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Institutional Corruption in Europe

and the Role of Information and Communication Technology (ICT) and e-Government

MASTER'S THESIS

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Erklärung zur Verfassung der Arbeit

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Kurzfassung

Seit seiner Gründung im Jahr 2010 hat das Edmond J. Safra Research Lab zahlreiche Studien erarbeitet, die zunächst eine erste Definition von institutioneller Korruption erstellte und folgend erweiterte Definitionen etablierten sowie Fallstudien zu ihrem Vorkommen analysierten. Institutionelle Korruption kann als ein systemischer Einfluss auf eine Institution verstanden werdern. Dieser Einfluss ist legal und wird bisweilen weitläufig als ethisch akzeptiert. Allerdings verhindert dieser, dass eine Institution seinen sozial definierten Zweck erfüllt und unterwandert daher das öffentliche Vertrauen in eine betroffene Institution. Es wurde gezeigt, dass die Idee der institutionellen Korruption Phänomene in vielen Bereichen breit erklären kann. Sie kann als eine Art Paradigma gesehen werden, das im Aufgabenbereich des organisationalen Designs angesiedelt ist. Indem die Merkmale institutioneller Korruption analysiert und die Rolle von Informations- und Kommunikationstechnologien (IKT) und insbesondere e-Government identifiziert werden versucht diese Studie ein allgemeineres Rahmenwerk zur Erweiterung der bestehenden Theorie zu institutioneller Korruption. Diese Arbeit zielt darauf ab, institutionelle Korruption durch multidisziplinäre Linsen zu betrachten. Dazu gehören die Bereiche Organisationsdesign, Datenanalyse, ICT sowie e-Governance. Neben einer grundlegenden Definition für diese Arbeit werden wegbereitende Schlüsselkonzepte wie Ëinflussökonomie", öffentliches Vertrauen oder ïnstitutioneller Zweckäbgegrenzt. Anschließend wird die Beziehung zwischen e-Government und Korruption beleuchtet. Darüber hinaus werden anhand der Literatur Herausforderungen einiger IKT Lösungen untersucht, dazu gehören Transparenz, Open-Government-Data, e-Participation und e-Democracy. Es wird ein empirisches Modell Anhand entwickelt und getestet, das die Beziehung zwischen e-Government und Korruption in der Europäischen Union auf Basis verschiedener freier Datensätze untersucht. Das Modell hilft dabei, die Auswirkungen von e-Government auf Korruption in Europa zu evaluieren und testet die in der Literatur beschriebene Beziehung zwischen Ungleichheit und Korruption. Anschließed wird das theoretische Fundament auf die Fallstudie der Öff-Label-Prescriptions", also aus dem Gesundheitswesen der EU angewandt. Die bestehenden Datenbanken und e-Government bezogen auf klinische Tests und Marktzulassungen neuer Medikamente werden vorgestellt und analysiert. Abschließend wird ein überarbeitetes e-Government-Lösung vorgeschlagen, die diversen Stakeholder, die Öff-Label-Prescriptionsïdentifizieren und verfolgen sowie insbesondere die Transparenz zu erhöhen und das Patientenvertrauen in neue Medikamente, die Industrie sowie die jeweiligen Regulierungsbehörden auf nationalem und EU Niveau zu steigern.

Abstract

In the years since its foundation in 2010, the Edmond J. Safra Research Lab has produced numerous studies that established and extended definitions of Institutional Corruption and analyzed some cases of its occurrence. Institutional Corruption can be defined as a systemic influence on an institution. This influence is legal or currently accepted as ethical; however, it prevents an institution from fulfilling its socially defined purpose, and in the process, undermines public trust in that institution. The idea of Institutional Corruption was proven to be broadly applicable to many domains. It can be viewed as a paradigm and as an issue of organizational design. By analyzing the features of Institutional Corruption and identifying the role that both information and communication technologies (ICT) and e-Government could play, this study is looking for a more general framework and expansion of the theory of Institutional Corruption. The aim of this paper is to approach Institutional Corruption from multidisciplinary lenses, such as organizational design, data analysis, ICT and e-Governance. We are interested in the definition of Institutional Corruption, to identify its enablers and key concepts, such as economy of influence, public trust, and institutional purpose. An investigation into the relationship between e-Government and corruption is performed; furthermore, the challenges and some of the ICT-enabled solutions, such as transparency, open government data, e-participation, and e-democracy, are reviewed and discussed, as presented in the literature. The relationship between e-Government and corruption in the European Union (EU) is also investigated by developing and testing an empirical model, based on different data sets, some of which were provided by Transparency Internationals and the United Nations. The model helps to evaluate the impact of e-Government on corruption in Europe. The emerging relationship between inequality and corruption in the literature is also tested in the model. Thereafter, the theoretical fundament is applied to a case study about the health-care industry in the EU and off-label prescription. Furthermore, the existing databases and e-Government systems related to the clinical trials and market authorization of new drugs are presented, and a new e-Government system is proposed to assist various stakeholders in identifying and tracking off-label prescription, as well as to increase transparency and restore patients' trust in new medicines, the industry, and the respective regulatory agencies at national and EU levels.

Contents

CHAPTER 1

Introduction

1.1 Motivation

On 23 June 2016, a referendum held in the UK decided – by 51% of the vote – that the UK should leave the EU. Among a number of factors, growing distrust of local government and European political systems and institutions played a significant role in the vote to leave; this distrust was shared by a growing group of European citizens. According to the latest poll, completed in 2016 [Eur17] for the European Commission (EC), only around a third of Europeans trusted the EU institutions (33%). Furthermore, fewer than 4 in 10 Europeans agree that their *"voice counts in the EU"* (38%). Another election, across the Atlantic, made Donald Trump the president of the USA; he ran his campaign on anti-establishment rhetoric and the economic frustration of a globalized economy, boosted by social media. These two events signaled a new wave of populism throughout the world, especially in Europe, where candidates such as Le Pen in France, Hofer in Austria, and Wilders in the Netherlands, although not winning outright, still managed to obtain substantial political gains, and even influenced the policies of other mainstream parties. There is resentment of European institutions, which are increasingly perceived to no longer be working for the "little guys," but rather for well-connected and wealthy special-interest groups in Brussels. There is also a general perception that powerful industry nations, such as Germany and France, have a disproportionate influence on the economic and political matters of the Union.

The forces behind this populists uprising have been on for a number of years now, and events such as the global financial crisis of 2008, demographic changes, and migration in the Union have fueled them. In addition to the socio-political changes in recent decades, including globalization, a global economy, and migration, there are also technological advancements and even changes in climate that have caused challenges for and placed

pressure on governments around the world to provide security and wellbeing for their citizens. A significant number of citizens in the world's wealthiest countries are beginning to perceive globalization as a vehicle that only serves the elite. Governments in these countries have, in most cases, been unable to respond properly to these challenges or keep pace with the increasing speed and dynamics of these developments. Given the numerous factors that can prevent an institution from acting in the most efficient manner, one of the most obvious of these factors is arguably financial interest, which plays an important role in almost all cases. The funding of institutions, and in the many cases, the conflicts of interest that arise as a result, are becoming increasingly visible to the public. As Kaiser described in his book [Kai10], there is perceived and growing influence of external groups and interest groups (lobbyists) that may potentially steer a given institution such that it cannot effectively fulfill its defined purpose (mission), and in the process, limit public trust. Material incentives have always played an important role in human decision making. Therefore, it is intuitive to assign blame for corruption to financial incentives. Apart from well-known, individual corruption in the form of bribery or *quid pro quo*, which is well established in Criminal Law, there is also shadow corruption, which Dennis F. Thompson defines as *institutional* [Tho95].

1.2 Problem Statement

The constitutional goals of large institutions erode over time in the course of their revision, whereby the goals of the founding constitution and its mission, which the public expect, seem to remain unchanged. If revisions are not openly discussed in the relevant institution, and if they are not done in a transparent manner, then such changes, resulting from influences that change the course of the institution, lead to the deception of this institution's clients, which include the population, customers, and consumers. The motifs can be numerous, for example, access to subsidies and grants, and the fulfillment of career goals. Furthermore, they are in the interests of small or large groups either outside, for example, lobbying associations, or within the institutions that did not want to or could not openly manifest, but nevertheless are working hard to accomplish their own agenda.

In contrast to individual corruption, which is covered by criminal law, Institutional Corruption (IC) is mostly legal, even if it leads to significant deception of the clients for which the institution was created. The damage it causes is considerable: not only does it lead to inefficiencies on a large scale in the private and public sectors and administration, but also to general mistrust and loss of trust in institutions of the economy and the state, to political disdain, and ultimately to the corruption of democracy.

Institutional corruption can, at times, be more damaging than individual corruption. Institutional corruption describes systemic, strategic influence, which is legal or even currently ethical, that undermines an institution's effectiveness by diverting it away from its purpose and weakening its ability to achieve said purpose, including the weakening of public trust or the institution's inherent trustworthiness [Les13b]. Institutional corruption is often carried out by "good souls," those with best intentions, and often as part of their

job. Moreover, in most cases, the institution "needs" the gains or benefits that corruption provides, and would even need them under a reformed system. For example, many institutions are underfunded, and pharmaceutical research costs money, which could not be easily funded by governments. Therefore, identifying a case of IC is often only a first step in finding alternatives to providing structure or resources that the institution requires.

The following questions arise: Are European institutions, at both state and EU levels, experiencing symptoms of IC to some degree? Is the increasing public mistrust in the EU an indicator of these problems? Can institutions' abilities to fulfill their goals be tested? How can systemic failures in institutions be identified, and what can be done about them? Lastly, are the developments in Information and Communication Technologies (ICT), social media, and e-Governments able to assist and provide solutions to mitigate the issues of IC?

1.3 Aim of the Work

The primary aim of this master's thesis is to investigate existing literature concerning the theory of IC. There is an emerging field of academics from various disciplines who are working on the issues that IC presents. In this thesis, the first goal is to investigate the definitions of corruption and IC and how they differ from one another, as well as to identify their enablers, and their impact on society and democracy. This thesis presents the key concepts and advances of the theory, as well as its challenges and future developments as addressed in the academic literature. Since the majority of research in the field is currently completed in the US, the findings of the American authors are first presented. While IC appears to be a universal trait of governments and societies throughout the world, nation-dependent specifics and challenges are expected. This makes the case of IC in the context of the EU particularly interesting. The steadily expanding EU is socially and culturally diverse, and this diversity is especially predominant in the structure, organization, and function of member-state institutions.

Furthermore, most research up to this point concerning IC has been completed in the fields of politics, law, and economic science. This study addresses the issue from a business-informatics perspective – namely more practically and business oriented. Institutions use a variety of software and ICT in day-to-day operations. This paper investigates the available literature in the area of e-Government and corruption to determine how ICT and e-Government could be leveraged to tackle some of the issues of IC. The interest lies in finding some empirical evidence regarding the connection between corruption and e-Government. Another interest focus is the existing anti-corruption e-Government initiatives and their utilization. Furthermore, this thesis will discuss the current e-Government strategies in the EU concerning corruption.

This study also applies both the theoretical fundament and the frameworks established for identifying IC to a chosen field in the healthcare industry, and identifies and proposes an e-Government solution that could potentially address some of the issues of IC. The

spreading practice of off-label prescription in the health-care industry – an issue that is gaining much traction at a European level – will be investigated; its link to the theory of IC will also be demonstrated. Off-label use refers to the use of a drug in other therapies in a way that deviates from its specified and scientifically proved uses. The EC and the European Medicines Agency (EMA) are already identifying the issues, and the first reports have already been published. An appropriate e-Government initiative will be proposed that would increase transparency, accelerate the understanding of the issue, and potentially change the way medicines are authorized in the European market. A new EU database for clinical trials and a corresponding information-technology (IT) ecosystem is currently being developed, and can be integrated with the proposed solution.

1.4 Methodology Approach

The term "Institutional Corruption" is still mostly unrecognizable in the European academic field, in comparison to the American one. The major parts of this thesis focus on the definitions, concepts, and challenges of IC, and approaches to mitigate it, as presented in the relevant literature. The first two sections present the literature review. The emphasis in these sections is on the definition of IC. The issue of IC are approached from a more interdisciplinary angle. Institutional corruption can be established as a paradigm – as an issue of the organizational design of an institution. This paradigm can be used to describe malicious processes in governmental institutions, private firms, or even whole industries. The approach proposed by Oliveira [Oli13] focuses on the organizational design of an institution, and involves the identification and measurement of the deviation of a given institution's strategic goals.

For the other goal to analyze the role of ICT and e-Government, first, an extensive literature review is performed to identify the drivers of corruption in society. The link between corruption and e-Government is examined empirically using multiple linear-regression models and testing. An analysis of the findings of similar empirical studies is also performed. Using the EU strategy documents, this thesis provides an evaluation of the current EU digital goals regarding corruption.

For the health-care case study, presented in Chapters 4 and 5, some of the relevant literature is examined, including European legislations and European officials' reports concerning off-label use. Off-label use is then examined through the framework of IC, and an overview of its various means of regulation is provided. The stakeholders and their goals are also investigated using publicly available reports. The existing ICT and e-Government applications and databases in the domain are identified and analyzed from publicly available functional-requirement and software-design documents. A new e-Government tool, which could increase transparency and provide valuable information for identifying and making decisions about off-label uses, and the tool's integration with existing systems and databases is proposed. Evaluation of the proposed e-Government tool through interviews with experts from the respective agencies, such as the EMA, was ultimately not performed, since it goes beyond the scope of this thesis. However, some

of the questions regarding this potential survey can be derived from this work. Further detailed studies and public discussions would be required to indicate sufficient interest in the issue of off-label prescriptions, and would lead to political involvement and decisions for new legislations in this area.

1.5 Structure of Work

This work is structured in five chapters.

In Chapter 2, the general ideas about and definition of corruption and its drivers are briefly introduced. This chapter looks at the damage that corruption of institutions has caused, especially to democracy. It further introduces the generally accepted agent-principle model to describe corruption. It also examines some of the "traditional" approaches proposed in the literature to tackling the issues of corruption in the public sector.

Chapter 3 is a literature review of published academic work about IC. It explores the history and development of the term "institutional corruption," which was coined by Dennis Thompson (1995) in his book "Ethics in Congress: From Individual to Institutional Corruption" [Tho95]. In this chapter, the definitions of institutional corruption are introduced, particularly the most broadly accepted definition by Lessig [Les13a]. Furthermore, important key concepts, such as economy of influence, public trust, and institutional purpose, are introduced, and the practical challenges associated with them are also discussed in this chapter. Then, an investigation into the implications of IC, and the work that has been completed to identify, model, and resist it, is conducted. In addition, this chapter looks at different authors who expand the concept of IC into a broader paradigm, which can be applied to various institutions, organizations, and whole industries, and provides a detailed discussion of the framework introduced by Oliveira and the conditions required for identification of cases of IC. At the end of the chapter, some examples of IC and a few proposed solutions are presented.

In Chapter 4, the established literature about e-Government and corruption is reviewed. It briefly discusses the concepts of governance and government; their history; their development in the recent years of digitalization of government services, social media, and web 2.0; and their role in assisting the traditional methods to fight corruption. In this chapter, the findings of a few empirical studies are also discussed, with the aim of looking for positive correlation between advancements in e-Government and a reduction in corruption. A new multivariable regression model was performed, using data from all EU countries (including the UK and Croatia). The rest of the chapter reviews the key benefits that e-Government delivers with respect to fighting corruption, for example transparency, open data, e-democracy, and participation; it also reviews strategies, implementation, and challenges in the EU, and introduces the goals of digital Europe 2020.

Chapter 5 briefly introduces the fundaments on which the case study in Chapter 6 is based. It explores the issues in the health-care industry that can be better explained through the lens of the IC paradigm. This chapter introduces the major issues and

dependencies as identified by the academic literature with regard to the pharmaceutical industry, clinical trials, the funding of medical studies, and the inefficiencies of the regulatory agencies, which have the social purposes of overseeing and governing the industry.

Chapter 6 is a case study that uses the established framework of IC to better explain the issues regarding the increasing levels of off-label prescription throughout the EU. The EC and EMA are currently investigating such practices and are deliberating together with all relevant stakeholders – doctor and patient organizations, insurers, pharmaceutical companies, and regulatory agencies. This chapter also looks into the current and future plans for digital procedures for the market authorization of new drugs, their clinical trials, and pharmacovigilance; it also proposes an information system – System for Tracking Off-Label (STOL) – which would simultaneously increase transparency and provide detailed information for better decision making at all (stakeholder) levels about the practice of off-label prescription. Chapter 6 also briefly reflects on and discusses the technical feasibility of implementing and integrating such a system.

The work concludes with a summary of its essential findings, and a proposition for future works and developments.

CHAPTER 2

Setting the Stage for Introducing Institutional Corruption

"Out of the pecuniary and political pressures and fashions of the time, economics and larger economic and political systems cultivate their own version of truth" John Galbraith[Gal04]

2.1 Democracy

There are many definitions for corruption, and every person intuitively has his own perception of what corruption is. This thesis does not begin directly with its definition about institutional corruption (IC). Instead, first it looks at a concept that seldom requires strict definition and is intuitive to understand: democracy.

