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GLOBAL COMPLIANCE ISSUES AND PROGRAMS
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GLOBAL COMPLIANCE ISSUES AND PROGRAMS

PROGRAM AGENDA

- **Implementing a Global Compliance Program: Practical Operational Challenges and Issues**
- **Sponsorship of HCPs: Understanding the New Landscape**
- **Negotiating, Managing, Auditing and Monitoring Third Party Relationships**
- **Global HCP/KOL Engagement Management**
- **Developing Effective Strategies for Working with the Business**
- **Medical/Commercial Boundaries in the Global Context**

Implementing a Global Compliance Program: Practical Operational Challenges and Issues

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

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”

Tone at the Top

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**

Rules v. Ethics

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?

Legal v. Compliance

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

Global v. Local

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

Sponsorship of HCPs: Understanding the New Landscape

Sponsorship of HCPs

- Astra Zeneca and GSK have both announced that they will end direct sponsorship of health care professionals to attend international congresses

- In October 2014, Eucomed and EDMA, the European trade associations for Medical Devices and Diagnostics, announced a joint proposal to amend their codes of conduct to prohibit direct sponsorship effective in 2018

EFPIA HCP Code – Sec 13.01

- Companies comply with national code criteria governing the selection and sponsorship of healthcare professionals
- For international events, code of HCP's jurisdiction applies
- Funding may not be offered to compensate merely for the time spent by healthcare professionals in attending events. (i.e.. Active vs. passive participation)

Recent Developments:

- Chinese 9 prohibitions
- French Sunshine
- Danish law
- Industry code disclosures in effect in UK and the Netherlands
- New laws in Russia, Eastern Europe
- EFPIA Code mandates transparency rules in 2015 for all member associations (first reports to be filed in 2016)
  - Aggregate reporting only where required by member country's data privacy laws

Transparency

- EFPIA and member country rules require disclosure of sponsorships
- Several countries have laws in effect or pending that requiring public disclosure of sponsorship
- In many countries prior notification of institution, government agency or other body is required prior to sponsorship
  - France: CNOM
  - Belgium Mdeon
  - Germany: Employer

Anti-corruption Risk

- Stryker Cease & Desist Order (Oct 2013)

  "From at least 2003 through July 2007, Stryker's wholly-owned subsidiary in Romania ("Stryker Romania") made 192 improper payments to foreign officials totaling approximately $500,000 in order to obtain or retain business with affiliated public hospitals. Stryker Romania recorded these payments as legitimate sponsorships of foreign officials' attendance, travel and lodging at conferences, and medical events, when in reality they were illicit payments made to obtain or retain business."

Anti-corruption Risk

- Stryker Cease & Desist Order (Oct 2013) (continued)

> "For example, in April 2004, a Stryker Romania salesperson submitted a form to sponsor a foreign official's lodging abroad to attend a conference. The form stated that a "business benefit[]" from the sponsorship was that, in return, Stryker Romania would receive a contract for the sale of a particular medical device. In addition, Stryker Romania internally discussed that the foreign official in question was "waiting to be confirmed as chief physician" at a public hospital, "thus becoming important" for an upcoming bid for a contract."

Negotiating, Managing, Auditing and Monitoring Third Party Relationships

Agenda

- Before you negotiate
  - What happens prior to discussing a deal?
- Negotiating
  - What should you be aware of, ask, and agree upon?
- Managing
  - What should you do and how often?
- Monitoring
  - What does monitoring look like?
- Auditing
  - What should you look for and how often?

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Before Negotiating or During Negotiations

- Due Diligence
  - Financial
  - Integrity / Compliance
  - Anything else?
- Where will the contract be maintained and who is responsible for the contract?
- Who is going to manage the relationship?
- Is there anything about this relationship that would require a change to your:
  - IT system?
  - Monitoring process?
  - Auditing process?
- ?
- ?
- ?

Does Your Company Have a Common Definition for TPs?

