



The Tenth International Pharmaceutical Compliance Congress Overview of the Anti-Corruption Landscape

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C H A N C E

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General Framework

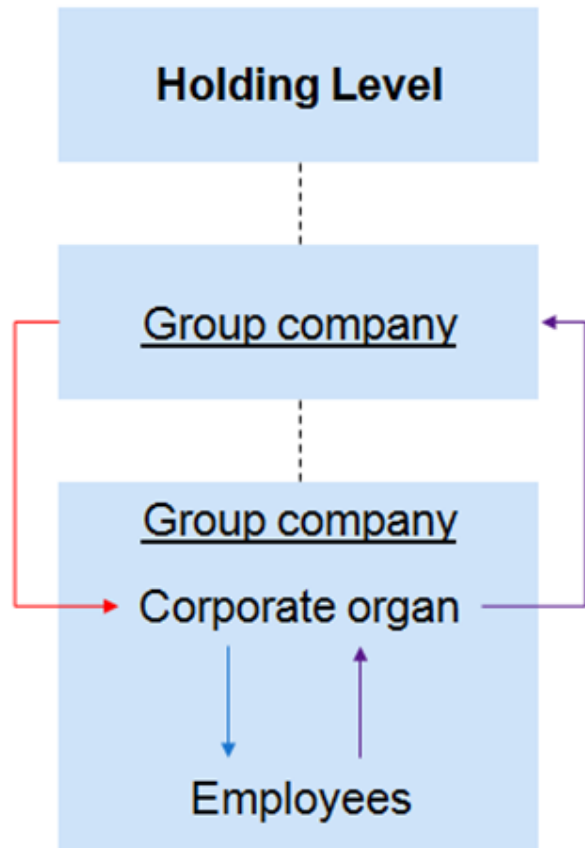
- Higher expectations as to the ethical integrity of business activities
- Globalization of business activities (“high risk jurisdictions” and “emerging markets”)
- More expansive reach of national laws with extraterritorial reach (FCPA, UK Bribery Act)
- Greater complexity of compliance systems as consequence of financial crisis
- Legal entities becoming subject of criminal investigations

International Observations and Trends: Responsibility of board members

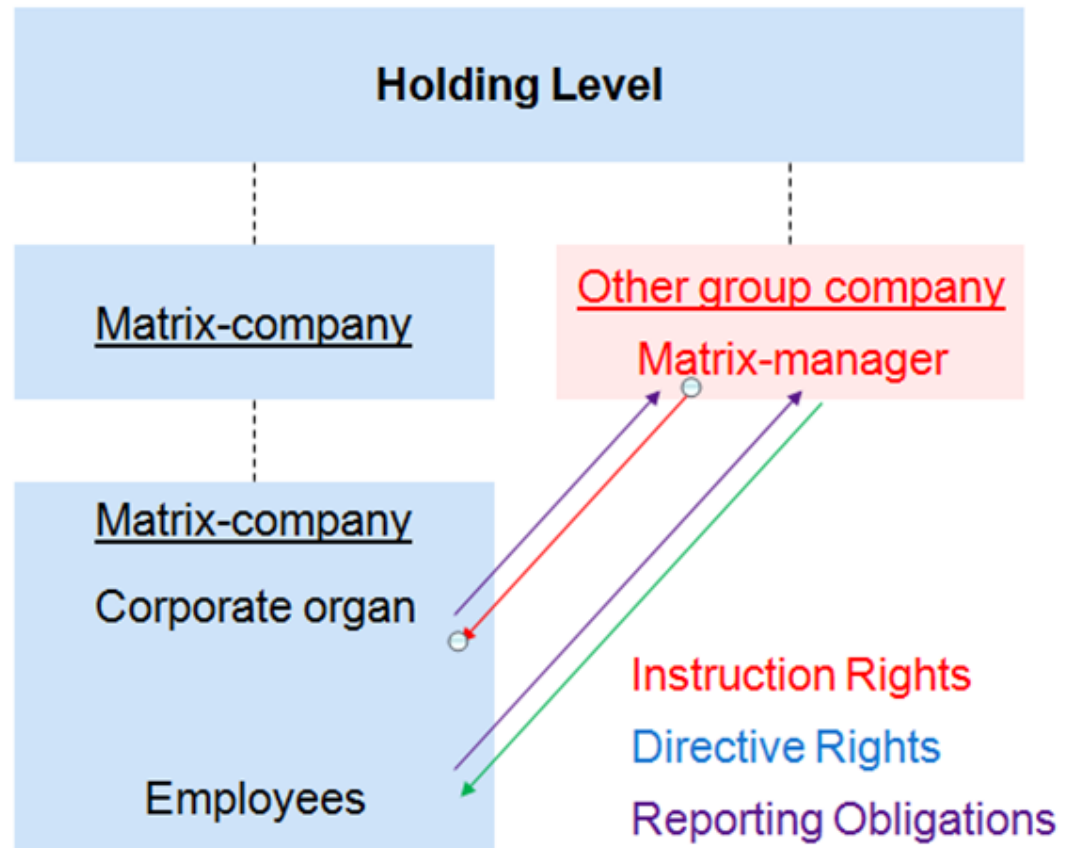
- Board members are increasingly subject to very intense scrutiny
- Several precedents have created high awareness regarding board member responsibilities, due to the breach of the duty to ensure a suitable compliance management system
- Responsibilities defined in countless:
 - national statutory law provisions
 - industry standards
 - court decisions
 - regulations and regulatory provisions
- Exposure of board members not only in prominent cases with high public attention but part of the ordinary course of actions
 - Example: Civil law litigation against former board members for damages as a consequence of criminal investigations

Complex Group Structures

Regular corporate structure



Matrix-structure



Complex Group Structures: Risks

- Matrix Structures: Reporting lines / instruction channels, as required under company law, differ from those that are actually used in practice
- Problem: Actual instruction channels and reporting lines often lack a legal binding basis
- Deficient delegation of instruction and directive rights in the matrix companies vis-à-vis matrix managers may cause the following liabilities:
 - Personal liability of board members of individual companies
 - Personal liability of board members on group-level
 - Personal liability of active staff members within matrix structure
 - Liability of individual companies and of ultimate parent company

“Compliance Governance” and risk mitigation

- To minimize exposure, board members have to establish and maintain an adequate Corporate Governance Organisation and functioning Compliance Management System
- Legal Instrument Organisational Guideline
- “Corporate Responsibilities and Corporate Compliance: A Resource for Health Care Boards of Directors”
 - Published by the Office of Inspector General of the U.S. Department of Health and Human Services and the American Health Lawyers Association in Spring 2015
 - Recommendations for board members “to ask the right questions”
 - Expected to become a sector-related benchmark

International Observations and Trends: Commercial bribery covering (private) HCPs

- Example: New German law governing commercial bribery for HCPs
- Will enter into force end of May/June 2016
- Previous anti-corruption law only covered government officials/privately employed clinic physicians
- The new law requires infringement of unfair competition law as part of an „unlawful agreement“ to prescribe drugs/medical devices, etc.
- Healthcare organizations need to carefully screen their interactions with (private) HCPs (e.g., cost-free provision of equipment, non-interventional studies, congress invitations, etc.)

International Observations and Trends: The role of industry codes of conduct

- Increasing importance of industry codes of conduct
- Public prosecutor are increasingly considering them as „safe-harbors“
- Healthcare organizations need to make sure that industry codes of conduct are properly implemented and binding for all employees
- Compliance with industry codes of conduct are increasingly subject of internal audits and investigations (otherwise this may be interpreted as a lack of oversights by the boards)