The success of today's democracy has much to do with the significant economic growth of the last century, enabled by innovations in science, engineering, and the discovering of better and more efficient forms of organization and production. This is what J. Schumpeter [Sch03] p.84 described as a *"gale of creative destruction"* and a *"[...] process of industrial mutation [...] that incessantly revolutionizes the economic structure from within, incessantly destroying the old one, incessantly creating a new one"* (p.83). Democracy helped to accelerate these trends by providing open access to anyone to freely enter into economics or politics, and to try new ideas to improve the status quo.

Democracy has been a system that provides a solution to one fundamental problem in human society: conflicts that inevitably arise between people, and which are often magnified by greed and the need for power and recognition. Its aims have been to keep those in power responsible for the broad public interest and to search for transparent solutions through public discourse, while systems of checks and balances and due process

restrain the abuse of power. However, this view of democracy might be somewhat idyllic, and throughout history, many expressed worries regarding issues of democracy, such as demagoguery, exploitation of political power, and tyranny of the majority. Nevertheless, democracy has its safeguards – regular elections, checks and balances, and divisions of power – which are all based on institutions to maintain its fragile balance. A brief examination of history, however, demonstrates countless records of institution failure and the constant need for reforms.

2.2 Assessing the Strength of Democracy

Democracy is mostly taken for granted. Moreover, democracies are more fragile and prone to corruption than one might expect. As English argues [Eng13], the establishment and stability of today's democracy in the western world was because of a number of unique conditions, which were not inevitable. Most important among these conditions, according to English, were the commitment to liberty and ethics, and the ability to generate economic wealth without the need to hold political power.

Inevitably, there will be strong interests opposed, which can weaken the inherently fragile democratic institutions. The public expects that these institutions are designed to always do the "right thing" and govern efficiently; however, democracy is a messy process, and it does not necessarily produce the "right" answer for any given problem. It cannot be sufficient for *"good government"* [Wik17] on its own. In private organizations, for example, there is an established hierarchical structure, which makes it easier to optimize outputs by creating incentives and imposing rules. In politics, the rules are constantly re-written by its players, who are seeking to gain political advantage. This means that institutions are not guaranteed to work for the public interest. The only way to steer an institution in the "right" way is through principled leadership, citizens' control and evaluation of the purposes that the institution should serve. Sometimes this depends on people acting for the "greater good" rather than in their best interests. The political competition however is necessary, as Thompson [Tho13] p.10 argues, and we as citizens *"not only tolerate legitimate political gain; we encourage it,"* since the system is based *"on politicians' seeking political advantage [...] to be elected or reelected. As long as they acquire those advantages in ways that do not undermine the democratic process [...]"*

The success of a democracy might be in its capability to do provide separation of politics and economics. Each of those domains is driven by competition, which further produces public benefits. Companies seek innovative ways to reduce prices and increase quality, while politicians compete for votes by promising to serve their constituency. Crucially the law is overreaching both of these domains. However, the law is not perfect, and there is an ongoing process of determining what is legal versus illegal behavior. The basic problem of politicians is maintaining power and determining which interests they will serve. This depends on economics, which sometimes presents a difficult case for separating the domains of politics and economics from each other.

2.3 Rent Seeking

The state is monopoly. Rent seeking can be explained as *"gaining wealth through the unwarranted use of political power"* [Eng13] p.17. When a company engages in lobbying, it tries to generate economic rent – for example, creating barriers to competition, setting up trade protection, and exploiting tax loopholes. These activities might even be legal; however, they could prove to be negative for healthy competition, which is the main drive of innovation and the generation of wealth for today's society. Measuring the cost of rent seeking is difficult; it should include the opportunity loss of all potential enterprises that could have been created and the wealth they could have generated if rent seeking was not a factor.

At first glance, it may seem that democratic institutions are inherently designed to prevent rent seeking. After all, it is expected that a majority would not allow a minority to benefit at its expense. Actually, the old, classical fear of democracy was the other way around –tyranny of the majority. However, it is possible for a small group to exploit a majority because gains can be aggregated, but costs are defused to the larger group, an example would be, a large tax cut or subsidy for few companies that are compensated with a few cent increases in public taxes or other negative network externalities as a company not taking into consideration the price of pollution. Not many would start a revolution over the loss of a few cents or pollution, but the gains for those few well-connected individuals and their companies could be significant. Following this logic, some of the legislations, which have been devised to benefit small minorities at the expense of many – such as copyright extensions, pork barrel projects, and massive subsidies – can be explained. They helped to create the income inequality that can be observed today.

On the other hand, industries are growing more complex, making it difficult to prevent all rent seeking. Some industries, such as the financial, health, food, and other sectors, which profited and grew from economic centralization and global interconnection, have made themselves of vital interest to society, and are becoming increasingly political. This grants them powerful leverage over governments (*Vital Interest will be explained in Section 2.6*). When evaluating the rent seeking behavior, the relevant actors (companies or industries) that are of crucial interest for a country, the European Union, or even globally, must be identified. By protecting these industries and companies of vital interest, governments influence other interactions in various institutions, such as in the area of regulation or prosecution.

2.4 Principal-Agent model of Corruption

The classical principle-agent model describes a situation in which one person (or entity), the "agent," takes decisions on behalf of another person (or entity), called the "principle". The dilemma occurs when agents are motivated by their self-interest, which is contrary to that of the principle. In these conditions, a moral hazard occurs. It is difficult (costly) for the principle to control the agent. The asymmetric information occurs because the

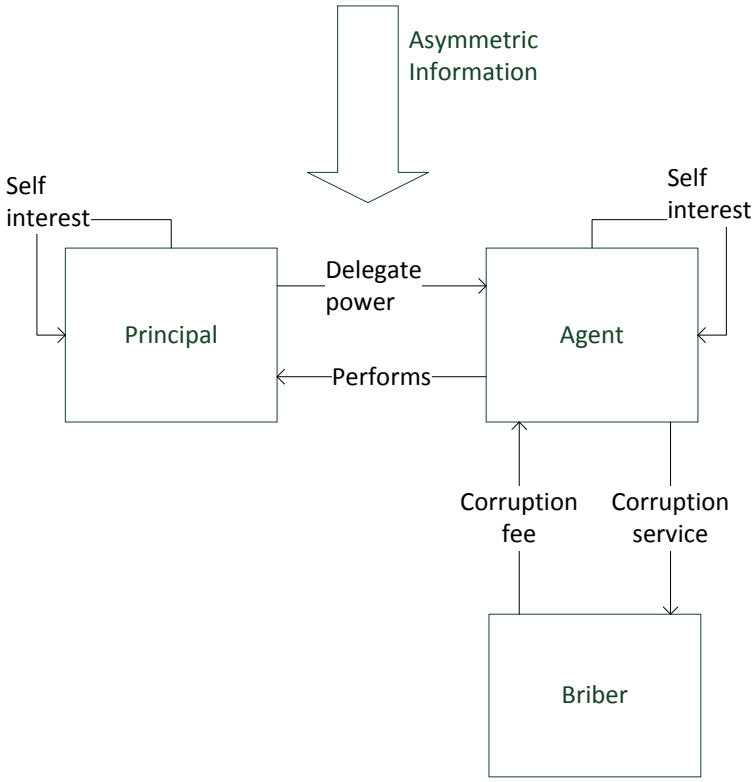


Figure 2.1: Principle-Agent Model - the Corruption Process

agent has more information than the principle, since it is involved with the day-to-day operations.

Some researchers have extended the principal-agent model to describe corruption. According to Smith and Betrozzi [SB98], this model can be applied to illustrate the relationship between government and citizens. The problem arises when the principal has no information about the agent's performance, even though the agent is paid for its work. For this purpose, the principle needs tools to monitor the agent's activities to hold it accountable. The model can be expanded to illustrate corruption in action. In their Paper Zhang and Zhang [ZZ09] p.112 illustrated the corruption process Fig. 2.1, by adding additional Briber into the Agent-Principle Model.

2.5 Enablers of Corruption

To understand IC, one must look at the general term of corruption and its enablers, which are already well established in the literature. Mauro [Mau97], p.2 describes corruption

as an economic rent, paid for *"something useful whose supply is limited either by nature or through human ingenuity."* According to the author, there are incentives for imposing artificial limitations, which are the source of corruption. Government subsidies, special industry regulations, price control, and trade can be viewed as sources of economic rent. On the other side, underpaid public administration, social and income inequality, and social culture can also enable corruption. Another major enabler of corruption is a lack of transparency.

Tanzi [Tan98] further distinguishes between direct and indirect factors that enable corruption. Direct factors include among many regulation, taxation, spending, and the discretion of public officials over important decisions; indirect factors include the quality of bureaucracy, the level wages in the public sector, institutional control and the penalty system, as well as transparency and leadership. Corruption is not limited to the public sector; Tanzi [Tan98] notes that corruption is perfectly available in the private sector as well, especially in the procurement process of large enterprises.

Klitgaard [Kli] famously formulated corruption as a simple equation: corruption is the sum of monopoly of power plus discretion, which is the ability of public officials to operate in a non-transparent fashion, minus their accountability. This equation is an oversimplification of reality and the complex processes driving corruption; however, it provides some general direction for describing the factors influencing corruption. Corruption can be driven by the abuse of power of unaccountable officials who can make discretionary decisions; however, the reality can be far more complicated, especially when taking into account the distinction between illegal and legal corruption. *"Legal"* is merely a definition on a political level. The (political) *"elite"* potentially has the ability to create the rules that can enable (and protect) or restrict corruption, as the model of Kaufmann and Vicente [KV] describes.

2.6 Vital Interest

Vital interest is a term primarily used in diplomacy to indicate the highest foreign-policy objective. A functioning financial system is of vital interest for any country. Fields, in his paper [Fie13], investigated some cases, primarily in the financial sector, of how a government would protect or prevent the bankruptcy of such vital organizations or industries. Such industries create significant rent-seeking opportunity and leads to unexpected complications. Paradoxically, those industries are becoming dependent on government, which in turn creates the conditions for corruption.

The economic meltdown caused by the banks in 2008 resulted in a large amounts of damage and public anger; despite this, not a single top executive in Wall Street was convicted. Some of the banks did not even change their management. In an interview for the NY Times, the US attorney general at the time, Holder [Sor13], expressed concern that the size of the banks influences the way in which they are prosecuted (or not): prosecuting a large bank, or any corporation of vital interest, could jeopardize the industry

as a whole, given its systemic importance. In popular jargon, the term "too-big-to-jail" was established to describe this occurrence.

The financial sector is not the only example of industry of vital interest. Other industries, such as energy, agriculture, and defense are treated in a similar way. These vital industries inevitably gain economic, regulatory, or political leverage, since it is expected that governments would ensure their survival. This is not the case for the majority of other small- or medium-sized companies, which do not expect to be bailed out by the government.

CHAPTER 3

The Difference Between Corruption and Institutional Corruption – Literature Review

3.1 From Corruption to Institutional Corruption

When a person speaks about corruption, he or she is usually referring to corrupt individuals or criminals who broke the law, bribed, or too a bribe for some personal gain. The concept of "corruption" indicates that something is not as it should be. English [Eng13] p.7 disrobes it as *"deviation from some realistic ideal."* Something is described as "wrong" because one knows it could and should be better. Talk about corruption typically brings to mind images of developing countries, where there is no rule of law, and political offices are distributed among a small and powerful clique to exploit them for personal gain. It is often defined as "petty" corruption, and is easy to visualize. It could take the form of bribes given to policemen to avoid penalty, or to bureaucrats to speed up license procedures, or to politicians to obtain a lucrative governmental contract. Such practices are easily described as "wrong." However, corruption is an ambiguous term. The ability to bypass some rules, especially in poorly governed countries, is valuable because it provides a path around "red-tape" regulations and enable individuals (and organizations) to achieve their goals. English [Eng13] p.8 rightfully asks whether there is a difference between the above-described petty corruption and expedited service fees, which are legal in developed countries. The latter can be viewed as a state exercising its monopoly of power. Yet a personal discretion exercised by corrupt official seems to be a much more significant form of abuse because it is not regulated (legal), since society expects that government officials follow clear rules and procedures.

Corruption in the public sector is often viewed as pollution caused by illicit private interests. Thompson has provided a more nuanced view. He first defined political corruption *"as a condition in which private interests distort public purposes [...] in ways that bypass or short-circuit the democratic process"* [Tho13] p.4. Later, this intuitive concept was expanded into the paradigm of IC, which is more broadly applicable to other types of institutions, not only to government. In fact, in the above definition of political corruption, the term *"public purpose"* can be replaced with *"institutional purpose,"* and the term *"democratic process"* can be replaced with *"legitimate institutional procedures,"* as Thomson did, by establishing the first definition of Institutional Corruption [Tho13] p.6: *"corruption occurs not simply because private interests are promoted, but because they are promoted without due regard for the rules of a legitimate process. In both cases [individual and institutional], private interests influence the public purposes improperly, but what makes the influence improper differs in each case."* However, defining *"legitimate institutional procedures"* is not easy. Thomson viewed them as the procedures *"necessary for the institution to serve its primary purposes effectively and credibly"* [Tho13] p.5. Even though institutional purposes can be *"multiple and contestable,"* for Thompson these procedures can be the guide for determining the difference between individual and institutional corruption. He further described the requirements that the procedures should be transparent, but most importantly, he stated that these procedures should be based on the purpose of the institution.

3.1.1 The US Congress in the middle of the "Birth" of the Idea of Institutional Corruption

The purpose of any government or, in the case presented by Thomson, the congress of the USA is to represent its constituency – the people. An interesting empirical study performed in 2014 [GP14] empirically analyzed over 20 years of data and over 1,700 policy cases in America to answer the following question: does the government represent the people?

They grouped policies according to public support, and calculated the likelihood that a policy could be voted in to law. The study found that public opinion was statistically insignificant for adopting any policy. For political and economic elites and "big money" interest groups, the trend was reversed. The study demonstrated that their interests were well aligned with the likelihood of either adopting or blocking of a given policy. However, the general public does not need regressions to perceive the system as unfair. Unsurprisingly, some people compare the US congress's low approval rating in recent years with the approval rating of the British crown before the 1765 American Revolution (supposedly at 15% at that time) [TIL13].

3.1.2 Political Corruption and the Introduction of the Institutional Corruption as defined by Thompson

With such a low approval rating, many voices in the US were calling for corruption in the political system and institutions. Thompson coined the term *"Institutional Corruption"* in 1995 in his book Ethics in Congress: From Individual to Institutional Corruption [Tho95] to provide a distinction between these two forms of corruption. Institutional corruption does not involve breaking the law or establishing ethical conduct. Instead, IC was established in the context of the ethics of the US congress as *"political gain [...] under conditions that, in general, tend to promote private interests"* [Tho95] p.30. Such political gains include campaign contributions, endorsements, and media support. The tendency to promote private interests at the expense of publicly defined institutional purposes was the corner stone on which the theory of IC was later built.

Thompson's definition of IC creates an important distinction from the well-known *"individual corruption."* This distinction is better visible if the definitions for each form of corruption are placed side by side. In purely individual-corruption cases, there must always be a motive, which allows a legal prosecution to be undertaken. With IC, hard evidence cannot be collected, and no legal prosecution is possible. Rather, the aim is to optimize an institution and its organizational system. In both cases of Thompson's definitions of corruption (individual and institutional), the subject of corruption is a public official. According to Thompson [Tho13] p.8, the relationship between citizens and officials comprises three key elements, which distinguish institutional cases from cases of individual corruption: 1) the gain is normally political, 2) the service is systemic rather than episodic, and 3) there is a tendency to undermine the democratic process or the core mission of the institution.

3.2 Dependence Corruption as defined by Lessig

Thompson's definition of IC attracted another scholar, a professor at Harvard University, Lawrence Lessig. In 2009, Lessig returned to Harvard as director of the Edmond J. Safra Center for Ethics, where he wanted to continue to explore the concepts of corruption, which were established by the center's former director, Thompson. Lessig has refused the notion of directly declaring something (for example, an institution) as corrupt; rather, he argues that in order for one to be able to condemn, one should first better understand the issue. He argued that an investigator should be able to present not only evidence for the benefit-service relationship, but also how this relationship weakens the democratic or legislative process [Les13b] p.4.

Including the democratic process in Thompson's definition of IC opens the subject to broad interpretations, according to Lessig. How can one evaluate which tendencies are *"undermining the democratic process?"* Lessig provides a simple example to illustrate the complexity: not only large corporations exercise their influence over government; a large worker union can also be viewed as a source of influence in the pursuit of its members' political goals, such as minimum wages, payed vacations, and medical leave. It

can be argued that each of those influences tends to undermine democracy, since only the voice and concerns of a small portion of the population are being heard. In many cases, politicians would seek political benefits by favoring and serving the diverse interests of unions, Non-Governmental Organizations (NGOs), industries, and businesses. How can we say in which case IC is undermining the democracy?

