

Business Ethics & Compliance - the Key to a solid business

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Introduction

Compliance is the result of good leadership

A company culture of ethics and integrity starts with strong leadership



- The **General Manager/CEO**, is the **face of the organization** and the *role model* for employees.
- How to **foster a culture of ethical behaviour** and which activities and tools can help you?



- The global/local **Compliance Officer** is an important stakeholder & facilitator to support you in **identifying, assessing, managing and controlling compliance risks**.
- **Compliance is a key Line Management accountability.**
- Working with integrity is a **professional skill required from each employee.**

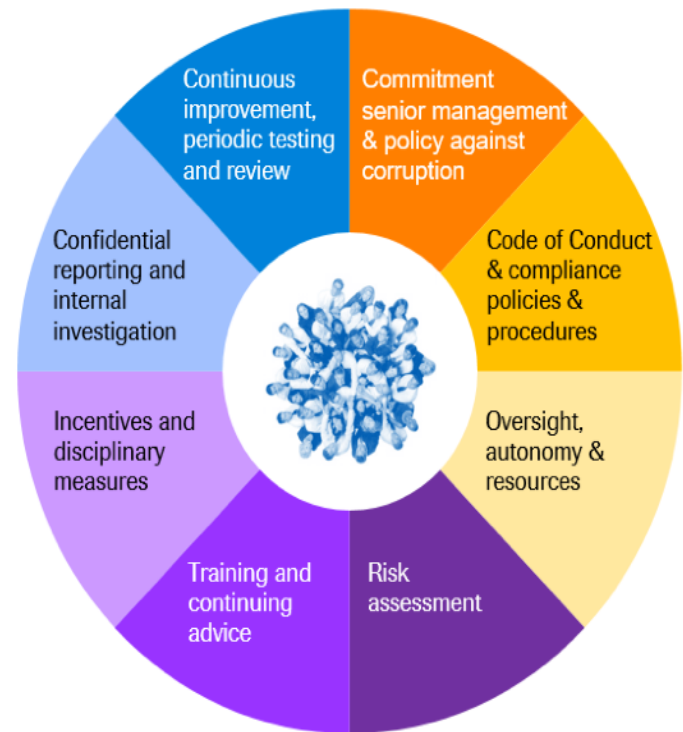
- **Right level of protection for the GM and the company**
- **Protect company's reputation and the license to operate**
- **No CIA, leading to a competitive advantage**

Comprehensive Compliance Management System

A comprehensive compliance management system consists of 8 different elements* to **PREVENT, DETECT & RESPOND** to **uncompliant behaviour**:

Guidance has been developed by several national authorities** with the purpose of supporting companies:

1. to understand which are the **aspects taken into account by authorities** in judicial proceedings;
2. in **self-evaluating** the effectiveness of **their compliance management systems**;
3. to ensure that they have an adequate **corporate defence**.



* Two elements are not specifically mentioned here: Mergers and Acquisitions, Third Party Due Diligence and Payments

** For example, “Adequate procedures” (UK Ministry of Justice, March 2011); “Hallmarks of an effective Compliance Program” (Resource Guide to the U.S. Foreign Corrupt Practices Act, US Department of Justice & the Securities and Exchange Commission, November 2012); “Evaluation of corporate compliance programs” (Fraud Section of the US Department of Justice, February 2017). These guidance documents are a few examples of the worldwide accepted standards in compliance management.

Elements of a Comprehensive Compliance Management System (I)

Commitment from Senior Management and a Clearly Articulated Policy Against Corruption

- **Tone at the top** and **lead by example**
- Not a paper program but **real and put into action**, led by senior management
- Adherence to ethical standards, **senior managers inspire middle managers** to reinforce those standards

Code of Conduct and Compliance Policies and Procedures

- Clear and comprehensive Code of Conduct and compliance policies & procedures
- Appropriate **internal controls** within the policies and procedures (risk-based)

Oversight, Independence and Resources

- **Senior level executive** (CO) oversees and implements the compliance program
- CO should have appropriate authority and **sufficient resources** for effective implementation
- Compliance function should have **adequate reporting lines** to ensure independence and a balanced approach
- Evaluation based on size, structure and risk profile of the business

Risk Assessment

- Should take into account the **external environment, industry sector, activities, potential business partners**, etc.
- Assessment whether and to what extent a company addresses the risks it faces

Elements of a Comprehensive Compliance Management System (II)



Ongoing Training and support

- **Communication is a cornerstone** of any compliance program
- Relevant **policies need to be communicated** to the organization, incl. periodic **training** for all directors, relevant employees and where appropriate business partners
- Training program should be built on a **risk-based** approach

