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Turning Healthcare Compliance into Innovation and Profit - Developing Healthcare Compliance into a Strategic Complementary Asset

A Master's Thesis submitted for the degree of
"Master of Business Administration"

supervised by
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Affidavit

I, **Angelika Wolf**, hereby declare

1. that I am the sole author of the present Master's Thesis, "Turning Healthcare Compliance into Innovation and Profit - Developing Healthcare Compliance into a Strategic Complementary Asset", 74 pages, bound, and that I have not used any source or tool other than those referenced or any other illicit aid or tool, and
2. that I have not prior to this date submitted this Master's Thesis as an examination paper in any form in Austria or abroad.

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Abstract

The European Healthcare systems will be changing dramatically in the coming years due to demographic shifts, budget constraints, and the need for innovation. The Healthcare industry is one of the industry sectors that is particularly vulnerable to corruption. While in the previous years the Compliance functions primarily focused on reactive and operational tasks, the time has now come to transfer Healthcare Compliance into a strategic asset, leveraging the knowledge on policies and regulations, but also on process weaknesses and unexplored correlations between stakeholders. It is worth evaluation the benefit from merging a legal-based Compliance function with an incubation oriented function, where ultimately the respective business will own the processes. Analysing the status-quo, elaborating on the various interests on the stakeholders groups, will be the basis to further explore how the potential of this function could be harvested.

The intention of the survey amongst Healthcare Professionals of seven European Member States was to find common reasons for corruption problems as well as the external root causes which led to them. Emerging technology enablers and disrupters are prompting many enterprises to rethink their strategy, and the Healthcare Compliance is on the front of the implementation of many of these. If leveraged strategically, the Compliance function can help to identify new business opportunities, harvesting the internal information from monitoring and auditing. Collaboration with government bodies for the compliant and successful implementation of policies and regulations will also be a new way to generate advantages in the reimbursement negotiations.

Value-based Healthcare, putting the benefit for the patient in the centre of the efforts, is changing the measurements for the sector. New ways to the patient, e.g. electronical services, create value but must be introduced by considering the legal framework, the different stakeholders, and the ethical aspects. The Healthcare Compliance function, integrated in the development of future business models, can be the competitive advantage for the long-term success and the establishment of new delivery models, new calculation models for reimbursement, and value-based treatment options.

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List of Abbreviations

CEO	Chief Executive Officer
CCO	Chief Compliance Officer
EFPIA	European Federation of Industries and Associations
FCPA	Foreign Corrupt Practices Act
GDP	Gross Domestic Product
NHS	National Health System
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
IPO	Initial Public Offering
M&A	Merger and Acquisition
OECD	Organization for Economic Co-operation and Development
OTC	Over-the-counter
R&D	Research and Development
SHI	Statutory Health Insurance
WHO	World Health Organization

1. Introduction

The citizens of the European Union spend more than one trillion euro per year on Healthcare, including activities to promote health, but also preventing, diagnosing or treating diseases. We spend money for rehabilitation or long-term care. There are large organisational systems behind the scenes ensuring a long and healthy life for as much Europeans as possible. The Healthcare sector is prone to corruption mainly due its many actors which have complex inter-relations. Because of severe violations of laws and regulations, fraud, corruption, and abuse of market dominance, many pharmaceutical companies experienced high fines and reputation damage and therefore went through massive internal restructurings.

The Healthcare industry is funded to a large extent by tax money, therefore the request for more transparency must be in the interest of every citizen. The patient should be treated with the most appropriate therapy, independent of the influencing power of its marketing authorisation holder. Doctors should be able to make sound and independent decisions. This is seen to be crucial despite the fact that they receive invitations from pharma companies to congresses as well as honoraria for speeches at these congresses.

Currently, there is no comprehensive EU legislation on corruption except the common definition of the criminal offences of active and passive corruption in the public and private sectors. The European governments therefore introduce local regulations and laws to ensure the equidistance between the crucial players in this business, e.g. Article 29 of the Treaty on European Union elaborates on the preventing and combating of corruption as one of the ways to achieve the objective of creating and maintaining a European area of freedom, security and justice. As consequence of major corruption cases in the US, coming from the Finance sector, all publicly traded companies had to implement new financial rules (Sarbanes Oxley Act). The pharmaceutical and biotechnology companies answer with the creation of a new function, the Healthcare Compliance function. Staff working in these roles was mainly responsible for the training of employees on the industry`s and company`s Code of Conduct, the monitoring and the auditing of the control steps in the business processes. The regular reporting of the results (so-called findings) and analysis to the senior management should help to mitigate the key risk areas of the company.

All globally acting corporations in the pharmaceutical industry have installed Compliance Officers, and Compliance departments. This function is currently responsible for the company`s Code of Conduct, anti-bribery and anti-corruption measurements, the policy management of the corporation, data privacy, and detecting and providing guidance on solving conflicts of interest. As soon as topics can be related to certain business units (e.g. marketing) the Compliance functions maintains oversight, the respective business unit is accountable for the control steps and related decisions. Compliance areas cover a wide span, as almost every business process must respect legal requirements. During the last years data privacy became more important, due to the new technical possibilities that the internet provides (e.g. social media, and new ways to the customer). Also the protection of the main asset of the company, the intellectual property, records management, and employment management overlapped with the Compliance responsibilities. Our world is becoming more complex and interactive, that is why re-thinking the Compliance function can provide the companies with a strategic advantage in the future. Compliance related information includes financial data (derived during audits, monitoring), information from external stakeholders like governments (changing policies also offer e.g. new ways to the customer), as well as day-to-day Compliance issues, which may be helpful for CEOs to understand and act upon the current industry challenges. A functioning Compliance framework gives a structured approach to the management of business risks (e.g. fraud, privacy and security risks). Such a framework should encompass policies and processes, monitoring, that facilitates timely oversight and ensures that processes are achieving according objectives, and auditing that ensures processes get implemented accordingly. A Compliance framework for all business owners of Compliance responsibilities helps ensure a consistent approach to risk management and can also be an effective tool to engage with internal stakeholders of the organization.

Whilst in the previous years the Compliance functions primarily focused on reactive and operational tasks, the time has now come to transfer Healthcare Compliance into a more strategic asset, leveraging the knowledge on policies and regulations, but also on process weaknesses and unexplored correlations between stakeholders. Limited resources (both financial and human) require bundling of forces within a company to meet the needs of patients and governments. The European Healthcare sector needs to re-think

the power of the data derived with the Compliance function to ensure sustainable and affordable Healthcare systems of the future.

1.1 Problem Formulation

The Healthcare industry is one of the industry sectors that is particularly vulnerable to corruption. As summarized by the European Healthcare Fraud & Corruption Network and other experts in this area there are several reasons for this fact. There is a gap of knowledge between providers of care and the end-consumer, the patient. The responsibility for deciding on the appropriate treatment is given to the hands of the providers. In Europe the Healthcare industry is rather fragmented and decentralised, making it difficult to monitor and compare service provision and procurement (Radulescu et al., 2008). Compared to other markets the pricing for Healthcare goods is much more in-transparent, also because of the ethical implications involved. It is very difficult to define the "right" price for a life-saving medicine, because this touches on ethical questions. Overall the payer of the Healthcare services is not the same as the direct recipient. Currently there is no direct way for the payer to verify that the service was provided and the patient on the other hand does not have the information about the billing process.

In today's dynamic business environment, with rapidly emerging trends associated with new business risks and impacting legal regulation, it's more challenging than ever for pharmaceutical and biotechnology companies to understand and meet baseline obligations. This includes complying with all applicable laws, regulations, and Compliance requirements across the organization as well as dealing with a broad range of voluntary commitments. In the evolving phase of the Healthcare Compliance function the perception of the senior management was having another administrative function in the company, mainly dealing with the increasing regulative burden. The recent years showed that this limits the function to an unjustified extent. As many CEOs (almost 80%) of larger internationally corporations see over-regulation as main concern it would have been a smart move to integrate the Compliance function for decision making purposes (Bernstein and Falcione, 2015).

This environment provides both threats and opportunities to the Healthcare Compliance function. If leveraged strategically, the Compliance function can be an asset for the organization to differentiate itself in the marketplace. The EU is currently working on an overall anti-corruption strategy, companies who develop (or help to develop)

solutions will have a clear competitive advantage in the future. Ethical companies will have to proof that their Compliance programs are working, and that their employees have understood why it is so important to play to the rules. Leveraging the full potential of the Healthcare Compliance function includes reflection on current business processes, but if executed smart it can lead to new ways to the customer and a better risk management. For all of us as citizens of the European Member States, it increases the value that is generated out of every euro supporting the health on longevity of the population.

1.2 Objective

Although there is a need for senior management to bundle resources and leverage more from every function due to budget constraints, the ethics and Healthcare Compliance function has experienced only modest incremental change in terms of performance measurement. In this Master Thesis I want to explore the potential reasons for this fact and provide suggestions how to develop the Healthcare Compliance function further into a strategic complementary asset to increase the innovative power of the European Healthcare industry.

By leveraging the hidden power of the Healthcare Compliance function to manage current and emerging risks more effectively than their peer organizations, companies can have a compelling means of gaining competitive advantage. It is worth evaluating the benefit from merging a legal-based Compliance function with an incubation oriented function, where ultimately the respective business will own the processes. Analysing the status-quo, elaborating on the various interests on the stakeholders groups, will be the basis to further explore how the potential of this function could be harvested. The Healthcare industry is changing and new business models will emerge, e.g. in the supply chain and in the decision-making process on optimal treatments. The Healthcare Compliance function can add value to the current systems by acting as complementary strategic asset.

1.3 Course of Investigation

Based on the current tight situation of the Healthcare systems in Europe, the Compliance function will be analysed in terms of additional future output. Europe as aging continent will have to look for new ways to ensure the high-quality standard of its Healthcare systems. Knowing and navigating the regulatory framework, even shaping the regulations, can be a strategic complementary asset for research based industries to stay innovative and connected to the society. Along current emerging trends the potential future of the Compliance function to become a strategic business partner by leveraging its potential will be evaluated. Stakeholder analysis comparing the divergent objectives of the players in the Healthcare systems and an analysis of existing data derived from surveys, discussed in the light of strategic management theories will provide a proposal for the reimaging of the Healthcare Compliance function.

2. Europe`s Healthcare and Strategic Management from a Compliance Perspective

2.1 Technological Innovation Strategy Formulation

In developed countries the Healthcare sector plays a big role in government spending. This is also true for Europe where the share of Healthcare expenditures in GDP increases. There is increased governmental interest in assessing the value of innovative medicines and technologies, therefore pharmaceutical and biotechnology companies in Europe need to explore new market opportunities. The principles of Porter`s Five Forces model and a stakeholder analysis will be used to analyse the competitive environment from a Healthcare Compliance perspective, combining the internal with the external view to provide suggestions for new business models and products with added value for the patients and payers. Porter recently added also a sixth force, the role of complements. The Healthcare Compliance function can be seen as such a complementary asset. The evolving of this function into a strategic advantage will be suggested in this Master Thesis. In the Healthcare sector the core competencies are similar for all companies, like IP protected by patents (both on molecules and manufacturing), but in the tightening regulatory and budget framework a monitoring function with in-debt knowledge of business processes can be the differentiating advantage to delivery more value and justify the price of an innovative medicine towards the governmental payers. Sometimes core competencies can become too rigid and have a limiting effect on the company`s ability to respond to a changing environment. Dynamic capabilities, like maybe the Compliance function, can enable to re-configure the organizational structure of a company by identifying new opportunities for business (Rindova et al., 2001).

Complements enhance the usefulness of a certain product. Often company`s in a changing environment do not recognize the potential of existing data or information they hold. It is worth to consider the information on the infrastructure of the Healthcare systems derived from audits and monitoring to capture the value offered by this complementary asset in a strategic way. The European Healthcare systems are highly regulated, therefore not all aspects of Porter`s model count to the same extent. The bargaining power of suppliers as well as the threat of new entrants and substitutes are

influenced by government institutions. There is maybe a shift in the bargaining power of customers due to social media and the better informed patient, and the competition between existing players in the Healthcare industry puts pressure on prices of many medicinal products in Europe.

Making this transformation of the industry segment possible requires a new overarching strategy. In the coming chapters I want to point out how the Healthcare Compliance function can enable and introduce the value agenda, as described by Michael Porter and Elizabeth Teisberg in their book “Redefining Health Care” (2006). There are emerging opportunities to increase the value of Healthcare. The question is, which organizations will lead the way and how quickly can others follow? The challenge of becoming a value-based organization should not be underestimated. According to innovation literature, this transformation must come to a certain extent from within the organization. Only physicians and providers, like pharmaceutical companies, can put in place the set of interdependent steps needed to improve value.

In this tough environment, providers need a new strategy that transcends traditional cost reduction and responds to new payment models. If providers can improve patient satisfaction, they can sustain or grow their market share. If they can improve the efficiency of delivering high quality care, they will start any contracting discussion with reimbursement bodies from a position of strength. Those providers that increase value will be the most competitive. A coherent innovation strategy builds on the company`s existing competitive position and provides direction for future development, exploring opportunities. Formulating or adapting this strategy requires analysing the company`s environment, evaluating its` strengths, weaknesses, competitive advantages, and core competencies. Research shows that sustainable success is based on exploration, but also on overcoming constraints of the status-quo, the not so easy part. Healthcare Compliance might be an internal function well positioned to deliver added value in terms of innovation (Barney, 1994).

2.2 Appropriating the Returns from Innovation

Significant scientific and engineering competencies are needed to develop new medicinal products, but this advantage is killed over time. Profiting from technological innovation is

ensured by protecting the IP, the core competence of each pharmaceutical company. Once the patents expire imitators quickly appear on the scenery, and even before patent expiry the increasing pressure on cost from governments introduce higher competition. According to the Teece framework, focusing on the appropriability regime and the complementary assets, can create added value for the company. For medicinal products the appropriability regime is derived from the strong regulatory framework with high entry barriers for competitors (Ceccagnoli and Rothaermel, 2008). Healthcare Compliance can be one new complementary assets, as the profit gained from the strong appropriability regime is shrinking in Europe. This is especially true for biotechnology companies, who were harvesting the benefits from legal protection for decades (Supreme Court decision in 1980). Industry performance can improve if the new strategy for Healthcare companies include specialized complementary assets. Healthcare Compliance activities generate data, which is owned by the company, and should be applied strategically.

2.3 Stakeholder Analysis of the European Healthcare System

The pharmaceutical market will reach nearly 1.3 billion US dollars by 2018, but Europe's share on it will fall from 24% in 2013 to 19% in 2018 (IFPMA, Fact and Figures 2015). Today, the cost of developing a single medicinal product sums up to over 1.5 billion US dollars compared to 138 million in 1975. Companies experience lost investments, because R&D expenditures often do not materialize in a market-approved medicinal product, protected for years by patents. In addition, reporting requirements are becoming stricter, raising the maintenance cost for a given medicine as long as it is being marketed (e.g. adverse event reporting).