Lessig looked to establish a more formal way to explain such questions by first trying to identify the process that the influence tends to damage. After such a process can be discovered, a declaration about IC might be appropriate. The institution around which Lessig chose to develop his thesis presents a case of IC that is somewhat easier to detect, and it is the same institution that Thomson used to define IC – the US Congress.

3.2.1 Definition of Dependence Corruption

In his paper [Les13b] p.11, Lessig makes the argument that, in the United States, legislators are dependent upon at least two publics. They are still somewhat dependent on the people to be elected in the general election; however, the funders in the money election conduct the candidate selection. Lessig concluded that the requirement to raise substantial support from a small group (funders) in order to be politically competitive makes the whole institution of the Congress effectively dependent on those funders. This clearly leads to a contradiction of the statement that legislators should be as *"dependent upon the People alone."* Funders are not a representation of the people, nor are they aligned with the people's interests. These two dependencies are, according to Lessig, as *"clearly in conflict."* [Les13b] , since it is not the what the Framers intended when writing the American Constitution, which is ensuring exclusive legislative dependency *"upon the People alone"*. This is what Lessig calls as *"dependence corruption"* [Les13b] p.14.

This dependence corruption can be viewed as a conflicting dependency that weakens the effects of the intended dependencies. Dependence corruption is a subset of IC, but is not exclusive to IC. In its most extreme case, dependent corruption can also be individual, and can be viewed as an overlapping layer of individual and institutional corruption. However, the overlap demonstrates that dependence corruption can be both individual and institutional. Some cases can indeed be cases of IC, while others might be solely individual.

There is major disagreement between Thompson and Lessig regarding dependence corruption. For Thompson, the only way to detect this sort of dependency is to fully understand the purpose of the institution and the procedures necessary to fulfill it. Lessig views this dependency as a redundant condition, since there are cases, for example, the US Congress, in which one can observe dependence corruption regardless of the procedures. For Lessig, the focus should rather be on finding the conditions that mark the conflicting dependencies. Dependence corruption, much like IC, cannot be simply identified from the behavior of any single actor in the system. It is inherited in the structure of the system. The institution as a whole is in need of reformation because even if every actor in such a system acts in the most benign manner, the outcome will still be corrupt. [Les13b] p.14.

3.2.2 Using Dependence Corruption to Establish the Definition of Institutional Corruption

All dependencies are not the same. Lessig tries to answer the question, whether worker union exercising political influence, as big business can do, should be included in IC or not. Even if the answer may seem obvious to some, if one attempts to rationalize, it is difficult to find a compelling argument for why the one can be an instance of IC and not the other. The political gain of obtaining more votes through the endorsement of a union does not look much different from money provided by a special interest, which in turn would translate into more votes for a political campaign.

For Lessig, answering such a question becomes somewhat easier by approaching it from the perspective of dependence corruption, which provides a clearer view of the political gain in both cases. The ultimate test, according to him, is the *"possibility."* It is impossible for every citizen to be of the funding class, since this is not economically feasible; however, every citizen can be a member of the said union – assuming that the union would be able to represent its members properly. Even so, this does not exclude the possibility of IC in the union; it just shifts IC from the election system to the union in question. On the other hand, the dependency created by large businesses cannot be achieved by any common citizen. Such means are only available to a small and wealthy percentage of the population, and this is what directly conflicts with the proper dependency designed for the institution – *"upon the people alone."* [Les13b] p.14.

In some scenarios, identifying conflicting dependency might be easier than trying to find and prove the weakening of either public trust or the democratic process. In others, this identification might be extremely difficult. The IC paradigm, however, presents the potential for application in a much broader context than solely the US Congress. With the establishment of the Research Lab for IC at the Ethic Center in Harvard, IC came under scrutiny, and many people from different disciplines were tasked with building significant research to obtain a better understanding of IC, how it operates, and some remedies.

3.2.3 Dependence Corruption Example in Europe - Political Finance in UK

Lessig has presented an interesting case of IC in the US political system. For him, a potential remedy for influence by campaign contributions could be more public funding for political campaigns. However, there are many countries in which the election system is already mainly publicly financed – especially in Europe. Winters, in his paper [Win13], illustrated how complicated the matter can be by examining the *"Political Parties, Elections and referendums Act"* that the UK adopted in 2000. The act aimed to reform the outdated legislations, and was specifically targeted at restricting the dependency on funding and regulating third-party involvement in campaigns. Winters identified some important differences between the US and UK approaches to the election system and their implications.

The existence of dependency does not necessarily make clear the harm it actually causes. Many can argue, and some studies (mainly in US) even demonstrated, that more campaign money does not always translate into an electoral payoff. On the one hand, the election of Trump in 2016 suggests that a candidate who rose less money than his opponent (Clinton) was ultimately able to win. On the other hand, it cannot be denied that donations are linked to privileged access, and thus create fundamental inequality between those who can afford to contribute larger sums (funders) and the rest (normal citizens). This inequality undermines the democratic principles and trustworthiness of the institution, as Lessig has argued [Les13b].

The main approach to addressing campaign funding both in the US and the UK was to impose a cap on donations. In the UK, campaign contributions are more strictly regulated, and there is a hard cap on donations, including loans. This legislation, as Winters[Win13] p.8 explained, aimed to serve two roles: 1) reduce electoral corruption, and 2) level the play field, which would provide equal political opportunity. Leveling the play field is important to promote political competition, and, as Thompson argued [Tho13], a fairly obtained political gain is not considered to be IC and should be encouraged. However, the cap on contributions in the UK was made on the aggregate sum of all donations rather than on individual ones. This eliminates even potentially fairly obtained political advantages, in the instance when a particular party can attract a large number of individual donations. The total sum would still be limited by the regulation, as though it was from a single, large donation, thus making these donations even more desirable.

Another concern about the limitation of donations is finding an alternative source of party financing. Even if engaging with a large number of supporters, small donations ultimately need to be supplemented with state funding. However, in times of financial instabilities and austerities, this could be a difficult sale to tax payers, even if the advantages outweigh the small increase in governmental expenditures.

The role of the media is another important topic. Regulations in the UK, for example, ban political advertisements on the television and radio; while this awards a potentially disproportionate influence to newspapers and their owners [Win13] p.14, freedom of speech prevents the introduction of limitations. Transparency seems to be a promising prescription for dependency corruption, since donation caps and regulations impose unforeseen consequences and are subject to broader interpretations. However, transparency raises concerns about privacy. Winters further explained [Win13] p.9 that in places such as Northern Ireland, where are there are long-standing historical grievances, disclosing donors could be a safety concern, which is why Northern Ireland is exempt from mandatory declarations. Also, an effect of more transparency could ultimately be the further undermining of trust in an institution.

3.3 Establishing the Theory of Institutional Corruption

After looking at the history and evolution of the idea of IC, this thesis breaks down the definition of IC and introduces the level of development and challenges faced in the

different areas of its theory presented in the literature. This thesis has already established that there are many nuanced definitions of corruption and IC in the academic literature. The works of Thompson and Lessig have laid the ground work for the development of IC theory. The working definition of IC that Lessig introduced, which has been widely adopted and frequently quoted by other researchers, is the one this thesis also adopts:

"Institutional corruption is manifest when there is a systemic and strategic influence, which is legal, or even currently ethical, that undermines the institution's effectiveness by diverting it from its purpose or weakening its ability to achieve its purpose, including, to the extent relevant to its purpose, weakening either the public's trust in that institution or the institution's inherent trustworthiness." [Les13a] p.2

A breakdown of the definition identifies the central concepts related to the emerging theory of IC. These concepts are briefly discussed in this section, and further discussion about their challenges and approaches to tackle these challenges are presented in subsequent sections. The first important concept is the idea of *"systemic and strategic influence."* There are many internal and external influences related to any given institution, and it is not possible to take them all under consideration. This thesis is interested only in the influences that are predictable and that occur regularly (systemic influences), and in those which create the observed strategic deviation of the institutional purpose. The institutional purpose is the second key concept of the theory. The definition does not imply that the purpose of a given institution is correct or that there is a defined purpose. However, it is important, and one of the major challenges for the framework of identifying IC is to agree on an institutional purpose that can be used as a baseline for discovering deviations. The continuous work of the influences and the subsequent deviation can create a drift in public opinion about the institution's work. The *"weakening of public trust"* is the third important component of the theory of IC. Some institutions, such as law-enforcement institutions, regulatory agencies, and health-care institutions, rely on public trust for their authority and recommendations. Significant social and political disturbances can occur when major institutions lose their trustworthiness.

3.4 Systemic and Strategic Influence

No entity operates in a vacuum. An *"influence,"* according its dictionary definition, is *"the action or process of producing effects on the actions, behavior, or opinions, of another or others"* [Dic] p.2. A given object, which can be a person or an institution, could be under diverse influences, such as the law or other norms, or markets. In the case of an institution, the influences acting upon it could be complementing or conflicting, depending on the institution's objectives. Lessig calls the sum of all relevant influences an *"economy of influence"* [Les]. This economy of influence needs to be understood well in order to produce policies to move an institution in a desired direction, which is normally determined by the institution's mission.

One easily identified influence is money. However, there are many types of influence that can have various impacts on any organization – extensive bureaucracy, social and

economic developments, and other agencies and industries; other influences can be conflicting ideologies, political power struggles, and grandstanding. As established in the definition of IC, the influences of interest are those which impact the strategic goals or purpose of the institution, and which are systemic in nature – regular, predictable, widespread, and often accepted in the practice of the institution.

One useful metaphor for illustrating these concepts, given by Lessig [Les13a], is a magnet having a barely noticeable influence on a compass: even a small magnetic force would be enough to produce a slight deviation of the direction in which the compass arrow points, and could draw the arrow away from the desired direction in the long term. This deviation is IC. The metaphor was further expanded by Parvanov [Par17], who noticed that some influences are unavoidable, and the only way to manage them is to account for their effects and adjust the course of the institution accordingly. The analogy offered was of flight compasses, which require continuous manual correction from pilots who fly close to the earth's poles, countering the deviating magnetic influence of the poles. The complete elimination of an improper influence is not always a possibility. Rather, periodical adjustment of the institution's organization and strategy is the best available alternative.

An economy of influence can be informally presented schematically with nodes, which represent the actors (or stakeholders), and arrows depicting the interaction between these actors, indicating the connection or the influence between them. As an example, in Figure 3.1, the relevant influences in the lobbying system is graphically represented. An industry interest in the diagram can be a company or group of companies, as well as NGOs or even other institutions and organizations, which hire a lobbyist to present their views on a public decision for a particular topic of interest that might come to affect the special interest. The lobbyist is dependent on the special interest because he or she is paid by it. There is a regular business-customer relationship between them. The lobbyist provides various resources to a member of parliament (MP), who can be a member of European parliament or national or local government, to help the member advance the interest of the lobbyist's customer. A direct money supply can be viewed as bribery; however, there are subtler ways to exercise influence, such as providing legal and other expertise to a legislator or decision maker. The report of Transparency International [Mul] noted that the connection between businesses and politics is growing, and this creates serious instances of conflicts of interest. There are particular concerns regarding the practices of individuals who are lobbying while holding public offices, or the post-employment of public servants in the private sector – the so called revolving door. Lobbying is presented in more detail in Subsection 3.9.1 of this chapter.

The expected outcome of any given influence is that it produces some sort of dependency. The dictionary definition of independence is someone or something NOT dependent on some dependence. As evident in the section on dependence corruption, it is expected that the representatives in a democratic society should be independent if they are expected to make decisions and govern based on merits. This is why a key objective of an institution is to establish a set of rules against dependence. Full independence is unachievable; the

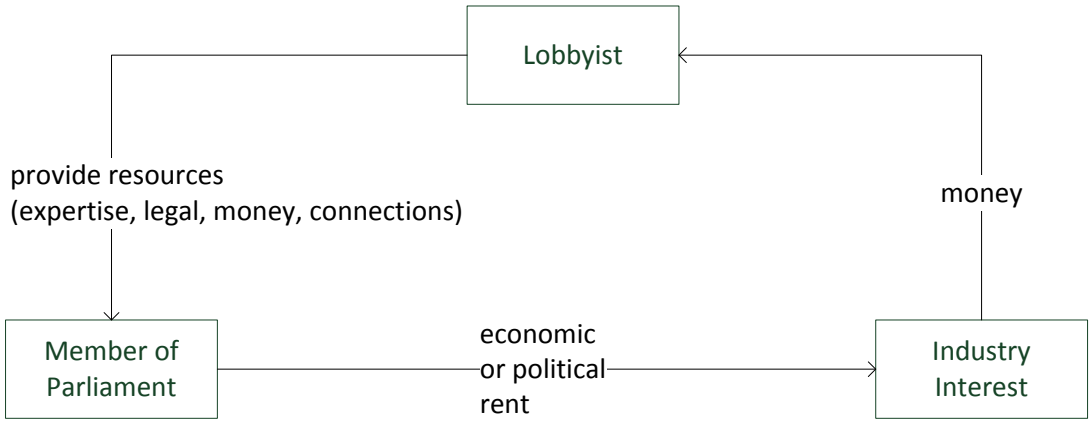


Figure 3.1: Economy of Influence Example– System of Lobbying

real goal is to identify the proper dependencies that can help an institution to fulfil its purpose. For example, independent legislator simply means that the legislator is dependent on the people, and independent judiciary means dependent on the law.

According to Lessig [Les13b], individuals continue to be responsible within the system of influences; however, their responsibility lies not in changing any particular individual behavior, but rather in changing the behavior of the system itself. For Lessig, the wrong doing of congressman is not the raising of campaign money, but the lack of effort to change this corruption of the system that depends on a small set of funders.

3.5 Public Trust

Another important aspect of IC is the public trust of an institution, which can be weakened or even completely undermined. Public trust is an ambiguous and often controversial concept. Sometimes, an otherwise trustworthy institution can fall under scrutiny because of an individual scandal, while corrupt institutions, which harm many people and societies, can maintain a high degree of public trust because of, for instance, good public-relations (PR) strategies, distorting facts, or deflecting criticism. This corruption of communication and facts is investigated later in this section. There is a risk of bringing to light cases of IC that could potentially increase public mistrust; however, the aims of transparency are to lay the foundation and groundwork of institutional reform and to restore trustworthiness.

Once public opinion about a given organization becomes critically low, it could produce considerable damage to any institution (and to private companies as well). This makes reformation even more difficult to achieve. When an institution loses its credibility,

people became more cynical, and there is the risk of an even greater loss of credibility of the whole system to follow. Examples include trust in democracy in the case of a compromised parliament, or trust in doctors and medical therapies in the case of perceived influences by "big pharma" on prescription-medication practices (examined in more detail in Chapters 4 and 5 of this thesis). Another example includes the loss of trust in the financial system – the aftermath of the effects of the 2008 financial crisis. Next in this section, two concepts are introduced: first, the concept of constituency and its importance in identifying the relevant actors (and stakeholders) for the analysis of IC cases, and second, the distortion of public view by a small group of rent-seeking actors.

3.5.1 Misaligned Constituencies

An organization serves its constituencies. A constituent – or a shareholder, if a private company is examined – is someone who authorizes another to act on his behalf. For example, voters are the constituents of the representatives they elect, and shareholders are the constituents of the executives of a corporation. As Fields [Fie13] suggests, the first step of analysis is to determine the constituencies that the institution in interest serves. Furthermore, he provides a simple example of who or what can be considered constituencies of a bank:

- Customers – they can be commercial customers (depositors or loan seekers) or big-money investors, interested in the financial products of the bank.
- Shareholders, since most of the banks are publicly traded
- Regulators – their imposed regulations are served by the bank; however, the reverse is also true, since regulators aim to serve the industry to produce regulations that are beneficial and encourage growth (or at least this is the aim of regulations).
- Executives – they serve all three abovementioned groups; however, they can also be viewed as constituencies of the bank, since their incentive is tied to the performance of the organization.

To further analyze IC, as per Fielsds [Fie13], one should answer the following question: does serving one group of constituencies create a conflict when serving another? One example could be the maximizing of profits and consequently the bonuses of the executives in an investment bank by trading on risky securities, which could potentially corrupt the goals of safe and sound management. An example in the public domain would be trying to simultaneously serve industry and public interests, thus creating conflicts that can be viewed as instances of IC. There can even be cases in which all constituencies' interests are aligned, and in which IC can occur nonetheless. A prime example was the mortgage bubble, which caused the financial crisis of 2008, in the US. Banks, lenders, and insurance companies made record profits, while the public was getting cheap credits to purchase houses and home owners enjoyed large increases in equity. The bubble is

easy to identify in hindsight; however, at the time, everybody in the system appeared to be winning.

In summary, companies and regulators serve multiple and often competing constituencies. This often leads to IC in the case where serving the dominant constituency does not serve public interest; however, in some cases, IC can arise even if the interests of all constituencies are mutually aligned. In the first step, it is of utmost importance to identify all involved actors and the constituencies that an institution serves. An analysis of the established hierarchy between the actors is needed in order to determine the economic or political connections and to identify the diverse interests of all potential actors, including general public interest. Furthermore, even in cases where public interest might appear to be served, IC may still be creating long-term systemic risks that harm economic and social stability.

