FOURTH ASIA PACIFIC PHARMACEUTICAL COMPLIANCE CONGRESS AND BEST PRACTICES FORUM
September 16 - 18, 2014

MINI SUMMIT I: CORE COMPLIANCE COMPETENCIES TRAINING -- PROGRAM BASICS

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PROGRAM AGENDA

MINI SUMMIT I: CORE COMPLIANCE COMPETENCIES TRAINING -- PROGRAM BASICS

- The Basics of a Compliance Program: The Global Standard for Effective Programs
- The Role of Values Based Ethics in a Compliance Program
- The Role of Governance, Decision Making and Escalation
- The Roles and Responsibilities of the Compliance Officer

Introduction: Compliance Risks

- The pharmaceutical industry presents one of the most complex operating and regulatory environments in any industry
- There is potential corporate liability for employee or third party agent misconduct, which may have a significant impact on reputation
- Also stakeholders expect that financial, legal, and reputational risks will be managed effectively
- In the case of a compliance violation, it is essential for a company to demonstrate that
  - Such an event was purely exceptional, or happens very infrequently
  - A compliance progam is in place which is capable of preventing, detecting, and responding to violations

Increasing Government Expectations

- Increasing expectations from governments worldwide that global companies manage risk effectively through compliance programs
- Governments expect compliance programs to be designed, implemented, reviewed, and revised, as appropriate, in an effective manner
- This means more than a paper program and must include adequate procedures to prevent, detect, and respond to potential wrongdoing
- Standards are evolving and are being raised

Evolving Risks of Non-Compliance

- What are the potential risks of non-compliance?
  - Criminal, civil, and administrative liability for acts of the company and its employees
  - Liability for senior managers and board members who are in a position to prevent, detect, and respond to violations, but fail to do so
  - Law suits by private parties, including patients, investors, and government payors
  - Debarment from doing business with governments or trading on stock exchanges
  - Loss of trust among physicians, patients, investors, and payors
  - Negative effect on share price
  - Tarnished public image and reputation
  - Increased scrutiny by regulators and stakeholders in the future

The Basics of a Compliance Program: The Global Standard for Effective Programs

Introduction

- What are the key elements of an effective compliance program today?
- Have these key elements evolved in practice since the OIG published its 2003 *Compliance Program Guidance for Pharmaceutical Manufacturers*?
- How do we document evidence of their implementation, and more importantly, evidence of their effectiveness?
- How can we be ready in a “click” to show the effectiveness of the program in a structured and documented way?

OIG's 7 Elements of an Effective Compliance Program: a Summary

1. Written Policies & Procedures
2. Designation of a Compliance Officer and a Compliance Committee
3. Conducting Effective Training and Education
4. Developing Effective Lines of Communication
5. Auditing & Monitoring
6. Enforcing Standards through Well-Publicized Disciplinary Guidelines
7. Responding to Detected Problems and Developing Corrective Action Initiatives

2003 Compliance Program Guidance for Pharmaceutical Manufacturers

Evolving Expectations Worldwide

- Culture of Compliance & Ethics
- Tone @ the Top
- Business accountability
- Risk Assessments
- Evolution of the role of Compliance to “business partner and enabler”
- Compliance in performance evaluations
- Integration of compliance function in business strategy setting
- Contract management (contractual clauses, templates)
- 3rd Party Program
- Guidance for alliances and joint ventures
- Pre-acquisition due diligence and post-acquisition integration
- Compliance considerations in electronic systems and processes
- Conducting “Root Cause Analysis”

The Role of Values Based Ethics in a Compliance Program

What are Values Based Ethics principles?

- Always knowing what is the “right thing to do”
- Having an internal compass that says how to act or react in each situation
- Not needing to be told what the boundaries are, since it is obvious
  - Is the right thing always clear and obvious?
- “Grandmother test”

Compliance Spectrum

Rules based culture:

- Every possible action that is allowed or not allowed is codified (in theory)
- Everyone knows what the rules are
- The rules are followed (almost) blindly
- Non-compliance occurs when the rules are ignored, unclear, too numerous or complex, perceived as burdensome or training is insufficient
- Large compliance organisation needed to monitor & control

Values based culture:

- Only core values are codified
- Core values are communicated and internally expressed across disciplines, so everyone knows what the values are
- Judgment is used to apply the core values
- Ethics breaches occur when the values are unclear, people ignore the messages or don't accept or "buy in" to the core values and choose not to comply
- Smaller compliance organisation needed to monitor / control
- Everyone becomes their own Compliance Officer

Why can't we just have Rules?

- The law in many countries has been evolving over centuries
- Often, laws are responsive to actions of the wrongdoers; one step behind
- The complex structure of laws, regulations, industry body codes of practice, and internal codes of conduct, policies, procedures and guidance may make it difficult for individuals to always know ALL the applicable rules
- It is not possible to write down everything that is, or is not, allowed
- There will always be some ambiguity of language or interpretation

Why can’t we just have Values?

- Values are highly personal to individuals, societies and companies
- It may be difficult to codify values accurately and unambiguously
- Values need to be applied with judgment, which also differs between individuals, often based on their experience
- It is impractical to hold people to account for not living up to their own, or their organization’s values

Compliance Programs Must Rely on Having Clear Rules AND Clear Values

- How many cases do you know of where the accused pointed to the rules and said what they were doing was allowed by the rules?
- How many times have you heard senior managers ask why individuals did not know that certain behaviour was wrong (even though it was not expressly forbidden in the rules)?
- So, how can you ensure that an organisation of thousands of individuals has both clear rules and clear values, and that everyone within the organisation understands them and will comply?
- Does the “red face test” really work?
- Will individuals still get it wrong with greater emphasis on values based ethics?

What are the lessons learned?

- April 2014 – Pfizer to pay $190M to resolve an antitrust lawsuit first filed in 2002 (Neurontin)
- April 2014 – GSK investigates bribery allegations in Jordan, Lebanon, Poland, as well as China
- April 2014 – Takeda & Eli Lilly ordered to pay $9B when US jury found they had “failed to adequately warn” about the bladder cancer risks (Actos)
- April 2014 – Novartis announces changes to senior management in Japan and investigates internal allegations of impropriety regarding clinical trials – “our company culture…in Japan needs to change urgently”

Were the rules clear?

Were the values clear?

Were these “exceptional cases” where a few individuals chose to ignore both the rules and the values?