Many research-based companies face a substantial drop in revenue, the time when their patents are due to expire. These challenges have not yet diminished the industry's innovative drive but have rather encouraged it to look for new ways to innovate. Open collaboration and new business models e.g. joint ventures between pharmaceutical are ways to increase the productivity of pharmaceutical research. Facilitating partnerships involving academia and the public and private sectors are other mechanisms to look for additional sources of innovation (Chesbrough, 2003).

2.3.1 Customer Perspective - Aging Populations, and Innovation in Treatments

Among demographic spending drivers, the aging population will create additional demand for Healthcare services in Europe. Much of the increase in life expectancy can be linked to treatment advances, especially for cancer and cardiovascular disease, and decreased infant mortality rates. The current Healthcare systems as well as the increased education of the Europeans ensure high quality medical treatment. But one should not take this for granted. Especially innovative treatments are often very costly due to the high research investments, and there is a tremendous need to introduce higher efficiency to the Healthcare systems of today.

In many European countries the purchasing and decision power of patients increase. The patients becoming more cost aware regarding the medical treatments and services they receive - including specialty pharmaceuticals and medical devices – and beginning to use their influencing power more precise and in a structured way. In countries where consumers have a choice between different health insurance plans and Healthcare providers, they are using their increased access to information to influence Healthcare decisions. The highly connected world and the increasing influences by all sorts of media makes it easier to spread the word and compare offers and treatment options. Information and knowledge leads to discussions how tax money should be spent for the good of a country`s Healthcare system. The availability and easy access to health-related information via the Internet, social media groups, and rating websites such as the UK's NHS choices site, are also increasing patient expectations around treatment options, product price, quality and transparency.

Biotechnology and pharmaceutical companies have started to develop more dynamic capabilities, enabling them to react quicker towards the demands of the aging population. The concept of value-based Healthcare points in this direction, too. The learning capacity of the organization is based on the ability and flexibility to adapt to the market changes. Research showed that opportunity identification is highly based on the experience of the founders (and senior management), the external knowledge must be combined with the internal capabilities to create new market opportunities (Gruber et al., 2015). Technological competence leveraging is a combination of both exploiting an existing technology and exploring competences to serve new customers (Daneels, 2007). Established medicines are already used widely, value-based Healthcare will work towards

adding services for patients to increase the benefit for the patient even more. Healthcare Compliance is needed to develop into this direction, considering the legal and data privacy framework in Europe.

2.3.2 Financing Healthcare Systems – Bargaining Power of Buyers

If the medicinal product is highly differentiated, buyers (reimbursement bodies) experience less bargaining power, because of the missing of alternative treatment options (Schilling, 2013). But due to the relative decrease in the identification of new block-buster drugs, the bargaining power of buyers increased through the last decades. Patented molecules are usually enough guarantee to maintain exclusivity for years but now the pharmaceutical companies are faced with the increasing need to further differentiate their products with add-ons, to justify the high prices for some specialized medicines.

A robust Healthcare system is an important pillar of every country's socio-economic development process, and sound policies for the pharmaceuticals sector are the fundamental condition for Healthcare systems to perform well. Healthcare systems are complex organisms through which medical products, services, and patient care are delivered to patients. A well-functioning Healthcare system fosters productive relationships between governments, patients, and the industry. The complexity and dynamism of the diverse environments of the Healthcare system (and its` stakeholders) are important factors the need to be considered for problem solving mechanisms. Organizational design principles can be applied insofar that conflicts in the principal-agent relationship (e.g. between governments and doctors) may be solved by introducing more independence (Fjeldstad et al., 2012). Value creation by opening up the innovation processes to more stakeholders can leverage knowledge, the pharmaceutical companies have understood that value creation includes various types of multiparty collaboration (Baldwin and von Hippel, 2011).

The pharmaceutical industry makes a major contribution to the prosperity of the economy. It contributes to employment (direct, indirect, or induced), trade (through imports and exports), expenditure on research and development (R&D), and technological capacity building. The OECD average spending on pharmaceuticals was 1.5% of its GDP in 2005 and 2006, continuously rising due to the increase in the elderly population and the

access to advanced-therapy medicinal products (ATMPs). The level of per capita spending varies across the EU. Ranging from 0.7% of GDP in Norway to 1.2% in Finland and Sweden. The expenditures on pharmaceuticals as part of GDP are highest in Hungary (2.6%), Portugal and the Czech Republic. The EU governments expect to tighten public Healthcare spending to just 2.4% annually over 2014-2018. Budgets constraint are highest in some of those countries most affected by the euro zone crisis - Greece, Portugal, and Spain. Theories of centralizing the current two-tier public/private system with one universal Healthcare fund are on the way to implementation. The rules for the game will change soon for many players. Northern European markets, including the United Kingdom, Germany, and Sweden, are expected to experience a recovery in Healthcare spending by 2018. But this will not stop them from continuing to implement reforms to increase competition among Healthcare providers.

All Healthcare system in Europe are lacking transparency on the financial oversight, nobody really knows in detail how the money is spent. Measurements being implemented should benefit the patient at the end of the day. If the investments diminish in the administrative activities, the overall quality of the Healthcare systems will shrink. The different financing mechanisms are associated with different risk of corruption.

Table 1. Financing Mechanisms and Associated Corruption Risk.

Financing	Characteristics	Associated Corruption Risk
Taxes	Free or almost free deliveries.	Informal or illegal payments, corruption in procurement, may affect quality of services.
Social insurance	Not every citizen eligible.	Excessive medical treatment, fraud in billing, diversion.
Private insurance	Voluntarily.	See above, risk selection.
Out-of-pocket payments	Not reimbursable.	Overcharging, inappropriate use of services.

Source: http://archive.transparency.org/global_priorities/other_thematic_issues/health/health_systems

There are differences among the European countries, some Healthcare systems are financed privately to a large extent (e.g. Switzerland, the Netherlands) others by the government (e.g. United Kingdom, Sweden). The underlying, common reason for corruption resides in the fact that an independent controlling and monitoring institution is missing in all of them. It seems also very difficult to justify the price for a certain medicine or a medical service. For an individual patient it is challenging and almost impossible to oversee all the forces at work. It is equally important for governments having measurements to control their tax money. Transparency International found that privately financed and controlled Healthcare systems are affected more by insurance fraud, unethical procurement and distribution of drugs, and low-quality treatment. Healthcare systems mainly funded by government institutions are faced with Compliance issues like a high incidence of informal payments, absenteeism and drugs being diverted for resale.

The Compliance function can help to shed light on the interactions between the stakeholders, resolving conflicts, because the function has a broader view of the organization and its environment. One initiative which will be effective this year, is e.g. the European Federation of Industries and Associations` (EFPIA) Transparency Initiative, requiring the publication of all transfers of value to doctors and medical institutions by the pharmaceutical industry. In the past, there had been no confirmed figures which made profound discussions impossible, from July 2016 on there will be facts. Everybody having access to the internet can check how much money is transferred between a certain

pharmaceutical company and a doctor or a hospital. The purpose of the collaboration will be stated too, e.g. speaker fees, sponsorships, R&D. Even if some privacy laws allow the recipients to forbid the mentioning of their names and business addresses (which is for instance the case in Austria), the raw numbers on an aggregate (anonymized) level will be helpful in starting constructive discussions on the pros and cons of this business relationship.

2.3.3 Government Regulation and Compliance

Almost all Member States of the European Union see an overall decline in tolerance of corruption. Corruption scandals, effective sanctioning, implementation of stricter anti-corruption and Healthcare transparency regulations, have all contributed to a general increased awareness and a decreased public acceptance. Self-regulation initiatives (as the one mentioned above) by the Healthcare industry support this common goal. Laws and regulatory requirements vary from sector to sector and across geographies. But all companies in the Healthcare industry and/or operating in the same regions experience very similar regulatory pressure.

The EU has already produced some legal documents on fighting corruption. Among the most important is Article 83(1) of the Treaty on the Functioning of the European Union, which recognizes corruption as a "serious crime with a cross-border dimension" (COM, 2011). Framework Decision 2003/568/JHA applies on combatting corruption in the private sector. The EU convention on the fight against corruption involves public officials of European communities or of the Member States of the EU. Every member state is obliged to take necessary measures to ensure that any act of passive or active bribery by public officials is a criminal offence and must be prosecuted and punished. According to the Council of Europe's Criminal Law Convention on Corruption, active bribery of public officials is defined as the "the promising, offering or giving by any person, directly or indirectly, of any undue advantage for himself or herself or for anyone else, for him or her to act or refrain from acting in the exercise of his or her functions". Similarly, passive bribery is "the request or receipt, directly or indirectly, of any undue advantage, for himself or herself or for anyone else, or the acceptance of an offer or a promise of such an advantage, to act or refrain from acting in the exercise of his or her functions".

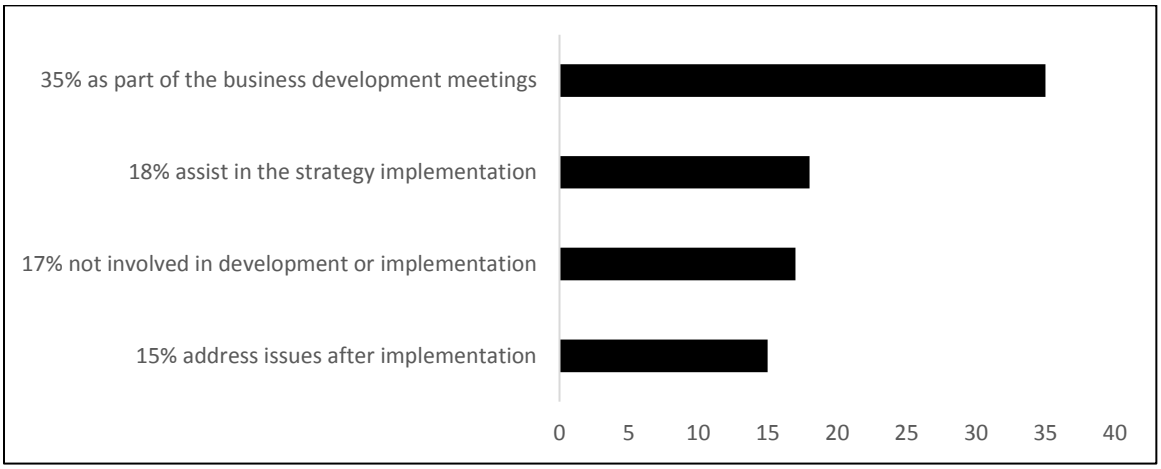
How can pharmaceutical companies, facing this tight regulatory framework, gain competitive advantage over their sector peers? By far means one solution would be doing a relatively better job of managing Compliance-related risks. Companies managing more efficiently their corruption risks may be able to pass associated cost savings along to customers, in the form of lower prices, and to investors, in the form of greater returns. Constant reflection on its` own performance and the changing policy framework provides an enormous advantage for every pharmaceutical company. Innovative solutions can be developed in close customer collaboration (with doctors, but also government institutions) and direct external collaboration with policy making bodies. Pooled internal collaboration in a central innovation information platform is another potential way to foster idea generation (Fjeldstad et al., 2012).

According to Porter, complements can have a certain role to enhance the usefulness of a product (Porter, 2006). The availability, quality, and price of complements influence the threats and opportunities for the company. Applying this logic to the Healthcare Compliance function, there is a potential for creating additional value. It is becoming 1) increasingly important to navigate safe through the legal framework (to ensure reputation), 2) data derived from Compliance activities is specific and a differentiating factor, and 3) the value can be captured by the company itself (Schilling, 2013).

Currently the Compliance related knowledge is not used to a full extent. The Compliance function is overseeing many key processes, is objective because not incentivized on the sales numbers, and therefore a perfectly situated in-house consultant for the senior management. Only 35% of Compliance professionals are currently involved in the development of the corporate business strategy. In contrast to many senior managers claiming that the policy and regulatory framework is complex and difficult to handle. Considering, understanding, and also reacting on the objectives of the tightening legal framework is a difficult one. Although the Compliance functions are included in the implementation of the business strategy, it would be even more appropriate to directly include the function in the generation of the business strategy. Healthcare Compliance is the function which, by definition, is the one knowing the most about policies and process weakness of the company. Not involving Compliance at all in developing the corporate strategy often leads to the current situation of only addressing Compliance issues late or too late. All this is a hint that there is a misunderstanding about the strategic asset that a

fully integrated Healthcare Compliance function can be. Considering the pitfalls upfront can be a timely as well as financially advantage on the market.

Figure 1. Involvement of the Compliance Function Regarding Business Strategy.



Source: Bernstein, S., Falcione, A. (2015): Moving Beyond the Baseline, State of Compliance Survey, PwC.

With Compliance becoming more crucial in successfully executing the business strategy, a diversely skilled Compliance team, holding back-ground knowledge in areas like business development, complex data analysis, and technology is a prerequisite. This may help the Compliance function in playing a more strategic role in the organization. It's the people in the department who help drive the function's identity across the company.

As mentioned above, European regulatory agencies are also pushing for increased transparency of transfers of value between life sciences companies and Healthcare professionals and institutions. The trend towards greater physician payment transparency is expanding globally, with France, Japan, and Australia recently adopting transparency regulations. By 2015, 70% of pharmaceutical sales will occur in countries which have HCP transparency regulations. The internet and new ways to communicate to the customer constitute another main area of regulatory concern. Safeguarding security and data privacy is likely to become even more challenging in the evolving Healthcare industry. Rising data flow and numerous organizations sharing sensitive information electronically escalates the risks of hacking and infection with malware and viruses. Healthcare Compliance is an ideally positioned function, working together with the company`s information security experts to ensure the safety of confidential and personal information

of doctors and patients, mandatory online records for every company when conducting, for example, clinical trials.

Addressing the drivers of corruption on a higher level requires EU-wide policies, every member state has to set and enforce anti-corruption rules (e.g. like the UK Bribery Act). An independent and effective judicial follow-up on corruption cases is required, and sound and transparent general procurement systems should be implemented. Communities and the general public have the right to expect that a company does not violate the basic obligations that society places on enterprises e.g. competition law. The complexity of the European Healthcare systems and the various principal-agent relationships are somewhat prone for unethical behaviours. The delegation of decision-making to doctors opens the door for improper inducement by the pharmaceutical companies (Jones and Hill, 2013).

Corruption is a complex phenomenon and single risk areas often include several types of corruption. Self-regulation of the pharmaceutical and biotechnology industry, for example through a Code of Conduct, is an important feature to proof the added value to the Healthcare system. To come to an analytically, practically and policy-wise meaningful recommendation and guidance, the Healthcare Compliance function is well-prepared to group the root causes for incompliant behaviour and provide strategic advice.

2.3.4 Transformation and Innovation

The change into a more patient-driven Healthcare system is becoming a major focus in the United States, Canada and, to a lesser extent, the UK and Brazil already. Providers and health plans in these countries will need to identify innovative ways to satisfy the unmet needs of consumers, who seek transparency, value, and convenience. Engaging consumers in shopping for health plans, selecting providers, and taking care of their own health are good first steps to strengthen relationships and build trust to ensure brand loyalty and market share.

