Who to involve/where to find the data? → Compliance, Sales, IT, Internal Audit, Investigations, the Business

ABAC Third Party Due Diligence

Due Diligence Renewals (2/2)

- Advices on risk-based renewal program (2/2)
  - How often? → 18 months to 5 years (low risk) is reported so far
  - By risk, by geography, or other considerations? → maybe start not with the riskiest area but most friendly management (quick hit, publicize the win and then next)
  - Continual renewals or finite periodic process? → depending on the staffing (e.g. high risk one year, medium risk another year and then low risk the next and then rolling up)

- Final thoughts
  - According to Regulators renewal programs are required → can be used to get budget
  - Efficiency is essential → Compliance needs to partner with the Business to push efficiency
  - Risks change → renewal programs must consider changes
  - Analyze the data → Assess if risk identification is effective and what the renewal risk profile is telling about the overall risk

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What is Fair Market Value and why is it relevant?

The concept of Fair Market Value is broad…

- "A price at which buyers and sellers with a reasonable knowledge of pertinent facts and not acting under any compulsion are willing to do business" (*Merriam-Webster*)
- "Payments for research services should be Fair Market Value for legitimate, reasonable, and necessary services." *(OIG's Compliance Program Guidance for Pharmaceutical Manufacturers)*
- ""The compensation for the services must be reasonable and reflect the Fair Market Value of the services provided" *(International Federation of Pharmaceutical Manufacturers & Associations (IFPMA))*
- "Any remuneration must be reasonable and reflect the Fair Market Value of the work" *(ABPI)*

… And has different impact

The development of systematic anti-corruption laws enhances the importance of FMV

North America

- USA Foreign Corrupt Practices Act (1977)

Europe

- UK Bribery Act (2010)
- German Act on Fighting Corruption in the Healthcare Sector (2016)
- France Sapin 2 (2016)

APAC

- Japanese Unfair Competition Prevention Act (1993)
- UAE Penal Code (1987)

South America

- Colombian Anti-corruption Act (2011)

Africa

- South African Prevention and Combating of Corrupt Activities Act (2004)

Transparency requirements lead to higher scrutiny of HCP engagements – information more easily accessible

North America

- USA (Federal and State laws)
- *Canada (upcoming code)*
- *Mexico (upcoming)*

Europe

- EFPIA
- Local laws and regulations
- *Medtech (upcoming)*
- *Generic (upcoming)*