Summary

- Just because your competitor is doing something, that does not mean that you can or should do the same

…and…

- Just because you **can** do something, that does not mean that you **should** do it (The Jurassic Park Question)

The Role of Governance, Decision Making and Escalation

What is Governance?

- *Corporate* governance has been defined as “the system by which companies are directed and controlled” (Cadbury Report, UK, 1992), or
  - the system of checks and balances, or
  - the system of risk controls / risk management
- *Organisational* governance relates to the structures, hierarchies, policies, procedures, and internal controls within the organisation
- Often mentioned in context of “tone from the top”; *HOWEVER*, what about “tone in the middle” and “tone at the bottom”?

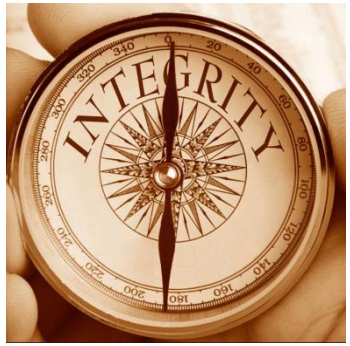
Linking Governance, Compliance and Assurance

- Having an effective *ethics and compliance programme* is essential to:
  - minimising risk
  - maintaining and building reputation
  - bringing competitive advantage
- All companies should have an effective *assurance programme*, usually run by an internal audit function, to assure Senior Management / Board of the effectiveness of the risk controls
- Effective risk management can help to reduce the impact when wrongdoing *does* occur

Decision-Making

- How do you make decisions?
  - Completely “gut feel”?
  - Completely “evidence based”? (based on which metrics?)
  - A combination of the two?
  - A different method?
  - Do you think that making decisions is *not* part of your role?
- Who do you liaise with for guidance or advice?
  - Legal
  - HR?
  - Medical?
  - Finance?
- How are decisions typically taken in your organisation?

For Ethical Decision-making, Use the Ethical Compass



- Is it consistent with our mission, values and spirit?
- Is it legal and ethical?
- Is it consistent with policy and Code of Conduct?
- Can I explain it to my family and friends?
- Would I be comfortable if it appeared in the newspaper?

Escalation

- How do you know what to escalate and when?
- Does your organisation have guidance for escalation, perhaps based on:
  - Level of risk e.g. likelihood x impact
  - Seniority of individuals involved
  - Amount of money involved
  - Potential reputational damage, e.g. local, regional, global
- Do you know how to escalate?
  - Within Compliance organisation
  - Within Business Units
- If you do escalate something, what support will you get / how will senior management react?

Organisational Power and Politics

- “Power” refers to the capacity that A has to influence the behaviour of B so that B does something he or she would not otherwise do
- Typical sources of power include:
  - Reference / respect, e.g. a respected former colleague or senior leader
  - Hierarchical or legitimate power (managers)
  - Expertise (knowledge / strength of arguments)
  - Ability to reward (often hierarchical)
  - Ability to punish (often hierarchical)

Descriptive Model of Political Behaviour

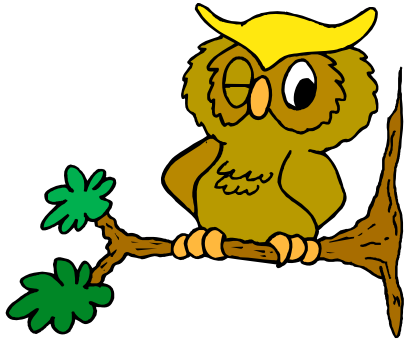
Politically Aware

Fox

"clever"

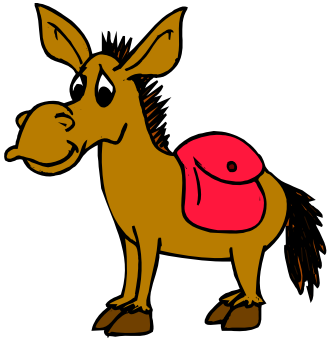
Owl

"wise"



Psychological Game Playing

Acting with Integrity

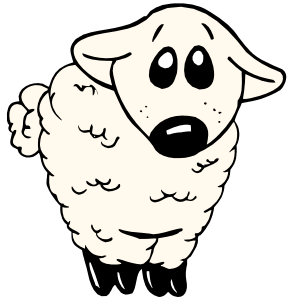


Donkey

"inept"

Lamb

"innocent"



Politically Unaware

Source: Baddeley & James, 1987

Summary

- Understand the governance structures within your organisation, including the “tones”
- Enlist core functions / individuals to help with decision-making
- Know what to escalate, how and when
- Cultivate political allies to help you influence appropriately
- Try to be more of a wise owl and less of an innocent lamb led to slaughter!

The Roles and Responsibilities of the Compliance Officer (CO)

Roles and Responsibilities of the CO

- The CO is responsible for the implementation and functioning of the compliance program that prevents, detects, and responds to potential violations of company policies; this includes **clear policies**, **effective training**, **monitoring and auditing**, and effective **responses to incidents**
- Resource for the Business
  - Respond to questions and advise the business on compliance policies, needs assessments, process flows and template agreements
  - Respond to specific questions about compliance related issues, HCP interactions, and sponsorships, grants and other support.

Roles and Responsibilities of the CO

- **Enable Compliance Operations (be informed)**
  - Give clear answers and guidance and explain rationale behind processes
  - Know and understand applicable laws, codes and policies in the market
  - Follow internal procedures and requirements to provide the business with clear guidelines (e-tools / templates)
- **Training and Counseling (be a resource)**
  - Help instruct new and current employees on company´s policies
  - Be prepared to answer compliance questions from employees on company´s policies and compliance generally
  - Anticipate the business needs that may require your advice and guidance
  - Work with the business to help it achieve its objectives in accordance with company values and ethics
- **Oversight (be vigilant)**
  - Identify potential compliance concerns before they arise and be proactive in raising and addressing them
  - Report concerns about improper activity
  - Identify lack of awareness of company policies and act to rectify

Defining Roles and Responsibilities for Legal and Compliance

- Key element of successful implementation is collaboration between Legal and Compliance
- For areas where Legal has primary lead, Compliance should refer issues to Legal
- For areas where Compliance has primary lead, Legal should refer issues to Compliance
- Approach enables consistency, builds teamwork, and reduces opinion shopping
- Key is developing the relationship on a one on one basis with Lawyers and Compliance Officers
- Compliance and Legal even if separate organizations, must always be closely aligned

What Does Success Look Like

- Individual and collective ownership of ethics and compliance expectations integrated into the day-to-day operations of the business
- A culture where employees reject unethical behavior and take responsibility themselves for ensuring that the company achieves its business and commercial objectives the right way
- Effective and close collaboration between Legal and Compliance with clear roles and responsibilities
- A compliance program that can demonstrate effectiveness in implementation
- Compliance officer involvement and commitment to make this happen

Questions?