Healthcare technology changes may be rapid and disruptive to established Healthcare models in Europe. The new communication technologies will allow more and faster interaction. Biggest challenge for people working in the Healthcare industry is now to detect future options to better serve the customers` needs. This was not that important in the old business days, but now high prized medicinal products are questioned more

often by the paying institutions, and in contrast to the past outcome, now the payers succeed more often. Although the core value for pharmaceutical companies still contains the patented molecule or medical treatment, any additional feature that could be added to a medicinal product would support the argument, that high quality is erasing the cost factor. The potential to improve the treatment and care process with new developments could not be underestimated. But careful measurements need to be taken, as patients are usually in a position of weakness in the Healthcare systems. Considering the value of crowdsourcing in the European Healthcare system one has to admit, that there are limitations. Integrating patients can only be done by clearly respecting the required safety and data privacy regulations. For the value-based Healthcare systems the voice of the user should be examined, for the development of new product-related services (Pötz and Schreier, 2012).

A conflict of interest often occurs when an individual or organisation is involved in multiple activities and interests, one of which could possibly corrupt the motivation for an act in the other. What we see in Austria in case of ELGA is a projection of the conflict, the doctors cleverly delegated the problem to the patients, claiming that data security could not be granted by the providers. Although they could not proof it, they abused the patients` feelings of insecurity to promote the opt-out of ELGA, and had been somehow successful with it. The Compliance function could offer facts and guides the discussion back to a more analytical based evaluation.

2.4 Current Benefits of the Compliance Function

Today`s dynamic business environment with emerging new business risks and impacting legal regulation is highly relying on the Compliance function to mitigate these risks in a proactive manner. The current main tasks of the function are concentrated around the writing and training of corporate procedures, monitoring and auditing the full implementation of the key processes, and to provide day-to-day advice in business critical decisions. The Healthcare Compliance function becomes increasingly important in negotiating M&A, as well as in the due diligence checks of numerous vendors and suppliers. Usually these activities generate data and conclusions, which, in most of the companies, is presented to the senior management to provide an oversight of the main

risk areas. In theory, new technologies for managing business data can enable companies to increase the efficiency and reduce the costs of Compliance management (like monitoring and auditing of risk areas) by automating and streamlining business processes. Technology has the potential to add significant value to Compliance management, providing faster analysis and executive summaries for senior management meetings. Unfortunately the Compliance function is still struggling with how to extract that additional value from existing technology tools. One challenge is that these tools may work well with defined processes and requirements, but often the companies to not fully understand the strategic capacity that could be generated. It can be difficult to access all the data needed to use the tools effectively, sometimes because the needed data is spread throughout the whole organization. A bigger challenge is that many organizations have not yet identified appropriate key performance indicators needed for measuring how well the business is managing Compliance risks and how well the Compliance function is contributing to business-related objectives. For the time being, many companies simply focus on the number of employees trained or the amount of business hotline volume, which only taps on the surface of what could be harvested out of the generated data.

A primary task of the Compliance function is monitoring and auditing of existing business processes. Analysing the findings, and reporting them to senior management in conjunction with suggestions how to fill the gap and minimize the future business risk in this area, is seen as current core competence. So far the perception. But there is growing improvement in the use of data analytics tools, which vary in complexity, and can provide broader coverage. They may provide efficiency gains for the Compliance professionals and freeing capacity for a more strategic role in the company. At the same time there is still a lot of data unused, waiting to be connected and analysed for business development purposes, or to detect trends helping to shape the future business strategy. The current approach is very much focused on activities of the past, new tools will allow to relieve the Compliance function from some operational burden and invest more time to deliver proposals for the future strategy of the company. One reason for being so reluctant here is the general failure culture in companies, and their capacity for change and reflection.

2.5 Needs of the European Healthcare Systems

The pharmaceutical industry is a significant contributor to employment and manufacturing in the EU. In the years 2000-2006 an increase of 5.6% in employment for the EU resulted from the development in the pharmaceutical sector (Kavanos et al., 2011). Pharmaceutical innovation is behind some of the greatest achievements in modern medicine. This industry is based on patented new molecules, and a high percentage of its revenues is still re-invested into new R&D projects. Today Europe`s people live longer and healthier lives than previous generations. Medical advances allow people to enjoy a better quality of life and increase their productivity, contributing to the overall prosperity of society. Pharmaceutical innovation creates jobs, accelerates technology, and represents an important source of income. Unfortunately, not everyone has yet fully benefited from these medical advances, and we somehow see the establishment of a two-class Healthcare system. Poverty and great wealth inequalities between and within countries mean that many do not have access to state-of-the-art Healthcare treatments. Addressing these issues is a complex challenge that requires long-term commitment from government, civil society, and the private sector. Through differential pricing schemes, donation programs, and technology transfer initiatives, the pharmaceutical industry has been added its part to help those in need to also profit from the benefits of medical innovations. Across Europe, governments, Healthcare systems, and other stakeholders are recognizing the call for innovation. Due to the work done in universities, academia and hospitals, as well as offices, advances in health technologies and data management can help facilitate new diagnostic and treatment options. However, the high cost of targeted therapies, personalized medicine, genetic-based medicine, medical devices, and other advances continues to add to the Healthcare cost burden. But every time it comes to identifying the main reasons for the high costs there is no clear, precise answer. Annual checks on the expenses show a lot of parallel treatments, in-transparent financing of hospitals and other medical organizations, operational inefficiencies, and frustrated doctors. Something must be going on there, and it seems worth to have a closer look at the stakeholders, their interest, and the need of patients. Where does all the tax money go? How do the stakeholders decide? Are these decision real independent decision? Who has the power? There is data that shows that some money is lost due to waste on unnecessary services, fraud, and abuse.

In a data and information driven age, the pharmaceutical companies must leverage the potentials of their products. Not only through conventional research activities, looking for new molecules. The structured and targeted use of limited resources will open the door for improvements. According to surveys made on the enabling factors of pharmaceutical innovations, the very early stage research is most successful if the information is shared and combined. Clustering of academia and industry in world class research institutions and a highly trained workforce, capable in providing support on core technologies (high throughput screening, gene sequencing, etc.) are prerequisites for the discovery of new treatments.

There is growing advocacy and activity around the shift from volume- to value-based Healthcare (VBC). Governments and other payers are developing and implementing strategies to align providers under new payment arrangements (e.g. payments based on fee-for-service, provider incentives to increase payment rates, specialization/intensity, and volume). Value-based Healthcare is re-thinking the process from manufacturing to the delivery of the medicine to the patient. It will be essential to understand the function of the gatekeepers along the line. There is an urgent need to improve the access mechanisms and support the players (mainly the doctors) to free them from the administrative burden. Although documentation is important and could not be removed in total, there must be solutions to minimize these activities, to ones adding value. The decision power of the stakeholders must not be influenced by conflicts of interests, the incentive schemes must be re-shaped to understand the trends, like e.g. a certain rush for specific recommendations for a particular surgery. There are forces acting on the doctors, who must be aware of their responsibilities. The same is for the pharmaceutical organizations. Influencing power on physicians and lobbying activities in the sector of patient organizations blur the lines between the main scope of the Healthcare systems and the peculiar interests of other stakeholders.

The European Member States have implemented already diverse initiatives and solutions to provide ideas for the future. It would be more than helpful to have an overarching guidance on the acceptable interactions between the stakeholders. EFPIA is in the driver seat, asking for more transparency and precise figures on the status-quo. Increased collaboration between the Member States will be absolutely mandatory to re-shape the Healthcare industry in Europe. Based on the 2008 WHO Report on “The Global

Burden of Disease" it will become absolutely important to prioritize the Healthcare needs. Starting by defining the most severe diseases, in terms of costs to society (absenteeism, impact on families, etc.), the EU needs to decide on policies that help us live healthier and more productive lives.

2.6 The European Healthcare Systems

In the European Union the Healthcare sector is organised in country-specific systems in which the Member States hold competences in the field of health policy. Roles and responsibilities are split between regulators, payers, Healthcare providers, the industry (suppliers) and patients (consumers). Usually all actors are present in each Healthcare system, the actual relationships as well as the decision power and payment mechanisms may vary. All actors can be actively or passively involved in corruption, actively meaning offer or initiating bribes or showing incompliant behaviours. The general definition for corruption always sums it up as the abuse of power for private gain, pointing explicitly out that there are two willing actors – the corruptor and the corrupted. In a complex network like the Healthcare system there is a blurred line between the actors. Therefore it is often not obviously evident if this is a single action (called fraud) or if there is a systematic approach behind. Overall the some actors switch the roles between decision maker and executer. It is required to think the process through to fully understand the action and motives behind. That makes the Compliance function so much interesting as it combines analyses and abstraction to be able to provide a sound strategic advice.

The varying role of the government as payer and regulator in the European Healthcare sector cannot be underestimated. In most countries, the government is the primary funder and provider of Healthcare services for the vast majority of the population. This is a very expensive responsibility, as costs continue to grow, overall global Healthcare spending as a percentage of GDP is projected to total 10.3% by 2018. The dedicated focus for government legislators remains pricing and reimbursement rules, as they try to minimize pharmaceutical spending growth. Reference pricing systems have already decreased prices in many European countries, but have not stopped government payers from pushing for even greater savings. In 2014, both Sweden and the UK secured pricing deals with drug manufacturers, on top of other efforts to drive down costs.

Table 2. Healthcare System Stakeholders.

Category	Subcategory
Patient	Individual patient Patients` organisations and pressure groups
Providers	Individual Healthcare providers (doctors, nurses, pharmacists) Healthcare institutions Healthcare researchers and research institutes
Payers	Public and private insurance Social security and public funding
Industry	Pharmaceutical companies Medical device companies Intermediary companies
Regulators	Non-Health (judiciary, procurement regulators)

Author`s own presentation.

Currently, the value-based strategy of pharmaceutical companies depends mostly on physicians, due to their integral role in Healthcare supply chain and delivery. The Deloitte Centre for Health Solutions' 2014 Survey of U.S. Physicians examined the expected levels of engagement in the U.S. and it can be expected that the figures for Europe would most probably be similar. Physicians are concerned about the consequences of potential financial risk as well as being held accountable for things unable to control. Greater transparency makes doctors feel more vulnerable as the journey of the treatment can be checked openly. There will be discussions on how to decide between different treatment options and the particular role of the payers in this scenario.

2.7 Impacts of Healthcare Corruption

The overall impact of corruption in Healthcare on the European society and on each inhabitant can be much larger than only the monetary value involved. There are direct and indirect consequences, tangible (like material) and intangible (social, psychological). We can see the effects in short term (price and quality of products) or in long term (Healthcare system). A study on informal payments in Lithuania distinguishes between the implications for access to healthcare, economic implications and implications for trust in the healthcare system (Larsson, 2010). Informal payments (for services that are to be

provided free of charge) not only limit access to Healthcare, they also damage official payment systems, distort Healthcare priorities, disrupt health reforms and can encourage unprofessional behaviour of doctors (e.g. providing quicker access for patients who can afford to pay). There are several impacts according to Larsson`s publication which are affected by corruption in the Healthcare sector. It may lead to a provision of services or procurement or equipment, and drugs above market prices (impact on price). It can be that patients not wishing to engage in incompliant practices, receive lower quality in the provision of Healthcare services, medical devices or pharmaceutical (impact on quality).

The overall objective of universal Healthcare coverage can also be harmed, and the inequality between socio-economic groups will become larger. An impact on access to Healthcare system is a consequence of the increase of the price. Due to the changes in the allocation of the health budgets the whole industry sector gets distorted. The expenditures on prevention, execution of anti-corruption policies, and costs for law enforcement of involved offenders (detection, prosecution, conviction, incarnation) have a severe impact on public budgets. This is difficult and complex to communicate to the wider public. That is maybe one of the reasons why the citizens of the EU sometimes see bribery as kind of normal business behaviour. Corrupt practices may lead to various consequences such as bad doctors driving out good doctors, meaning that not competence is the criteria but the willingness of the doctor to participate in the corrupt system, also called Unfair Competition. Cross-border collaborations are also influenced e.g. increase in incentives for parallel trade of pharmaceuticals or off-label use of medicines. Also brain drain of medical staff can be triggered by corruption, a loss in productivity of the Healthcare system can be seen in countries with a high degree of corruption. Further impacts on society are distrust in the services by the government and the whole Healthcare system of a country.

This illustrates that the overall impact of corruption on the society and on individuals can be larger than the value of the sums involved. It is a complex interaction that makes the actual consequences often not visible immediately. It needs to be thought through carefully to come to a conclusion if an action is violating the integrity of the Healthcare system. Creating strategic control measurements around the corporate goals to ensure efficiency, quality, innovation, and customer responsiveness (a balanced scorecard approach) helps to navigate through the complex environment of the European

Healthcare systems, both leveraging the potential of a medicine and adding value to the patients (Kaplan and Norton, 1992).

3. Analysing the Business Risks of the European Healthcare Systems

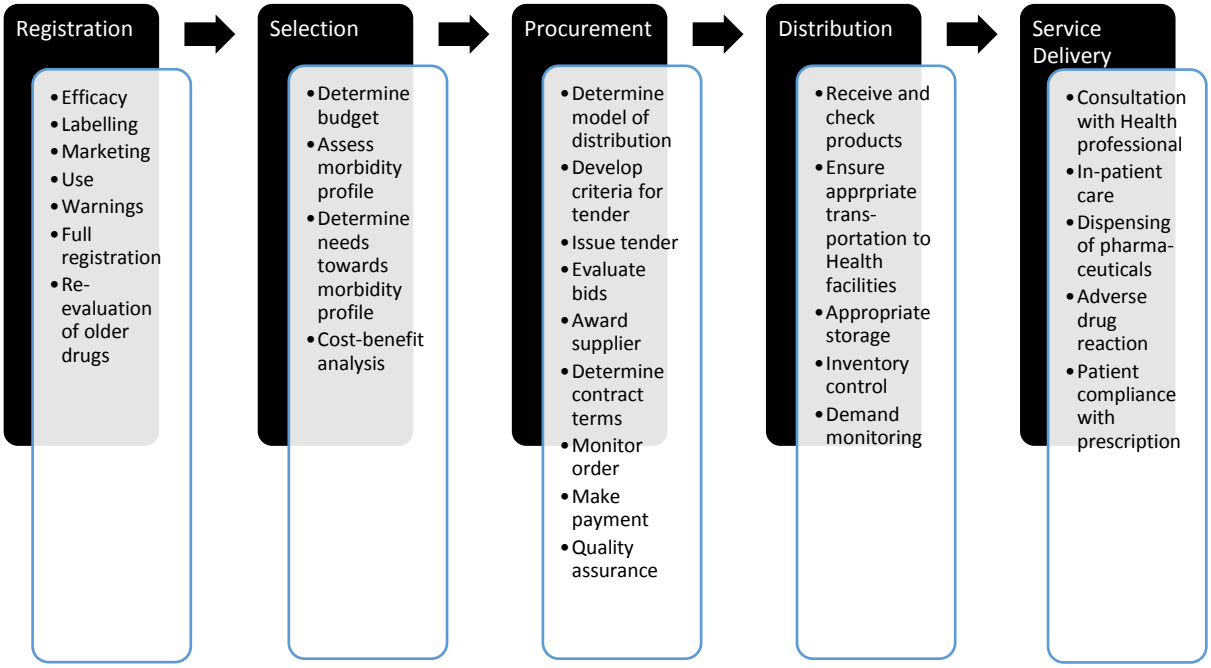
3.1 Healthcare Compliance Risks During Selection and Delivery of Pharmaceutical Products

The delivery and selection, the supply chain of the pharmaceutical sector, contains basic features which are almost identical across all EU Member States. The distribution system includes wholesaler, retailers and parallel traders, supplied by two types of sources: originator companies and generic companies. Tenders are the main type of supply for hospitals, pharmacies are using mainly the wholesaler channels. Retailers of pharmaceutical products are primarily community pharmacies, other distribution channels are self-dispensing doctors, hospital pharmacies, and for Over-The-Counter (OTC) products, which are prescription free, pharmacy outlets, medicine stores, supermarkets and petrol stations. For the Healthcare market of prescription medicines the consumer (the patient) differs from the decision maker (the prescribing doctor), and often also from the payer (the reimbursement institution). This complex network makes the Healthcare sector vulnerable for corruption, which occurs throughout all stages of the supply chain including:

- Bribery/extortion/kickbacks in the authorisation and procurement of pharmaceuticals, like financial or other advantages (money, discount, loan, donation, gifts or entertainment, information, preferential treatment, offers of employment, etc.). A kickback is a form of negotiated bribery, often to persuade the other party to cooperate in the illegal settings.
- Collusion in procurement (like bid-rigging and market division), like arrangements between bidders in a tender. Collusion is a horizontal relationship restricting competition and harming the public purchaser, in the form of bid-rigging, price fixing or market division.
- Favouritism in procurement – conflict of interest/unethical donations (in selection for restricted tender or by direct ordering for example), like preferring acquaintances, friends and family over strangers to unfairly distribute positions and resources.