- Many companies presume that the definition of TP is clear and understood.
- Is a Vendor, a Supplier? Is a Vendor an Agent? Is an alliance partner a Supplier?
- Not everyone may be clear as to whether a TP may be a:
  - Vendor; are all vendors the same?
    - Management consultant vs IT Consultant vs Travel Services vs Copy Services
  - Supplier
    - Raw materials, external data provider
  - Agent
    - Contracted sales force, Contract Manufacturer
  - Strategic Alliance Partner
    - Call center provider; joint venture partner, clearinghouse provider, internal audit co-sourcing provider
  - Legal, Tax, Lobbyist
  - Distributor, Reseller
- What about your TPs TP?

What is a Third Party?

- The Law Dictionary (Black's Law Dictionary):
  - 1. A person not connected to a contract but may be affected by its outcome.
  - 2. A person other than the defendant and the plaintiff that is brought into a case.

- Investopedia:
  - An individual or entity that is involved in a transaction but is not one of the principals. The third party often has a lesser interest in the transaction than the principals.
- Wiktionary
  - 1. someone not directly involved in a transaction. A third entity in the Seller (first party) and Customer (second party) relationship. A Seller may employ a third party to perform specific services to augment the value of a product. For example, a manufacturer may employ a third party to pack and distribute a product. A computer manufacturer may augment their product with software from a third-party supplier.
  - 2. someone only incidentally or tangentially connected to an incident or dispute; someone other than the principals; a bystander or independent witness.

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What does your TP Agreement Say?

- [Contractor] shall establish and maintain **a reasonable accounting system** that enables [Company] to readily identify [Contractor]'s assets, expenses, costs of goods, and use of funds. [Company] and its authorized representatives shall have the **right to audit, to examine, and to make copies** of or extracts from all financial and **related records** (in whatever form they may be kept, whether written, electronic, or other) relating to or pertaining to this [Contract or Agreement] **kept by or under the control of the** [Contractor], including, but not limited to those kept by the [Contractor], its employees, agents, assigns, successors, and subcontractors. Such **records shall include, but not be limited to,** accounting records, written policies and procedures; subcontract files (including proposals of successful and unsuccessful bidders, bid recaps, etc.); all paid vouchers including those for out□of□pocket expenses; other reimbursement supported by invoices; ledgers; cancelled checks; deposit slips; bank statements; journals; original estimates; estimating work sheets; contract amendments and change order files; backcharge logs and supporting documentation; insurance documents; payroll documents; timesheets; memoranda; and correspondence.

What does your TP Agreement Say?

- [Contractor] shall, at all times during the term of this [Contract or Agreement] and for **a period of ten years after the completion of this** [Contract or Agreement], maintain such records, together with such supporting or underlying documents and materials. The [Contractor] shall at any time requested by [Company], whether during or after completion of this [Contract or Agreement], and at [Contractor]'s own expense **make such records available for inspection and audit (including copies and extracts of records as required)** by [Company]. Such records shall be made available to [Company] during normal business hours at the [Contractor]'s office or place of business and **[subject to a three day written notice/without prior notice]**. **In the event that no such location is available, then the financial records, together with the supporting or underlying documents and records, shall be made available for audit at a time and location that is convenient for [Company]**. [Contractor] shall ensure [Company] has these rights with [Contractor]'s employees, agents, assigns, successors, and subcontractors, and the obligations of these rights shall be explicitly included in any subcontracts or agreements formed between the [Contractor] and any subcontractors to the extent that those subcontracts or agreements relate to fulfillment of the [Contractor]'s obligations to [Company].

What does your TP Agreement Say?