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MINI SUMMIT VI: CORE COMPLIANCE COMPETENCIES TRAINING -- ADDRESSING CORE COMPLIANCE RISKS

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PROGRAM AGENDA

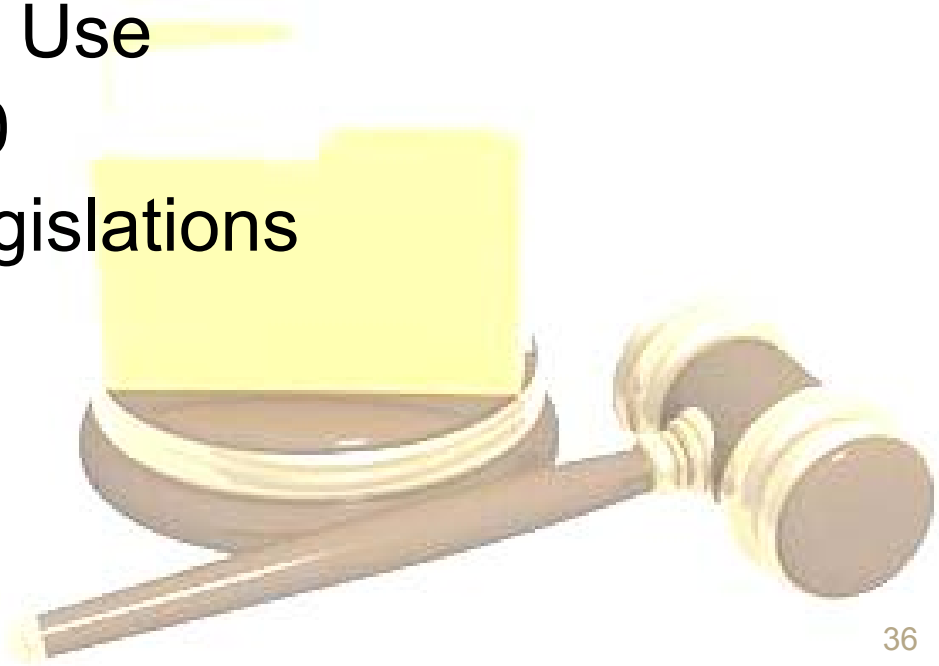
MINI SUMMIT VI: CORE COMPLIANCE COMPETENCIES TRAINING -- ADDRESSING CORE COMPLIANCE RISKS

- The Basics of Anticorruption
- The Basics of Disclosure/Transparency
- The Basics of Pricing, Reimbursement Tendering and Public Procurement
- The Basics of Data Protection

The Basics of Anticorruption

The Environment

- US FCPA: Foreign Corrupt Practices Act (1977)
- OECD anti-bribery convention (1997)
- UN Convention Against Corruption (2003)
- Directive 2001/83/EC (article 94) – Medicinal Products for Human Use
- UK Bribery Act 2010
- Local anti-bribery legislations



“It is unlawful to bribe government officials to obtain or retain business”

Three key questions:

Who?

Any official of a state-owned business

Why?

To induce an official to use his/her influence ***improperly*** to affect or influence any act or decision. No need of success.

How much?

Anything of value in cash or kind

What is Corruption?

Definition by Transparency International TI

The misuse of entrusted power for private gain

Where Should We Focus?

Transfers of Value (ToV)

- Hospitality
- Fees for Services
- Educational Grants
- Medical Education Programs
- Patient Organisation Support
- Market Research
- Research: IIS, studies, surveys

Sensitive GOs

- Tender Committees members
- Product & Site regulators
- Health Economics & Pricing Authorities
- Policymakers
- Former Government Employees

Third Parties

- Sales and Tender intermediaries
- Vendors e.g. Event Planners, CROs, etc
- Logistics intermediaries
- Joint Ventures & Acquisitions

How Can We Mitigate Risk?

Right Intent

Why?

- Clear business needs
- Objective

Who?

- Fair Selection Criteria

How much?

- Modesty
- Frequency
- Proportionality
- Fair Market Value
- Proof of activity

Risk assessments, review of business plans

Transparency

- Standards
- Approval process
- **Documentation**
- Value transfer tracking
- Escalation

Perception

- Authorities
- Public
- "Media" Test

Hypothetical example
HCP sponsorship & geographical location

- Your company has been asked to present data from a pivotal clinical trial at this high profile and respected annual symposium
- The location is not close to an international airport and could be perceived as lavish or associated with leisure
- However the location was chosen by the congress organisers
- **Your company needs to decide on whether it will:**

  a) *present data at the symposium*

  b) *sponsor HCPs to attend – and if so, which ones?*

"Since you have already been convicted by the media, I imagine we can wrap this up pretty quickly."

Example:
Email exchange between employees

From: Franchise Director
To: District Manager, Sales Representative

OK

From: District Manager
To: Franchise Director

OK. Please accept this – she is the main decision maker in tenders.

-----Original Message-----
From: Sales Representative
To: District Manager
Cc: Franchise Director

Please give your OK to financing the training: „Procedures for the award of public contracts – practical aspects". Venue – AB (a ski resort). Ms. XY – the Head of the Public Procurement Department in hospital C. Training cost – 2,000.

This is a part of the post-tender obligations to be fulfilled, tender won for 2 years.

Thank you.

Fictitious

Focus on principles: People follow people….

