Promotional Compliance Monitoring: Past, Present, and Future

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Promotional Compliance Monitoring Defined

• Monitoring is the ongoing, near-time analysis of data sources to proactively identify, trend and respond to potential compliance “signals”

• Monitoring is distinct from auditing, which is typically retrospective and often limited by time, frequency and scope

• Monitoring results inform corrective action plans, including full-scale compliance investigations, policy changes, enhanced training and communications, additional monitoring, focused audits and other programmatic responses
Allergan shall establish a comprehensive Field Force Monitoring Program (FFMP) to evaluate and monitor sales representatives’ interactions with HCPs and HCIs.
Pfizer’s Promotional Monitoring Program: Promotional Quality Assurance (PQA)

**Mission Statement**

Promote Pfizer’s commitment to integrity by proactively monitoring and analyzing U.S. promotional activities to identify potential compliance signals and providing Pfizer legal and business colleagues with real-time information supporting decision-making and legal risk mitigation.
High-Level PQA Process

RAMP™
Risk Assessment and Mitigation Planning

Prioritize Products and Identify Focus Areas

PQA
Promotional Quality Assurance

Conduct targeted monitoring, review and escalate findings

Responsive and Corrective Action

Respond to identified issues as appropriate
The PQA Story: Past

Launch of state-of-the-art monitoring program

Multiple Data Sources
- Email
- Sampling Records
- Call Notes
- Verbatim Records
- Other Records

Robust Review and Escalation Process
- Collaboration with Legal, Compliance, Data Owners
- Formalized reporting and escalation

Strategic Staffing Model
- Team background: Legal, Pharmacy, Nursing, Audit, Sales, Quality Assurance, Technology
Continuous Improvement: Process and Technology

**Process**

- Refinement of review and escalation process
- Updated reporting
- Product On-boarding

**Technology**

- Enhanced records review platform
- Data sharing and trending
- Process automation
The PQA Story: Future

New Data Sources and Monitoring Approaches

Sources

• Prescriber and Diagnosis Data
• Healthcare Professional Payment Information
• Social Media

Approaches

• Integration across data sources
• Enhanced geographic trending
• Statistical and regression analyses
PQA Success Factors

• Strong, regular collaboration with Compliance, Legal, and Business Colleagues
• Development of product-specific expertise
• Effective leveraging of existing technologies and data sources
• Continuous process improvement
• Transparency in communication
• More informed certifications
Questions?