Favouritism is based on an informal relationship including a mutual but unequal exchange of favours.

Table 3. Processes in Selection and Delivery of Pharmaceutical Products.



Source: Cohen J.C. (2006), Pharmaceuticals and corruption: a risk assessment. In Global Corruption Report, Transparency International.

3.2 Survey Results (Seven Selected Member States)

3.2.1 Methodological Note

To address the objectives, desk research was used, combined with a survey among Healthcare Compliance Professionals from the seven selected Member States. The Healthcare Compliance Professionals are working for an international pharmaceutical company, knowing the industry sector very well. Interviewees were asked about their experience during the last five years, all information gathered was analysed to produce a reasoned snap shot of the respective European Member State. The intention of the survey was to find common reasons for corruption problems as well as the external root causes which led to them. The aim was to gain a better understanding and a general picture of the impact of corrupt practices as well as existing policies in the respective countries. The

survey asked also for describing typical or prominent cases of corruption, and the collection of good and inappropriate policies and preventive actions to control corruption in Healthcare. The following analysis of affected stakeholders, and the opportunities derived from new business models including new ways to the customer should complete the hypothesis of using former control functions in a more strategic way to ensure innovation and sustainability in the European Healthcare systems.

The combination of the derived results of the current situation of the Compliance function and the innovation strategy development process should provide a new understanding of the potential of this control function. Healthcare Compliance could become an innovation promotor once the value added is included in the organization`s innovation strategy.

3.2.2 Austria

General Characteristics of the Healthcare System

Austria is a country with a federalist structure, the government is the regulatory body in all types of Healthcare services provided within the 9 Länder. Since 2002, the Austrian hospitals (except for Vienna) have been privatised, now the hospitals are responsible for their own budget. The mandatory social Health insurance is the key contributor of Healthcare expenditures, 70% of the budget derives from insurance contributions and taxes. The federalist structure results in a decentralized financing system by assigning duties to 21 Health insurance funds over the country. In the hospital sector the financing system is pluralistic, 40% of hospital care is paid by social Health insurance contributions. There are regulations predefining the contribution levels, and every employee shares the costs with its employer for 50%. Austria is one of the richest countries in Europe, spending a relatively high percentage of GDP in comparison to other EU Member States (11% Austria, 9% EU average). The Austrians can afford to privately pay for some Healthcare services and products. The physicians are paid mainly on a fee-for-service basis, patients organisations are well embedded in the system.

Survey Results

According the survey among Healthcare Compliance professionals in Austria, one interviewee said that bribes are not considered as real problem, but also mentioned that there is a general tendency to make informal payments to obtain better treatment or to move up waiting lists of publicly funded Healthcare providers. In the industry sector of medical equipment one respondent said that companies try to influence the doctors by offering personal benefits, like paying congress registration fees. This does not happen in the pharmaceutical procurement sector, a rather highly regulated area. The new anti-corruption legislation was mentioned by respondents as appropriate risk minimizer. Doctors working in private practice and in public hospitals are likely to steer patients towards the private Healthcare services. Uninformed patients may accept unlisted and unnecessary treatments in Austria. Several respondents report about a general tendency for oversupply of services.

Compliance professionals knowing the Austrian market state that there is a high pressure from pharmaceutical companies on reimbursement lists of the national Health insurance agency. Companies are often performing indirect lobbying, using the media landscape to influence the decisions. Pharmaceutical companies have reduced their marketing budgets in the last years, sponsorships for conferences have been decreased or even vanished due to the change to a centralised procurement process. The marketing activities of the sales force of the companies switched from the pure sales personnel to a more specialized access personnel.

3.2.3 Croatia

General Characteristics of the Healthcare System

After an important reform in 2005, the Croatian Healthcare sector has been transformed into a decentralized system. With the Ministry of Health being responsible for policy making, the management tasks have been delegated to municipalities and local authorities. The Croatian Healthcare system is mainly funded by the Health Insurance Institute, combining the contributions of employers and employees. Also local governments are increasingly supporting the public expenditures. General practitioners are acting as gate keeper to the secondary care, provided by public hospitals. Direct

services are financed on a fee-for-service basis, capital and technology are funded by the government. Croatia has already introduced a performance based payment system in 2002 to reduce the duration of stay in clinics and to decrease the related costs (Voncina, 2012). The total Health expenditures are 7.8% of the GDP, which is below the European average. The Healthcare system is social insurance based, the doctors are paid on capitation. The average waiting time for a major surgery is rather long compared to other EU Member States.

Survey Results

The interviewed Healthcare Compliance professionals pointed out that the bribing of doctors and nurses is a corrupting activity to receive better and faster treatment in Croatia. Favouritism is taking place a lot. The same is for corruption in the procurement sector, where modification of technical specifications to fit one manufacturer can be seen. One survey respondent reported that it is also common for pharmaceutical companies to offer personal benefits to physicians to make them prescribe a particular medicine.

3.2.4 Czech Republic

General Characteristics of the Healthcare System

The Czech Healthcare System is mainly based on the mandatory SHI, privately owned Health facilities and the free choice of service provider. The Ministry of Health acts as policy-making authority, regional bodies and insurance funds are charged with providing equal access to Healthcare. Regional authorities register the Healthcare provider, the insurance funds are setting up the contract with the providers (Bryndova et al., 2009). Since seven years, ten Health insurance funds are collecting the mandatory contributions, both for employer and employee. Total expenditures are below the EU average, whereas the public spending is above (84% vs. 73% EU average).

Patients in the Czech Republic can choose between providers, but they need to sign up first with a primary care physician. Payments to general practitioners are based on capitation and a fee-for-service scheme. Based on age and gender of the insured, the funds are performing regular ex post risk adjustments by adapting the contributions.

Survey Results

Corruption in the procurement of medical equipment is a serious issue in the Czech Republic. All stakeholders in the Healthcare system, e.g. companies, hospital management, authorities, are heavily involved in persisting with the corrupt mechanism. The situation is much better for the provision of pharmaceuticals, because there had been government initiatives to solve the problem. Overpriced pharmaceuticals are no longer common due to several prosecutions of some big pharma companies. The interactions between the companies and the national certificatory body (the price setter) had been improved since then.

In the case of medical equipment, politics are highly influenced by corruption. Key decisions are made by few powerful individuals who influence the public officials, mainly by providing political support or promising important and well paid jobs in a government institution. Another much seen behaviour is the paying of kickbacks and the funding of political parties. Based on the survey results, also extortion is relatively common. Respondents see the main causes in the reliability and independency of the players in the system. The lack of transparency and independent control mechanisms allow corruption mechanism take place. Unethical and corruptive activities are seen as relatively risk free.

3.2.5 France

General Characteristics of the Healthcare System

The French Healthcare system is funded by a single governmental payer, relying mainly on social insurance. Approximately two-thirds of the Healthcare expenses is covered by the Statutory Health Insurance (SHI), financed through employer and employee contributions. Tax revenues are becoming more and more important during the last years. Reimbursement rates are fixed by law in France, the government negotiates on tariffs with the Healthcare providers. France has high co-payment rates on medicinal products and daily hospital fees. Therefore the French people invest in voluntary Health insurance for better coverage. Policy making is shared between the government, the SHI, and the local communities. The Ministry of Health is signing a contract every three years with the SHI to define goals, decide on the management and the governance of the SHI.

The Healthcare sector is divided into public and private institutions. Self-employed doctors are paid on a fee-for-service basis, and mostly providing the services in the private hospitals. France is working with a kind of half-half-gatekeeping system, incentivizing the visit at the general practitioner to avoid heavy usage of specialists. The social care sector is mainly providing the services for the elderly and the disabled. All hospitals are funded on the basis of hospital stay groups, only long-term care and psychiatry are excluded. Payment and tariffs between the private and the public providers are still different (Morel et al., 2012).

The total French Health expenditure constitutes 11.6% of the GDP, which is above the EU average. Also the private insurance is far above the percentage of most of the other European countries (14% vs. 4%). Overall, the government is paying more for the Healthcare system compared to the EU average. The rather low percentage of private out-of-pocket financing is significant, this percentage is really low (only 7%). The Healthcare system is based on social insurance, the general practitioner`s role is financially empowered, the doctors are paid on a fee-for-service basis. The accessibility of doctors and treatments is intermediary.

Survey Results

The rather low corruption perception in the Healthcare sector is based on the rather few cases of unethical practices in the authorisation and procurement of pharmaceuticals, according to the survey respondents. The close relationship between the pharmaceutical industry and the physicians is seen as the biggest Compliance risk factor. Bribery and kickbacks, especially to decision making bodies, like hospital pharmacists, have been mentioned during the interviews. Activities infringing competition law are also observed, e.g. price arrangements between pharmaceutical companies. The overall lobbying power of the pharmaceutical and biotechnology industry is very high in France, having impact on important political decisions for the Health sector. Main Health authorities and administrative institutions are very often infiltrated of people linked to the industry sector.

3.2.6 Germany

General Characteristics of the Healthcare System

Also Germany has a Statutory Health Insurance System (SHI), covering a wide range of Healthcare services. More than 200 public insurance funds do exist, including almost the entire population (mandatory). For people whose salary exceeds a certain amount, the possibility to switch into a private Health insurance is possible. Also self-employed people and civil servants have to take private Health insurance. The German Healthcare system is financed through insurance premiums, tax subsidies, and other insurance contributions. The private sector is funded with out-of-pocket payments and private Health insurance, which are based on the individual risk profile. Public insurances are based solely on the income. The Federal Ministry of Health is taking care of legislative framework and supervision. The Land governments are taking care of the hospital infrastructure and the public health. The most important corporate body is the Federal Joint Committee (G-BA), formed by the umbrella organisations for doctors, dentists, hospitals, and SHI funds. They have regulatory power, like quality assurance of hospital treatment and regulation of pharmaceuticals (but not the market authorisation).

The hospital and the ambulatory care systems are separated, ambulatory Healthcare is provided by private for-profit companies/institutions, the patient is generally referred to the ambulatory by the family doctor (financially encouraged best practice). The German Healthcare system is cost-intense, total expenditures of 11.6% of the GDP are above the EU average. Private insurance finances a good part of the total health spending. The system is based on social insurance, gatekeeping by a general practitioner is financially encouraged. German doctors are paid on a fee-for-service basis or on capitation. The overall quality in terms of access is very good, the patient is treated without long waiting periods.

Survey Results

The general outcome of the survey says that the perceived corruption is very low in Germany, highlighting the procurement of medical equipment with its high transparency and lack of corruption. The highest risk for corruptive activities are seen in the close interactions between the pharmaceutical companies and the prescribing doctors.

Promotional activities are often including banned gifts (personal benefit), trainings and congresses (in fancy locations) and other economic benefits to influence the doctors.

3.2.7 Hungary

General Characteristics of the Healthcare System

Hungary`s Health insurance is mandatory, voluntary insurance is playing only a minor role. The expenditures are paid by a combination of insurance contributions and transfers of general tax revenues, the Tax Office is collecting the money. The money is collected in the Health insurance fund, the National Assembly sets the annual contribution rates. The central Hungarian government decides upon further steps, like contracting. The main regulatory body in the Healthcare system in the central government, who is directly controlling the National Health Insurance Fund Administration (NHIFA). Local government is owning the Healthcare facilities, the State Secretariat of Health operates the state hospitals. The municipalities are responsible for primary Healthcare. Unfortunately the gatekeeping function of primary care doctors has not been very successful so far in Hungary. Doctors are either employed at a hospital or they work as private entrepreneurs contracted by the NHIFA. The private out-of-pocket financing of the Healthcare systems is higher than the EU average (26%), whereas the total expenditures constitute 7.8% of the Hungarian GDP.

Survey Results

According to the Eurobarometer, the corruption perception in the Hungarian Healthcare sector is high, there are severe issues in the medical service delivery and the procurement of medical equipment and pharmaceuticals. Interviewees mentioned the use of intermediary companies as corruption technique, to profit on a fee-for-service basis both from the hospitals and the company selling its product. False tenders with specific requirements result in preferred suppliers “winning” the bid. The intermediary companies transfer the money to political parties via fictive invoices for fictive services.

Informal payments are not perceived as corruption as they are not explicitly forbidden by regulations. All respondents mentioned this common practice. The amount and numbers of informal payments did not change at all after the end of the former socialist

regime. It is still very common practice in hospitals, but also when the patient is visiting the doctor. The current political situation (absolute majority, two-thirds, weak or no opposition) is hindering the independence of institutions, including the judiciary, media, audit office, and also public prosecution.

3.2.8 The Netherlands

General Characteristics of the Healthcare System

Since 2006 the mandatory basic Health insurance provides coverage for basic services, but there is also a mandatory private insurance scheme as well. Citizens are free to choose between different insurance companies, which are not allowed to deny applicants. There is a risk-adjustment scheme for the insurance companies to compensate based on the risk profile of their insured population. All insured people older than eighteen contributed through employer (income dependent). The Dutch are also paying an individual flat-rate premium. For long-term treatments there exists a separate mandatory scheme, financed through income-dependent contributions. A third complementary financing scheme is also in place but it is voluntarily. In the highly regulated Dutch Healthcare system the Ministry of Health, Welfare and Sports is responsible for the availability and the determination of the basic benefit package, but the price is negotiated between insurers and the Healthcare providers. There is a separate, independent control function, the Netherlands Health Care Authority, who is responsible for supervising the insurance companies. Primary care is usually private, general practitioners have a gatekeeping function and are paid through a combination between capitation and fee-for-service. Secondary care is provided by hospitals. 30% of the doctors are working for hospitals, whereas the remaining 70% are self-employed. In general, patients can select their service provider, however, there are maybe some restrictions set by the insurers.