APAC

- Japan (code)
- Australia (code)
- *Saudi Arabia (upcoming)*

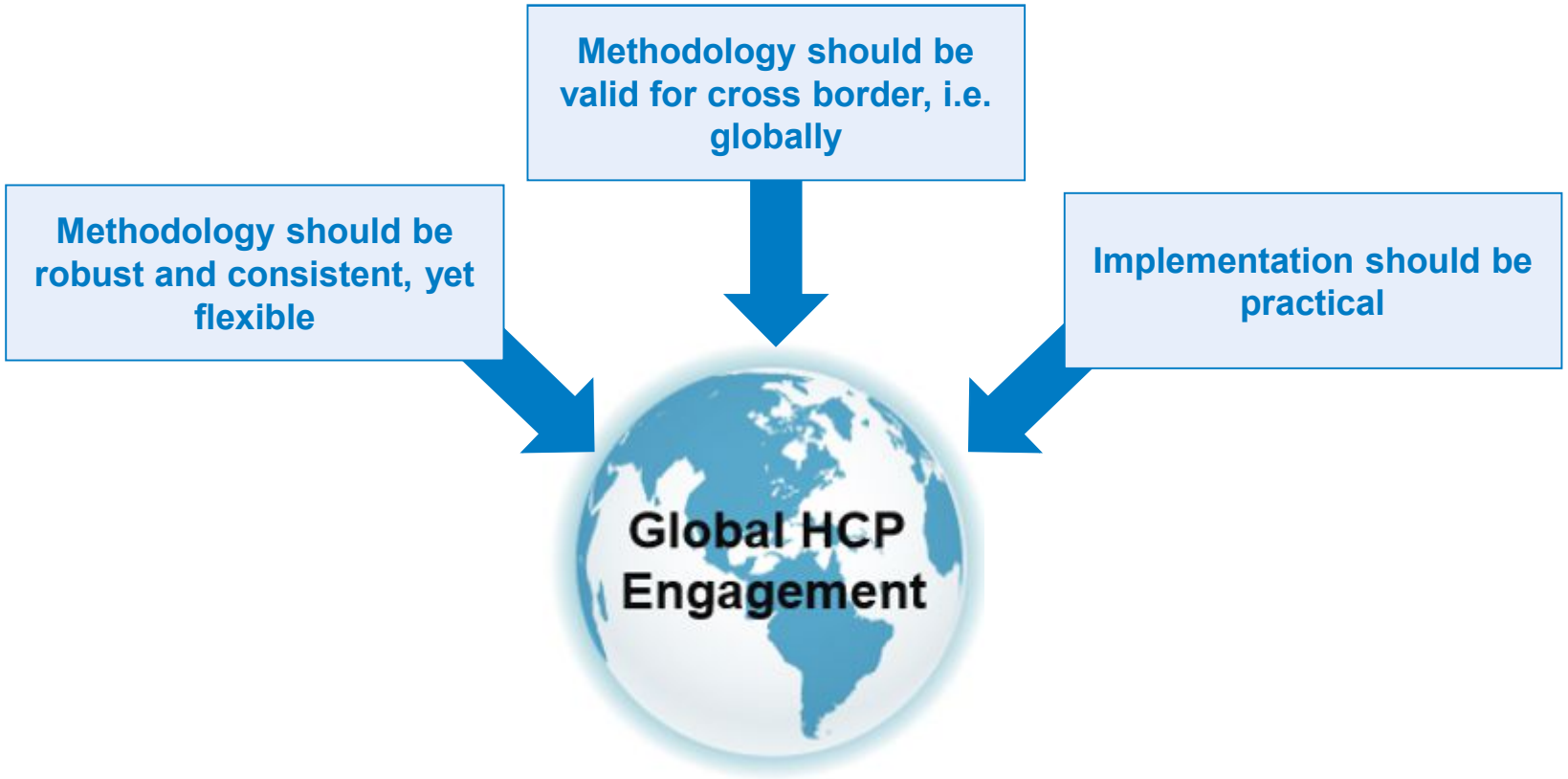
South America

- *Colombia (upcoming)*

Africa

- No report currently

Setting fair market value for HCP engagements should address three broad categories of challenges



Implementing global FMV methodology is challenging

Best practice Fair Market Value methodology is based on four key principles

1. **Pay market rate for consultant's time, not for the value of the service**
   Since paying for time, rates should not vary based on type of service

2. **Assure methodology supports higher fees for higher expertise**
   Required to pay "Thought Leader" higher fees

3. **Create an effective process for evaluating physician expertise and determining "Thought Leader" status (i.e. Local, Regional, National, etc.)**
   Required to avoid kickback allegations

4. **Ensure all elements of the fee determination are grounded on objective and transparent data analysis**

FMV methodology designed to be:
Flexible, Consistent, Objective and Auditable

Similarly, a robust HCO engagement FMV methodology mitigates risk of disguised discounts or kickbacks

Understand the nature of the engagement.

- Assess business need and vendor selection
- Identify activities to be performed under the agreement

Identify cost components and resource needs.

- Deconstruct project costs or fees by service components or activity
- Perform in-depth research on select components of the engagement to determine resource needs (including qualifications)

Assess fees for FMV and reasonableness.

- Conduct a cost build-up analysis (materials, labor, FMV for HCPs, and etc.)
- Determine approximate gross profit margins for the engagement and evaluate estimated margin to appropriate benchmarks

Provide objective program assessment and implementation consideration.

- Provide feedback on reasonableness of fees and suggested fee revisions
- Provide compliance considerations and recommendations to minimize risk through implementation agreement

Questions for discussion

How to ensure consistency across regions and within a region?

How to handle rate differences across regions?

How to handle pushback when implementing changes?

How to set rates where data is not readily available?

How to enforce usage? I.e. how to ensure methodology is used?

How to handle HCO FMV?

How to build buy-in with the business?

How to structure KOL tiering, and how to avoid confusing selection and tiering criteria?

How to structure and implementation program?