COMPLIANCE PROGRAMS AND MEDICAL DEVICE DISTRIBUTORS

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Why does it matter?

“Distributors can do things that we cannot do.”

“I don’t know how the Distributor does it. In fact, I do not want to know.”

“Corruption is the Distributors problem, not mine.”

“Why do you think we use Distributors in those markets?”
The Regulators view... It matters!

“Corporations must supervise officers and employees to ensure illegal payments are not made through third parties.” (Public Prosecutor Office, Germany).

“Corporations must keep reasonably accurate accounting records related to commission payments made to third parties” (Serious Fraud Office, UK).

“Companies are liable for the actions of agents working on their behalf” (SEC, US).

“Corporations are responsible for ensuring sufficient corporate control over third-party consultants regardless of whether a decentralized business structure is in place.” (US Government).
Reality Check

• 4 out of 5 recent FCPA cases in the life-science area involved Distributors or Agents.
Elements of a Distributor Management Program

- Risk Assessment
- Screening/Data Collection
- Due Diligence
- Risk Scoring
- Contract/Certification
- Training
- Monitoring
- Remediation
• What is the go to market strategy?
• Who are your business partners?
• What is the Business and Compliance environment?
• What are the expected activities of the third party?
• 3rd party Gatekeeper meetings
• Be a close advisor and contributor to the business.
Elements of a Distributor Management Program

• Get to know your business partner
• Comparable questionnaire
• Reliable external sources
• In-house or third party?
• Technology, workload
• Tiered risk-based approach
• Identify and follow-up on Red Flags

Due Diligence
Elements of a Distributor Management Program

- DD Results
- Regional Specifics
- Business Practices
- Public information
- Past Experience
- Transparency International
- Strategic Importance
- Size of Business
Elements of a Distributor Management Program

- Minimum contractual requirements
- Audit rights
- Termination Rights
- Compliance provisions
- Specific Anti-Corruption Policy
- Certification in writing
Elements of a Distributor Management Program

- Formal Training Program
- Timing?
- In person / online?
- Refresher trainings
- Audience?
- Content
- EUCOMED / ADVAMED Training Deck
- Continuous Guidance (establish relationship)
Elements of a Distributor Management Program

- Set up a global Distributor Monitoring Program
- Tiered and risk-based approach
- In-person visits
- Participation of the business
- Recertification, reports
- Constantly reassess scope and program
• No action is not an option
• Further fact finding and Investigation?
• Escalation?
• Other areas or regions concerned?
• Documentation, inclusion and consequences
• Compliance incentives?
• Adapt risk scoring
• Monitoring, ownership
- Part of Enterprise Risk Management Program
- Define scope
- Identify, source and evaluate individual risks
- Interviews, workshops, document review, online surveys, targeted reviews
- Assess, plan, execute, follow-up, monitor
Case Studies (1)

During an on-site monitoring visit of a small local ASEAN distributor, the legal & finance team discovers that the distributors records, including distributors spent on sponsorships for HCPs to attend 3rd party congresses, consist of a mere xls-sheet, with no further supporting documents available.
In the course of a training event for new distributors, one distributor representative seriously questions the prohibition of paying for meals of HCPs’ family members, and leaves no doubt that he may not interpret this requirement very strictly.
A suspicion arises that a distributor pays for personal side trips of HCPs after attending a third party congress. The distributor vehemently refuses to allow any audit of its corporate books. One of the given arguments is that the confidentiality of business secrets of other multinational companies prohibits the distributor to grant access.
During a Distributor Due Diligence, it is discovered that one minority shareholder of a Distributor is an active HCP in one of the hospitals which is supplied by the Distributor.