3.5.2 Corruption of Language, Facts and Accounts

Public relations and the distortion of facts are also important aspects relative to public trust. Both special-interest groups and recipient institutions make use of PR to hide, manipulate, and distort facts and to preserve the status quo. However, in many cases, it is difficult to agree on the facts, which could be used to manipulate public opinion, especially if one takes into consideration that even in clearer cases there are different opinions– for example, the Tabaco Lobby of the last century, where significant resistance from interest groups produced arguments for denying the harmful nature of smoking. Media propaganda, nondisclosure, funded studies, obfuscation, and biased research can be efficient strategies for swaying public opinion.

3.6 Institutional Purpose – the Baseline for Identifying Institutional Corruption

The establishment of a baseline in the public sector is more difficult than in a private company. Corporate self-inflicted IC seems to have less profound implications, since board members and executives have a much firmer grip on their organizations and can control the behavior of their companies. It can be difficult to establish a baseline of corrupt behavior, especially since one, and probably the most important, of the purposes of a private enterprise is to maximize profit for its shareholders. As Salter [Sal10] identified, the executives' bonuses dependency on short-term oriented performance fuels a company's dependency on quarterly results, in comparison with pursuing long-term objectives.

Different is the case of finding the purpose of public organization. The institution should serve the people. But the people are not agreeing, homogeneous body; therefore, it is often not possible to clearly determine their will and demands. Often these demands can be quite controversial, divided, conflicted, and short sighted, which does not make them an easy-to-establish baseline to follow for developing policies and governing. Furthermore, populism has been a problem for democracy since its inception, and is especially relevant

in today's Europe. Even the measure of popular sentiments through polls can be highly subjective and dependent on the wording of the poll, the methods for conduction, and the political agenda.

Light [Lig13] observed that even if an institution was theoretically fully committed to the *"will of the people,"* it does not eliminate the possibilities of mistakes and terrible decisions, the results of which can be detrimental to public trust. This would mean that a loss of public trust is not a sufficient indicator for IC. A trustworthy institution can suffer a sudden loss of public trust because of a single accident, while a corrupt institution can enjoy positive PR. The baseline for identifying IC is clearer if an institution's mission can be clearly defined, and if it has founding documents of principles and ethical standards. The baseline can be established if the institution can identify its societal goals, and if they can be reliably measured for deviations. Sometimes, the baseline becomes clearer only after it has been violated. At other times, corruption can be perceived as individual, and can overlook the institution's systemic and structural problems, which might have preceded the observed corruption or illegal behavior.

3.6.1 Expanding the Theory of Institutional Corruptions

While Thompson [Tho13] and Lessig [Les13b] have built the theory of IC around the US Congress and its dependency on lobbying money for political campaigns, the concept of IC can effectively be applied in different institutional settings that do not involve politics or elections, and beyond the public sector to search for the appearance of IC in private firms and even whole industries.

Institutional corruption provides a powerful concept to identify systemic, but legal, structural forms of corruption, which are sometimes not realized (consciously) by the involved individuals, but that are usually highly perceived by the public, although not always for the right reason. The strong contrast of IC from other typically illegal forms of corruption requires different remedies.

To develop the study of IC, one needs to develop measurements for its types, its extent, and the degree of corruption. This would move the study from being heavily example (case) based to being a more traditional, qualitative research. Institutional corruption can then be used to complement other studies of institutions, and to inspire reforms or policy changes. Miller [Mil] approached this issue by identifying individual actors and their actions that corrupt the purposes or processes of an institution.

Wight[Lig] has applied the concept of IC to the health-care sector. He looked at the responsible governmental agency – the Food and Drug Administration (FDA) – and the pharmaceutical industry as a whole. In his works, he found evidence in a number of studies demonstrating how corporate practices have produced dependence corruption in health-care institutions, doctors and patients, corrupted research, and medical knowledge, which led to producing drugs with little or no benefit (approximately 90% according to independent reviewers), or worse side effects, along with generating higher sales, receiving more public funds, and thus creating a self-reinforcing cycle of high prices, protected by

government, generating further funds for production and marketing of even more (and in some cases harmful) drugs.

Case studies aside, there are clearly identifiable similarities in both presented cases – the US Congress and the health industry (the health-care industry will be analyzed in more depth in Chapter 5). In both cases, some deviation from the institution's societally relevant mission can be identified. The resulting dependent corruption is an enabler for both individual (venal) and institutional (systemic) corruption. In many cases, personal enrichment can be identified as its driving force. Pursuing one's self interests (or becoming wealthier) is a basic driving force of human entrepreneurship. The way to mitigate, or at least minimize, such dependencies in public institutions and government, is to identify them, which than can these institutions to fulfill their originally intended purpose.

3.6.2 The Institutional Purpose

The cornerstone of IC is finding deviations in the purpose of an institution, thus undermining its efficiency and creating public mistrust. This is easier said than done, since different stakeholders can disagree about the purpose. Often though, it is not the purpose that creates disagreement, but rather agreement regarding how the social mission of the institution should be realized, especially under the conditions of limited resources. This is often a source for partisan divide and political fights. The purpose or the mission statement is normally defined in the form of written language, and it is often ambiguous and open to interpretation.

There are disagreements among IC theorists about how to define the purpose. Newhouse [New14] p.562 defines an *"obligatory purpose"* as *"the purpose for which the institution's activities must be conducted in order to avoid wronging others."* She argues that since the decisions and laws that are made in institutions could negatively affect the people, only the purpose defined explicitly by the people should be used as the baseline for an IC analysis. However, this cannot be applied in some private organizations because they are not bound by such obligatory purposes. For this reason, she argues that only institutions in which externally defined obligatory purposes can be identified should be subject to the analysis of IC theory. Furthermore, she provides an in-depth analysis of different categories of purposes, and concluded that IC should be pursued only in cases where fiduciary duties can be identified and the institution entrusted with managing the public interest is failing to do so because of some external influence. In her opinion, the pursuit of commercial self-interested activities cannot fit into the model established by IC.

Of course, a fiduciary relationship makes it easier to identify the institutional purpose, since there is a clearly defined "principle," which can be viewed as the source of legitimation for the purpose of the "agent" (the institution). Oliveira views the purpose as justification for the institution's existence. Therefore, even if it is possible to establish that a given institution was established based on the *"wrong reasons,"* a *"legitimate purpose"* for this institution could still be rationalized [Oli13] p.8. This is why, for Oliveira, the theory of IC should remain agnostic to the purposes and the methods used to define it. If only the

principle is considered as the sole source of the institutional purpose, then one cannot explain the cases in which the institution is corrupt despite working in alignment with its principles. This complication, according to Oliveira, is because an institution can have different sources for its purposes, defined on different levels in the institution– inside or outside, which can even be contradictory to one another. While, deviations can be judged by law in cases of individual corruption, IC provides no clear means for the establishment of such a baseline. Analysts of IC should concentrate on understanding the stakeholders or sources that define and legitimize the purposes of an institution based on their needs and interests.

3.6.3 From Institutional Purpose to Institutional Goals

An institutional purpose can always be traced back to society. The founders or stakeholders of the institution may decide on the purpose, or it may be imposed externally from other sources, such as society or an industry. The purpose reflects the mission statement of an organization, and it is often broad, idealized, and hardly useful in the day-to-day operations of the organization. It can be viewed rather as the long-term goals or the grand mission of the organization.

Since the institutional purpose tends to be broad, it must be translated into more specific goals that can serve as a guideline for the employees of the organization to follow in order to achieve its purpose. Furthermore, the behavior of the institutional members can be observed related to the roles they play in the organization and their relation to the achievement of those goals. Oliveira [Oli13] p.14 further makes the distinction between *"ascribed"* and *"achieved"* goals. Through establishing more specific goals, an IC analyst can make claims about the grand mission of the institution and whether or not there are deviations from it. These are the ascribed goals (or purposes); they are derived from the planned goals, and they serve as the necessary baseline for identifying IC. Furthermore, it should be emphasized that from the perspective of organizational theory, there will always be inefficiencies and mistakes in any organization. No perfect organization exists, and human beings are not rational agents. It is impossible to expect that an organization would pursue its ascribed purposes at all times. There are many ways in which the organization could drift from its ascribed goals. Institutional corruption can be viewed as one such drift, according to Oliveira. The evaluation of the level of achievement of the ascribed goals is what he referred to as achieved goals.

3.7 Institutional Corruption can be defined as Institutional Design Problem

The conceptual framework of IC by Thomson and Lessig was initially applied in a narrow case of the US congress and political campaign contributions. By referring to the founding materials and constitution, it was easy to follow that, in a democratic system, the ultimate legislative authority belongs to the people who delegate this authority to

their elected officials to represent them and to use this authority exclusively for public purposes.

Oliveira [Oli13] looked for ways to extend the reach of the framework and make it more applicable to different institutions by examining the organizational theory, and more specifically organizational design. Institutional corruption can be viewed as some sort of institutional dysfunction. If an influence is defined as systemic, strategic, and legal, and is said that it causes IC, then, by looking into the organization of the institution, its ascribed goals, and its processes, one can identify how this influence was created in the first place, and find corrective measurements. The design aspect of the theory aims to answer the following questions: Is it the design of the institution that creates the conditions for the given influence? What are the protection mechanisms in an organization against such an influence? How does one measure the result of such an influence on the goals of an institution?

Designing an organization for efficiency is important; however, as Daft [Daf10] points out in his book *"Organization Theory and Design"*, the managers of any organization are bound to respond to the various requirements and needs of different stakeholders. Effectively meeting the needs of these stakeholders can sometimes be considered more important than the mere efficiency of the organization. Understanding the structural and contextual dimensions of an organistion is important for designing the organization to be both high performing and effective. There are many elements that should be considered when designing an institution, for example, size, technology, environment, information flow, goals, and strategy; however, design theory goes beyond the scope of this thesis, which concentrates only on the purpose and the goals of an institution. For in-depth analyses of the other factors, refer to [Daf10]. As Oliveira establishes in his framework [Oli13], in order for an institution to be described as institutionally corrupt, the institution should not be able to achieve its ascribed goals because some design flows divert the efforts of its members or create incentives for them to work for different (often even contradictory) institutional goals.

One can distinguish a few types of inefficiencies in an organization. Some inefficiencies stem from single or small groups of individuals acting improperly – either on purpose and for self-interest (individual corruption), or unintentionally. The lack of resources (budget) or competences (human capital) to achieve the desired institutional goals can also be a source of inefficiency (performance issues). Inefficiencies can also happen even if all members of the organization are working to achieve the goals of the institution. However, if a plan is "badly" designed, then even working with the best intentions would produce flawed results. While these examples are problems of design, not all of them are instances of IC. As Oliveira [Oli13]points out, every case of IC can be viewed as a design problem, but not every design problem is IC. In his framework, he identifies three key mechanisms that form part of organizational design. In order to achieve its purpose, an organization breaks its overarching goals into smaller goals and tasks that then need to be correctly communicated to its members, who are responsible for their execution. These mechanisms are further discussed in relation to the solution that ICT

and e-Government can offer.

3.7.1 Breaking down Overarching Goals

A purpose is often defined on an abstract level. In the day-to-day operations, the members of the organization need specific tasks and guidelines to accomplish their work. The purpose should be broken down into smaller goals, which could be further broken down at different levels of granularity. Better design can be achieved only if the granular goals are compatible with the overreaching goal of the institution (its purpose). If the goals are not adequate for achieving the purpose, then this can cause IC. There are many ways in which the breakdown structure can introduce deviation from the ascribed goals. It is important that such deviations are identified and resolved in a timely fashion. [Oli13]

Information and communication technologies can help in this area with digitalization, the increase of automation, and continuous Plan-Do-Check-Act controlling that can deliver the data needed for the evaluation and audit of the outcomes of the institutional processes. Furthermore, ICT can track the resources of the organization or help to identify measurable targets and increase the efficiency of the institution. This process- and resource-oriented organization is much matured in the private sector, and since the introduction of the new public-management paradigm (which is discussed in a later chapter about e-Government), it is rapidly being adopted by governmental institutions around the world. However, beyond effectiveness, there is a need to track the degree to which the organizational goals are being achieved and whether they are aligned with the overreaching institutional purpose. A clear and goal-focused strategy must be developed and maintained. Satisfying the needs of the various stakeholders should be an important factor in such a strategy.

3.7.2 Creating Motivation for Reaching the Goals

The right motivation of the workforce is essential for achieving institutional goals. However, creating the proper incentive system can be a challenge. Motivation can be indirect, for example, offering rewards or wages for achieving the goals, or it can be direct – this is the motivation that an individual draws from personal satisfaction for accomplishing an objective or from the success of the organization in which she or he is working. If direct motivation exists, and the individual and organizational goals are aligned, then there is a better chance of the institution fulfilling its purpose. The more ambiguous and prone to interpretation the goals are, the more difficult it is to agree on how to accomplish them. Oliveira [Oli13]argues that by having directly motivated members who are aligned with the institutional purpose, the organization can stay on course and has the potential to self-correct in case of a deviation. However, in practice, indirect motivation is more prevalent in terms of both tangible rewards, such as money, and intangible rewards, such as lust for power, fame, and recognition. Increasing the transparency of the institution can help the public to keep some of the said incentives in check.

3.7.3 Communication of the Goals

An institution's goals and incentive structure need to be communicated. This is done mostly by using written language in form of guidelines, plans, and laws. It is an art in and of itself to be able to unambiguously convey the meaning of goals and rules with words. Imprecise communication can cause a misunderstanding and thus create a drift in the organization by making its members work towards other goals rather than those of the organization. Such a drift can be done purposefully, in the case of individual corruption, to advance personal interests by gamming the rules, for example, following the latter of the rule but not its intent. [Oli13]

In large and complex organizations, some formal systems and the standardization of informational exchange are unavoidable in order to manage the large amount and complexity of information. They need to be built for storing and sharing the information; however, they can also be utilized to analyze the data, gathered in the organization, and discover deviations from prescribed standards. The development of specialized ontologies, the semantic web, expert systems, and artificial intelligence suggests that more automatized rule creation can be developed. Further sharing and collaboration strategies and tools can be deployed to ensure that all members of an organization are well informed and empowered to contribute to the continuous development of the institutional strategy. The Information and Communication Technology (ITC)can be further utilized for broader involvement of many stakeholder groups, such as customers, other agencies, private and non-profit organizations, and unions, in the rule and decision making, and to harness their feedback. The internet provides a useful platform for developing tools for the open exchange of information, collaboration, and learning.

3.7.4 Framework for Identifying Institutional Corruption

A stepwise procedure for identifying IC was proposed by Oliveira [Oli13] p.23-24. In this procedure, an institution's ascribed and achieved goals are compared. The framework is schematically visualized in Fig. 3.2.

