Fourth International Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

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Pre-conference I - International Compliance Program Basics

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International Compliance Program Basics

- How can we maintain a robust Compliance Program in the ongoing difficult economic environment?
- How can we maintain a robust Compliance Program in the changing internal environment of the pharmaceutical industry?
- What key changes will present the major challenges of the future?
- How will the increasingly complex regulatory environment and increasing focus from authorities impact us?

Let’s begin by taking a look at the external environment…

External Environment

- Ongoing economic crisis
  - World-wide context
  - Evolution of our industry model
- Regulators adopt new approaches
- New US sentencing guidelines emphasise need for strong compliance & ethics program
- HCPs having fewer face to face meetings with reps
  - Regulations changing
  - Lack of time
- Information revolution
  - Many sources of unregulated information for HCPs and patients while pharmaceutical industry is heavily regulated
  - HCPs increasingly technology aware; less paper oriented
  - Regulations for social media / electronic media need to catch up

Internal environment

- Budgets flat or marginal increase – need to prioritise efforts to maximise outcomes
- Perception that current economic climate increases risks dramatically[1]
- Portfolio reorganisation leads to restructuring / redundancies across all departments, resulting in loss of expert knowledge
- Increased pressure from external sources, e.g. greater enforcement resources in FDA, new UK Bribery Bill
- New ways to reach potential patients and HCPs are attractive uses of scarce resources, e.g. social media
- Difficulties in getting information out of systems to meet reporting requirements, e.g. aggregate spend

[1] Turteltaub, Journal of Health Care Compliance, May-June 2009 stated 85% of compliance & ethics professionals see risk of failure increasing due to economy

Elements of an Effective Compliance Programme

1. Implementing written policies and procedures
2. Designating a compliance officer and compliance committee
3. Conducting effective education and training
4. Developing effective lines of communication
5. Conducting internal monitoring and auditing
6. Enforcing standards through well-publicized disciplinary sanctions
7. Responding promptly to detected problems and undertaking corrective action
8. Avoiding “bad actors”

Adapted from OIG (US Office of Inspector General) Guidance for Pharmaceutical Companies

Elements of an Effective Compliance Programme

Discussion

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2. Designating a compliance officer and compliance committee
3. Conducting effective education and training
4. Developing effective lines of communication
5. Conducting internal monitoring and auditing
6. Enforcing standards through well-publicized *international* disciplinary sanctions
7. Responding promptly to detected problems and undertaking corrective action – *investigations process*
8. Avoiding "bad actors" – *not hiring / keeping people with a tendency to work outside the rules*

Trends / Hot Topics

- Greater enforcement resources
- Greater transparency demanded, e.g. US Grassley Bill
- Tougher laws and penalties for bribery and corruption, e.g. new UK Bribery Bill
- More emphasis on effectiveness of Compliance Programs, e.g. Germany, new US sentencing guidelines
- Due Diligence requirements
  - 3rd parties
  - Potential acquisitions
- Off-Label activities
- Use of Social Media
- Individual consequences of failure

Recent cases

- EU; various pharma; 2009 / 2010 – antitrust probe
- Germany; non-pharma; 2009 – role of Compliance Officers and their criminal liability
- Switzerland; Pfizer, Eli Lilly, Bayer; 2009 – price fixing fines totalling $5.7m
- UK; J&J; 2010 - executive jailed for his part in Greek healthcare corruption
- USA; Eli Lilly; 2009 – off-label promotion of Zyprexa led to fines totalling $1.4bn
- USA; Pfizer; 2009 – Bextra (& others) off-label promotion led to fines totalling $2.3bn

Main Conference Preparation

- Transparency initiatives, e.g. Transparency International, US Grassley Bill, what companies are doing
- Bribery and corruption – OECD convention, e.g. FCPA, new UK Bribery Bill
- Changing HCP interactions
- Off-Label activities – information to patients
- IFPMA / EFPIA code changes
- European Pharma Package
- Cross border agreements, e.g. Pfizer's 2009 Corporate Integrity Agreement

Discussion

- What works for your companies?
- What changes are you seeing internally and externally?
- What impact will these changes have on your Compliance Programs?
- Are you seeing a shift in the types of incidents reported in your companies?
- Do you have any questions for us?