The overall cost for the Dutch Healthcare system is 12% of the GDP, which is above the EU average. Both the public expenditure and the contribution of the private insurance as percentage of the total spending is higher than in other EU Member States. But also the quality of the overall Healthcare service is higher, so it seems that it is worth the money. The Dutch people enjoy fast access to doctors and important surgeries, and cancer therapies.

Survey Results

The Dutch Healthcare system is not very much prone to corruption. The Netherlands are one of the European countries with the lowest corruption perception in the EU. Survey respondents identified some integrity violations, like inducement or conflicts of interest. Improper interactions between industry and Healthcare professionals are identified as main reason, but no real severe corruption cases are reported.

Nevertheless some physicians are abusing the system by so-called up-coding, where many codes are summed up to maximize the doctor`s income. Exaggeration of Health conditions to increase the payments have been observed, resulting in too high claims, which are under closer evaluation now. Counterfeit drugs and off-label use of medical products are also serious problems in the Netherlands. But this holds also for the other six examples.

3.3 Key Healthcare Compliance Risks in Europe

3.3.1 Informal Payments in Medical Service Delivery

Most interviewees mentioned pure greed as the main risk for corruption. If a human being holds a powerful position it is often just the possibility that makes one think: “Oh, what if I take a little more, nobody will find out…” In many Healthcare systems in Europe the physicians are working in public hospitals and run also their own private practice, which makes it possible to steer patients towards private Healthcare services. The patient may receive oversupply of unnecessary treatments, caused by an information gap and a lack in transparency. In the European countries with low salaries, like Croatia, many doctors feel that they deserve this extra money, so also economic factors do have an influence. In Hungary, even the Ethical Codex of the Hungarian Medical Chamber states the acceptance of informal payments to doctors, because of the current bad shape and dysfunction of the country`s Health system.

The general attitudes and the local social value system is different between the European Member States, this is both for the offering pharmaceutical companies and the medical staff, therefore having rather low resistance towards corruption. This is especially true for Germany, where the main causes for corruption derive from an attitude to gain

personal benefit. The players of the German Healthcare system want to get a share for themselves, also personal prestige among their peer group seems to be a motivator.

3.3.2 Certification and Procurement of Medical Equipment

A lack in control measurements is often seen, leading to an easy to influence reimbursement system, where suppliers put pressure on parties to receive certain treatments requiring specific equipment to be covered by the insurance bodies. Healthcare professionals also see the high marketing budgets as a risk per se. There is an inverse relationship between the product quality and the pressure from sales, dependent on the margin (the higher the margin, the greater the intensity of the marketing activities and expenses). In countries like Croatia the large administrative burden can be seen as cause for corruption. Control and audit mechanisms are insufficient due to a lack of capacity for inspections and external controls. Sometimes the monitoring and inspection staff are not well trained. Governments who are implementing a central procurement system and nationalising all hospitals, like Hungary, are increasing the lack of transparency even further.

3.3.3 Authorisation and Procurement of Pharmaceuticals

In general the treatment with pharmaceuticals is well regulated, especially in Austria. But the survey showed that some pharmaceutical companies are increasing their pressure being listed on the reimbursement lists of the national Health insurance agency. There are several techniques in indirect lobbying, in Austria for instance the media can be used as tool for creatively exercising influence. Political backing and active involvement of politicians create a relatively risk free environment in countries like the Czech Republic. In Hungary, all media is even controlled/owned by the state, therefore the knowledge about the corruption activities in the country are not investigated further. Also here, the enormous marketing budgets may lead to improper interactions with Healthcare professionals, e.g. bribes, presents, holiday trips. Doctors are influenced to change their prescribing habits, a certain over-prescription and a general over-medicalization of the population is highly possible. It has to be made clear by strict regulations that corruption is a crime (still a grey legal area in Hungary).

In Croatia the regulatory framework is probably too strict, the inflexibility is increasing the corruptive practices. In France, the authorisation and procurement of medicinal products is related to corruptive risks, because severe conflicts of interests are hindering fast decision making. Consequentially there are human losses and health damages for individuals. If decisions are taken, there is a lack of control bodies regarding effective application and/or sanctioning mechanisms. The root cause for this weakness is a general lack in transparency in the decision-making processes in the French Health sector, the strong lobbying of the pharmaceutical companies, and the fact that whistle-blowers are not protected well enough.

3.3.4 Pharmaceuticals and Medical Devices

Manufacturers want to take advantages of unfair competition (higher margins, higher market share, etc.) due to corruption. Not fully examined new medicinal products of less quality are pushed on reimbursement lists only for quick commercial success. The lack of reliable and independent control mechanism allow corruption to take place. But this goes both ways: there is a lack of moral values of those who are involved in the business of pharmaceuticals and medical devices. Lack of police and judicial independence (like in Hungary) leads to a lot of activities never being punished, therefore encouraging more corrupt activities. The high economic power of suppliers and companies give them the capacity to even enforce decisions such as allocation of resources of governments.

3.4 Suggestions

All of the survey respondents notice a change in attitudes towards corruption in their countries, compared to rather high levels of tolerance some twenty years ago. As main reasons for this the interviewees mention growing awareness of consumers (patients) and the work of Non-Government-Organisations, doing a great job in communication the severe consequences of tolerated corruption on society. Establishing an industry environment unfavourable to corruption can be a first move from the governments. In Austria, the Criminal Law Reform of 2008, and the establishment of the Office for Prosecution for Corruption and the Federal Anti-Corruption Bureau are important

developments in this fight. On the legal side, higher penalties have a strong dissuading effect, public examples of convictions serve as warning sign to lower levels.

Changes in the procurement of pharmaceuticals should be made, it has been shown that centralised procurement led to high pressure on prices of pharmaceuticals, decreasing the incentive of companies to invest in their sales force. Therefore the number of improper inducements and sponsorships have decreased, and the companies re-direct their efforts towards R&D. Self-regulation of the pharmaceutical industry by ethics policies are currently not regarded as helpful by the public. These policies are seen as made for the purpose of public relations only, whereas organisation of self-regulation functions quite well in the medical sector. For example, in Germany, invoices from doctors undergo a plausibility check by the doctors` associations and by the Health insurance companies. The German insurance companies are legally obliged to have a specialized operational unit dealing with (potential) cased of fraud.

Increasing transparency in the management of medical treatments can also be introduced by the hospitals, which is working very well in Vienna since 2008/2009. Also Croatia had this measure in its Action Plan Anti-Corruption Strategy in 2012. The country introduced a national waiting list which is publicly available, and eBooking. The supervision of the contract execution and the spending of funds from the Statutory Medical Insurance is another way to ensure oversight and control.

The area of governments` and insurers` expenses on pharmaceuticals is recently under restructuring in many countries. In the German Healthcare sector it has become one of the most transparent. In Germany it is possible to retrieve data on the marketing, usage and medicines that individual doctors prescribe, limiting the informative and financial power of pharmaceutical companies remarkably. The doctors can rely on an objective information resource and are reacting very positive on the feedback they receive for instance on the price and efficiency of a medicinal product.

The authorisation of pharmaceuticals can be improve by empowering the decision-making agency and its employees. Double-checking and splitting the tasks is a good move, employees of the agency should not have any conflicts of interest (no links to clients). Inspections are performed with at least two persons, comparable salaries in the agency reduce also the risk of corruption. The interviewees also suggest to increase the

independence and efficiency of police and prosecution, also against even prominent members of the establishment.

Most of the European Healthcare system are spending too much money, therefore the governments working on Healthcare reforms. One feature of the Czech reforms introduced a mandatory payment to doctors and hospitals as co-funding by the patients. Although these are tiny payments, the patient feels that he can influence the treatment and that wiped out also informal payments, since people now feel that they already paying the right doctor.

Standard pricing of pharmaceuticals is important to be transparent. There are many different processes for price setting in the Member States, the Czech Republic has an innovative mechanism, first evaluating the benefits of the new medicine, before placing it into categories (with a standard price each). Innovative products are often difficult to categorise, they are assessed on a more individual basis. The best step is the final publication of the findings, allowing public consultation and open debates. This introduces flexibility to the pricing system, to adapt to new market situations and breakthrough innovations. Besides it prevents the over-pricing of medicines and prevents corruption. The setting of incentives is also seen as crucial point to prevent corruption. Hospitals should focus on improving the efficiency of their facility in order to provide better treatment and healthier financial results. Medical institutions are reimbursed per category of ailment, each treatment of the category has been given a standard price. If the procedure can be performed in a more efficient manner, the medical institution can retain a larger margin of the fee.

Several interviewees state that control mechanisms (like auditors and financial inspection) does not work well in every European country, especially in the Czech Republic. The European Commission and European Court of Auditors have addressed this issue by freezing all transfers of structural funds. This led to a reform of the old structures. The lesser money due to the on-going economic crisis in Europe has also made corruption more visible and therefore helps to stop these activities. Corruption is a very complex problem with numerous players involved. Partnerships with internationally operating organisations like the Central Corruption Prevention Department help local institutions in the area of information exchange, operational documentation and training.

One clever move against informal payments can be the formalising of payments, basically mimicking the informal payments but in a transparent and legal way. The Czech Republic tried so in allowing for a transfer of a selected doctor, funded by formalised payments. This initiative did not succeed, there was only limited incentive for the doctors to participate since the fees were to be shared with the hospital as well as taxed, so the remaining amount was only one fifth of the previous informal payment.

Influence by the government as regulatory body can also negatively impact the interactions of the stakeholders. Like in Austria, a number of Czech insurers finish their financial year with a positive balance, while others end up with a loss. Insurers are private not-for-profit organisations, having contingency reserve funds. Health insurance is mandatory and therefore all payments constitute public money. The Czech ministry of Health intervened and the profits of the successful insurers were redistributed to the non-performing ones. So, this disincentive for efficiency and profit making resulted in the insurers adapting to this change and the next reporting period no insurer was making profit anymore. This is definitely an opportunity lost, because a price competition between the insurers would have been a benefit for all citizens.

In those European countries where there is insufficient protection for whistle blower, legislative initiatives are implemented or recommended. Individuals who help in discovering criminal pacts need to be bolster in a legal framework encouraging them to support the police. In France a new type of offence within the French Commercial Code has been created, which makes it no longer necessary to actually prove the existence of a criminal conspiracy preceding the offence. In the Healthcare industry, France enacted a new law in 2011, which requires a declaration of interest to be published by independent Healthcare experts. This act should further guarantee the independence (no conflict of interest) of public authorities who are responsible for the assessment of pharmaceutical products. In the Netherlands all relationships between Healthcare professionals and the industry must be made transparent since 2012. This code requires a declaration of interest to prevent improper influencing in the generation of scientific opinion reports and clinical treatment guidelines. On the other side, Healthcare companies must disclose all transfers of value they have with Healthcare professionals and independent experts. The general tendency of the creation of publicly available information like lists of experts employed by

regulatory agencies is a good move to decrease the effect of conflicts of interest and generate a sense of awareness also among the society.

The interactions between public officials and the industry are weakly regulated in many Member States. There is considered to be a lack of transparency regarding the work between Members of Parliaments and lobbyists. A precise Code of Conduct regulating political lobbying is highly recommended. Public Officials are being rewarded with benefits, which must be earned with correct behaviours.

For countries like Hungary the current political situation is hindering the fight against corruption. The recent implementation of an anti-corruption policy, which followed international recommendations, may not reduce the high risk of missing of independent controlling mechanisms. Compliance experts involved in the survey see the risk that the new regulations will not be implemented fully and correctly.

All EFPIA members will implement an important transparency initiative in 2016, making the numbers of the transfers of value between the industry and the doctors and Healthcare institutions available for everybody with internet access. The Netherlands have already implemented this regulation. The Dutch Transparency Register Healthcare is online since April 2013. This database facilitates financial disclosure, specifying how much money a Healthcare professionals receives from which company and for what kind of service. The Dutch Transparency Register is financially supported by a government organisation and has an independent secretary. This is seen as a much better solution than for example the Austrian way, which requires every pharmaceutical company to publish and maintain the data on the company`s own webpage.

4. Leveraging the Healthcare Compliance Function`s Potential

The survey of Healthcare Compliance professionals shows that stronger pressure from regulators and legal enforcement are leading to improved Compliance standards in most countries – and consequentially in most pharmaceutical companies working in this environment. But it is also obvious that there is a dangerous gap between the perceived effectiveness of a Compliance program and the reality in the companies. Programs driven from the companies` head offices are focused on policies and training. Understanding of corruption risk at an operational level – with due diligence, monitoring and auditing – is not performed effectively, and if performed not early enough.

International laws and Compliance programs are deterrents, and rather defensive measures. This counter argument is often used to label the Compliance departments as "Nay Sayer`s", but this is a misinterpretation on both sides. The new objective to change this attitude is identifying a way to use Compliance programs as strategic tools to provide intelligence to executives in managing risk. They are learning to navigate difficult markets and new demands from existing markets more adroitly. Corruption is mainly a human risk and therefore asks for human solutions, backed by a technical and procedural Compliance architecture that reflects real risks of the collaborative working relationships. If Compliance is a cultural norm in a company and seen as everybody`s responsibility, early warning indicators (derived from e.g. monitoring) can pick up problems early enough to be able to implement improvements.

4.1 Exploring Strategic Risk

In former times, most pharmaceutical companies were very much focused on quantifiable risks and had the tendency to measure business risks for reporting them as part of the enterprise risk management. With all the data derived through auditing, monitoring and the output of Healthcare Compliance decisions, it is possible to consciously expand from a pure quantification approach to a more qualitative approach. The pharmaceutical industry is holding plenty of soft data for issues like regulation and policy shaping, communication outwards or reputation activities.

A closed-loop interaction with the business for collecting information from the customer and the external environment on the one hand, and a Healthcare Compliance department who proofs to be an enabler and value-adding function on the other hand are the two sides of the new coin (Chesbrough, 2003). For this purpose, the Compliance function must be integrated early enough in business strategy planning activities. This allows the evolution into a more consultative and advisory role right from the beginning.

The survey results show that one big risk area for companies in the Healthcare segment is the loss of reputation, in Europe mainly through unethical marketing practices and the overpricing of medicines. The increased trend towards transparency makes reputation risk a high priority. Future successful business strategies must integrate the environmental changes, like new communication models and a new way of interacting with the customers, both the physicians and the insurers. An accurate anticipation of the future trends can be seen through the feedback received from the control functions. With the knowledge from internal processes and the information from the external environment, smart companies should be able to adapt their business strategies into a more proactive version. A Deloitte survey from 2013 pointed out that especially for the Healthcare and life sciences sector in Europe, companies see the potential for disruptive business models (due to the upcoming demographic and economic changes).