- Costs of any audits conducted under the authority of this right to audit and not addressed elsewhere will be borne by [Company] unless certain exemption criteria are met.
- If the audit identifies overpricing or overcharges (of any nature) by the [Contractor] to [Company] in **excess of one half of one percent (.5%) of the total contract billings**, the [Contractor] shall reimburse [Company] for the total costs of the audit.
- If the audit discovers substantive findings related to fraud, misrepresentation, or non performance, [Company] **may** recoup the **costs of the audit work** from the [Contractor].
- Any adjustments and/or payments that must be made as a result of any **such audit or inspection** of the [Contractor]'s invoices and/or records shall be made within a reasonable amount of time (not to exceed 90 days) from presentation of [Company]'s findings to [Contractor].

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Managing TP Risk – Taking A Better Approach

- Auditing efforts should be a piece of regular monitoring; cycle should feed each other
- All personnel should be trained in interview and elicitation techniques on a regular basis
- TP Risk Assessments should follow a standard methodology across the company with deviations understood
  - Understand how a TP risk assessment is different from an internal risk assessment
- TP risk assessments should be monitored for effectiveness
  - Any fraud or corrupt act not appropriately anticipated by the risk assessment should require improvement in the assessment
  - Factors to include in evaluating TP Risk
    - Quantitative and Qualitative

TP Risk Factors – A Sampling

- TP management's demonstrated focus on ethics, integrity and quality
- Nature & extent of the relationship among local business management
- Changes in business ownership and operations
- Level of subcontracting; TP's use of sales agents, consultants, sub-distributors
- Interaction with government officials
- Lack of hotline or lack of hotline complaints
- Number of times audited and level of audit findings
- Level of cooperation
- Turnover of relevant management personnel
- Level of "riskier" activities: regulatory approvals, zoning approvals, customs
- Services significantly above or below fair market value
- Gaps in inventory
- Significant increases in sales or other metrics
- Compensation / incentive model
- Requests to handle matters alone
- Lack of document and data retention overall or when requested

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Big Data and Data Analytics is the Solution!!!!???

- Forensic data analysis is necessary and helpful
- However, it is not the end all, be all
- Too many companies are mainly relying on data analysis to identify “red flags”
- Putting aside the issue of false positives and the associated vetting process:
  - What if the fraudulent or corrupt act is not in the data?
  - What if the fraudulent or corrupt act looks like just like another transactions in the data?
  - What if the IT organization is involved in the fraud or corrupt act?
  - What if the data is not available at a granular level?
  - What if the data is within a legacy system in another country where sales are not relatively significant?
- Do you have access to the data involving TPs?
  - If so, what level of data and would it be helpful?
  - Is the level of data you are receiving consistent with the level of data required by the contract with the TP?

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The Lost Art of the Interview and Elicitation

- Effective live interviews and meetings cannot be replaced by data analysis
- As a result of cost and limited resources, more and more companies are relying on data analysis to inform their risk assessments as well as their investigative procedures
- Surprise inspections are not has frequent
- Cultural sensitivity is sometimes too sensitive
- Typical interviews
  - Not sufficiently planned or overly planned
  - Lack sufficient understanding of the business
  - Rely overly on a checklist of questions and procedures to be performed
  - Do not sufficiently integrate initial data analysis
  - Provide the TP with more notice than necessary and allow for deferrals
  - Allow TPs to take advantage of sensitivity to their culture
  - Lack sufficient local support with the right skills
  - Are part of auditing versus monitoring efforts

Global HCP/KOL Engagement Management

HCP/KOL Engagement

- Key opinion leaders (KOLs) are utilized globally, yet consistent approaches for onboarding, contracting and measuring performance remain elusive

- Disparate treatment of KOL/HCPs across entities/BUs can create optical issues and so-called “bad” evidence

KOL Engagement Challenges

- Foreign Officials & PEPs
  - Services alignment
  - Immediate family members
- Due Diligence
  - Sanctions
  - Privacy considerations
- Notice & Consent
  - Pre- and post-engagement
- Tier & Fair market value
  - Consistent process across legal entities and Bus
  - Rates can vary between entities/Bus
- Tracking and reporting transfers of value
- Demonstrate utility