Tone at the Top

- **Compliance is the responsibility of every individual**
- **Everyone can contribute in their own way**
- **Everyone can make a personal commitment**
- **No need to wait for processes**
- **Ethical business is the only sustainable business**

The Basics of Disclosure/Transparency

Transparency Regulations: Fundamental Elements

Jurisdiction or Regulatory bodies

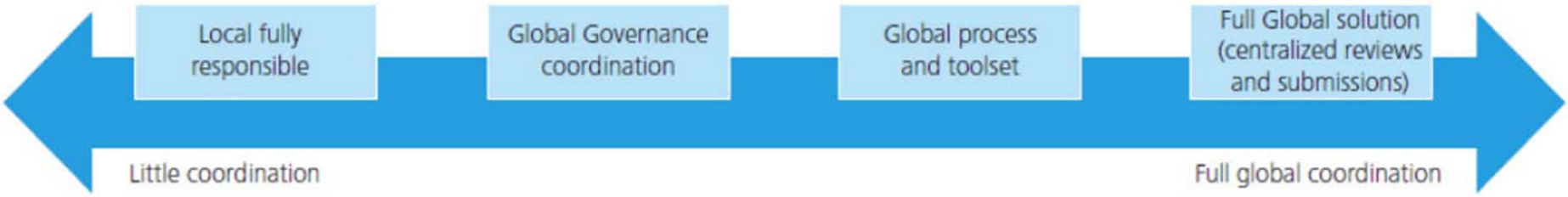
- Laws in US, France, Slovakia
  - Pakistan is considering HCP transparency law
- Industry Codes in UK, Netherlands, Europe, Japan, Australia
- Timing of reports can be annual or otherwise
- Scope of disclosure reports are usually HCPs or HCOs
  - HCPs may not be just physicians
- Transactions covered are aggregate payments & other things of value provided to HCPs/HCOs
- Exceptions may include threshold amount, below which payments are recorded, but not disclosed
  - $10?

Important Considerations

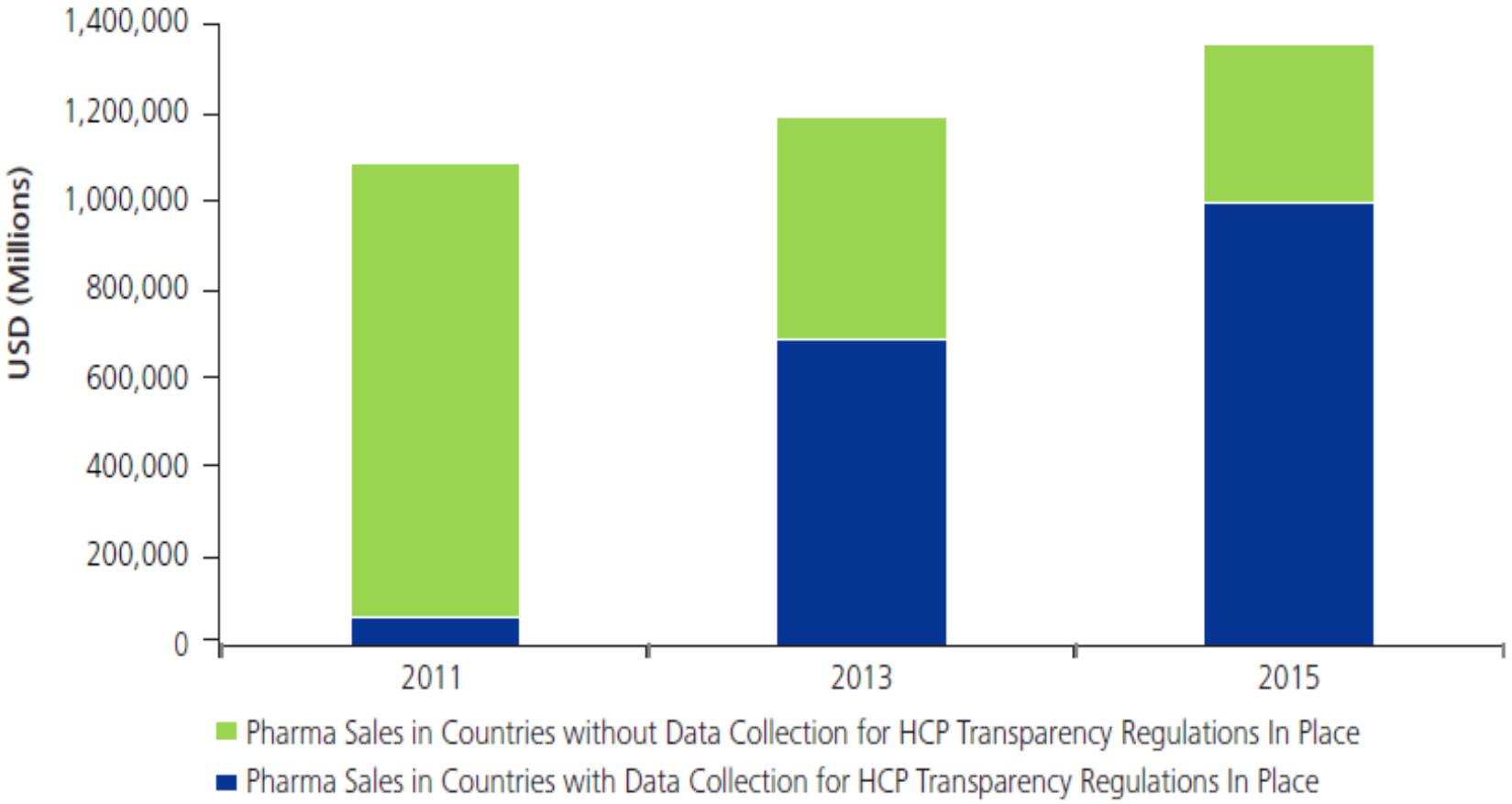
The proliferation of these regulations is prompting life sciences companies to consider important questions, such as:

- Expectation of more laws or regulations being passed in other regions
- Whether new laws should be addressed by implementing a global solution, or should each country's offices manage efforts locally
- How much can we leverage the systems and data investments made in the U.S. and other countries to develop global capabilities?
- What controls should we put in place to make certain that the data we are collecting is complete and accurate?
- Who in our organization should own this responsibility?
- What are other organizations doing?

Global HCP/O transparency continuum



By 2015, over 70% of pharmaceutical sales will occur in countries with HCP Transparency regulations!



Source: 2012 The Economist Intelligence Unit.
2011: US States only: CA, MA, MN, WV, VT
2013: Japan, UK, France, Australia, Croatia, Slovakia, US (anticipated), France (anticipated)
2015: 2013 countries plus EFPIA (anticipated)

Similarities and Nuances

Similarities

- **Data elements** — The overlap in required data for the various regulations is significant, which lends itself to standardized data capture from each market.
- **Interaction types** — Many of the regulations require reporting commercial and educational activities such as speaking, consulting, hospitality, gifts, sponsorships, etc.
- **Granularity** — Providing itemized lists of transactions by date is common across virtually all of the regulations.
- **Frequency** — Many reports must be posted or submitted on an annual basis.
- **Technology components** — The technology needed to develop reporting is consistent across current requirements and with technology typically existing in organizations today.
- **Fundamental capabilities** — The business, legal, and technology capabilities are fundamentally consistent across country requirements.

