



# **Global Compliance Programme Operational Issues: Infrastructure, Monitoring, Auditing and Managing with Limited Resources**

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# **Key Elements of an Effective Compliance Programme: an Evolving Global Standard**

- Compliance Office/Infrastructure
- Implementing written policies and procedures;
- Conducting effective training and education;
- Developing effective lines of communication;
- Conducting internal monitoring and auditing;
- Enforcing standards through well-publicized disciplinary guidelines; and
- Responding promptly to detected problems and undertaking corrective action.

# Leadership: A Key Success Indicator

- Support of the Senior Management Team
- Support from Board
- Regular updates to and buy-in from audit committee



# Organizing and Operating an Effective Compliance Programme

- Competing resources and priorities
- Organizational complexities, e.g. matrix, geographical, activity, brand
- Organizational issues and culture
- Functional silos

# Organising and Operating the Programme

- Defining boundaries of Compliance vs.:
  - legal
  - internal audit
  - human resources
  - security

# Key Compliance Design Considerations

- Risk-based approach
- Where to set the bar: global vs. local
- Value-added to the business
- Consistency and simplicity across functions and geographies
- Strong leadership
- Respect for autonomy and country “differences”



# **Operationalising a Compliance Programme**

- Embedding compliance in the business
- Corporate responsibility and reputation management
- Compliance processes as improvements to good business controls and to assist with assurance

# Conducting A Risk Assessment: Core Activities that Create Compliance Risk

- Engaging the services of HCPs
- Post-marketing studies and other clinical studies
- Sponsoring HCPs to attend meetings and events
- Gifts and entertainment
- Visits to Company facilities and other travel
- Charitable and community support contributions
- Sponsorship and grants
- Political contributions
- Facilitating payments
- Actions by agents, consultants, joint-venture partners, distributors and other third party representatives



# Risk Areas – HCP Contracts

## Key risk area

- Service contracted not addressing a business need
- HCP not qualified to provide the contracted service
- Level of compensation not in line with fair value rates and/or time required to perform service
- Service provided deviates from contractual agreement
- Payment insufficiently tracked and documented

## Compliance objective

Fee for service activity addressed clear business need

Mitigate risk of misuse of contracts as promotional tool or inducement

Enforce established fee limits

HCPs are paid for genuine service they provide

Mitigate risk from lack of transparency in handling of payments

## Action taken

Critically review stated business need

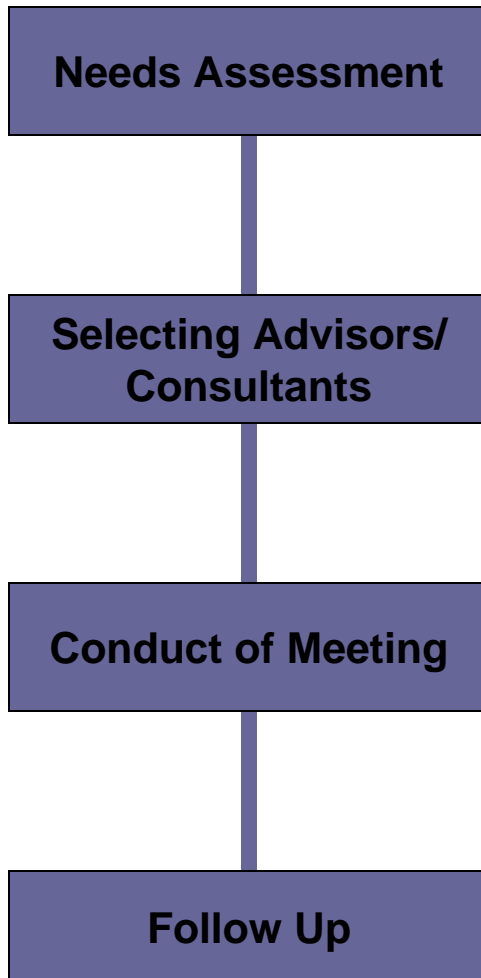
Review background information provided on HCP and qualification to provide the service

Review contract terms and fees for service or time are set according to local fair market rate / limits

Review service while it is being provided or review results are in line with contractual agreement