Medical/Commercial Boundaries in the Global Context

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

Back to Basics

- Commercial personnel should always speak on-label, and their actions should be consistent with on-label uses
- Off-label questions directed at Commercial personnel should be redirected to Medical employees
- Medical personnel should ensure that their statements and actions cannot be construed to be promoting the product

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
- 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 HCPs, 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

Developing Effective Strategies for Working 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

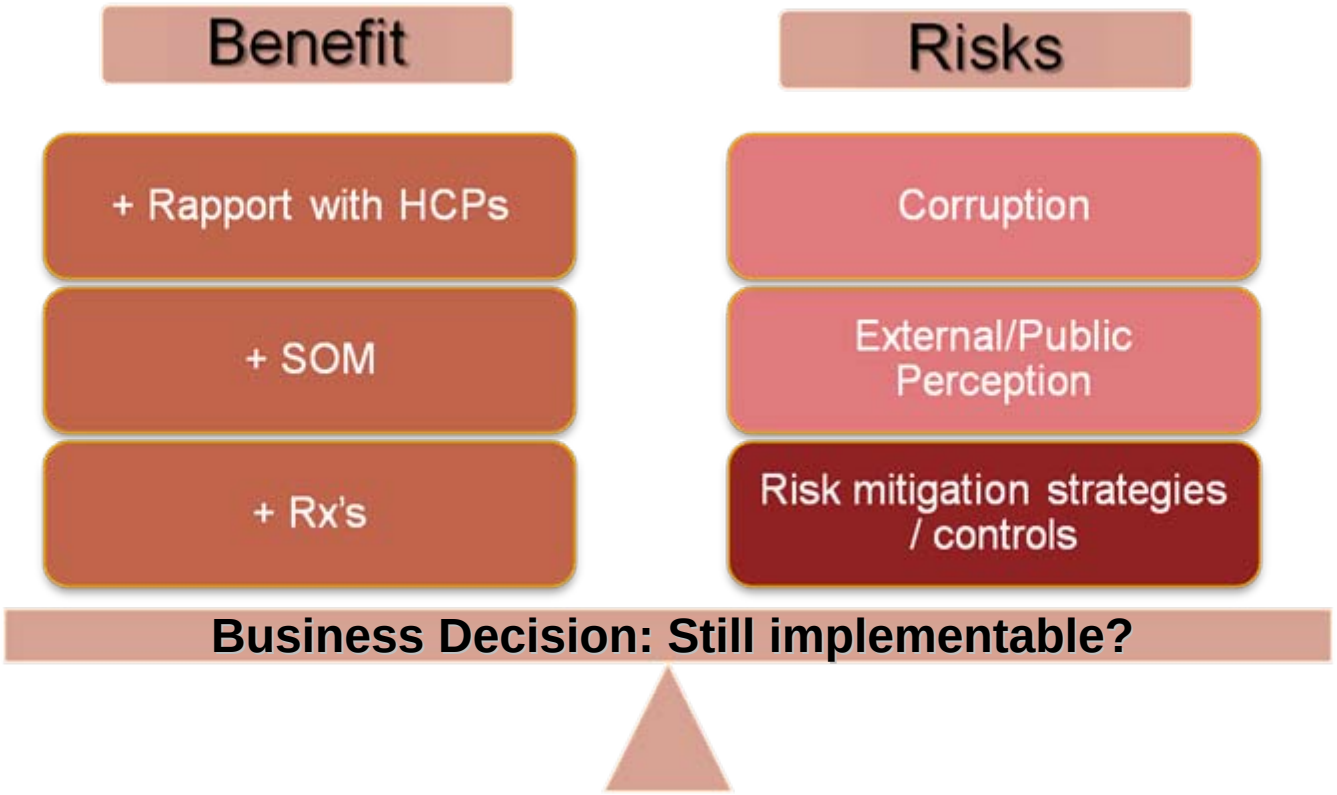
Business Need to:

- 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?