Nuances

- **HCP/O Definition** — The type of vendors and customers that are required to be tracked are typically the same (e.g., doctors, dentists, pharmacists, etc.,) but there are some differences; for example, in some countries, students and/or nurses must be tracked. There are also differences in the types of HCOs that should be tracked.
- **Exclusions** — Each regulation tends to provide its own list of activities or amounts that need not be disclosed; for example, discounts, specific types of loans, amounts under a certain threshold (e.g., France - €10).
- **Cross-border** — Regulations differ as to whether transactions should be disclosed based on the HCP/O's country or the country which initiates the value transfer. Currently, the trend is for transactions to be disclosed for an HCP/O, no matter where they originated.

Local or Global Solution?

- There is a great deal of redundancy in the data, IT capabilities and processes required to meet the disclosure requirements by each country with applicable regulations

- This redundancy has led many companies to begin development or consider future development of a center of excellence with shared capabilities to service several or all countries with HCP's transparency requirements within a company

- Any further opportunity to coordinate across the industry to develop data, IT capabilities and operations which can be shared by multiple companies

What Can Be Centralized?

1. Monitor environment for new regulations
2. Interpret disclosure regulations and translate into system requirements
3. Define/update guidelines or policies, business processes and standard operating procedures (SOPs)
4. Train individuals on new policies, procedures and SOPs
5. Build technology capabilities based on approved requirements
6. Enter HCP/O spend data entry into source systems
7. Monitor data quality
8. Correct data errors in source systems
9. Maintain HCP/O master data
10. Develop and execute communication plan
11. Execute/produce draft disclosure reports
12. Review disclosure reports prior to submission internally
13. Review HCP spend data with HCPs and make updates to data, if needed
14. Submit disclosure report (or post on web)
15. Support technology

Challenges to Success

Driving Adoption and Change in Business	Maintaining accurate HCP/O lists	Collecting data from 3rd Parties	Managing HCP privacy concerns	Gaining consensus on global requirements

OWNERSHIP
?

The Basics of Pricing, Reimbursement, Tendering and Public Procurement

Procurement: Overview

- The primary function of a procurement of pharmaceuticals is to obtain the required items at the right time, in the correct quantities, and at the most favorable prices
- The procurement office for a health authority compiles a list of requirements, identifies potential suppliers, selects the most cost-effective supplier for each product, secures firm supply contracts, and makes sure that the suppliers and the health system comply with contract terms
- Competitive tenders are used for many pharmaceutical procurement in public-sector pharmaceutical systems

Procurement: Overview (continued)

- To maximize the benefit of pharmaceutical purchases, corruption and favoritism in procurement must be minimized.
- Avoiding the appearance of favoritism is important as well so the tender process should be as transparent as possible under national procurement laws
- A formal tender process includes medicine selection,
  - quantification, preparation of tender documents and contracts
  - notification and invitation to bid, formal bid opening
  - collation of offers, adjudication and supplier selection
  - contract award
  - performance monitoring of suppliers and clients
  - enforcement of contract terms if necessary

Procurement: Overview (continued)

- Reliable suppliers are essential for effective procurement, and a prequalification process is typically used
- Tender adjudication and selection of suppliers determines the costs of medicines and defines the integrity of the procurement process
- Adjudication is on formal written criteria and must be free from influence by special interests
- Accurate and timely information is critical at each stage of the process, and lack of effective information systems is a main cause of delays and inefficiencies
- The information system must be able to-
  - Produce information for quantification and tender documents
  - Collate offers for adjudication
  - Issue notifications of award and purchase orders
  - Track order status and compliance with contract terms
  - Manage communications with contract suppliers
  - Track suppliers' performance for future tenders

Pricing and Reimbursement: Overview

- Significant differences exist in pricing and reimbursement across the region
- Some countries, such as Brazil, utilize HTA assessment for pricing
- Others such as Mexico use reference prices
- Others (e.g. Chile and Argentina) leave it to the companies to decide price. However, changes are occurring with Colombia, for example, transitioning from free pricing to reference pricing
- In terms of reimbursement, there is a wide range of payers — from health plans and insurers, to hospital financial management and health department officials

Compliance Issues in Procurement/Reimbursement

- New tendering processes create compliance risks
- Government official interactions in tendering/pricing
- Interactions with competitors
- Use of third party agents, regulatory consultants, or tendering consultants
- Warning signs in third party compensation

The Basics of Data Protection

Core Principles of Data Protection in Asia Pacific-Current State

- **Philippines:** The Philippines' data privacy Act, which was signed into law in August, 2012, is the first uniform privacy law for the country

  It is a European-style data protection law with procedures to be followed in the collection, processing, and handling of personal information
- **Singapore:** On October 15, 2012, the Singapore Parliament passed the Personal Data Protection Act 2012 (PDPA), with the main data protection provisions becoming enforceable on July 2, 2014. The PDPA takes a high-level approach and addresses:
  - the collection, use, and disclosure of personal data
  - the transfer of personal data outside of Singapore
  - the protection and retention of personal data
  - the right to access and correct personal data
  - sanctions and enforcement mechanisms

  The PDPA also provides for the creation of a Data Protection Commission with the authority to fine an organization an amount not exceeding S$1 million for rule violations

  A private right of action for persons suffering loss or damage resulting from a violation of the PDPA also is available

Core Principles of Data Protection in Asia Pacific-Current State

- **Hong Kong:** Hong Kong's Legislative Council amended its main data protection regulation, the Personal Data (Privacy) Ordinance (Cap. 486), with effect from October 1, 2012

  The ordinance sets forth principles related to:

  - the purpose and manner of collection of personal data
  - the accuracy and retention of personal data
  - the use of personal data
  - the security of personal data
  - information that should be made generally available
  - access to personal data

  Although the ordinance prohibits the transfer of personal data outside of Hong Kong except in specified circumstances, these cross-border transfer rules are not yet in force
- **Taiwan:** Taiwan's personal data protection Law came in effect on October 1, 2012. The definition of "personal data" has expanded under the new legislation, which applies to all individuals, legal entities, and enterprises collecting personal data

Core Principles of Data Protection in Asia Pacific-Current State

- **Australia**: Passed the Privacy Amendment (enhancing privacy protection) Bill in late November, 2012

  It sets out the Australian privacy principles and strengthens the power of the regulator
- **China:** In December 2013 the People's Republic of China (the PRC) passed the Resolution Relating to strengthening the protection of information on the internet (the "Resolution")