Review relevant payment documentation, e.g., expense accounts, budget reports

# Advisory and Consulting Boards



- Bona fide need
  - Non-duplicative or cumulative
  - Appropriate number of members
- Members selected for expertise, qualifications
  - Not prescribing potential
  - Note: “advocate/influencers/KOL” development
- Written agreement
  - Clear deliverables
  - Fair market value for services, reasonable expenses
- No strings attached
- Content of meeting matches purposes/needs
  - Not disguised messaging/promotion
- Appropriate venue
  - Modest social/entertainment
  - No expenses for spouses/guests
- Feedback is captured and used

# Risk Areas – Advisory Boards

## Review and approval

### Documentation

Lack of necessary approvals from Nominated Signatory and Line Management

### Agenda

No clear business need defined  
Lack of time for discussion and feedback

### Material

Material has promotional character

### Set-up and participants

Excessive number of participants  
Excessive number of meetings  
Inappropriate criteria for selection of participants  
Involvement of sales staff

### Contracts

No contracts in place  
Payment of excessive fees

## Execution

### Agenda

- Significant deviations from planned agenda

### Material

- Deviation from approved content

### Set-up and participants

- Actual attendance insufficient to satisfy business need
- Individual contribution insufficient to satisfy business need

### Speakers

- Presentation aimed at driving promotion

## Follow-up/Documentation

### Advisory Board results

- Incomplete documentation of results obtained and of intended use of information

### Material

- Incomplete retention of presented material

### Contracts

- Not all contracts retained

# Key Risk Areas - Meetings

## Review and approval

### Documentation

- Lack of necessary approvals

### Agenda and meeting set-up

- Insufficient time dedicated to meeting content
- Meeting covers off-label content

### Venue and hospitality

- Unsuitable venue, lavish hospitality and entertainment

### Participants

- Invitation of spouses/partners
- GPs invited to scientific meetings

### Local Rules

- Limits and approvals

## Execution

### Agenda

- Significant ad-hoc changes

### Material

- Changes to material and presentations after approval

### Venue

- Hospitality above approved level

### Speakers

- Presentation deviates from agreed topic or content

### Participants

- Large number of cancellations leads to excessive hospitality
- Spouses/partners present

## Follow-up/Documentation

### Budget and expenses

- Actual cost deviate from approved budget

### Contracts

- Not all contracts retained

### Material

- Relevant material not retained

### Participation

- List of participants not retained

# Dealing with Third Parties Acting on Behalf of a Company

- What are the standards that apply?
- How must third parties demonstrate compliance?
- What due diligence?
- Using contractual reps and warranties
- Practical and relationship issues
- Ongoing monitoring of 3<sup>rd</sup> parties



# **A Critical Challenge: Implementing Effective Due Diligence**

- Identifying gaps in existing protections around relationships with third parties, incl. agents and distributors, consultants, HCPs and suppliers
- Putting effective due diligence processes in place, appropriate to the size and scope of the risk, to assess potential contracting partners
- Integrating due diligence with ongoing supplier management efforts

# Components of Effective Due Diligence

- Identify and categorize third parties/vendor types
- Develop criteria to evaluate risk by vendor type and assign to tiers
- Develop due diligence procedures related to tiers of risk
- Assess as-is processes and procedures to determine gaps between existing and proposed due diligence requirements
- Develop a triage process to review results of due diligence
- Develop system to maintain due diligence results
- Develop monitoring protocols for compliance with enhanced due diligence processes (e.g. vendor spend analyses)

# Key Training and Education Issues

- What types of learning platforms should be used?
- How can global training and education requirements be tracked?
- What types of systems or documentation methods can be used to ensure attendance and comprehension?
- Who should receive the training?
- How much customization/tailoring should be allowed at a local level?
- What are the issues around translation of company policy and training into other languages?