Initially, units of analysis must be determined. In the second step, the ascribed purposes of an institution are found in its vision- and mission-statement documents, while their implementation is often provided in strategy documents. They can serve as a baseline for future comparison. In the third step, the institutional design is analyzed, and the ascribed purposes are translated into more concrete organizational goals, which can then be regularly evaluated for deviations. This can help identify internal (departments and employees) or external (for example, lobbies) sources of influence. An analyst must identify the reason for institutional dysfunction by answering the following questions: Is the dysfunction the result of performance or design? Which mechanism or combination of mechanisms is contributing to the observed institutional behavior – is it the breakdown structure, the incentive structure, or are there formalization and communication issues? Evaluation of the achievement of the institutional purpose is conducted in the fourth step. If a deviation between achieved goals and baseline (the ascribed purposes) can be

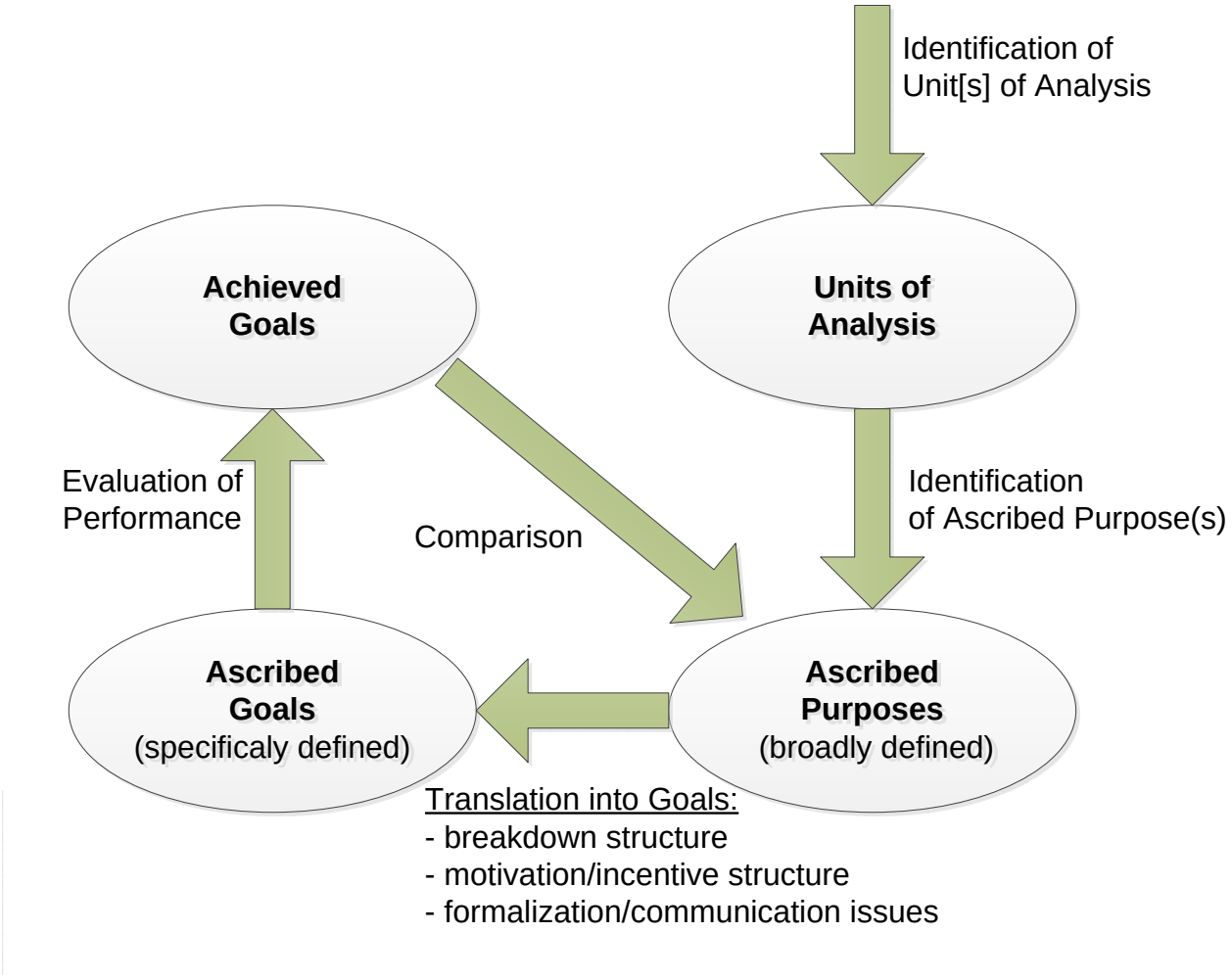


Figure 3.2: Institutional Design – approach to identify Institutional Corruption by Oliveira (2014)

identified, then one may affirm that there is some level of IC. Oliveira's approach places emphasis not only on the importance of identifying IC, but also on the ability to trace the mechanism that is causing it and on identifying the channels through which it propagates – for example, it could be the result of poor policy making, influence by interest groups or lobbyists, or rule bending and gaming as described in [Sal10]. The approach was applied exemplary for evaluating payment to physicians in Austria by Sommerguter-Reichman and Stepan [SRS17].

3.8 Measuring Institutional Corruption and the Outcomes

Searching for better evidence strengthens the theory of IC. However, to be able to develop better benchmarks of IC and extend it to include various institutions, more dimensions should be identified and measured[Lig13]. One might already be able to find some measures, for example, spending time seeking monetary contributions distracts an MP from his daily duties and distorts his or her priorities. The time MPs spend meeting lobbyists can be measured and used as quantification of IC. More qualification is typically needed, especially in areas where institutional and decision-making processes can be corrupted[Tho13].

One of the major differences between quid-pro-quo-type corruption and IC is the legal nature. Dependencies can however create conditions for continuous quid pro quo corruption, which is just short of illegal. This creates the problem of measuring IC in a broad spectrum – ranging from totally altruistic gifts to significant policy influence on certain policy areas or issues. Light identifies three factors involved in such influences, and argues that finding ways of measuring them will advance the theory of IC from its anecdotal nature [Lig13]:

- The size and scope of the dependence
- The response of the dependent actors in the system
- The actions of the actors exercising the influence

According to Light [Lig13] p.5, one needs to establish 1) the boundaries of IC, 2) the corrupt behavior and measurement of its size and scope, and 3) the degree of dependency and the response of the dependent actors. The boundaries of IC are not easily drawn and compared to the traditional, venal corruption not clearly definable. However, the effects of IC are perceived strongly by the public. Furthermore, even if those boundaries were definable, they would still be subject to speculation and polarization about what IC is and is not. The public is rarely in agreement; this is evident in the differing opinions about many political topics, for example, the migration crisis, austerity, the handling of the Greek debt crisis.

3.8.1 Size and Scope of a Dependence

The size and scope for measuring a dependence would vary from one institution to another. For example, Light[Lig13] offers various degrees of dependency from *"deeply and continuously dependent"* on the both ends to *"choosing to become dependent in order to gain wealth and influence."* The latter is the case in the mental-health domain, where medical (psychiatry) institutions have become dependent on the funding of drug manufacturers, which has led to swift changes in how patients are diagnosed and treated, and how policies and regulation distorted and corrupted the social mission of all the organizations involved [WC15]. Furthermore, the actors who play a role in the IC process need to be identified. There is a need for a formal way of deciding which actor should be included by researching the system. Beyond the lobbyists, there are more ambiguous boundaries that need to be established case by case.

3.8.2 Measuring the Responses of Actors

Another important goal is to find a way to measure the response of the dependent parties or persons "trapped" in the corrupt system. Sometimes, the level of distortion of the process by IC can be objectively detected. For example, in the case of the US political context, there is empirical evidence that fundraising has become an almost full-time job. Even if representatives have the best intentions of serving their constituency, their financial dependency causes them to dedicate the majority of their time to raising money and campaigning. This becomes clear when comparing the total numbers of meetings of committees in the House of Representatives, which fell from 782 to 287, or the reduction of meetings in the Senate from 429 to 175 for a period of approximately 20 years [Les15].

There are various degrees of corruption for different agents, ranging from one trying to maintain high integrity within a corrupt system to others moving completely in the sphere of venal (illegal) corruption. In any case, the underlying issue of IC is easier to be overlooked. Such differences in the type and range of responses by the actors trapped in systematic corruption should move beyond simple "good" versus "bad" judgment. The organization must be analyzed in terms of influence gateways, access, levers, and the prerogative powers of different positions [Lig13].

3.8.3 Measuring the Behavior of the Actors Exercising the Influence

Institutional corruption is not a self-emerging phenomenon; it has its roots in the sources of influence. These sources are actors who create platforms to promote various types of interests and to entrench themselves. These special-interest groups do not only provide institutions with funding, but also with information, studies, consultation, and tactics for advancing or blocking certain policies. In many cases, the institution relies on these resources and actively seeks them. This dependency corruption is a structural relationship of resources between corrupting and corrupted actors. Documentation of the degree and the types of these relationships is essential for finding solutions to reduce them, and

should lead to creating benchmarks for all potential corruption sources. Light [Lig13] proposes some dimensions for a potential benchmark:

- The scale of how close the dependency is of the legal-breaking hairline
- Classification of the strategies and tactics used by the corrupting actors
- The scale of how much the outcome deviates from public interest

3.9 Examples of Institutional Corruption and the Corruption of Democracy

The success of democracy was due to the separation of economics and politics, which allowed free access and encouraged competition, and simultaneously provided the tools for citizens or customers to keep those in charge accountable. Competition is governed by powerful institutions, which are created with the purposes of enforcing "fair" rules and maintaining the balance between the competing interest groups. However, these institutions are not immune to the corruption inflicted by such groups.

The cases of petty corruption and its solutions are rather unambiguous and swift. This is the way in which a criminal needs to remain hidden to escape prosecution. The problem with IC is that it is too ambiguous and invisible. It first needs to be deliberated. Often, the complexity of modern institutions can make such a task difficult. The institutions are subjected to an economy of influence, which can also be dynamic and ambiguous. These powerful institutions can be easily captured by influence. As English [Eng13] p.16 put it best, *"democratic politics generates centrifugal forces that systematically threaten to corrupt our political institutions."*

The responsibility for poor institutional outcomes is also often unclear. The problems that arise from multiple decisions are not easily solvable by a single decision either. The challenge of IC is that it is an inherited feature of a democratic system; however, it is the best-known system that is currently available.

3.9.1 Lobbying - Money and Regulatory Capture

One common example of IC is lobbying. On the one hand, lobbying is an important part of democracy, and it is connected to the values of freedom of speech and the right to petition one's own government. However, it also creates an environment in which a few well-connected and resourceful individuals can dominate and influence political decision making. Lobbyists help shape legislations, and in many cases, they are even drafted by them. Over time, regulatory protections, which serves the public, are slowly being stripped to benefit special-interest groups. This is what is referred to as regulatory capture.

The practice of lobbying dates back to 1830 when people representing private interests were meeting MPs in the lobbies in the House of Commons in the UK to advance their goals. However, lobbying can have a controversial and often negative image among the public. There are countless press titles of the type *"Power of car-industry lobby makes scandal inevitable"* [Obs15], which contribute to this image. In his book Corporate Europe [Cro13], Cronin, an old-time Brussels insider, revealed multiple cases of influence of public policies from powerful corporate interests in various industries, such as the tobacco, oil, banking, and food industries. The public's perception of lobbying is negative, especially because of such stories about certain practices of influencing policy. However, it is not the aim of this thesis to analyze or condemn lobbying practices. There will always be some lobbyists who push their agenda to the boundaries of what is legal and even beyond, but should their misconducts be projected onto the practice of lobbying as a whole, which has deep democratic roots. The issue is not the existence of lobbying, but the disproportional power of the resourceful few who have access to policy and decision making.

Kaiser presents an interesting case about lobbying in his book *"So Damn Much Money – the Triumph of Lobbying and the Corrosion of American Government"* [Kai10], in which he follows the history of Gerald S. J. Cassidy, a funder of one of the largest Washington lobbyist firms, who first utilized earmarks, which are a way for the congress to appropriate funding, for his clients. At first glance, the story might seem easy to condemn; however, the realities are more nuanced, especially if it is taken into consideration that the initial, and even currently some of the largest, customers of Cassidy and Associates were universities, some of which were able to obtain governmental funding for their research for the first time. Not many people would argue that universities receiving money for research is a bad thing, as certainly many senators did not in 1986, when a vote protected and solidified the earmark system from critics. As Kaiser reported, the proponents of earmarks would have won, but the realities of the system they were defending, a system of granting money based on peer-review and competition, were compromised by demonstrating that only a handful of elite schools across the USA were obtaining grant money. The system of earmarks was and continues to be exploited by various private and public organizations. A question arises that can be the subject of many philosophical debates: is a flawed system a justification to create another flawed system just to circumvent the original one?

The institutional structure of Europe is not as simple, and is certainly less studied than the American one. Industry, lobbyists, and think tanks play a key role in policy and decision making; however, the mechanisms and the impact remain largely unstudied. The Union, with its (soon to be) 27 member states, creates the most complicated political environment imaginable. This complexity presents a challenge for scholars and for policy making. In some areas, such as the health-care industry, lobbying is done mostly on national levels, and is largely not regulated or transparent. As Green [Coe09] reports in the book Lobbying the European Union, the cross-border industry has much success with lobbying on national levels, and concentrates its efforts on the few major countries in the EU that

can actually influence policies. From Green's analysis, lobbying in Brussels has a more defensive character *"against the destabilizing activities of the Court and Commission"* [Coe09] p.190. Some of the major players have little to do with the industry, and more to do with *"organized professions and publically run or funded health-service organizations"* [Coe09] p.191. Colliding interests in pork-barrel policy make institutional influences dynamic, and they present substantial challenges to draw a clear picture of their sources. In both distinct political environments – the US and the EU – it becomes clear that the issues are largely the same; however, their manifestation is different.

There are approximately 10,000 registered individuals and organizations in Brussels, as reported by the EU transparency register [Reg], representing various interests, which have daily access to EU institutions. Their goal is to shape the policies to match the needs of their customers' businesses, but also citizens and other organizations. The register was established in 2011 to address the many concerns about transparency. The register is an online database where lobbyists must declare and update certain information, including who they represent and how much money they spend. The registrants are separated into the following groups [Reg]:

- Professional consultancies, law firms, and self-employed consultants
- In-house lobbyists and trade, business, and professional associations
- Non-Governmental Organisation (NGOs)
- Think tanks and research and academic institutions
- Organizations representing churches

The voluntary nature and the incomplete and unreliable information of the register are common criticisms of Transparency International [Mul] and Cronin [Cro13], among many. The EU Parliament is attempting to address some of these issues by calling for the Commission to make the register compulsory by 2017 [Reg]. Transparency is part of the solution; however, it can also have a blinding effect because of overload of information; sometimes conflicting, complex language; and overlapping regulations. Vague language in regulation is rich turf for exploitation, and is sometimes purposefully included by the interested industry. Money streams are legal in the realm of IC, and are used for funding, lobbying, or campaign contributions. Money may not always buy direct results; however, it is undoubtedly of great influence in shaping decisions. It may be difficult to always measure its outcomes; however, it is a good starting point for looking for IC. Following the money often leads to interesting discoveries. Money is the fuel that runs the world, and politics in particular. It funds institutions and allows lobbying to shape legislations or postpone reforms, which could end in disaster, and damage public trust in the institutions involved.

3.9.2 Think Tanks

Apart from lobbyists, who are typically under public scrutiny, there is another system of influence that is less known to the public, namely think tanks, which have significantly increased in size and influence, using undisclosed corporate funding to sway lawmakers in favor of their donors. Historically, think tanks have played a key role in society and in conducting research as independent institutions. However, in recent years, there have been indications [Wil13] that many think tanks are used as a vehicle for corporations to validate their own policy agendas. In the EU, think tanks were included in the creation of the transparency register, which still remains voluntary. As of March 2017, there were 542 registered think tanks. Siim Kallas, a former vice president of the European Audit and Anti-Fraud commission, stated in his speech [Datb] that think tanks can be viewed as *"universities without teachings"* and no students, which means their research is not subjected to peer review and academic rigor. He also acknowledged the transparency issues of US think tanks, which have become politically powerful and reversed the process of *"research first and draw their conclusions second."*

Think tanks in the EU are not as excessively funded as their US counterparts, and have less political influence; however, they are still a large source of influence, since they can participate in hearings and consultations as experts, and indirectly sway (influence) policy decisions with their research. As Williams[Wil13] p.4 puts it, *"The only way to trust think tanks is to trust their independence, but they are largely dependent on the very system that renders them untrustworthy."* Nonetheless, they are an essential part of democracy as a space for thinkers and scholars to share knowledge with policymakers; however, this must be done solely in public rather than corporate interest. Many think tanks seem to have ties to corporate interests and are not open to disclosing the conflicts of interest of their conducted studies. Furthermore, serve as a *"parking"* for politicians who are returning to government, or as incubators for new ones [Data].

3.10 Proposed Solutions to Institutional Corruption

Institutional corruption is a valuable and important concept; however, its definition is complicated and open to interpretation, which impedes its practical application. One of the main difficulties of IC is the establishment of a baseline against which corrupt deviations can be compared. Thompson and Lessig approached this issue by devising a relatively simple and intuitive framework based on a rather clear-cut case – the US congress. It works because it relies on legal and historical analysis. However, to analyze more nuanced cases of IC in which there were not historic and sophisticated institutional designers, it would be impossible to apply the same methods.

The framework proposed by Lessig has its advantages: it needs only to find the intended dependency and compare it to the competing dependency. As he argues, the intended dependency of the Congress is on the people; this conflicts with the dependency of the funders of political campaigns because they are not a representative sample of The People. His framework also avoids partisanship and political rhetoric. There is only a need to

demonstrate a distortion of the intended purpose; this distortion is not even required to be substantive in order to indicate corruption in the institution. There is no need for "bad" policy-outcome evaluation, although "bad" outcomes are normally the result of IC. A "simple" dependency evaluation should be sufficient.

However, the dependent-corruption analysis proposed by Lessig requires some historical evidence for the purpose of the institution. This might work well for the case of the US congress, but it can be difficult to extend to other institutions without a similar "rich" history. Furthermore, not all dependencies produce harmful changes. If one considers dependency from an evolutionary point of view, then it is possible that some dependencies can be beneficial. While Lessig tries to identify the "right" dependencies, this can prove to be a source of divisive discussions.

3.10.1 Exclusive Benefit Principle

The fiduciary relationship (also known as the agent-principle relationship) exists between two actors. The fiduciary (agent) works in the name of and for the interests of the trustor (principle). The fiduciary obtains power from the trustor to perform its duties in the most efficient way. Also, as in the agent-principle model, the asymmetric information creates conditions for power abuse. This is a main concern in fiduciary law. Pierce [Pie13] attempts to provide another solution to enable reformers to examine IC in other cases in which historical data is not available or is much more ambiguous, especially in institutions that fall into the category of fiduciary relationships. Pierce draws analogies to existing fiduciary law, and argues that similar principles can be used to expose IC.