  This nationwide, legally binding set of rules follows a series of developments in the PRC, such as the several Regulations on standardizing Market order for internet information services from March, 2012

  The Resolution obliges internet service providers and other businesses to adopt necessary security measures to protect personal information, to state the purposes of the collection and to obtain consent from data subjects

Core Principles of Data Protection in Asia Pacific-Current State

- **Malaysia:** In January 2013, Malaysia's personal data protection Act 2010, also a European-style legislation, come into force

  It has heavy penalties for non-compliant companies
- **Japan:** Japan's Act on the Protection of Personal Information has been effective since 2005 and provides moderate regulation
- **South Korea:** South Korea's Personal Information protection Act 2011 may be the strongest law in Asia

Core Principles of Data Protection in Latin America-Habeas Data

- A constitutional right in many Latin American countries which permits an individual to petition a court to help it protect his or her privacy, including his or her image, privacy, honor and freedom of information
- The action can be brought against anyone holding information, and it empowers the complaining party to request a correction or even destruction of personal data held by a third party.
- Brazil (1988), Columbia (1991), Paraguay (1992), Peru (1993), Argentina (1994), Ecuador (1996), Bolivia (2004)
- Traditionally, only brought and asserted by the affected individuals. But more recently, Latin American courts have begun to take a broader view for groups or classes of individuals

Core Principles of Data Protection in Latin America-Consent

- Most laws require express and verifiable consent before data from any person is gathered
- Colombia's Law 1581 (2012), for example, requires parties collecting personal data to obtain and retain verifiable written consent and to notify each person of
  - the purpose of the data collection or processing
  - the intended use of the personal data
  - the data owner's privacy rights
  - how the data owner can access the responsible party's policies regulating the processing of personal data

Core Principles of Data Protection in Latin America-Absence of Uniformity

- Each country has its own privacy laws
- Often their political subdivisions have their own laws too.
- Mexico, for example, has its own national data privacy law but the states of Colima, Guanajuato, and the Federal District of Mexico City also have their own

EU Directive 95/46/EC

- Translated into national laws, e.g. UK Data Protection Act 1998
- “Personal data” means any information relating to an identifiable natural person
- “Processing” means any operation carried out on personal data, whether automated or not
- “Personal data filing system” means any structured set of personal data whether centralised or not
- “Data subjects” have the right to request a copy of their information from organisations
- Permits the cross-border transfer of personal data to other countries, but only if their privacy laws are deemed “adequate”
- In order to attract additional trade and commerce with the EU, the trend in recent privacy legislation and in proposed legislation throughout the region is to adopt an EU-based model, in the hopes of obtaining that adequacy designation

USA HIPAA Privacy Rule

The Health Insurance Portability and Accountability Act (HIPAA),1996:

- Defines Protected Health Information (PHI)
- Gives patients rights to access and amend their PHI
- Includes electronic, paper or oral information
- Relates to health, healthcare treatment, and payments for such treatment

Compliance Program Considerations

- Patient data in Clinical Trials, e.g. use of analytics
- Employee HR data, e.g. sickness, involvement in compliance investigations
- Internal / external Reporting Lines
- Case notes regarding compliance investigations, whether proven or not
- HCP data in Field Automation Systems / Reps' "little black books"…
- Disclosures / Transparency Reporting for HCP Transfers of Value
- "Bad documents"

Summary

- Remember that “data subjects” have the right to see their data
- State clearly the purpose of the data collection
- Collect only enough data required to fulfil the purpose
- Keep the data accurate and up-to-date
- Keep the data secure
- Safely destroy the data when no longer needed to satisfy the original purpose
- Beware of “bad documents”, including hand-written notes

Questions?

FOURTH ASIA PACIFIC PHARMACEUTICAL COMPLIANCE CONGRESS AND BEST PRACTICES FORUM
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MINI SUMMIT XI: CORE COMPLIANCE COMPETENCIES TRAINING -- EVOLVING ISSUES, RISING EXPECTATIONS

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PROGRAM AGENDA

MINI SUMMIT XI: CORE COMPLIANCE COMPETENCIES TRAINING -- EVOLVING ISSUES, RISING EXPECTATIONS

- Conducting Effective Third-Party Due Diligence
- Developing Effective Commercial/Medical Boundaries in Interactions with HCPs
- The Role of Analytics in Monitoring and Program Oversight
- Building Effective Relationships with the Business

Conducting Effective Third-Party Due Diligence

Third Party Risks--Overview

- Under many anti-corruption laws third parties who are acting on behalf of a company may create liability for a company if the third party engages in improper conduct
- A key test in determining liability is did the company know, or should it, through the exercise of due diligence, have known of that the third party would engage in improper conduct
- Conducting due diligence on third parties and engaging in proper oversight are key elements of any effective compliance program

Third Party Diligence

Risk Assessment

- The third party framework should be based upon a risk assessment of how the company conducts business, how, when, where, and why it uses third parties, and how it supervises the work of those third parties
- The first step to implementing any due diligence review is a well considered cost/benefit analysis and risk assessment of the hiring, retention, and oversight of third parties.
- A comprehensive risk assessment serves as the cornerstone of the design and operation of the third party due diligence review procedure, as it informs such key program design questions such as the scope, intensity, resources, organization and controls in the review

Third Party Diligence

Heightened Review for Third Parties "In Scope"

- For those third parties "in scope," a review should follow, both in vetting for suitability and risk signs and in overseeing their work
- Common elements that should be present in any effective procedure:
  - Ask preliminary questions on a variety of relevant issues, including, but not limited to, qualification to perform the work, staffing, level of experience, references, and company history. These responses are typically provided by the third party in a written questionnaire
  - Conduct reference checks with other parties with whom the third party conducts business
  - Conduct background search for news concerning the third party's prior conduct, as well as the conduct of the third party's owners, officers, directors, senior management, and those executives who are principally involved in the relationship with the company
  - Document results

Addressing Warning Signs

- During any review, be alert for the classic warning signs of corruption, such as excessive requests for compensation, substantial amounts sought in advance, payments going to third parties subcontractors, payment only upon “success,” or involvement of government officials in the company or its operations
- If there are still questions or unresolved warning signs, leave open the option of a further review with additional follow up questions and due diligence review relating to actual or possible problems
- If warning signs cannot be resolved, decline to begin a relationship with a new third party or terminate its relationship with an existing third party
- Companies may seek to address potential warning signs -- if possible and prudent -- through enhanced reporting, more training, a more robust compliance program for the third party, anti-corruption contract clauses, more auditing, ongoing monitoring, and/or other risk mitigation strategies