4.2 Sources of Innovation and Profitability

Emerging technology enablers and disrupters are prompting many enterprises to re-think their strategy, and the Healthcare Compliance can be on the front of the implementation of many of these. Social media, big data and higher interconnectivity between stakeholders are risk areas because of the important aspect of data privacy in Europe. Especially for pharmaceutical companies, it is key to learn how to thoughtfully handle personal data. The Compliance function holds the skills to evaluate the benefit-risk balance for the company, for example collaborations between the company, patients and government institutions. Usually European governments are reluctant in implementation new technologies. Companies who seek out and proactively provide innovative solutions for the improvement of the current issues of the Healthcare sector will have a strategic advantage. It is likely that in the near future reimbursement negotiations will change to a

more holistic approach. If the companies are able to deliver more services than just the new medicine, they will have a higher chance for success.

Mobile Health is expected to be one valuable new partner in the shift towards a more patient-centric, value-based delivery model. The potential to further improve efficiencies, increase patient safety, better coordinate care, and facilitate payments is the driver behind this trend. Care and monitoring of the health status that previously required a visit to the hospital can be managed remotely at home or work. To make this happen potential data privacy issues and the legal framework needs to be considered. The differentiation of the Healthcare stakeholders and the adjacent responsibilities require new structures regarding final treatment decisions. Through exponential increases in data, computing power, connectivity, miniaturization of hardware and advanced software capabilities at lower costs, Artificial Intelligence will rapidly accelerate the development of next-generation medical devices. New ways to the patient and the doctor will be detected and could cause serious disruption in the delivery of Healthcare services in the future.

New diagnostic devices that enable early detection of illness and quick diagnosis could proof to be impactful. There are already medicinal products on the market which use optical sensors and non-invasive devices to measure key physiological metrics. Non-traditional players are entering the market, increasing competition and offering new consumer-facing technologies like the pulse-reading devices and software designed to log activity and health data. Strategically clever collaborations and partnerships might be an add-on for existing medicines and a motivation for the population to take care and responsibility for their health status. The preventive part of the Healthcare systems in Europe is becoming more interesting to the governments. Being more proactive in this business area could be a clear advantage in the reimbursement negotiations with the payers of the Healthcare systems.

Managing chronic diseases such as diabetes, cancer or depression may as well profit from the new experience in personal care. Applications that remind people to take medications or help them tracking important health parameters can work more smoothly together and transmit patients` data to doctors' records. In this process of separating good ideas from unpromising ones, companies which have internal complementary assets to support a smart strategy and selection will have an advantages in negotiations with the governments. Compiling, accessing, sharing, and applying big data and analytics can drive

more efficient and robust business and clinical decision-making. Increased transparency, for example, providers leveraging vast amounts of patient data gathered from a variety of sources to determine the clinical value of specific treatments could be a first step to make them better. In addition (and under way in Austria) medical institutions and other care providers can share/access patients' medical records to help eliminate unnecessary testing and/or medication, the basic idea of the electronic Health Record for patients in Austria. Sharing information to the benefit of all is a two-sided medal and the concerns of all stakeholders must be considered. Also in this risk area the Healthcare Compliance function may add value to balance the needs of the patients with the new possibilities that technology offers.

Despite the promise of new science and technology innovations, challenges exist to widespread adoption. Technology advances can be too expensive for public Healthcare systems already struggling to fund basic services. The money needs to be spent with care, potential conflicts of interest must be discussed and solved. Physicians indicate that a lack of interoperability is a barrier to adoption, so setting the industry standard is a highly attractive objective for any pharmaceutical company to compete in the changing market. While patients are comfortable with the idea of using technology in new and different ways and are interested in using e.g. Mobile Health in the future, safeguarding information security and data privacy is likely to become more challenging in an increasingly connected European Healthcare environment. There are several stakeholders involved, it is very likely that there are uncovered conflicts of interest, which need to be discussed and clarified. During the discussion of ELGA, for example, the doctors are faced with the conflict between their public duty (to provide adequate treatment) and their private interest, as their decision are transparent to other doctors or stakeholders.

Economic stagnation has seriously hampered the ability of Member States to invest in innovative new treatments and in world-leading research. Innovative therapies, such as Personalized Medicine, might play an important role in facing these challenges and help in addressing the Healthcare systems` needs. In the future we should be able to identify underlying molecular diseases mechanisms more precisely and treat a specific disease based on its molecular mechanism rather than symptoms. However, the value of the Personalized Medicine depends largely on the external environment. Healthcare

Compliance can add value by supporting the regulatory and market access structure to encourage the further development.

Compliance and the industry can be a partner for policy makers in developing a more sustainable and predictable medicines expenditures, for example with stability agreements like in Portugal or Romania. Pharmaceutical companies e.g. could improve their strategic risk management by increasing the frequency and budget for monitoring and managing strategic risks, being closer to the daily business and therefore being able identify risks. Together with the EFPIA`s initiative, e.g. the recent transparency initiative, public will know more about actual expenditures. Data derived from independent institutions can help to lift the burden on Healthcare. Increased and compliant patient empowerment and involvement (a better preventive Healthcare) will save costs and can be that complementary asset provided by Compliance to add value and increasing the Health outcome per cost. For example, better decision support systems, co-developed with government, institutions are a first step.

4.3 Financial Sustainability in European Healthcare Systems

If European countries do not make important efficiency gains in the running of their Healthcare systems, the EU`s Healthcare expenditure could increase by one third in 2060 according to estimations of the European Commission. Every pharmaceutical company able to offer additional new technologies of delivering and organising the provision of Healthcare will have a strategic advantage. The Healthcare Compliance function is capable in adding creative value to the portfolio, by applying analytic skills (vendor due diligence, ranking the key risk areas, etc.). A promising avenue to explore is to find a better balance between the company`s investment in hospital care, primary care or care outside of Health settings. A more patient-centric approach results in different business risks, as patients are consumers, but their financial power is maybe limited. E-Healthcare, respecting the Compliance and data privacy requirements, can help reorganize care delivery with tools to enhance prevention, diagnosis, treatment and management of Health. In an aging population it is important to keep the patient as much as possible away from passive consumption on Healthcare. Emphasizing the patient`s responsibility for his Health status should be a central strategic element also for pharmaceutical companies. This may be a

paradigm change for some, but the gain in reputation cannot be underestimated. Compliance professionals are prone to guide their business colleagues along the new ways to the customer.

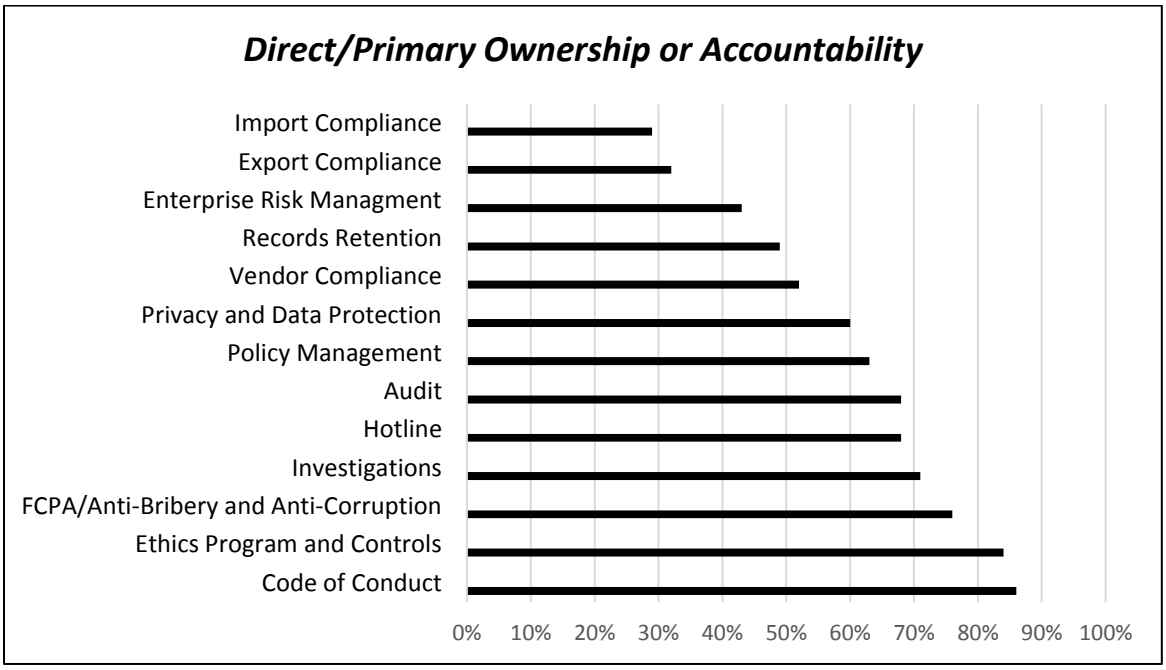
The EFPIA transparency initiative, implemented by the Compliance professionals, will soon shed light on the honoraria that Healthcare professionals receive from companies for providing presentations at meetings, or being invited to congresses. The comparability of the data may induce a general discussion on the amount and the quality received. It is expected that market clearance decreases the corruption. Existing conflicts of interest will be visible, public awareness will be increased, and companies may use the money for more sustainable investments.

Many European Member states are improving and enhancing hospitals and other medical facilities. Primary care centres are an option to ensure effective delivery of services close to the citizens` homes, with lowest level of complexity and cost. The pharmaceutical industry (and its Compliance functions) has a unique role to contribute to the return to economic growth in Europe. Innovative medicines are estimated to have contributed to a great extent in the past. Today, however, companies are facing pressure that risk mitigating the positive impact that innovative medicines can have on Healthcare outcomes. Innovative medicines have been targeted for cost containment. The added value that the Compliance function can provide is internalizing the external stakeholders` need, in the administration or the maintaining of treatments, and add this to the medicinal product. More integrated solutions, distributing the responsibilities in a new way among the patient, the payer and the supplier will ensure affordable European Healthcare systems.

4.4 Scope of Responsibility of Healthcare Compliance

Coming to a new understanding of Compliance obligations, where those obligations sit in the organization, is a key step in maturing the Compliance program.

Figure 2. Current Responsibility of the Healthcare Compliance Function.



Source: Bernstein, S., Falcione, A. (2015): Moving Beyond the Baseline, State of Compliance Survey, PwC.

Integrated Healthcare Compliance enables the function to add more value and innovative power to the organization. The current situation often limits the Compliance function to administrative tasks ("Compliance is handling Compliance in our company"), whereas a more mature approach could be the integration of the Compliance function as valuable partner in business development decisions.

The future biotech/pharmaceutical Chief Compliance Officer (CCO) will…

- Play an early role in market entry decisions, especially if with higher risk profiles. Using robust data analytics capability, CCO will advise on various subjects ranging from jurisdictional regulations, political risk from state-controlled systems, and traditions and customs which could be interpreted as risk for corruption.

- Be an important key advisor on the ramifications of various business model options, as well as business transformation risks, as companies struggle with the implications of Healthcare reforms and the needs of R&D productivity improvements.
- Provide insight for senior management on the effectiveness of the company`s Compliance program, as well as the status of risk throughout the pharmaceutical value chain. Insightful reporting also enables transparency and supports disclosure reporting requirements about transfers of value to Healthcare professionals.
- Be a strong business partner, helping guide an effective Compliance program with greater investments in data analysis while helping the commercial organisation examine how information on customers can be harvested in an ethical, compliant manner.

4.5 Collaboration – Innovating Processes via Partnerships

Today`s environment is in need of impulses for innovation, pharmaceutical companies find themselves facing more complex ethics and Compliance risks than ever before. The risk mitigation can be improved by adding oversight and overcoming the common view that regulations slow down development. In fact, innovation and Compliance are not mutually exclusive objectives for a company. In a time of increased scrutiny, global companies operating across the differentiated legal landscapes of Europe, a dedicated Compliance function can instead be an asset supporting strategic agendas. Studies have found that establishing a culture of integrity and fostering a clear public perception are linked to greater profitability. There is plenty of evidence that managers can be tempted to cross the line between the legal an illegal in pursuit of greater profitability (Jones and Hill, 2013). Avoiding reputation damage is a goal which should not be underestimated especially in times when media is so quick in spreading the word.

4.5.1 Establishing a Governance Structure

Governance mechanisms are mechanisms that principals put in place to align incentives between principals and agents and to monitor and control agents. Pharmaceutical companies need first to establish an internal Compliance culture and structure, before

seeking out for external partnerships. The establishment of an effective governance structure for Healthcare Compliance includes:

- Committed involvement of senior management in the program development
- Specifying and assigning the responsibilities and accountabilities
- Allocating budget, resources, and staff
- Assembling a Compliance Committee for advisory tasks, approvals, and assistance for the implementation of ongoing operations
- Establishing initial and baseline protocols for reporting monitoring and audit results to the board

The internal Compliance infrastructure lays the groundwork to move ahead and develop the Compliance function further.

4.5.2 Collaboration and Challenge

Within smoothly operating organizations, various business functions (internal stakeholders) should be hold accountable to exercise ownership over a related Compliance risks. For example, employment and labour risk is typically owned by human resources, manufacturing risk by engineering. The Healthcare Compliance function is moving into a role of a couch and internal advisor, coordinating activities, monitoring effectiveness of implemented control processes, and cover (such as ethics) that are not covered by other business functions.

Ideally, the Compliance function becomes the company`s internal promotor for collaboration and integration, connecting the dots, reducing knowledge gaps and redundancies. The Compliance function is absolutely key for information gathering from business changes, due to the frequent contact with all business units (especially with the customer facing employees). For businesses relying on growth through an IPO or M&A strategy, the Healthcare Compliance function can lead to the formation of structures and the implementation of processes that may be required or expected by investors, acquiring companies, and stock exchange listing rules. During times of major changes and disruption, Compliance can also help support and protect the company culture. Ultimately, a successful Compliance program brings the organization together around a process of proactive, streamlined risk management.

External effects must also be taking into account. In Europe, there are different stakeholders involved in decision making like, categorizing of medicines, pricing, and reimbursement. A clear trend towards stricter assessments of cost-effectiveness by the payers creates a sense of urgency for pharmaceutical companies to adapt for successful market access. Compliance can add the information needed to quickly adapt to changing policies, analysing the potential consequences for the business. The future payer networks in Europe will look differently. It is a core competence of Compliance to perform due diligence and identify and understand payer networks. In a cost-constrained Healthcare environment, successful companies need to define a strategy to clearly communicate the advantages of their products in terms of cost-effectiveness. Specialised teams (including Compliance) should engage with payers and provide the cost-effectiveness required to convince the reimbursement institutions. A compliant and successful market access is highly dependent on staff capable to navigate in the new infrastructure.

4.6 Operational Efficiency – Improving Internal Capabilities

Biotech and pharmaceutical companies tend to have strong technological capabilities, including patented products and functional competences, such as manufacturing abilities. In the light of cost saving, services added to products can be that add on the Healthcare system payers long for. Data on the internal processes of the company, derived during audits and monitoring can constitute a basic tool for assessing a firm`s competitive advantages, and further on in the development of a new business strategy.