# Addressing Cultural Differences

- Varying standards of behaviour
- Adapting to different cultures when “selling” the policy abroad
- Potentially culturally offensive statements
- Understanding religious customs
- Sensitivity to education and economic norms
- Special challenges in developing nations
  - Practices necessary to do business
  - Crime cartels
  - Kickbacks vs. cultural customs of gift giving

# Communication and Privacy Issues

- How should issues such as hotlines and other anonymous means of communication be managed and tracked at a global level?
- How is effective communication ensured across cultures and languages?
- Who is responsible for “delivering the compliance message” in various countries, and is it consistent with corporate standards?
- Use of confidential information
- Guidance from the CNIL (French Privacy Authorities)



# The Roadmap to an Effective Monitoring/Auditing Programme

- Identify areas for potential monitoring/auditing
- Development of areas of focus
- Budget support
- Written protocols
- Development and use of metrics
- Deployment of resources
- Utilization of technology
- Effectively communicating results

# Potential Challenges to Developing Effective Monitoring/Auditing Functions

- Data quality
- Systems integration
- Under-developed key performance indicators
- Financial resources
- Human resources/staffing
- The aggregate spend challenge



# Potential Challenges in Deployment of Resources

- Personnel issues in performing monitoring/auditing
- Training of personnel
- Collaboration with HR/Legal/Internal audit
- Follow-on investigations
- Corrective Action



# Potential Challenges in Utilization of Technology

- Real time monitoring
- Transition issues
- Dashboard Metrics
- System Development and Integration
- Vendor Performance

# Potential Challenges in Communicating Results to Management

- Effective lines of communication between the compliance officer and Board/Audit Committee/senior management to communicate monitoring metrics and programme performance
- Focus on key performance indicators
- Metrics and nature of the reporting will evolve over time, based upon the evolution of the programme in general and the sophistication of the monitoring function

# Potential Areas to be Considered for Monitoring

- Government Price Reporting
- Payments to HCPs (e.g. advisory boards, speaker programmes)
- Clinical & Research Grants/Studies
- Continuing Medical Education
- Medical Affairs Guidelines
- Samples
- Free Goods
- Patient Assistance Programme/Indigent Patient Programmes
- Debt Forgiveness/Reduction
- Contractual Payments (Discounts, Rebates, Admin. Fees)





# Potential Areas to be Considered for Monitoring (continued)

- Conventions/Symposia/Foundations
- Data Purchases
- Non-clinical Grants
- Value-Added Programmes
- Gifts, Meals, and Hospitality
- Promotional Materials/Sales Aids
- Off-Label Promotion
- Privacy
- Data Integrity
- GXP/FDA Related Issues
- Publication of Clinical Study Data



# **Development of Areas of Focus for Monitoring/Auditing**

- Risk matrix
- Use of surveys
- Internal assessments
- Government enforcement efforts
- Ability to monitor-technology and resources

# Budget Support and Allocation of Resources for Auditing/Monitoring

- Priority of monitoring in the compliance context
- Allocation of resources
- Funding support
- Capital and operating commitments
- Staffing of audit functions in cost-constrained climates



# Written Protocols for Monitoring/Monitoring

- Develop written protocols for the monitor function
- Training of staff on monitoring function
- Establish framework for assessment of monitoring programme operation

# Development of Compliance Metrics

- Within areas of focus identify key data needs
- Fashion approach based upon measurement capabilities
- Development of metrics is context-specific
- Utilize metrics that can provide notice of the need for further review
- Utilize results to achieve and communicate compliance programme goals

# Possible Metrics to be Considered for Monitoring Engagement of Physicians

- Number of consultants retained per product
- Number of speakers retained per product
- Utilization of speakers who attend speaker training
- Direct payments to physicians
- Indirect (via vendor) payments to physicians
- Programme design and content of advisory boards

# Possible Metrics to be Considered for Sales Representative/MSL Monitoring

- Identify potential off-label promotional activity by sales representatives/MSLs by observation of interactions with HCPs
- Conduct full-day, potentially random, direct inspections and observations of the messages and materials delivered

# Possible Metrics to be Considered for Sales Representative/MSL Monitoring (cont'd)

- Number of inspections conducted proportional to the size of the sales force/MSLs
- Inspections conducted across all regions in which the company operates.
- Inspection report prepared by compliance personnel to include:
  - the identify of the sales reps/MSLs;
  - the identity of the monitor;
  - the date and duration of the inspection;
  - the topics discussed during the inspection; and
  - identification of any potential off-label promotional activity.