Dealing with Third Party Risks

- **Standard Contractual Provisions**
  - Model contractual language with anti-corruption representations and warranties
  - Payment restrictions (check/wire only; no third-party payees or countries)
  - Finite contract term (1-2 years)
  - Right to terminate and indemnification
  - Audit rights
- **Annual Certifications**
  - Not a foreign official or affiliated or related to a foreign official
  - Abide by anti-corruption laws, including local laws
  - Has not previously engaged in questionable conduct and will not in the future
  - Is prohibited from making improper payments
- **Periodic Audits**

Monitoring and Auditing Third Parties

- Include a systematic and consistent way to monitor, audit, and review third party relationships
- Monitoring may be built into a company's internal controls through its finance function (i.e., a reconciliation of expenses and reimbursement claims against contractually required documentation and supporting documentation)
- Another control is to identify a person within the company who is designated as the point of contact with the third party and manages the relationship between the company and the third party
- Also establish a written audit plan that is based on a reasonable sample of third parties, that considers the nature of the third parties' activities, and the risks inherent in specific countries or regions where corruption risks with the use of third parties are greater

Developing Effective Commercial/Medical Boundaries in Interactions with HCPs

Key Issues on Medical/Commercial Interactions

- Scrutiny of relationships involving commercial and medical activities has increased worldwide as regulators and other stakeholders have become concerned about the integrity of pharmaceutical product manufacturer marketing, education, research, and publication practices
- These activities potentially implicate many international and local laws and professional standards governing product promotion, bribery and corruption, unfair competition, and research

Areas of Medical Responsibility

- Clinical research, compassionate use/expanded access, publications, and educational support strategy and planning, as well as for any other non-promotional activities with medical content
- Medical activity budgets for medical education funding, sponsorships of HCPs to attend medical or scientific meetings, charitable donations
- Medical employee and Consultant compensation and evaluations should not be tied directly to the volume of product sales or delivery of promotional messages
- Medical personnel should not report directly to commercial

Commercial Involvement in Medical Activities

- Commercial personnel should not formally or informally direct or influence medical activities, except in clearly defined circumstances
- Commercial personnel may provide high-level input in identifying areas of educational need or charitable donations and regarding research budgeting and overall priorities
- Commercial personnel may provide administrative assistance to medical projects under the supervision of medical
- Unless solicited by medical, commercial personnel should not play a direct role in soliciting, identifying, or reviewing potential individuals or institutions for medical consulting or grant-making activities

Medical Communications

- Medical communications with external parties should primarily focus on scientific, medical or educational content
- Delivery of commercial messages or materials in conjunction with medical communications is inappropriate
- Commercial personnel and Consultants should not respond to questions about unapproved uses of products or any other product; such questions should be referred to medical for appropriate follow-up
- Commercial should refer all requests for clinical, pharmacoeconomic, and other technical information from insurers/payors/government purchasers or evaluators to medical

Interactions with HCPs

- Commercial influence or control over medical consulting and grant-making activities may lead to the perception that such payments are being used improperly
- Medical consulting relationships, grants, and/or advisory board meetings should be offered only to those individuals or institutions that meet a pre-defined need, and should never be offered to enable or facilitate the delivery of a promotional message.
- Commercial should have no role in funding, convening, or selecting medical Consultants or advisors, other than in limited circumstances constituting legitimate market research or when commercial participation is justified by the objective of the discussion in accordance with the needs assessment for the activity

Clinical Research

- Inappropriate commercial influence over research activities may lead to concern among regulators and other stakeholders that a company is compromising the scientific basis for the research, compromising patient benefit, and using research as a means to reap commercial benefit or advantages from Healthcare Professionals, and thereby undermining the legitimacy of the resulting data
- Commercial should have no role in developing clinical study protocols, recruiting patients, providing experimental drugs, developing or analyzing data, retaining clinical trial Consultants or contract research organizations, or drafting clinical study reports or study publications
- All human interventional and non-interventional clinical research, as well as non-clinical research, should be overseen by the appropriate medical function without commercial input in respect of study design, unless otherwise justified by medical

Scientific Publication Activities

- Medical should be responsible for scientific publication activities, which should be independent of commercial control or influence
- Commercial control or influence over otherwise legitimate scientific publications may lead to scrutiny from regulators and other stakeholders, particularly where those publications discuss investigational products or unapproved uses of products
- Commercial influence may lead to a perception of bias, raising concerns that scientific publications are promotional in nature, lack quality and objectivity, or potentially mislead Healthcare Professionals, patients, and government evaluators
- A clear distinction should be made between bona fide scientific publications (e.g., poster presentations created by Medical personnel) and those intended to be promotional in nature (e.g., promotional monographs developed by a marketing vendor)
- Any scientific publications intended for distribution through a promotional channel (e.g., via the sales force) should be subject to internal pre-review and approval for such use
- Undisclosed financial, editorial, or technical support (ghostwriting) by any employee or vendor acting on a company's behalf should not be permitted
- Funding for scientific publication activities should come from Medical budgets, separate from Commercial control or influence
- Commercial should not be involved in the authorship, review, or approval of scientific publications or presentations

The Role of Analytics in Monitoring and Program Oversight

How Effective is your Compliance Program?

- Develop evaluation process / checklist, based on the “seven elements” and other relevant points
- Develop measurable goals and benchmarks with senior managers
- Set up a system to measure goals achievement
- Involve the Board in creating the program
- Regularly update the Board – risks, audits and investigations
- Investigate why goals are not met (if they are not)
- Assess funding levels and support for the program

About Analytics / Metrics

- Snapshot in time
- Several snapshots give trends over time
- Help to indicate:
  - whether or not we are achieving our goals
  - where to take action / put the emphasis
  - what action to take
- Rounded perspective – whole company / whole compliance program

What Tools are Available?

- Any tool that can be used to turn data into useful, insightful information:
  - Complex, expensive computer systems
  - Data warehouses
  - Access databases
  - Excel spreadsheets
  - Paper based tools
- Use your company's existing tools to begin with, then define new ones as your confidence grows

What to Measure?