Technology – in the form of big data analytics - is crucial to operations. Enforcement-driven transparency initiatives are driving significant energy and resources into global Compliance monitoring and auditing. The pharmaceutical companies need to come up with defined key performances indicators, who smoothly translate the audit results in processes changes. Gaps in the knowledge of the employee, or cross-country wide inefficient use of resources can be avoided with thorough analysis and actions as consequences.

The use of big data analytics is also on the rise in the commercial activities of the biotech and pharmaceuticals industry, with companies building large data basis about the customer interactions and include statistics to increase transparency. Healthcare

Compliance is able to ensure that these interactions consider data privacy laws and that concerned staff are properly trained when applying the new technology.

There are differences between the typical mobile(m)-health and big data approaches. In general, m-health projects are relatively democratized, having low entry barriers entry and capitalize on the individual mobile phones. Although the impact can be rapidly appreciable, the tangible rewards for the company are often very limited (Tomlinson et al, 2013). In contrast, the big data approach demands more technical skills, like specialized equipment, interoperability standards, coherent data collection, analysis systems and regulatory oversight. Beyond the technical aspects, the organizational culture of quality is important for an effective Health information system. Healthcare providers and system administrators in most countries have not been trained in data science. Compliance professionals can add value in acting as intermediary or facilitator to help integrate the useful information into the European Healthcare systems, for the good of all stakeholders.

The analysis of linked data sets from different sectors can provide new opportunities to improve health outcomes for the European populations by also to spur innovation. In the U.S., for example, Healthcare and city authorities decided to pool data to direct social and Healthcare. They created an integrated data system that allows for the coordination of efforts to increase the efficiency of emergency department services and the care of patients with diabetes. Geographically pooling census data, tax payments and lead concentrations detected in blood tests, it could be possible to use the integrated system to map and stratify risks for lead exposure. From the perspective of the industry sector, the segments which could profit the most from a specific treatment could be identified and the companies can develop a more customized product. Healthcare Compliance professionals should be included to ensure that all data privacy related risks are considered and solved to ensure patient safety.

The use of big data is particularly complex, but it offers the greatest potential rewards for the Healthcare systems. Beyond the technical aspects, an organizational culture of quality is one of the key drivers of an effective Health information system. The Compliance function can support good data collection by establishing European norms, oriented globally, because the collection of information from individuals is fraught with ethical, regulatory and technological issues. Anonymization of data must be robust, monitored and enforced, because the risk of accidental or intentional breach of data privacy laws may

be especially high in countries known for corruption problems. As the full potential of the big data approach to improve Healthcare becomes clearer, there is of course a right for the citizens to harvest all of the benefits. In the coming years, the cost of aggregating and coordination resources and services electronically will decrease, the big data approach may deliver large benefits.

4.7 Healthcare Compliance as Complementary Strategic Asset

Healthcare Compliance as strategic complementary asset is a prerequisite as a clear governance and decision-making framework is needed to inform each stakeholder in the Healthcare system of its accountability. Biotech and pharmaceutical companies should wisely use their influencing power to set the rules for the cooperation between the multiple stakeholders, e.g. universities, professional societies, government agencies, insurers and patients. Compliance issues often persist due to a lack of clear agreements on accountability and ways to solutions being not clear enough. In an emerging field such as big data, where protocols are still being developed, governance plays a major role in assuring stakeholders that there is a system in place for dealing and resolving issues. That is where I see the Compliance professionals in the senior management teams step in and serve as facilitator or moderator to move from a reactive to a proactive, norm-forming approach (Wyber et al., 2015).

Europe has moved from a period of relative economic stability into times with more economic volatility. Demographic and epidemiological trends that were far away on the distant horizon in the early 1980s have simultaneously begun to come into force. New communication technologies have empowered the individual patient into a more and more important stakeholder in the Healthcare systems of today. The patients can see and say more about the companies and institutions they deal with and the medicines they take, than at any previous time in history.

Developing a biotechnological drug or a new molecule takes a long time and involves high costs and substantial risks for the company. In the past, pharma`s business model circled around products for chronic diseases, and marketing them to doctors. The focus was on turning them into blockbusters. Today, it is concentrating on personalized medicines (highly specialized), marketing to the Healthcare payers – who use different,

and more rigorous selection criteria turning drug reimbursement to one of the crucial steps before product launch and profitability.

But despite the external shifts, the organisational culture at many pharmaceutical companies has changed very little. According to Heidrick and Struggles (2011) the industry`s declining scientific productivity is linked to cultural influences. A key organisational issue is a certain lack of creativity, and the missing coordination between R&D and Commercial functions. One possible reason is the fact that most senior executives have been trained on business in the old days, when the blockbuster model reigned supreme. Recruiting personnel from the existing culture is likely to happen, but hindering changes required. How can Healthcare Compliance play a strategic role in the reform of the status quo and the former business model?

4.7.1 Creating a More Innovative Culture

One can say that the exorbitant marketing budgets are a Compliance risk in itself, and this point of view is not completely wrong. It seems also strange that there has been such a shift to the marketing expenses, when in contrast the R&D expenditures had been somehow neglected during the blockbuster times. Although there are legal frameworks developed by the EC to foster the research, companies are still reluctant in doing more research with already marketed products. The new value-based and patient-centric business model offers new market opportunities, like hiring from a broader pool of talents. Integrating the Healthcare Compliance professionals in the strategic planning from the early beginning would add an important quality aspect. If used smart, the advisory role of the Compliance professional can act as coordination between the R&D and Commercial functions, facilitating the collaboration by providing input on the framework in which the company is operating. Limits can also be something to trigger innovation, also by meeting half-way. The integrative and explanatory function of Healthcare Compliance can add value to the product lifecycle and can speed up the decision processing once the senior management realized the synergies for the company.

4.7.2 Tone From the Top

Both employees and shareholders need to know where they stand, so it is crucial for the executives to set clear ground rules for the new business models. The switch from a rather dominant position that pharmaceutical companies once held, to a more collaborative approach is a tough lesson and the Healthcare Compliance function is a good sparring partner in this challenge. The senior management should harvest the knowledge by including Compliance in strategic decisions, by asking for tailor-made trainings making them capable in navigating the new regulatory landscape. Many European countries will reform (or have already started) their Healthcare system due to the cost constraints and the demographic shift (aging population). To ensure the quality of the Healthcare system for future generations, the efforts must include all stakeholders.

Reputational risks will increase in the coming years and companies with diverse management teams capable in owning Compliance and integrate the ethical perspective into their decision-making will have a competitive advantage. Setting the right tone from the top is critical to building trust and value with shareholders, employees, customers and business partners. Healthcare Compliance function can add value by constantly demanding ethical leadership from senior management. Today, leaders are articulating the ethical values and principles they want others to work by. If these are not regularly measured or evaluated (monitoring and auditing), they may be often undermined by the leadership teams' behaviours. Survey respondents said that, on occasions where tone from the top had been undermined it was due to leadership not acting as role models and their actions not matching the ethical message being communicated (Schein, 1996).

Healthcare Compliance should act as the key function effectively measuring and reporting on the ability of the organisation and employees to act with integrity, or whether leaders are just playing lip service to ethical behaviour. Especially biotech and pharmaceutical companies need to demonstrate adequate procedures to prevent bribery if they are not to be caught by, for instance, the UK Bribery Act. The Act has powers to hold senior management liable for abuses within their own businesses, sales channels or by their third parties and agents. Role modelling should never be underestimated and the Compliance function can support and coach the business leaders to demonstrate ethical leadership.

4.7.3 Lessen the Layers

Too much bureaucracy can be a burden for creativity and innovation, and big companies tend to be rather bureaucratic. Due to its analytical tasks, Healthcare Compliance can strengthen its efforts to streamline and standardize processes as much as possible to free the employees for the more challenging and innovative projects. Many companies already started to implement data systems for standard activities like event organization and clinical trials management. The new communication technologies offer even more opportunities. Process and bureaucracy aren't nice words and never desirable, but having processes, structures and clarity is an enabling tool rather than a tool of constraint. Healthcare Compliance must act as promotor of this perspective to be a change agent in the upcoming reforms of the European Healthcare systems. There are non-negotiable rules and regulations, e.g. implementing an electronic Health record system comes with solving all data privacy related issues, but there is always room where flexibility can be introduced. Sound evaluations are key for excellent company performance. Still many internal processes, controls, and business actions are inadequate and behind the actual needs in the Healthcare systems. Chaos is the main problem, not an excess of bureaucracy. As companies grow, and as the European Healthcare systems becoming more interactive, there is tremendous need for a function guiding the activities through muddy waters.

Hierarchies can clarify roles and encourage better performance. At worst, a too hierarchical structure may also hinder teams and stakeholders by building borders rather than bridges. Working successfully together always includes a certain element of de-powering experience, therefore a moderating and mediating function like the (independent) Compliance professional might be a nice option to approach for consultation. Soft law, or non-legislative modes of policy making, is becoming increasingly common in the European Healthcare system of today. The Nordic countries have a long tradition of soft law used to coordinate policies. A key question is that of the role of Compliance. Why should independent actors comply if they are not formally obliged to do so, and what happens if they do *not* comply? For example, in the case of the Healthcare reform in Sweden, a solution could be achieved during a policy conflict between stakeholders at different governing levels. An interesting observation is the fact that the presence of a hierarchical structure may play an important role even in soft law governance. Voluntary agreements between the companies and government authorities

was honored in the end by both parties, underlying the mediating actor effect of Compliance professionals in the negotiations. Also various forms of informal social pressures such as shaming, peer pressure and moral responsibility can help enforce Compliance in a case of open policy conflict. All these Compliance mechanisms have relevance outside the Nordic setting, too (Fredriksson et al., 2012).

4.7.4 Tighter Focus on Third Parties and Collaborations

In today's globalized Healthcare world, the average company has numerous third-party relationships - be it with a supplier, a distributor, a government institution, a doctor, or even a patient. Third parties help the company grow its business by opening up new areas of collaboration. Yet, they also bring along new risks - including IT security risks, safety risks, anti-corruption risks, environmental risks, operational risks, regulatory Compliance risks, and quality risks. Some of these risks are usually assessed and analyzed by service providers during the acquisition to determine whether or not the business relationship is a good move. Doing business with someone they can trust is an important factor, and does of course have an impact on the price negotiations. But after the acquisition third-party risk management and due diligence usually takes a backseat. This approach has serious drawbacks. Third-party risks which are not identified and mitigated in time can fall back on the company`s reputation and lead to serious issues which affect profitability. It doesn't matter if the issue is caused by the third party. Ultimately, the company who acquired the third party is held responsible by regulators and customers for not doing enough and reacting promptly enough to uncover and address the issue appropriately. That is a bit of a dilemma for companies. On the one hand, they need to expand their market and stay competitive which involves, to some extent, increasing their third-party network. On the other hand, if they happen to do business with a non-compliant third party, they could get drawn into trouble.

Regulators have become much more alert and strict in their oversight of third party risks. A spate of regulations such as the Foreign Corrupt Practices Act (FCPA), the UK Bribery Act, the EFPIA Transparency initiative and so on have increased the pressure on pharmaceutical companies to enhance third-party due diligence. They need to effectively evaluate third-party risks, monitor business processes, conduct due diligence

assessments, and identify potential gaps that could create new risks or Compliance violations, and proactively address and remediate issues that arise.

Healthcare Compliance is becoming increasingly important in this field. Whenever the company is defining or adapting its` business model or the strategy the Compliance functions should have a seat at the table. Once the third parties have been assessed and the benefit-risk is determined, it supports the senior management enormously in e.g. judging the offer and being able to come to educated decisions. Also the development of exit strategies should include representatives from the Compliance function.

The joint work of business and Compliance function on lobbying strategies is another field for adding value to the Healthcare sector. The European regulatory framework should encourage companies to innovate and grow. Tighter resources lead to a more careful assessment if the investment is allocated to the most promising research fields. The European market needs to stay competitive in the research sector, innovations can be triggered by careful set long-term goals. High quality of the European Healthcare systems can be ensured by an objective view on results, the open-access to clinical trials results as well as transparency in the transfer of values between the stakeholders. We could, for example, re-work provisional decisions that would make it possible to bring the medicinal product faster to the market but without sacrificing quality for patients. The level of reimbursement for the drug could also evolve throughout its` lifecycle, in line with the observed medical benefits and risks.

Healthcare reforms are encouraging this diversification. Payers and Healthcare providers are examining the benefits and drawbacks of participating in the new public and private insurance exchanges. Companies and payers attempt to estimate the outcome and develop strategies for growth and innovation in the new environment, strategic support from Compliance help them making informed decisions. When an organization appropriately leverages its enterprise governance risk of Compliance strategies, it can obtain a holistic view of the company`s risk profile. The management board has to prioritize but this is where a company`s Compliance resource can be the most valuable.

4.7.5 Internal Sources of Innovation

Investigations, audit, and monitoring serve as a powerful tools to ensure that business ethics and Compliance continue to improve the companies` performance. Many organizations simply do not incorporate the outcomes of monitoring activities into their ethics and Compliance management efforts. Without stringent and designed to fit techniques, processes are likely to fail or are out of date as external challenges antiquate a business process. The Open Compliance and Ethics Group`s (OCEG) "Red Book", a framework for ethics and Compliance management, emphasizes the importance of regular review of an organization`s external and internal changes that may impact a business process, in addition to review of a process`s activities to ensure Compliance with its objectives.

Because of the confusion between monitoring and auditing, it is helpful to distinguish between the two. Monitoring occurs within the activity's operational structure and closer to the underlying activity's occurrence. It may be conducted by operational management or involve an expert outside of the operational line where the expertise does not exist within the management structure. Auditing generally describes activities that are conducted by parties more independent of the respective operational management. While auditing may occur long after the activity took place and to allow for the problem to be corrected, auditing may do better at ensuring that operational management effectively manages the business activity. Monitoring allows for earlier identification and correction before a problem becomes systemic, leading to more severe damage for the company. The outcome of internal assessments like monitoring must be more than identifying actual of potential non-Compliance. It must lead to management taking actions that correct and prevent the business risks. It may also include identifying changes to the underlying process or external environment that may require adaption of the business activity.

Given all of this information, the Compliance function should be reporting and presenting the results in a way that senior management can best implement steps to mitigate the business risks. For example, a new process may be best served by very basic but active monitoring in the early stages to ensure that the crucial process steps are followed and to spot variations. Next to the existence of a controlled process itself, monitoring is perhaps the best tool to ensure that an activity meets its ethic goals. It is

wise to use monitoring to a process's strategic advantage and to constantly adapt the control steps to a changing environment. It an important responsibility of the Compliance professional to ensure that internal control measurements remain dynamic to the process itself as well as in terms of the external framework the company is operating in, to get the greatest value from it.