The exclusive-benefit principle is an essential principle in fiduciary law. The principle of the fiduciary duty demands "undivided loyalty from a fiduciary to its trustor" [Pie13] p.3, and can be used as a baseline for judging deviations that lead to corruption. Concentrating on conflicts of interest is more productive than arguing about whether the produced outcomes by the institution are "good" or "bad" for society. In law, if the court declares that a relationship is a fiduciary one, then the focus is mostly on the arrangements between the parties, and does not account for intent. The exclusive benefit is the driving principle, and the law regulates only one of the parties – the fiduciary, since this is the party that has the delegated power and the ability to misuse it (even unintentionally). In such cases, the requirement is adherence to the exclusive-benefit principle, thus providing a legal baseline that can be used to measure deviations [Pie13]. The fiduciary relationship is one of dependence. On the one hand, the fiduciary can abuse its power because of the asymmetry of information. On the other hand, the benefits from having a trustor will be reduced if the delegated power is lessened. After all, one goal of a government is to overcome its citizens' collective action problem.

Loyalty is also a fundamental concept in fiduciary law. It infers bias in decision making, but places the burden of proof on the fiduciary. Once the trustor challenges that a transaction can produce a conflict of interest between the fiduciary's obligation and self-interest, the defendant must present proof to the contrary. The scope of self-interest

is not limited to financial benefits. Reformers of institutions do not need to look for a smoking gun and try to explain how current legislations might be wrong. Instead, they should be interested in the reduction of IC if conflicts of interest are identified, for example, as Pierce [Pie13] argued, deviation from the undivided loyalty baseline. The institution itself should be able to rebut such charges; otherwise, it can be considered to be institutionally corrupt and in need of reform.

3.10.2 Blinding

One of the primary problems of IC is that it could create bias. The dependency of the funder might cause a bias in the way in which a decision maker or other public official behaves and change the outcome of his or her decisions. This outcome is what motivated the funder in the first place. The problem with "bias" is that a baseline is required for comparing what the outcome would have been without the dependency and uncorrupted institution. This is a challenging task, as evident so far. Robertson [Rob13] discussed three types of solutions, provided by the literature, targeting potential conflicts of interest: 1) banning all situations that can cause the dependency, 2) relying on the decision maker to resist the influence, and 3) transparency – disclosing all potential conflicts of interests.

The first solution – banning – is the most intuitive but also the most complicated to implement, and is subject to many discussions and objections. Banning funding also does not solve the problem of the institution's need for this funding and the availability of alternative sources. For example, an industry funds bio-medical research billions of dollars, which cannot be replaced by public means.

The second solution does not prohibit the dependency, but rather informs and relies on the decision maker to resist the influence. Plenty of evidence in the scientific literature, summarized by Robertson [Rob13], suggests that individuals are rarely able to recognize and successfully suppress biases and behave as though they have not been exposed to those influences, or to correct the biases even after they have been recognized.

The last common solution is transparency – disclosing all the potential conflicts of interest and dependencies, and allowing the public to regulate the behavior of the decision makers. This is the most widely used approach today. Every westernized country in the EU and the US has a legislation that requires disclosure of donors or other conflicts of interest. Journals require disclosure of the funding for research. Full disclosure has its own problems too; it requires judging of the disclosed information and deciding how the disclosed dependency has influenced the decision maker, if at all, and to what degree. There is a need for a baseline to compare what the outcome might have been without the influence, which is a source for speculation. Such speculations could also lead to growing cynicism and disenfranchisement among the public, if everything is perceived as corrupt, and could further erode trust in the institution.

An interesting alternative idea, suggested by Robertson [Rob13], is to use blinding techniques to reduce the impact of IC and the bias that it potentially creates. Blinding of researchers and their subject is routinely carried out in medical research and in many

other sciences. It is known that humans are not the optimal preceptors or interpreters of information, and blinding is encouraged as much as possible in scientific research. Editors of journals blind themselves to assess the merit of a given article rather than being influenced by an author's prestige. In academics, professors blind papers when grading to avoid favoritism.

The approach described by Robertson [Rob13] borrows from science and applies it to mitigating the outcomes of dependent corruption and IC. He recognized that a dependency consists of several functions, and by identifying them in an IC case, one could use blinding to filter the bias that would have arisen. The three functions of dependencies, as described by Robertson, are as follows:

- Subsidy – this is what the funder provides to a decision maker or an institution. Its most common form is money. Subsidies are difficult to eliminate, since they are mostly needed for the production of institutional outcomes, and the loss of funding would need to be supplemented from a different source.
- Selection – this is the ability of the funder to select the decision maker or institution that would receive the subsidy. The funders would prefer to select like-minded decision makers who are inherently biased toward the funder's preferences, and who would most likely carry out the funder's agenda. Selection creates a demand effect, where potential recipients actively try to appear attractive for funding.
- Identification – the funder receives the opportunity to influence decisions through the subsidy and selection. The bias occurs because the decision maker can identify the funder, and is tempted to internalize the funder's preferences. Institutional corruption materializes through privileged access to the decision maker.

The blinding solution proposed by Robertson [Rob13] p. 11 aims to keep the subsidy and limit the selection and identification functions. The funder's selection can be replaced with a regulator to either randomize the selection or provide options for informed selection. Randomized selection is probably not incentive enough for a funder, and could unnecessarily blind much useful information. Informed selection would offer the funder a way to specify factors and criteria for recipients, but not directly select them. The crucial role in this case is played by the regulator (the intermediary), who must maintain the incentive for the funder by intelligently selecting according to the criteria while preventing both the funder and recipient from identifying one another. This scenario describes more regulated and ethically behaving lobbyists. The intermediary regulator becomes a new surface for influence and potentially only a shift of IC, if not designed carefully.

CHAPTER 4

E-Government and Corruption - Literature Review

4.1 E-Governance and e-Government

Now that the definition and issues of IC have been discussed, the next part of this research reviews e-Government and its connections to anti-corruption strategies, as presented in the literature. First, some definitions must be established for "governance" and "government," since there is an important distinction between these two terms. "Governance" is a broad term for all the processes of governing through laws, rules, and norms. "Government" is defined as the institution (or a variety of entities) that has the authority and responsibility to govern, make decisions, and create formal obligations. [Wikb] Governance exists on multiple levels, and can also be applied at a corporate, international, national, and local level. [ESC] Corporate governance, for example, refers to the collection of a private company's established internal mechanisms, which provide information and accountability for its stakeholders. Another definition of "governance" is the encapsulation of all procedures and institutions that guide the collective activities of a given group [XH09], p.128. "Good governance" is globally accepted as a prerequisite for development. Furthermore, it is the responsibility of government to meet the needs of all people, and not only the needs of selected groups in the society. The United Nations (United Nations (UN)) established the eight principles of "good governance": participation, rule of law, transparency, responsiveness, consensus-oriented, inclusiveness and equity, effectiveness, and efficiency. [ESC]

Governments, on the other hand, are the institutions; these are the actors that make the immediate decisions, and can also set long-term policies. In comparison, "governance" is

a long-term process, which is concentrated more on the goals than the rules themselves. Therefore, as Hua [XH09], p.129 suggests, "governance" is more interested in the outcomes (substantive rationality), while "government" concentrates on the outputs (procedural rationality). Both outcomes and outputs are important, although the public tends to be more interested in the outcomes.

4.1.1 Recent History of Governance

To understand today's requirements for "Good Governance" and its challenges. This section briefly examines its evolution in the last century. In the history of mankind, governance has undergone many transformations. The last major paradigm in the theory of governing was arguably the establishment of the New Public Management (NPM) paradigm, which can be dated to the government of Prime Minister Margaret Thatcher in the UK; she initiated significant changes to the way in which government works in areas such as expenditure planning, financial management, procurement, performance evaluation, and civil service. The term NPM was crafted soon after, in late 1980 to beginning of the 90s, when major industrialized countries were adopting this approach, which was described as a gold standard for administrative reform. [Mat11], p.185

The New Public-Management (NPM) paradigm is the more "businesslike" or "customer-oriented" approach to managing public-service organizations. New public management promotes professional management and parts with the established rigid bureaucratic traditions in public administration. It changed the way the citizens and businesses are treated through the introduction of more customer-centered approaches and Customer Relationship Management (CRM) in the public sector.

E-Governance is the next significant revolution in public management that has already changed and will continue to change the relationship between citizens and government. E-governance can be broadly defined as the use of Informational and Communication Technologies (ICT) to do business with the government.

4.1.2 The "e" that Precedes Governance and Government

E-Governance is a new paradigm in the age of ICT, and seeks to utilize technology to implement processes and structures with the purpose of achieving "Good Governance". At a service level, it aims to provide citizens and businesses with anywhere-anytime access to governmental services. At a transparency level, it contributes to the functioning of democracy by providing information, collaboration, and involvement in decision-making processes [XH09]. E-Governance is often defined as the use of technology to do the following: improve the relationship between the private sector, the public sector and citizens; advance the democracy; support economic development; and efficiently deliver services. In this sense, e-Governance is contextually inclusive of e-Democracy and e-Government. The term "e-Government" encapsulates the usage of ICT by governmental institutions to provide information and services to the public and increase the efficiency of the institution's work. There are multiple definitions of e-Government. The Organization

for Economic Co-operation and Development (OECD) defines it as *"the use of information and communication technologies, and particularly the Internet, as a tool to achieve better government"* [Ser03], p.11. The EU expands the definition: *"[...]e-government involves much more than just the tools. It also involves rethinking organizations and processes, and changing behavior so that public services are delivered more efficiently to people"* [Mar] p.2.

Some researchers include e-Government as a subset of e-Governance, while others define them separately [PS17], p.3. Fan et al. [FY09], p102 distinguish between internal and external e-Government initiatives: internal initiatives aim to increase the internal efficiency of an institution, while external initiatives provide value-added services to the public, in addition to that. This thesis will adopt this definition of e-Government: the delivery of governmental services and information on the Internet. Under e-Governance, this paper will refer to the use of ICT for effective management in the public sector and all kinds of governmental institutions. E-Governance is, in this sense, the umbrella term.

4.1.3 Stages of E-government

Digitalization is the driving factor of government transformation. The evolution of government digitalization in the past two decades can be divided into different stages of maturity. Karen and Lee [KL01] proposed the following four-stage development model:

- Stage 1 (Cataloging) – this is the initial stage of building the infrastructure and establishing an online presence for a government or agency. In this stage, mostly information about the agency and its procedures are published. This stage was completed in the US and Europe in the last two decades.
- Stage 2 (Transaction) – in this stage, e-services were implemented. Citizens and business are able to perform certain tasks over the Internet at any time and without much paperwork. The citizen is now the customer; this requires full transformation of how the institution works, provided by the NPM paradigm. Most institutions in the US and Europe have some level of completeness of this stage, which was done in the last decade.
- Stages 3 and 4 (Vertical and Horizontal Integration) – these stages are focused on transforming governmental services rather than digitalizing and modernizing existing processes. In comparison with the way in which e-commerce revolutionized the private sector in terms of process and product, in this stage, e-Government begins to revolutionize the governmental service itself. Instead of fragmented services offered by individual agencies, there is a more integrated approach between different (vertical) and functional (horizontal) levels.

One could argue that the third and fourth stages are developing at the same time, with a strong focus on horizontal integration in the future, and the first attempts at this

integration already taking place now. The end goal is central access to all governmental services from a single portal (shop). Services, such as employment market; social security; health care; taxes; income, statements and deductibles; and address registration, will be horizontally integrated into overreaching, end-to-end processes, with citizens being active developers, participants, and controllers of these processes. In these stages, the predominant force is connecting and exchanging information between different agencies (horizontally) or similar agencies at the local, national, and even EU levels (vertically). In EU, for example, registering a business is required in one country; however, tax agencies in other countries in the union can access data internally (international service networking).

4.1.4 Informational and Communication Technologies (ICT) as Agent of Change

The Internet and social media – which includes blogging, wiki, social network, and streaming services, and whose main characteristics are web 2.0, crowd sourcing, and user-generated content [Bea10] – are disruptive innovations. The improvements in ICT have traditionally tended to favor the ruling class. For example, the telegraph, and then the telephone, helped to increase the effectiveness of colonial administrative control. The rise of broadcast technology (radio and television) increased the number of ways in which propaganda could be spread for the government. The Internet and social media create a new dynamic, which is yet to be fully utilized. "New media" helps to address rising concerns through the instant sharing of information and the creation of resistance groups; the most prominent examples of this being Arab spring, the 2007 campaign for the prime minister in Australia, the 2009 Iranian elections, the 2016 failed coup in Turkey, and the 2016 US elections. Some governments are trying to censor and limit access to social media, while others are starting to utilize it for partisan and political propaganda.

The phenomenon of social media predominates in politics by creating social interaction between politics and the public. Successful examples in the US include the Twitter usage of President Trump, and the revolutionizing of campaign finance by relying on small donors' contributions, utilized in the 2016 Sanders campaign for the Democratic Party's primary.

Social media provides users with the ability to share information in real time. It empowers its users by giving them platforms to speak about their ideas or to challenge others. WikiLeaks is another example of an anti-corruption website, which provides anonymity for whistleblowers to publish sensible information and expose corrupt dealings.

4.1.5 The road to Gov 2.0

Social media and web 2.0 have revolutionized the world, and now their influence on governance is becoming apparent. In recent years, there is even the infiltration of the term "Gov 2.0" in connection with the utilization of social media for government applications. There are numerous characteristics that distinguish Gov 2.0 from "traditional" e-Government

implementations [CK08]. In Gov 2.0, content is not only published by government, but also actively created by users. Furthermore, communication is interactive, data are open and reusable, and control is becoming decentralized and democratic.

A case study from 2012 [GO12] evaluated the current Gov 2.0 developments in the four leading EU member states – Germany, France, Italy, and the UK. The study evaluated these states' e-Government strategies, especially their approach to Gov 2.0, by looking for the presence of recognizable Gov 2.0 tools, such as microblogs, podcasts, wikis, video sharing, social network portals, and mashups. In the implementation of the EU strategy, the major states did not explicitly point to Gov 2.0; however, it was apparent that considerable, although still not sufficient, work was done in the area of citizen interaction with the public sector. The study [GO12] found the UK and French initiatives to be more citizen-centric, and positioned them in the *"innovators"* and *"early adopters"* categories, respectively, on the Rogers and Schoemaker's spectrum in the framework of innovation diffusion regarding Gov2.0 implementations. Italy also indicated early-adopter characteristics, identified by its narrow use of Gov 2.0 tools. Germany's strategy, on the other hand, still mostly concentrated on service efficiency and delivery (the supply side), and was placed in the *"early majority"* category of the framework. The study [GO12] concluded that the major EU countries in 2012 were between the *"decision"* and *"conformation"* stages of innovation diffusion.

4.1.6 Techno- vs e-Centric Governance

E-Governance is mostly viewed from a technological perspective – focus is often on the technological capabilities and efficiency it provides – since technology is the main enabler for its implementation. Hua [XH09] views e-Government as much more than the automation it provides. For him, it is a major socio-economical and politico-administrative innovation based on ICT, and to realize its full potential, e-Government strategies must abandon their technological bias. Hua argued that while e-Government is an automation of government, the reverse is not necessarily true. Technology is a necessary condition, but not a sufficient one. The implementation of automation in the public sector does not mean better or more open governance; sometimes, if done incorrectly, it could produce the opposite effect.

E-Governance implementations must be based on open and democratizing principles. They should be aligned with specific and appropriate governance goals; failure to do so would result in ICT not being able to offer the full benefits, such as democratization, efficiency, and transformation of the work of the government, that are often implied. The emphasis should be on the impact and outcomes of e-Governance rather than the outputs, and on effectiveness rather than efficiency alone. Practical implementations should focus on the needs of diverse groups, such as aged people, migrants, and the disabled. Hua [XH09] p.128 calls this approach *"excellent e-governance"* which involves much more than just the technology underneath. Excellent e-Governance is the mixture of *"governance processes, structure, and technology to provide administration, which is*

efficient, effective (outcome-driven), politically manageable, and open and democratic (governance-centricity)." [XH09] p. 130

4.1.7 Framework for e-Government Projects Evaluations

It the previous sections, it was established that e-Government is no longer optional; it is a necessity for better government within institutions and organizations, and technology plays a key, but supportive, role. For e-Government projects to be successful, the people and policies must have the leading role, according to Gupta and Jana [GJ03]. The elements of such projects include an information-technology leader (CTO), decision-making commission, statewide architecture, and a proper policy framework. There are already many implementations of e-Government projects, and evaluating their success requires the means to identify and measure the performance indicators of a given project. However, the goal of this measurement should not be a tracking record or collection of items and numbers only, but should rather be to provide a true way to assist performance and offer insights for optimizing and reengineering, if needed. In the private sector, a highly developed culture of performance measurement is already a vital part of the operations of most modern organizations. Without establishing measurable goals, some specifics of a mission's delivery could be lost. Setting goals and expectations as well as performance indicators, and identifying the responsibility and accountability chain are among the most important success factors, not only of an e-Government project but also in building an organization as a whole [GJ03].