- Define the goal as accurately and specifically as possible:
  - Understand which area of compliance program has most violations
  - Understand why there is a higher proportion of reported violations per head in country x than elsewhere
  - Reduce reported violations in all countries by x% every year
- Einstein said “If I were given one hour to save the planet, I would spend 59 minutes defining the problem and one minute resolving it”

Practical Implementation

- What gets measured gets done - be careful!
- Start with the behaviour you want to see, then measure something to drive that behaviour
- Just because you can measure something doesn't mean you should
- Be very careful with proxy measures - is it a true proxy?
- Every measure takes effort - it's better to have a few great measures than lots of mediocre ones
- Decide what to change and take action
- Tweak the measures over time
- If a measure changes over time, is this good or bad?

Common Monitoring Requirements from Recent CIAs in the US

- Speaker Programs
- Rep ride-along
- Emails
- Rep call notes
- Rep expenses / meals with HCPs
- Samples distribution
- Medical information enquiries
- HCP Message recall (from rep visits)

What will you measure?

- Numbers of compliance investigations
- Numbers of calls to the reporting helpline
- Payments to HCPs (will transparency reporting requirements help with this?)
- Payments to third parties, including % paid to distributors
- Rep expenses
- Unsolicited requests for information and where they typically come from (region, therapy area, etc.)
- Other metrics?

Building Effective Relationships with the Business

What are the Challenges Inherent to Building Effective Relationships with the Business?

Working In The Grey Area?

- Situation unforeseen & not previously envisaged
- Lack of precedent/ experience with this situation
- Policy open to interpretation & not clear how it applies
- Difficult to envisage how it might go wrong in future
- Regulators don't always enforce their own rules
- The goal posts often shift
- Time pressure, lack of facts, lack of confidence
- Do we really understand the intent?
- " It's difficult to do"

Other Challenges Re Partnership With The Business?

Confusion over exact nature of ECO role

Multiple & flexible definitions not always clear

Affinity to your original Home function

Feels like Geo Leader Exerts pressure

Gratitude to Affiliate leadership/ promoted to lead team

Unsure how Functional leadership & career Aspirations impacted

Charismatic senior leadership at different stages E&C maturity?

Controls fly in face of "good" customer experience

ECO embedded 99% time in affiliate, distant from other E&C.

Controls inhibit innovation/ speed

E&C leadership can be lonely & isolating

We want to be liked and part of a team

Going with gut is very qualitative

Confidence we know the business & policies well enough

What's easy to say in Corporate doesn't necessarily translate into affiliate realities

Once agreed locally, pressure to get global support can force ECO into advocate role

Can I really count on the function to back me up?

How Can a Successful Compliance Leader Overcome Those Challenges?

A Careful Balancing Act

Enable Ethical Business Decision Making

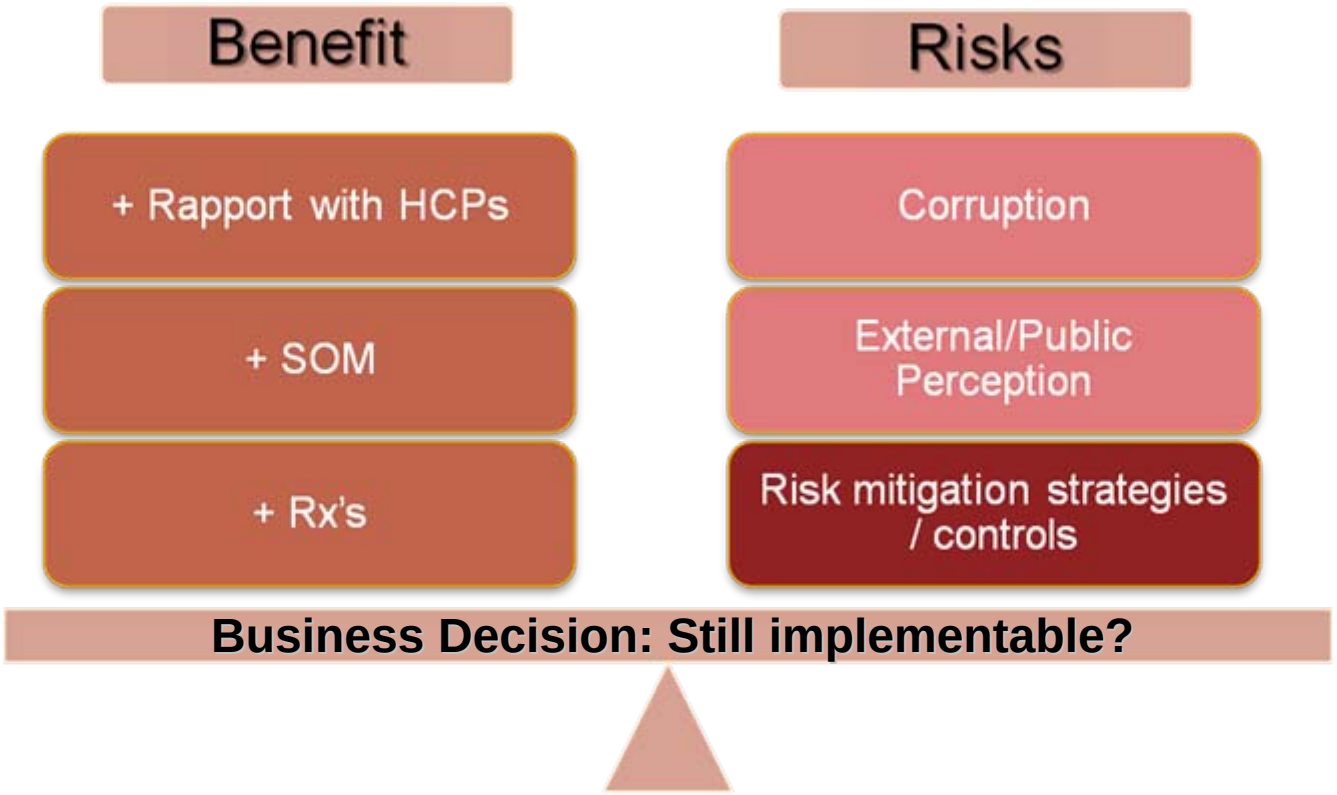
Business Need to:

- Own & approve the decision
- Understand the why of a decision
- Be aware of the risks / What it would take to manage the risks
- Understand the benefits of making a good holistic decision

Ethical Decision Making Support Model

- Clarify the dilemma: what are we deciding?
- Generate options: what's possible?
- Evaluate alternatives: what is preferred?
- Select a course: what are we going to do?
- Apply the learning: what did we learn?

Takes Effort to Help Business Think Holistically



Watch For The “Pendulum”!

Police
Take a stand
Elevate

Helping people to make difficult decisions in difficult situations

Recalibrate continually

Business
Partner
Enable

Questions?