Incentives and Disciplinary Measures

- Compliance program should apply from “*the board room to the supply room – no one should be beyond its reach*”
- **Appropriate disciplinary sanctions** in place and applied
- **Positive incentives** can also drive compliant behavior (performance evaluations, promotions and rewards)

Confidential Reporting and Internal Investigation

- **Anonymous reporting policy and procedure (WB)** should be in place to report cases of unethical behavior and non-compliance
- Adequate **process for investigating** allegations and documenting the company’s response, incl. disciplinary or remediation measures

Continuous Improvement: Periodic Testing and Review

- Compliance programs should be regularly **reviewed and improved**
- Think critically about weaknesses and risk areas
- Internal controls should be periodically tested through **targeted audits and monitoring to ensure efficacy**

Tone & and action - at the Top

What does compliance mean for a General Manager(CEO) ~

Tone



Action



The **General Manager** should:

- continuously **communicate values & expectations** (town halls, LT meetings, etc.)
- expect the same from **LT members**
- his or her **actions** tell employees what counts and what is not accepted - **be a Role model together with the CO**
- **own compliance**



Oversight is key*

- Know what happens in your organization and discuss within the LT
- Understand and assess areas of risk
- Ensure adequate improvement actions on relevant risks
- Ensure monitoring is performed

* Concrete activities to ensure adequate oversight are illustrated hereinafter in this booklet.

- Assign to **Leadership Team** members clear and specific **compliance responsibilities** (performance evaluation)*
- Hold them accountable
- LT is **GM's emissary** to spread the word on the importance of ethical behavior

* Example of a compliance objective: no relevant audit or monitoring findings in the department's activities during the year.

Accountabilities of the compliance function

Facilitator or controller?



The CO /
HCO
Contact

not the decision-maker, reviewer or approver for single activities within a process («controller»). Clear focus on processes instead of single initiatives

ensure adequate knowledge & training for business owners & employees so that they can perform their tasks correctly and are able to identify and assess potential risks («facilitator»)

support business owners in the design of efficient processes with relevant key controls

provide management with tools and information to exercise oversight function and assess risks & business opportunities

support management in «trust but verify» task

The CO should be a **business facilitator** but at the same time ensure adequate governance framework and challenge people if certain activities involve excessive risks.

The Role of the Chief Compliance Officer

Board Level:

- CCO not in the best place to know what is going on.
- Workforce will be skeptical because the “CCO is not one of us” and because often, board members are considered difficult to reach by the workforce.
- Workforce may view the CCO as the “ethics police”.
- Workforce will conclude that management is not trusted.
- Authority of the CEO is diminished.
- [Sometimes, because of recent serious compliance failures within management, interim assignment of the CCO to the Board is necessary.]



The Role of the Chief Compliance Officer

Legal:

- ❑ Fundamentally a bad choice because of the embedded conflict of interest; the lawyer's job is to defend the organization; the CCO's job is to bring the bad news to the top management, to help keep the company out of the dog house, and to help restore the company's reputation when ethical or compliance problems have visited.
- ❑ It is inevitable that the CCO's role and stature will be blanketed by the lawyer, and that the CCO's information and advice will be filtered.
- ❑ It is particularly important for the CCO to collaborate with all departments within the company and especially with the Legal department, which is why a horizontal relationship should be more adequate.



The Role of the Chief Compliance Officer

Human Resources:

- ❑ Most ethics and compliance issues are management issues, not employment issues.
- ❑ HR has a narrowly-focused specialized mission; placing the CCO under HR would tend to obscure the importance of the position.
- ❑ Less likely to be perceived as having authority.
- ❑ Less likely to be adequately resourced.
- ❑ It is particularly important for the CCO to collaborate with all departments within the company, including with the HR department, which is why a horizontal relationship should be more adequate.



The Role of the Chief Compliance Officer

Directly to the CEO:

- ❑ The CCO's place within the organization is with management - directly responsible to the CEO.
- ❑ The center of gravity for all company operations lies with management.
- ❑ Management has the first line of responsibility and accountability for ethical business conduct.
- ❑ Management is the first responder to ethical crises.
- ❑ The workforce tends to act when it perceives management really wants it to act.



The Role of the Chief Compliance Officer

Directly to the CEO:

- ❑ The ethics/compliance officer articulates to others that ethics initiatives are that of the CEO, and not “the latest from the ethics office”.
- ❑ A practical reason is that the CEO is the giver of authority, and holds the ultimate decision on resourcing the ethics office.