The reality of e-Government projects violates all of these made assumptions. Typically, there are many shareholders, and often, decision makers are unable to agree, since they have different opinions and ideologies, and conflicting objectives. The quantification of many of the variables is also difficult, and political uncertainties cannot be reduced to probabilities. "Soft" methods or a combination of different methods (multi-methodology), as described by Mingers [Min97], are needed to define and measure the problems in e-Governance and IC. E-Governance are hybrid systems with the majority of the parts being soft systems. An approach for modeling e-Governance and institutional corruption must be able to understand complex systems and incorporate different views on the problem.

The Internet is a useful medium for communication between business organizations and their clients. A company can use the Internet to deliver services, conduct satisfaction surveys, and receive feedback from its customers. Customer satisfaction is one of the top priorities for a business. The public sector and e-Government are beginning to act more business-like, and measuring a citizen's satisfaction with their e-services is important. One method for doing this is the Multi-criteria Satisfaction Analysis (MUSA), showcased with the evaluation of a Greek e-Government portal [Bea13]. It is based on multi-criteria decision analysis, and can be used to identify the following: customer preferences, the weak points of an e-Government portal, and the areas for improvement. Data are collected through a specially crafted survey, and the customer satisfaction is then evaluated as a multi-criteria analysis problem.

4.2 “Traditional” Anti-Corruption Approaches According to Public Administration Literature

To fight corruption, most countries rely on a variety of approaches (factors), the most prominent of which are evaluated by the empirical studies [SE08] and [Kim14]. Some of the most relevant approaches include the following:

- establishing professionalism and bureaucratic quality
- establishing the rule of law
- targeting behavioral-cultural factors
- targeting economic factors

These individual approaches are discussed in the following sections. This will help to identify the variables for this study’s empirical model in order to investigate the combination of the “classical” and e-Government approaches on a European level.

4.2.1 Establishing Professionalism and Bureaucratic Quality

Establishing knowledge and professionalism in public administration can be an important shield against political influence [SE08] or against influence from the private sector and special interests [Sti90]. Public officials become more inclined to pursue public interest. The public integrity of an institution depends on its competency and anti-favoritism principles. In the EU code of Conduct [oC], competence in the public sector is one of the most important traits of an institution, along with independence, impartiality, and fairness of the processes. This code [oC] also advocates for a high code of ethics and the service the public, beyond serving self-interests.

Some institutional strategies include continued training and education to provide employees with sufficient skills. However, building work experience takes time, and a degree of institutional stability is needed in order to keep the most experienced and knowledgeable agents inside of the institution. The advantage of having experienced agents – who have already built their informal networks, understand the procedures, and have stronger identities – is that they would be less susceptible to political influence. Additionally, they are more efficient in their work, and have the ability to both critically evaluate processes and organization and properly handle special (individual) cases [SE08], p.300.

By establishing a bureaucratic system, discretionary power can be reduced. Furthermore, a system of control can help to identify not only cases of petty corruption and bribes, but also other unethical behaviors or even human errors. However, this control system is less effective in the cases of IC, or when the institution is captured by special interests, political or economic elites who are able to influence policy and/or decision making directly or indirectly. This could be somewhat minimized by implementing standardized work

procedures, which, in theory, are less susceptible to the influence of a single person [SH04]. Traditionally, the functions of the control system are to prevent discretion and to enforce more responsibility and accountability in the organization. Nonetheless, this control system and how it can be updated to trace more systematic types of corruption should be considered. Another aspect of an administrative reform is the merit hiring for and promotion of institutional positions, which include clear and formal rules, responsibility, and accountability (see administrative reform) [Bea10], p.264.

4.2.2 Rule of Law

A law-enforcing system is a key anti-corruption factor, and is normally a government's first approach, with the main goals of establishing administrative reforms, new regulations, anti-favoritism practices, and whistle-blower protection[Kim14], p.386. In her book, Susan Rose-Ackerman [RA99] describes corruption as risk-taking behavior. When a strong legal system is in place, the risk of corruption increases. Business can calculate these risks and the consequences of being caught. If law enforcement is weak or the penalty is "cheaper" than the compliance, a business might decide to risk evading the law. Furthermore, if the risk of detection is low, a public official could also be persuaded to conduct corruption activities. As Bertot [Bea10], p.265 argues, administrative reforms aim to reduce opportunities for corruption, where law enforcement ensures an increase in the cost for such behavior. To avoid such scenario, an agency has to invest in intensive internal-supervision systems. Auditors, investigators, and law-enforcement departments are key actors in this ant-corruption strategy, which is most prevalent in Europe and North America, where strict laws on corruption are already well established [Kim14], p.386. However, the problem with "legal corruption" remains. Furthermore, some of the drawbacks of those approaches are the costly and time-consuming nature of such investigations, which often disrupt the normal operation of an institution [SE08], p.302.

4.2.3 Behavioral-Cultural Factors

There is an important critique on placing too much emphasis on control and prevention of corruption, best expressed by Gabel [Geb12], (abstract) who said that there is *"[. . .] discourse of a mechanistic conception of human nature as rational and self-interested. This leads to an over-emphasis on institutional engineering and the strengthening of oversight and control [. . .] while neglecting the social-moral components of human behavior as well as the political processes of their generation."* She further emphasizes that such an approach only leads to reducing the meaning of concepts, such as *"ethics," "integrity,"* and *"prevention,"* to simple *"rules," "rule-conforming behavior,"* and *"control"*.

The strengthening of laws and undertaking law-enforcement initiatives do not guarantee success in the fight against corruption. Instead, the success of such strategies depends on the behavioral-cultural specifics of the country. In some countries, for example, gift-giving is considered as part of the tradition. In other places (east and south), clients are inclined to pay *"express fees"* to speed up public services [Kim14], p.387. This gap between

governmental and social culture is difficult to bridge. Some studies, such as Seleim [SB09] and Husted [Hus99], seek correlations between culture and corruption. To change human behavior by establishing high ethical and professional standards and building institutional integrity takes much longer than establishing other anti-corruption systems in institutions. This approach is also ineffective in cases of political corruption, where the interests of the rich or other interest groups can sway power in their favor [Kob02]. The targeting the behavioral-cultural factors can be viewed as empowerment of the people by allowing them to participate more actively in shaping their institutions [Bea10].

4.2.4 Economic Factors

In the public sector, a high amount of corruption is linked to decreasing economic growth and investments[Tan98], and higher and ineffective government expenditures. This results in larger fiscal deficits [Mau97] and less spending on welfare, which is directly connected to inequality [BB03]. Bertot [Bea10] p.265, attributes this focus on economic issues as driver for corruption to the rise in globalization since 1990, and provides the example of the anti-corruption convention, which was signed in 1997 by Organization of American States (OAS) and Organization for Economic Co-operation and Development (OECD). His critique is that the majority of anti-corruption initiatives are yet to focus more on information issues rather than only concentrating on economic developments and aid. Even one of largest international institutions, the World Bank, still holds the view that *"Economic policy reform should be a main pillar of an anti-corruption strategy in many countries"* [Gro] p.1.

The economic approach relies on the fact that human behavior is guided by economic conditions [Kim14], p.387. As citizens and public officials become affluent, the conditions for corruption are mitigated. At the very least, the temptation of bribes or favoritism decrease when public officials are well paid. The annual surveys of Transparency International (TI) indicate that there is less corruption in high-income countries[Int]. By comparing the data of 37 countries, Park [Par03] found that economic freedom, along with socio-political stability and rule of law, are the major factors that influence corruption. However, even with high income, he argues that there will be politicians or public servants who will seek personal gain.

4.2.5 Income Inequality

Income inequality is another factor that can be associated with corruption. Inequality, as a factor of corruption, has been gaining popularity, especially after the 2016 US election, and an increasing number of studies are trying to link it to the increasing IC in western democracies. The study [AP10], which performed a granger-causality test, found that there is bidirectional causality between income inequality and corruption in both the short and long term. It is somewhat intuitive to assume that with an increase of inequality in a society, the tendency toward corruption among the group that is left behind will be much higher. Furthermore, since corruption also contributes to inequality, the interplay

between the two can create problems for a society. The authors of the study [JsK16] also found significant interaction between democracy and inequality. Professor Lessig speaks about the "equality" of citizens in his book [Les15] p.15, and such inequality is *"a corruption of the idea of a 'representative democracy.'"* He refers not to wealth equality, but to the equal voice and ability of people to influence their government, which he argues is not the case in modern politics. This is an intuitive concept, and numerous studies presented in this thesis demonstrate that money can provide access to politicians and influence policy making or regulations. It should be investigated if higher income inequality in a country would indicate higher citizen inequality as well.

4.2.6 How E-Government enhances Traditional Anti-Corruption Strategies

Excessive control in institutions has its limitations. First, it could interfere with the efficiency of the institution's service delivery. Shafritz and Hyde[SH04] investigated how over-conformity and unnecessarily strict rules can lead to "impersonal service," which is especially problematic in cases where more individual care is required. Excessive control may prevent officials from doing their work because of fear, which leads to an increase in service delays and overall red tape, and thus promotes more corruption, since the business normally requires its interactions with public administration – such as receiving licenses and permissions – to be done as fast as possible. Therefore, trying to control corruption with an increase in oversight could lead to less effective institutions, or even more corruption. Controlling is also a significant cost center for government, and the potential savings of anti-corruption initiatives are difficult to estimate and measure. Bureaucratic rules can also quickly become outdated, and updating them is time consuming and costly because public servants must be trained in the changed procedures. E-Government can significantly enhance those "traditional" anti-corruption strategies. It utilizes ICT for service delivery, and achieves efficiency and transparency while simultaneously reducing the costs of the service. It could provide valuable information for the institution itself, for example, ICT could effectively monitor work processes and generate reports for management, thereby saving digital data, which could be accessed by higher-ranking officials or audit departments at any time and faster. Ultimately, the data can be provided to the public for the highest level of control achievable at the moment. Other valuable information, for example, bidding prices, could then be compared in the government-procurement process against all bidders or the prices of all public contractors, which can be tracked and renegotiated. The digitalization of processes significantly reduces the level of a single public agent's discretionary power. Fan et al. [FY09] lists some of the anti-corruption strategies that e-Government can achieve:

- Prevention – simplifies processes and rules, and uses ICT and online transactions to eliminate gatekeepers and discretionary powers.
- Enforcements – digitalization makes it easier to protocol and track decision-making processes, which allow for easier audits and control

- Access – publishing institutional information online builds public trust and provides stronger means for public control and feedback.
- Capacity building – the technological part of building e-Government, particularly software development and ICT infrastructure

4.2.7 Experience of Using ICT as Anti-Corruption Tool

E-Government has empowered citizens by not only enabling flows of information to citizens, but also creating possibilities for upward flows to government to improve decision making and enable horizontal flows of information. Many e-Government initiatives do not mention corruption in their design; however, there are inherited anti-corruption benefits associated with them, such as the following [Int13]:

- A reduction in information asymmetries between public officials and citizens
- A limit on discretion, and thus limited avenues for bribes
- A reduction in interaction between citizens and administration through the automation of processes
- The removal of intermediaries
- An increase in transaction transparency and citizens' control
- The providing of tools for citizens to report, give feedback, survey opinions, track satisfaction to improve the quality of the offerings, and identify corrupt behavior
- The providing of a platform for citizens to organize, petition, and shape decision making

Davies and Fumega [DF14] have further categorized ICT interventions as follows:

- Transactional reforms – the main goal is to automate and modernize government processes, which in turn limits discretion and provides means for corruption detection
- Transparency reforms – opening information and making the works of the state and institutions visible to the public

Dupuy and Serrat[EDS14] offered seven other categories for anti-corruption tools based on ICT:

- Transparency portals publishing key governmental information

- Open data portals providing data sets in machine readable formats
- Service automation and citizens' self-services
- Online right-to-information requests allowing citizens to request specific governmental information
- Crowd-sourced reporting and controlling, which allow for reports of corrupt occurrences
- Online corruption reporting
- Issue reporting, which allows for the identification of problems in administrative processes

The first three of these seven categories are normally government-led. The first two seek to increase transparency, and the third aims at transaction-automation reforms. The rest are civil society-led, with the fourth and fifth categories seeking transparency reform, while the sixth and seventh seek transaction reforms. [EDS14]

4.3 Empirical Studies Showing the Connection of e-Government and Corruption

The connection between corruption and e-Governance is often investigated in use cases on an anecdotal basis, with a focus mostly on single-agency or governmental functions, such as budgeting, transactions, procurement, public projects, and grants. This study examines this connection empirically. There are some older empirical studies [MJ12],[SE08],[Kim14],[Elb13] that statistically try to explain the relation. They rely mostly on the recognized indexes (explained in more details later in this Chapter) to measure of corruption and e-Government, and try to explain the connection between them by relying on the classical regression model to investigate this relationship. The model can be written as follows:

$$y = X\beta + u$$

Where:

y - dependent variable corruption (stochastic),

X - regression matrix (of all explanatory variables),

β - "true" coefficients (which are estimated),

u- unobserved error vector (random).

4.3.1 Measure of Corruption

(Corruption Perception Index (CPI)) proposed and maintained by Transparency International since 1995 provides a score for most of the countries of how corrupt their public sector is perceived to be. The index is based on multiple independent surveys and expert assessments. It uses the scale from 0= "highly corrupt" to 10="highly clean" country. Majority (3/4) of the countries score below 5 [Int]. Few researches have already tested the CPI in their works and comparing it to other indexes Husted [Hus99] found that CPI is more comprehensive and reliable. Further the CPI is evaluated every year and it is based on at least 4 different surveys per country, which further improves its reliability. While Europe and North America have traditionally higher scores the corruption remains one of the biggest global problems. We normalize the index and use scale from 0 to 1, for better numerical interpretation considered that e-Government index is given in the same scale.

The Corruption Perception Index CPI has also several limitations. It doesn't implicitly differentiate between systematic (IC) and normal (venal) corruption; instead it provides aggregate level of corruption of the public sector as perceived by the citizens and businesses. It is impossible to distinguish what is the relation between the two types of corruption. Although it could be expected that in the developed countries the systemic (institutional) corruption is proportionally more represented in the index, since the rule of law and enforcement in these countries are very well established and illegal venal corruption is rigorously investigated and prosecuted compared to the developing countries. Authoritarian regimes and undemocratic countries tend also to benefit only a tiny fraction of the ruling class, and the law in such counties is often forged to enable such behavior. We hope, no country in Europe, even with some of their governmental and political flows, can't be viewed in such extreme.

4.3.2 Measure of E-Government

In majority of studies the primary explanatory variable for representing e-Government, is the e-Government Development Index (EDI), which was developed and is maintained by the UN, and which has been tracked since 2001[UN.b]. The scale of the index is from 0 to 1, with a higher score indicating higher development in the e-Government sector. The index aggregates three different indices:

- Online-Service Index – a measurement of a given government to engage in e-Government initiatives, and the quality of the provided services
- Telecommunication-Infrastructure Index – a country's ICT infrastructure evaluation
- Human-Capital Index – based on the UN Development Program for measuring the human development in a country.

For this study's model, the aggregate index – the EDI – is used. A study [Elb13] has already investigated the index at a more granular level, and found that the most important

components of the EDI were telecommunication infrastructure and the quality of online services. Human capital, on the other hand, did not play much of a role. Furthermore, increasing Internet adoption showed significant correlation with CPI. However, according to Husted [Hus99], corruption destroys confidence in the public sector and leads to a reduction of human capital. Selem and Bontis [SB09] also argue that investments in education lead to institutional stability, and that the effectiveness of an ICT approach against corruption depends on the human capital and education in the country. Their hypothesis, which can be tested, is that corrupt countries typically have lower levels of human capital. For this reason, this paper does not exclude human capital from the model. Technological infrastructure is costly, and although most European countries have relatively developed infrastructure, as reported by UN [un.a], its costs should be taken into consideration.

4.3.3 Results of the Empirical Studies Performed at a Global Level

The study [MJ12] concluded with significant evidence that developments in e-Governance reduce overall corruption in a country. In fact, it found that for every 1% increase in the e-Government Development Index (EDI), there was a 1% decrease in corruption. Additionally, a Probit test was conducted to prove the causality. The results surprisingly demonstrated that e-Government had a more significant impact on corruption in developing countries than in already developed countries. The study [MJ12] explained these results with the higher degree of corruption enablers, such as lack of transparency, discretionary power of the bureaucrats, an insufficient legal system, and a monopoly of power, in these developing countries. They can be effectively addressed by e-Governance initiatives, which demonstrate great impact on venal corruption in particular, thus contributing to an overall CPI reduction over the researched period.

