Preventing private sector corruption through corporate self-regulation

Compliance systems and their cosmetic use in the pharmaceutical sector

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Content of the Presentation

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1) Corporate Self-Regulation (SR) in the pharmaceutical sector

2) SR vulnerabilities in corruption prevention

3) Enhancing the effectiveness of SF: Enforced SR and the Italian Legislative Decree No 231/2001
1. Corporate self-regulation

✓ Compliance system:

“An organisational structure implemented within the company and designed to monitor employees’ compliance with external and internal standards and rules” (Carson, Mrazek, Hawkins, 2008)

• Centralised bodies operating worldwide within the group
• Single authorities present in every business unit (divisional Compliance Offices, Legal Departments, etc.)
Duties of the Compliance Officer:

- Establish standards and procedures to prevent and detect corrupt conducts
- Conduct risk assessment evaluations
- Deliver practical and periodic communication (also through training programmes)
- Provide guidance (also by implementing and publicising the anonymous/confidential system to file complaints)
- Monitor (investigations and inspections)
- Audit and conduct periodic evaluation of CS
- Enforce CS through disciplinary proceedings
Corporate self-regulation

☑ Legal framework on liability of legal persons:

1) EU:
   - 1998 Joint Action on Corruption in the Private Sector
   - 2002 PIF and its Second Protocol
   - 2005 Convention Against Corruption Involving Public Officials
   - 2003 EU Council FD on combating corruption in the private sector

2) CoE:
   - 2002 Criminal Law Convention Against Corruption
   - 2003 Civil Law Convention Against Corruption

3) OECD:
   - Convention on Combating Bribery of Foreign Public Officials in International Business Transactions 1999
   - 2009 Recommendation of the Council for Further Combating Bribery
   - 2009 Recommendation on the Tax Deductibility of Bribes to Foreign Public Officials
   - 1976 Guidelines for MNEs

4) UNCAC 2005
The Pharma sector is particularly exposed to the risk of corruption (TI, 2009):

- Level of governmental involvement in a number of core decision-points (Cohen, Mrazek, Hawkins, 2008):
  - Market authorisation and registration
  - Drug selection (reimbursement lists) and price setting
  - Procurement
  - Distribution
  - Prescribing and dispensing
  - Inspection

Forms of corruption occurring in the sector (Vander Beken, 2007):
- Gifts and lavish consulting fees rewarding ‘good’ prescribing behaviour
- Financial support to medical journal and journalists
- Financial support to university pharma research
Pharma industry invests heavily in the promotion of its medicines. In 2010 promotional expenditure increased (PM Group):
- 0.5% in the top five developed markets (France, Germany, Italy, Spain and the UK)
- 2.2% in the rest of Europe

Drug promotion:
- Sale reps (‘performance bonus’)
- Third parties (subsidiaries, distributors, wholesalers, consultants, vendors, etc.)

U.S. SEC 2012 FCPA enforcement actions:
- Payments improperly recorded as legitimate expenses for promotional activities
- ‘Black money’ created through false or padded invoices (also through collusive vendors, e.g., travel agencies, restaurants, etc.)
- (Pfizer and the so-called ‘Point Programme’)
2. Vulnerabilities of Self-Regulation

✔ Research project:
  • MNEs identification:
    - 11 Pharma MNEs in the TI 2012 Report on Transparency in Corporate Reporting
    - Targeted: 3 Belgian branches of top-scoring pharma MNEs
  • Research activities:
    - Interviews with 3 Compliance Officers
  • Provisional findings:
    - The compliance system has been poorly developed. Fault lines:
      • Risk assessment
      • Standards’ dissemination and training
      • Guidance and whistle-blowing systems
      • Monitoring of sale reps

✔ Reports confirming the findings (PricewaterhouseCoopers 2008)
3. Enhancing Self-Regulation

✓ The Theory of Enforced Self-Regulation (Ayres and Braithwaite, 1992)

Companies are better suited than external governmental agencies to prevent crime:

• Rules are tailored to match the company’s set of risks associated with its way of doing business
• Rules adjust more quickly to changing legal and business environments (potential to engender creative solutions)
• Rules are more likely to be embedded in the corporate culture and ethos and abided by employees
• Internal control systems are more likely to be effective in monitoring and detecting employees’ compliance with rules
Hindrance: companies might not necessarily be willing to spend time and resources to make CS effective, unless tangible benefits are offered (“positive incentives” in Ruhnka and Boerstler 1998)

2-step model:

1. Public enforcement of privately written rules (approval of the corporate self-regulatory scheme)

2. Public monitored private enforcement of those rules (application of a lenient sanctioning regime in the trail phase)

Examples in:
- US, UK, Austria, Spain and Italy (Legislative Decree No 231/2001)
Enforced self-regulation

✓ The Italian Legislative Decree 231/2001:

Model of criminal liability that applies to companies when the offence has been committed in its interest by:

- An individual in prominent position within the firm (art. 5, let. a)
  ‘Persons who represent, manage or direct the entity or sub-unit with financial and functional autonomy; or persons who exercise, also de facto, the management or control thereof’

- A subordinate (let. b)

When deriving from organisational failure (art. 6 and 7), i.e. the absence or ineffectiveness of their organisational models (CS)
Enforced self-regulation

✔ The Italian Legislative Decree 231/2001:
  ➢ Discharged criminal liability
  ➢ Mitigated sentence

If the company proves:
• The adoption of an organisational model containing:
  • Risk assessment
  • Protocols on standards and procedures to prevent crimes
  • Regular updates and appropriate financial resources
  • Disciplinary system and sanctions
• The existence of an internal supervisory body with autonomous and independent powers
• The circumstance that the offence, when committed by high-level management, is an expression of an abnormal behaviour (not of structural negligence)
Enforced self-regulation

✓ (Legislative) minimum requirements for effective CS:
  • Standards and procedures to prevent and detect corrupt conducts
  • Risk assessment evaluations
  • Practical and periodic communication
  • Guidance
  • Monitoring mechanisms (investigations and inspections)
  • Audits and periodic evaluations of CS
  • Enforcement of CS through disciplinary proceedings

✓ Tangible benefits for companies in the trial phase (mitigation of the sentence, exclusion of liability, deferred prosecution agreements, amnesty programmes, etc.) – SR integrated in the criminal justice system