The Role of the Chief Compliance Officer

Conclusions:

- The CCO should be part of management with a direct line to the CEO.
- The CCO should be a link between management and the workforce.
- The CCO must be given adequate resources (IT systems, personnel) and authority or will be discounted by both management and the workforce.
- The CCO must be given independence in order to act in the best interest of the company, when dealing with breaches of compliance.
- The CCO should not be dismissed or penalised by the management for performing its tasks, especially when conducting investigations, applying measures to mitigate risks or notifying the top management with a compliance breach.
- The CCO should have a seat at the table whenever the CEO meets with other “direct reports” and should participate in major business decisions.
- The CCO should remain focused on ethics and compliance and not be given competing assignments.
- In larger organizations, the CCO’s role should be a fulltime dedicated position.



The Role of the Chief Compliance Officer

Conclusions:

- In smaller organizations the CCO may be a part-time position (“dual hatted”); the other duties should be compatible duties.
- The CCO must have ready access to the Board, which has the obligation to be knowledgeable about and to provide oversight of the ethics and compliance program.



Formal vs. substantial compliance

Country X - 1057 actively visited HCPs: 387 received ToV (more than 1 out of 3)

Full respect of the directives, SOPs and external regulations

FORMAL COMPLIANCE



FORMAL COMPLIANCE?



Did we eliminate all risks, including the reputational risk?

Behavior of the company in line with a set of rules and SOPs

Country Y – 4.000.000 in Grants & Donations for 2015 (1st in the country, responsible for 24% of national HCO spend of EFPIA members)

Full respect of the directives, SOPs and external regulations

FORMAL COMPLIANCE



OR ... SUBSTANTIAL COMPLIANCE?



Did we eliminate all risks, including the reputational risk?

The capacity to identify the most relevant areas of risk and prevent and mitigate those risks

8 consultancy agreements with the same HCP during the 2015 (75.000 euro total)

Full respect of the directives, SOPs and external regulations

FORMAL COMPLIANCE



Did we eliminate all risks, including the reputational risk?

Compliance challenges - Monitoring

Monitoring is an essential element of the “oversight and trust & verify approach” considering that:



provides overview of the compliance situation and assurance

supports awareness on potential compliance risks and remediation

improves internal processes (efficiency), controls and decision-making (accountability)

enhances governance framework and protection to management in case of external investigations

provides Transparency

supports positive evidencing of good practices

helps to reduce audit findings

Key aspects for the use of a forensic auditor

Plan the investigation – When the client hires a Forensic auditor, the auditor is required to understand what the focus of the audit is. For example, the client might be suspicious about possible fraud in terms of the transfers of value given to Healthcare Professionals. The forensic auditor will plan their investigation to achieve objectives such as:

- Identify what fraud, if any, is being carried out
- Determine the time period during which the fraud has occurred
- Discover how the fraud was concealed
- Identify the perpetrators of the fraud
- Quantify the loss suffered due to the fraud
- Gather relevant evidence that is admissible in the court
- Suggest measures that can prevent such frauds in the company in future



Key aspects for the use of a forensic auditor

- Collecting Evidence – By the conclusion of the audit, the forensic auditor is required to understand the possible type of fraud that has been carried out and how it has been committed. The evidence collected should be adequate enough to prove the identity of the fraudster(s), reveal the details of the fraud scheme, and document the amount of financial loss suffered and the parties affected by the fraud.
- A logical flow of evidence will help the client in understanding the fraud and the evidence presented. Forensic auditors are required to take precautions to ensure that documents and other evidence collected are not damaged or altered by anyone.



Key aspects for the use of a forensic auditor

Common techniques used for collecting evidence in a forensic audit include the following:

- Substantive techniques – For example, doing a reconciliation, review of documents, etc
- Analytical procedures – Used to compare trends over a certain time period or to get comparative data from different segments
- Computer-assisted audit techniques – Computer software programs that can be used to identify fraud
- Understanding internal controls and testing them so as to understand the loopholes which allowed the fraud to be perpetrated.
- Interviewing the suspect(s)
- Reporting – A report is required so that it can be presented to a client about the fraud. The report should include the findings of the investigation, a summary of the evidence, an explanation of how the fraud was perpetrated, and suggestions on how internal controls can be improved to prevent such frauds in the future. The report needs to be presented to a client so that they can proceed to file a legal case if they so desire.

To sum up, a forensic audit is a detailed engagement that requires the expertise of not only accounting and auditing procedures but also expert knowledge regarding the legal framework. A forensic auditor is required to have an understanding of various frauds that can be carried out and of how evidence needs to be collected.





REAL COMPLIANCE/GOOD BUSINESS/INCREASED PROFIT

