Implementing a Global Compliance Program
Practical Operation 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 <u>individual</u>
- Everyone can contribute in their <u>own way</u>
- Everyone can make a <u>personal commitment</u>
- <u>No need to wait</u> for processes
- <u>Ethical business</u> 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

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

Recommend		Avoid
Knowing the Business		Treat all partners the same
Understand your Partner & Build Effective Relationships		Going Native
Protect Independence		"Owner of Solution"
Advisor Role (Be relevant)	**Maintain Credibility**	Lead Advocate for the Business
Objective Advice		
Be Available	**Advocate Integrity** ensure company´s vales and ethics	Who's got the "monkey?"

Playing your role credibly is critical for success

Recommend

Avoid

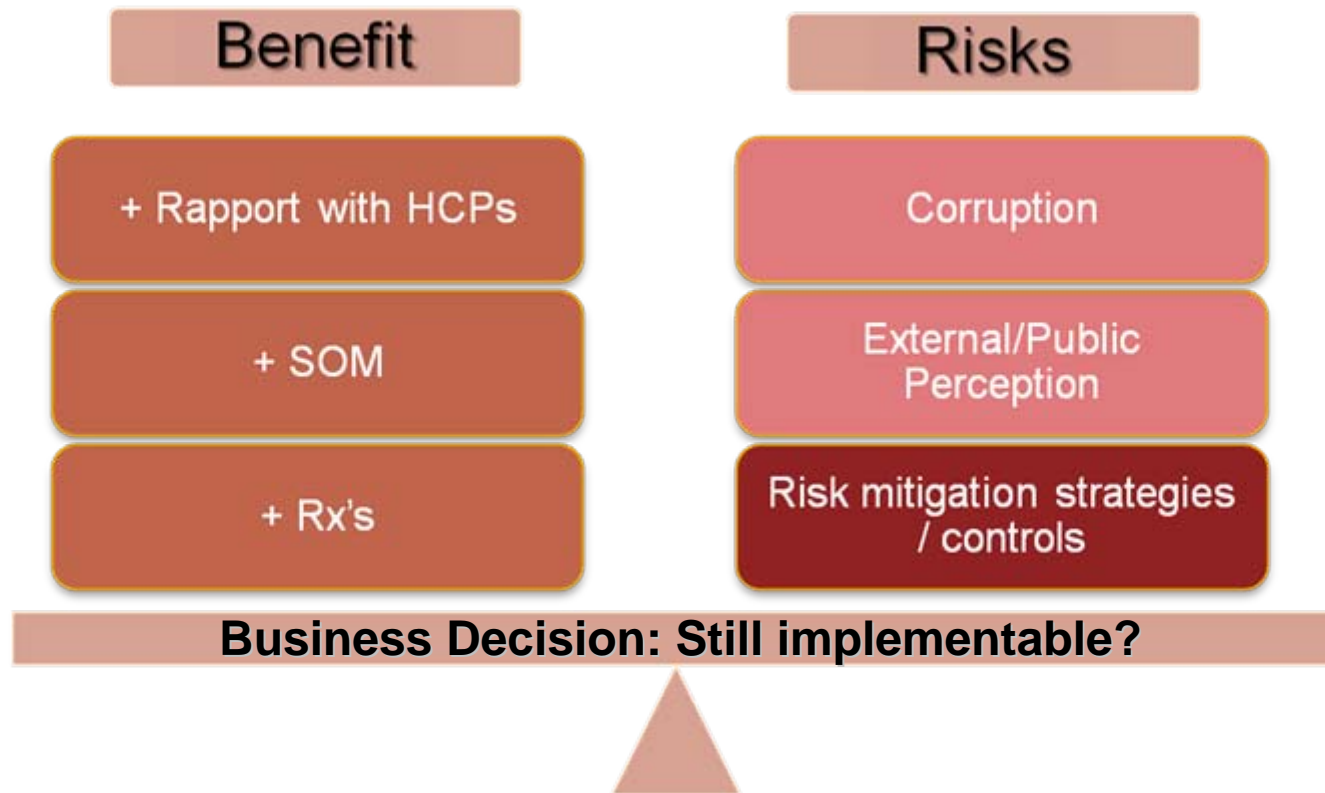# Enable Ethical Business Decision Making

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?
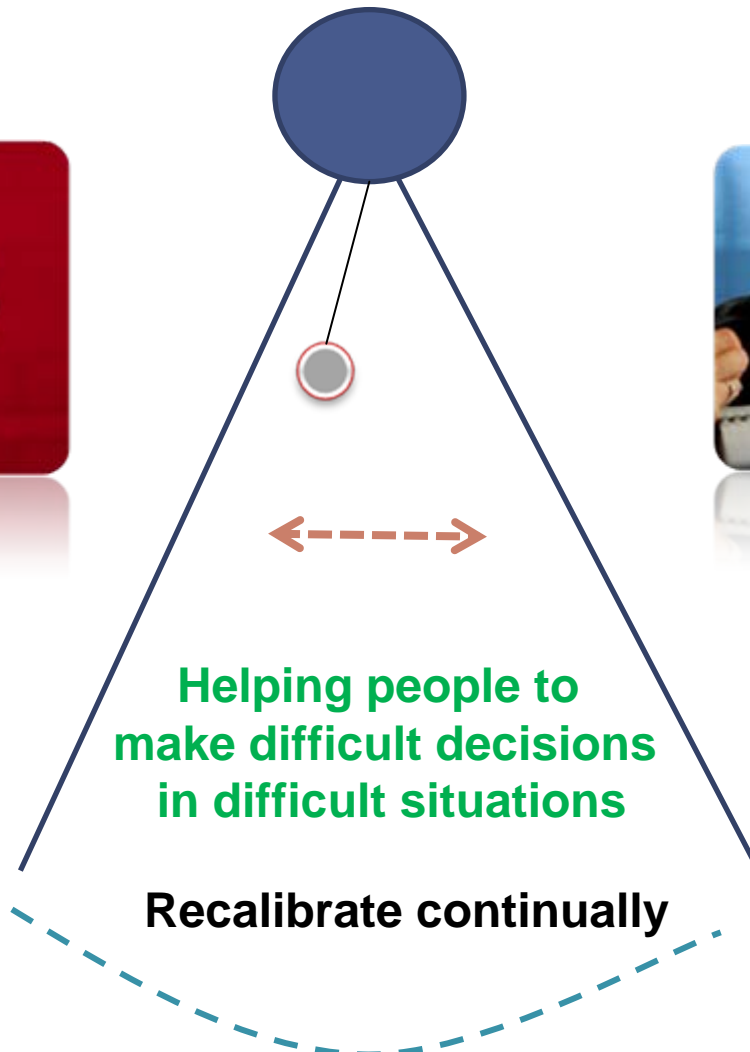- Apply the learning: what did we learn?

Takes Effort to Help Business Think Holistically

Benefit	Risks
+ Rapport with HCPs	Corruption
+ SOM	External/Public Perception
+ Rx's	Risk mitigation strategies / controls

Business Decision: Still implementable?

Watch For The "Pendulum"!

**Police
Take a stand
Elevate**

Helping people to make difficult decisions in difficult situations

Recalibrate continually

**Business
Partner
Enable**

Questions?