Developing An Effective Global Anti-Bribery Compliance Program

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Why Is This So Important?

- Recent rise in enforcement activity
- Substantial criminal and civil penalties for companies and individuals
- Health care professionals outside US are often public officials
- Requires appropriate books and records, and adequate internal controls

Development and Implementation Steps

- Established Anti-Bribery/FCPA compliance working group
- Revised Corporate Policy on Anti-Bribery and related matters
- Developed and implemented live global training program to reach over 1100 employees
- Devloped, approved and implemented Corporate Directive on Compliance with the US Foreign Corrupt Practices Act
- Developed, approved and implemented Global Finance Directives on FCPA controls
- Developed and implemented computer-based global training program (in 27 languages) that reached over 13,000 employees

Underlying Anti-Bribery Principles

- Advocate for your products on their merits
- Do not "buy business"
- For example, do not pay or provide benefits to doctors or other public officials to induce them to:
 - Prescribe products
 - Place products on formulary lists
 - Take or not take regulatory action

Revised Corporate Policy

- "Anti-Bribery and Related Matters" policy gives core guidance
 - Comply with FCPA
 - Follow local anti-bribery (or anti-corruption) laws and industry codes, especially if they are stricter than FCPA
 - Avoid anything that gives rise to even the appearance of a bribe
 - Applies to all employees worldwide

Revised Corporate Directive and Business Unit SOPs

Corporate Directive

- Provide a framework for analyzing potential FCPA issues
- Assure compliance with the FCPA's books and records, and internal controls provisions
- Examples of legitimate and improper transactions with foreign officials
- Issues to be alert to when retaining third parties

SOPs

 Revise existing Business and Finance SOPs, and require creation of new SOPs, to ensure issues involving payments to foreign officials are properly addressed

Proposed Training Overview

- Ensure that all employees know what their responsibilities are under the Anti-Bribery Corporate Policy and the FCPA
- Provide multiple levels of job-based customized training:
 - Required level of knowledge
 - Risk of encountering an FCPA issue

Proposed Training Specifics

Training Level	Training Audiences	Content
Intense	Worldwide pharmaceutical attorneysCompliance attorneys	 Advanced and pharma-specific concepts Numerous issue-spotting hypotheticals Company policies and procedures
Moderate	• Finance managers and analysts	 Basic and pharma-specific concepts Few issue-spotting hypotheticals (finance oriented) Company policies and procedures
	Balance of attorneys	 Basic and pharma-specific concepts Few issue-spotting hypotheticals Company policies and procedures
General	International business unit executives and directorsBalance of Finance	Basic and pharma-specific conceptsCompany policies and procedures
Overview	US: Business unit executives and directors, sales representatives, and human resources	Basic and pharma-specific concepts Overview of company policies and procedures
	International: Sales Representatives	 Basic and pharma-specific concepts Overview of company policies and procedures