4.7.6 Using the Right Measures and Rewards

Many biotechnology and pharmaceutical companies might be measuring and rewarding the wrong things. For example, they use purely financial criteria to measure innovation. They reward scientists for developing new molecules to the point immediately prior to testing in humans – which encourages researchers to push unviable compounds further down the pipeline. Sometimes they promote their best scientists to management positions, although scientific capabilities are no guarantee of managerial excellence. It is better to rely on a measurement system that combines financial and non-financial metrics (motivation and commitment). Flexibility is also key to be able to measure different kinds of innovation, for example, scientists should be incentivized if a molecule reaches proof of concept. This would encourage them to focus more on developing compounds with a real chance of success in the clinic, and, probably equally important, it strengthens the collaborations between R and D.

It is also important to promote a new failure culture, providing incentives for terminating weak drug candidates or marketing ideas as quick as possible. Punishing failure socially or economically discourages risk-taking and kills creativity. Many pharmaceutical companies have inspiring corporate vision statements, clear corporate policies, lengthy Codes of Conduct, business conduct lines and numerous trainings and communication around ethics. If companies are serious about ethics and Compliance, they must have a real commitment from the senior management on the subject of Healthcare Compliance. But they also need to define ethical behaviour in the corporate context and develop a strategy to reward the desired behaviour.

Healthcare Compliance can add value to the Human Resource function, helping them in designing incentive programs the way that employee`s objectives include behavioural

expectations. Companies, especially in the Healthcare sector, should push toward a performance culture, embed in the corporate strategy. Both results and behaviours should be part of the performance measurements, and employees should be hold accountable for meeting these expectations. It must be ensured that payment, especially for executives, is comparable from a competitive perspective. Compliance can test the reasonableness and present to senior management for making informed decisions. Senior management should be reminded about their important role in demonstrating high ethical standards. Employees still need to understand what ethical behaviour looks like and they need to see their managers modelling this behaviour every day.

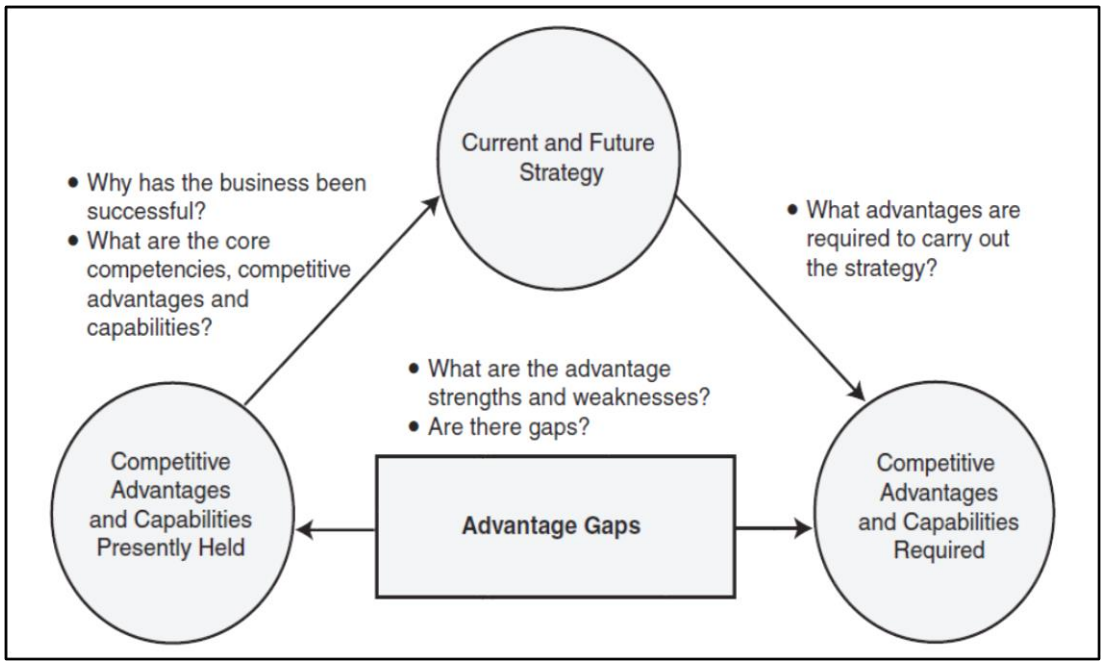
4.8 Healthcare Compliance – Strategy of the Future

Strategy has been defined as the match an organization makes between its internal resources and skills, and the opportunities and risks created by its external environment. According to Porter, strategy is, "first, an organizing process involving both formulation and implementation". Whereas the Compliance function is delivering operational excellence it should be integrated in the more dynamic parts of strategic management. Companies are missing out if they are not fully implementing the ethical and sustainable decisions they make. Second, strategic management involves constraints and considerations that have its` origins both inside and outside the company. Senior management must be clear in setting objectives and consider the fact that every function can add value to the performance of the company. Third, "strategy is essentially an integrative exercise", it is about combining the underlying values of a company. Navigating the open questions and future challenges of the pharmaceutical sector through a range of complex, cross-disciplinary considerations will lead to innovative answers and a more profitable usage of resources.

A company`s culture alters only when the people who work in it change their thinking, talking, deciding, and acting – and that can be only the case if top management leads the way. The pharmaceutical industry in Europe is going through a time of substantial change. Any company that wants to transform well will have to concentrate on delivering more value, not charging high prices. The companies will have to enrich its products with additional services, and become an even more integrated part of the Healthcare systems. Leveraging the potentials of control functions, like Healthcare Compliance, can form

organizations with the courage to explore and make risky, but informed business decisions. Economic market disruptors such as cost constraints, evolving digital business, and demographic shifts increase the expectations towards Healthcare Compliance to take a more proactive role in front line processes. If Compliance aims to gain or maintain a key strategic role for senior management, it is important to ask the right questions during the process of strategy development. Instead of re-communicating the regulations the Healthcare compliance function should concentrate on elaborating on the "Why" and "How" aspects of the controls processes.

Table 4. Strategy Development.



Source: Highered.mheducation.com/Chapter3/Analysing Internal Strategic Resources and Capabilities.

Addressing the risk challenges of tomorrow, the European Healthcare sector should look outside traditional structures. For pharmaceutical companies, a new focus on gathering and analysing data and appreciating external perspectives, including customers, is required. The Healthcare Compliance function is able to add significant value to adapt the current business models, constituting a new complementary strategic asset (Jones and Hill, 2013). Identifying Compliance as an internal key resource is currently not that easy to see, because it is not so obvious on the financial balance sheets. The returns from transferring an existing assets into more productive employment can be substantial. If a

company`s assets are easily replicated (expiry of patent), then the company must invest in developing new sources of competitive advantage, Healthcare Compliance being a prominent candidate.

Table 5. Analysis – Healthcare Compliance Function.

Author`s own presentation.

The future Healthcare Compliance function in the Healthcare sector will play an early role in decisions about new markets, advising on jurisdictional regulations, and political risk from government controlled systems. New business models will require support to successfully react on the implications of the Healthcare reforms. Compliance will provide insight for senior management on the effectiveness of the company`s Compliance program and the status-quo of the business risks across the pharmaceutical value chain. Insightful and reflected reporting also enables transparency and supports the EFPIA disclosure reporting requirements about transfers of value within the Healthcare system. Compliance will develop into a strong and useful business partner, helping to guide an effective Compliance program, including data analysis, which at the same time supports the commercial department to examine how customer data can be used in an ethical,

compliant manner, identifying new and innovative ways to the customer, which ensures the sustainability of the European Healthcare systems for future generations.

5. Discussion and Future Prospect of Healthcare Compliance

The coming years will hold tremendous challenges for the European Healthcare system. The aging population, the increased connectivity of all involved stakeholders, and the possibilities that new technologies may offer will change the rules of the game. Although one wishes that everybody has access to the best available treatment option, the Member States can only provide this by carefully spending their budgets. Tighter regulations and more transparency is changing the landscape for government, patients, and the pharmaceutical industry. As the corruption survey of seven selected Member States pointed out, there are some differences between the countries, but the common outcome is that the best functioning systems are those with transparent money flows, adequate salaries, and independent decision making institutions. The European countries are different, in their political situation, their history, and their societal values. But the overarching common goal is the appropriate usage of budget to add value to the Healthcare systems keeping it affordable for future generation, for as many people as possible.

The pharmaceutical industry plays an important role, and this role will change due to the upcoming or already implemented Healthcare reforms. Compliance programs, implemented to ensure business ethics, are still grappling with serious corruption, because people are relying on the wrong measurements. The best companies – particularly those from countries with the toughest legislation – already realized that they are missing out on opportunities if not fully harvesting the potential of the Healthcare Compliance function. Turning Compliance programs into a complementary strategic asset provides intelligence to senior management in dealing with business risk. They are learning to navigate difficult markets more adroitly.

Companies operating in Europe should embed corruption risk into strategic planning by identifying the differences between the markets but also seeking for the common root cause for it (derived from audit and monitoring results). Looking beyond country-level generalities companies can evaluate the business risks and structuring their deals supported by the Compliance function. External due diligence and an even closer look at third parties (which will be often needed to add service to medicinal products) will be prerequisite to spur for innovation in Europe. Field force are an invaluable source of

information about the market. Compliance can facilitate the information flow between external and internal stakeholders to mediate the different needs and improve the quality of decisions.

Structuring the new business model around the customer and its` need is a first step in exploring new product types. That requires a shift from the specialty department and discrete service to organizing around the patient's medical condition. Today the legal framework is really complex and Healthcare Compliance add expertise in finding the right measures considering data privacy and safety. The opportunities for pharmaceutical companies are broad, but it requires the identification of new complementary assets to develop a new strategy. For example, services added to the medicines may offer a better quality of life for patients with chronic diseases, when they can be treated at home. Healthcare Compliance supports the safe delivery to the patient and the integrated services (Porter, 2013).

Current measures for quality and success in the Healthcare systems (especially regarding the criteria used by reimbursement institutions) will rapidly change. The key performance indicators internally must reflect the external environment. Compliance can be used as analysing function to ensure that the appropriate parameters are measured. The focus on pure volume based strategies will change to a value-based business model. Selling the medicinal products will much more rely on negotiations based on data showing the long-term cost effects and the value, that an innovation will add to the Healthcare system (like avoidance of follow-up visits, faster return to work of the patient, incentives for self-monitoring). It is no longer enough to submit data proofing additional two months of life expectancy but about the quality of the gained life. As patients becoming more involved in the decision making process, it is crucial to include the Compliance function early enough into projects like electronically supported patient care. Greater transparency enables better planning of resources. The EFPIA initiative on the transfer of values between pharmaceutical companies and Healthcare professionals may have the consequence to reshape the allocation of resources. As health care providers come under increasing pressure to lower costs and report outcomes, the existing systems are wholly inadequate (Kaplan et al., 2011).

The resources and capabilities of an organization are the key considerations in formulating its strategy. Understanding the relationships between resources, capabilities,

competitive advantage, and profitability is the way to sustainability (Grant, 2001). Healthcare Compliance, if integrated wisely into the strategy development, can help to improve informed decision making. Collaborations between the stakeholders must be evaluated from a Compliance perspective, concentrating on the most promising ones. Government and pharmaceutical companies should engage in new policy frameworks to reflect the needs of the European Healthcare systems. There are treatment plans more appropriate for specialized, bigger hospitals, but some or much care takes place at more-convenient (and cost-effective) locations. Satellites may deliver less complicated care, with complex cases referred to the specialists. If complications occur whose effective management is beyond the ability of the satellite facility, the patient's care is transferred to the hub. Collaboration and innovation includes of course a supporting information technology platform. Historically, health care IT systems have been separated by department, location, type of service, and type of data (for instance, images). ELGA is a positive Austrian example, Compliance and data privacy are prerequisites for implementation. Additional services to medicinal products like electronic devices for treatment tracking, can be a powerful innovative tool. Compliant IT system can enable measurement and new reimbursement approaches, and tie the parts of a well-structured delivery system together (Porter et al., 2013).

Healthcare Compliance as complementary strategic asset is based on the ability of senior management to understand and value this internal source of information as innovative culture is longing for critical minds that explore new ways to the patient (Chesbrough, 2013). The hinderer image of Compliance in the biotechnology and pharmaceutical industry can be changed into a function, which knows the right paths to quality. Most corruption issues derive from short-term thinking and pressure on employees to achieve inappropriate goals. Due to the restructuring of many big pharmaceutical companies, some hierarchies have been vanished, the layers are less now. An innovative culture can be established with the right tone from the top, role modelling the expected behaviours. The results and analysis show that corruption is also based on the setting of the wrong objectives. Independent decision making and a clear and defined scope of responsibility is important to improve the quality of the outcome. Physicians and all other stakeholders in the European Healthcare system must be incentivized differently. Healthcare Compliance professionals and politicians may define new performance

indicators, e.g. eliminating unnecessary checks, reducing waiting time for surgeries by improving hospital organization, etc.

New business opportunities can be identified and enabled by harvesting the internal information from monitoring and auditing. Knowing the organization`s weaknesses allows you to look for complementing partnerships in the supply chain, e.g. to deliver directly to the home of patients. Collaboration with government bodies for the compliant and successful implementation of policies and regulations will also be a new way to generate advantages in the reimbursement negotiations. Operational efficiencies introduced because of Compliance and transparency initiatives will free the employees in the Healthcare sector to concentrate on the patient and the medical service they aim to deliver. Healthcare Compliance professionals may act as translator between the pharmaceutical company and the Healthcare institution.

Taking a risk-based approach to Compliance execution makes good business sense in this highly regulated environment. Healthcare organizations should re-think their governance processes for risk-related decision making, secure adequate allocation of resources and trained employees, and develop appropriate remediation programs. Healthcare Compliance needs to participate in strategic decisions, and proactively provide value to the senior management. Strategy plans should be developed involving Compliance, to leverage the potential of the function. Close relationships with key stakeholders inside and outside the company offer insights to help the business identify and mitigate Compliance related risks. The Compliance function should not only rely on audit and monitoring results, but build partnerships with the business to ensure effective managing of all issues. The complementary strategic asset of Compliance can be leveraged by improving the effectiveness of the function by introducing new data management systems for the operational tasks, freeing the function to provide strategic advice and supporting innovative initiatives (Jones and Hill, 2013).

Whereas few executives keep on with an exploitation strategy regarding the Healthcare Compliance function, there are more and more CEOs understanding the added value that this function can provide. Exploring the strategic risks associated with the changes in the legal framework, the demographic shifts, and the cost constraints in Europe, control functions like Healthcare Compliance might the ones to consult for informed decision making. All stakeholders need to learn a new way of interaction, clever

companies have already trained their failure culture during audits and monitoring. Pharmaceutical companies and the whole industry need to work even closer together to solve the problems of the coming years. The Healthcare Compliance function, integrated in the development of future business models, can be the competitive advantage for the long-term success and the establishment of new delivery models, new calculation models for reimbursement, and value-based treatment options.

Healthcare Compliance can be leveraged the most if used as a complementary strategic asset, according to Porter. Competition among the European affiliates of the biotech/pharmaceutical companies may become even more aggressive in the coming years and an overarching strategic in-house counselling function might be that missing link to trigger the innovative processes. Tight regulations had slowed down the old, traditional ways, now it is time to rely on the innovative energy, the business consulting skills, and the strategic input of the Healthcare Compliance function.

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