In comparison, the empirical study [SE08] evaluated e-Government against the "traditional" anti-corruption approaches by controlling for professionalism, bureaucratic quality, the rule of law, and political stability. The study [SE08] had accomplished its two goals. First, it found that "traditional" anti-corruption methods can offer positive results at a country level. Along with the usual economic perspective, three additional strategies – professionalism, quality of bureaucracy, and rule of law – were also found to be statistically significant in influencing corruption. Secondly, the major question about the connection between e-Government and corruption is also answered with evidence. The two distinct approaches – e-Government and e-Participation – were statistically significant, but the effectiveness of those two approaches cannot be precisely determined. Overall political stability was also found to be an important factor. More democratic and transparent societies have more tools against corrupt practices. Other socio-economic factors, for example, cultural context [Hus99], should be taken into consideration when implementing anti-corruption initiatives. This is also valid in the area of e-Governance.

Similarly, empirical study [Kim14] found that rule of law, followed by e-Government, was the factor with the highest impact on corruption. It stated that all factors together would likely contribute to clean government, while the rule of law is the fundamental

precondition on which all other efforts can be built. Further models presented evidence that if e-Government and efficiency in an institution were to be combined, this could be a powerful tool against corruption. E-Government can be effective if it is utilized by high-quality bureaucracy and is compatible with the socio-cultural environment. A mature technical infrastructure was also found to be a prerequisite for success.

A more recent study [Ion16] in 2016 was based on surveyed conducted on more than 1,800 managers and employees of large corporations in the top 20 list e-Government readiness list 2012 established by United Nations (UN). The overwhelming majority of the interviews (on average 82%) acknowledged e-Governance as an effective tool for the fight against corruption. Only 4%, on average, had concerns about the danger of corruption, which could be enabled by ICT.

Another study [Elb13] analyzed data between 1995 and 2009 from 160 countries by using the Random Effect (RE) model. The study included Internet adoption, which it obtained from the World Bank's World Development Indicators (WDIs). For the rule of law, the study tested with two different indexes – the Rule of Law Index (from WDIs) and the Property-right Index, developed by the Heritage Foundation – to compare their robustness. Other corruption predictors, included Gross Dpmestic Product (GDP), inflation, trade protection, and country urbanization (from the WDIs), freedom of the press. Additionally, the study [Elb13] tested the causality between each of the explanatory variables and corruption by utilizing the Panel-Granger Causality Test, which is more efficient for testing time-series data. The findings of the study were that e-Government reducing corruption is statistically significant in all models, and an increase of 0.20 in the EDI leads to 0.25 to 0.43 in the CPI. The Gross Dpmestic Product (GDP) and rural-population ratio were also significant in given equations (chosen specifications). However, inflation, trade protection, and freedom of the press were only somewhat significant in one of the equations, making them poor predictors. The impact of law enforcement, when measured either by using Rule of Law Index or the Property-right Index, was also statistically significant in all equations (with expected negative sign).

All these studies fit their regressions with data about countries at a global level. It is expected that such studies would be more general because they take the entire population of the world's countries into consideration. However, this study aims to apply the method to a smaller, specific subset – all EU countries. The EU member states tend to be more similar in terms of their economic, political, and social factors, such as economic wealth, democracy, rule of law, technical infrastructure, and human capital, when compared to the rest of the world, yet they are still diverse compared to each other. This is one of the major challenges of the EU in trying to harmonize law, market competition, labor, and government across its 28 diverse member states.

4.3.4 Investigating the Linear Regression Assumptions between EDI and CPI

As noted in the previous section, the both EDI and CPI indexes are often used in the literature in simple regression models. To check the "quality" of this relationship, the assumptions for a model of relationship between EDI and CPI were examined, where CPI is the outcome or dependent variable.

$$CPI = \beta_0 + \beta_1 EDI + u \tag{4.1}$$

All available datasets from 2003 to 2016 were used to estimate the regression equation. Table 4.1 displays the summary statistics of the variables for the 28 EU member states (including Croatia). The table was created using the stargazer package for R language for computational statistics [Hla15].

Table 4.1: Summary Statistics

Statistic	N	Mean	St. Dev.	Min	Max
CPI	224	0.633	0.180	0.280	0.970
EDI	224	0.696	0.108	0.474	0.919

The regression line of the estimated Equation (4.1) can be viewed in Figure 4.1. The model summary is given as R output. The estimated coefficient is $\beta_1 = 1.29631$, which indicates that an increase of 1 base point on the EDI would increase the CPI by 1.29631. Increasing of the CPI indicated an overall reduction of corruption – the higher the CPI score, the "cleaner" the perception of the country.

Coefficients:
Estimate Std. Error t value Pr(>|t|)
*(Intercept) -0.26937 0.04970 -5.42 1.55e-07 ****
*EDI 1.29631 0.07057 18.37 < 2e-16 ****
—
*Signif. codes: 0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1*

Residual standard error: 0.1134 on 222 degrees of freedom
Multiple R-squared: 0.6032, Adjusted R-squared: 0.6014
F-statistic: 337.4 on 1 and 222 DF, p-value: < 2.2e-16

Next, the assumptions of the linear regression models were checked. They are defined as follows:

1. linearity – the expected value of the dependent variable (Y-values) can be expressed as a linear function of (each) explanatory variable X.

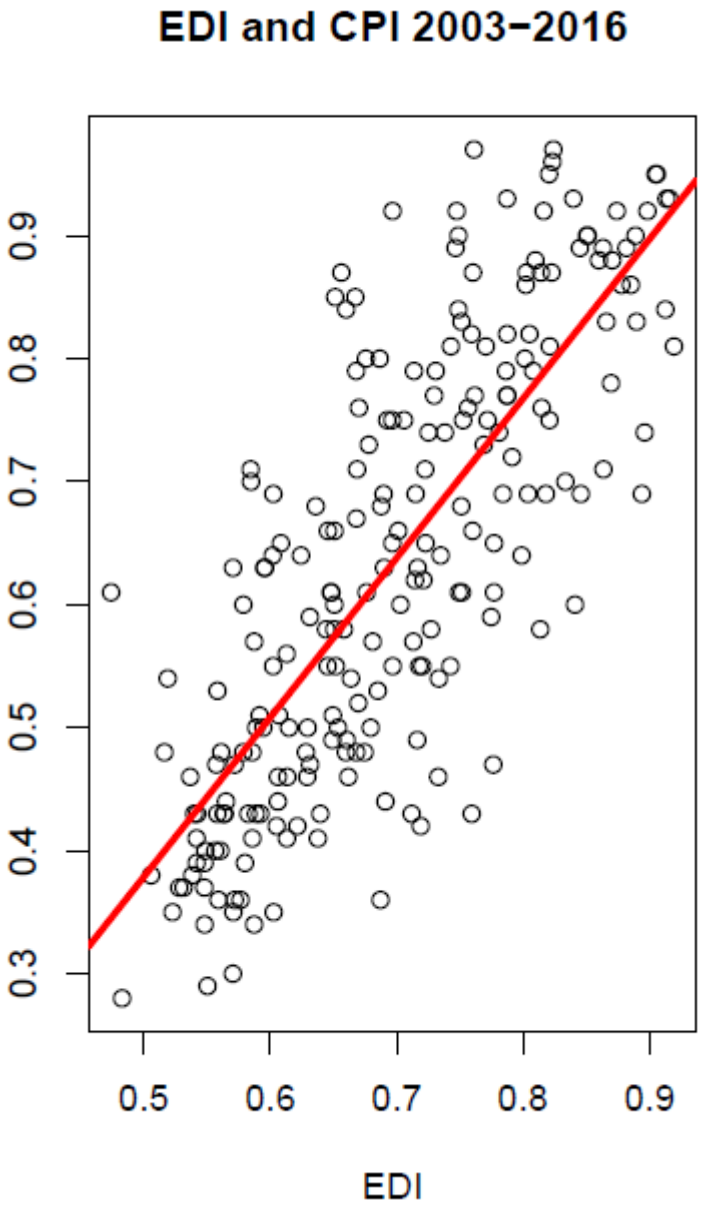


Figure 4.1: EDI and CPI 2003-2016

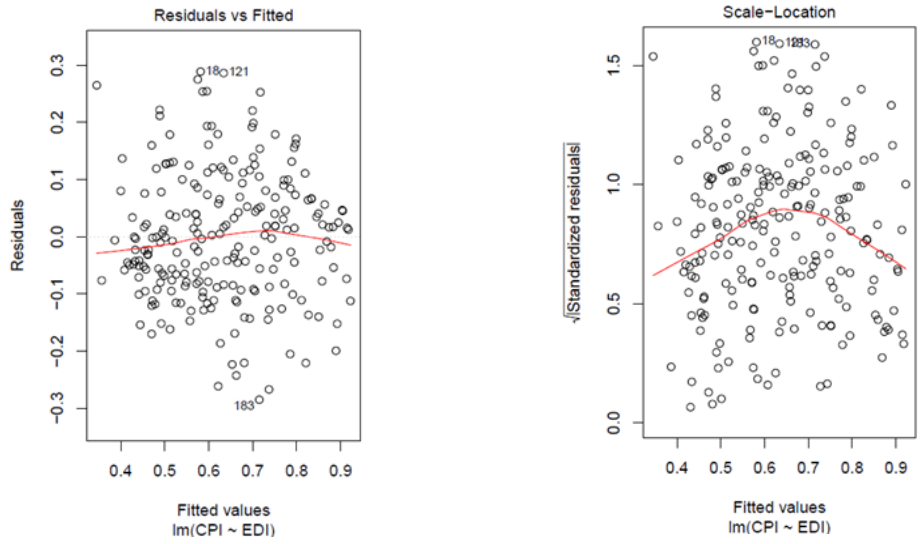
2. independence of the errors – the errors are independent (they do not depend on the X-value). There is no correlation between consecutive errors (particularly in the time series).

3. homoscedasticity – variations of the observations around the regression line (the residuals) are constant and are not dependent on the X-value (homoscedasticity can also be expressed, since the error terms along the regression are equal).

4. normality – For the given value for X, Y-values (or the error) are normally distributed.

Linearity can be assessed from the scattered plot (Figure 4.1), and there appears to be a clear linear relationship between EDI and CPI. The assumption (2) depends on the study design and data collection in order to determine its validity. The indices used are widely accepted in the literature and other empirical studies [MJ12], [SE08] and [Kim14], which have already investigated the relationship between EDI and CPI. However, it could be argued that some observations could be dependent on each other because time (year) is part of the observations. For example, one might expect that the corruption index for a given country in a given year (for instance, Austria in 2016) is somewhat dependent on the country's performance in the previous year. To check the other two linear-regression assumptions (3) and (4), the diagnostic plots of R were plotted, and the model's residuals (errors) were examined. To check the homoscedasticity assumption, the plot of the residuals versus the predicted (fitted) values were examined. The theoretical line is not perfectly flat, and there is slight "bending", as illustrated in Figure 4.2a, which can be further amplified by studying the scale-location plot (Figure 4.2b), where the standardized residuals are square-rooted. This makes it easier to see heterogeneity. However, no models sit exactly on the theoretical line, and in the case of this study, the line is "close" enough. Furthermore, there are no apparent clusters; therefore, assumption (3) can be accepted with relatively high confidence.

The assumption (4) for normality of the errors' distribution, can be checked by a Q-Q plot (Figure 4.3), where the observed standardized residuals are compared against ordered theoretical residuals to determine whether the residuals were truly normally distributed. The standardized residuals do not perfectly follow the theoretical diagonal line. The slight bow shape of the line indicates that there is some excessive skewness of the residuals – there are slightly more errors in one direction. The outliers 18 and 121 are data points for Luxemburg and Finland, respectively, where the relatively low EDI does not represent the high level of corruption cleanness (a high CPI). On the other end, the outlier 183 illustrates that even a high EDI in Italy does not result in a "good" corruption score. The EDI alone cannot be a sufficient predictor for corruption. In the next section, more control variables are introduced into the model to see whether the "predictability power" of the model can be improved.



(a) Residuals vs Fitted

(b) Scale-Location

Figure 4.2: Diagnostic R-Plots

4.3.5 Expanding the Model

After the relationship between the EDI and CPI were more closely investigated, this study now expands the model by controlling for the effects of the other factors, which were identified in the literature, that affect corruption- Bureaucratic Quality, Rule of Law, Economic factors. The EDI alone is not sufficient to explain the CPI.

$$CPI = \beta_0 + \beta_1 VAR_1 + \beta_2 VAR_2 + \beta_3 VAR_2 + ... + u \tag{4.2}$$

For control variables, the World Governance Indicators (WGIs), provided by the World Bank, were chosen; they are often used in the literature. The WGIs summarize the opinion of citizens, business, and experts around the world on six key aspects of governance, and the scale for the indexes is from -2.5 (worst) to 2.5 (best) [Bana]. These six indicators are listed below, together with detailed descriptions of the data sources and methodology for creating them as well as short descriptions about what they are supposed to measure [KM09] p.6:

- Voice and Accountability – represents the ability of citizens to determine their government and participate in decision making. This indicator also captures the transparency of the government, freedom speech, expression, association, and the freedom of the press.

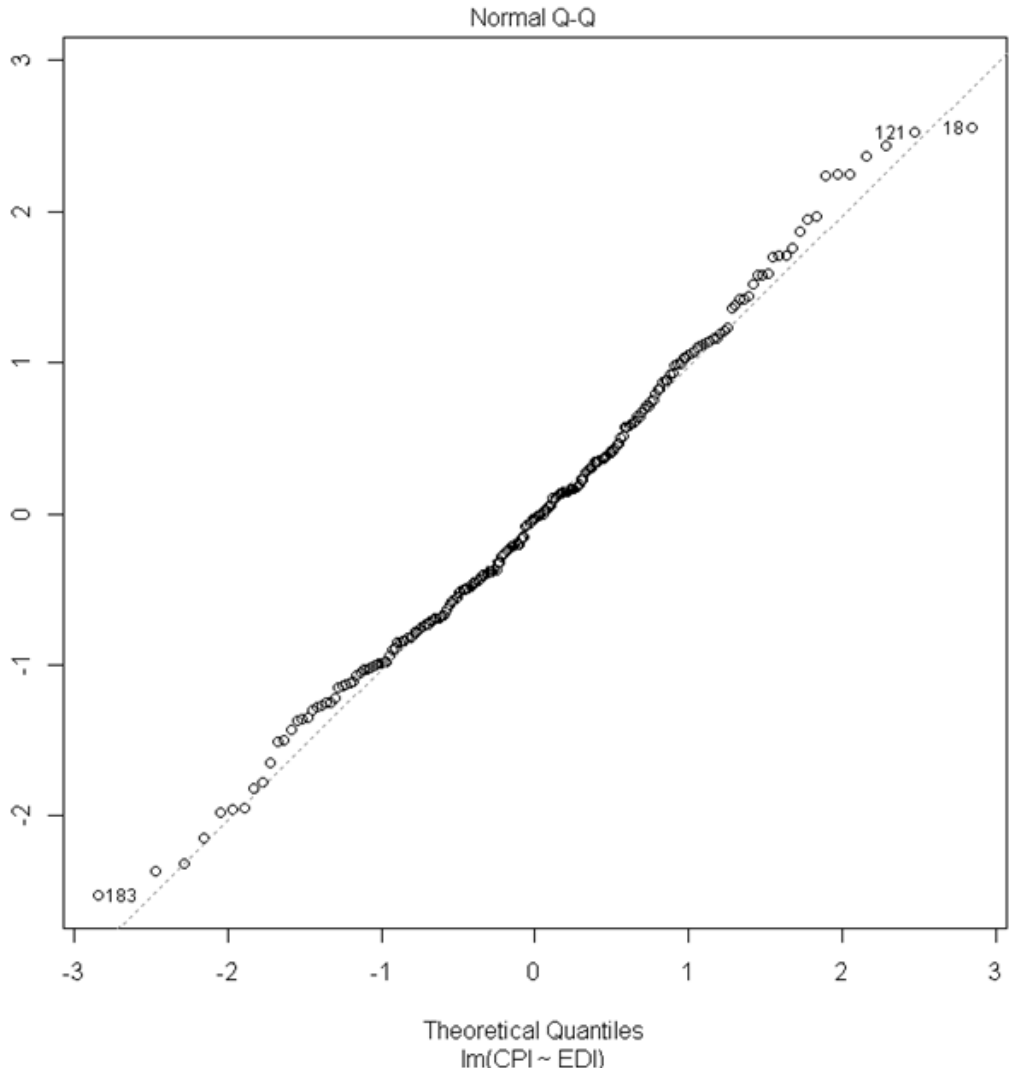


Figure 4.3: Q-Q R-Plot

- Political Stability – represents the likelihood of destabilization and overthrowing the government, including by valiance and terrorism.
- Government Efficiency – represents the quality of the public sector and its independence from political pressure, the quality of policy making, and the commitment of the government to implement those policies.
- Regulatory Quality – represents the ability of government to regulate the private sector and promote its development.
- Rule of Law – represents the quality of law enforcement, the policy and the courts, and society's confidence in the universal abidance of the law.
- Control of Corruption – represents corruption, either venal or systemic, as well the "capture" of government by elites and private interests.

To represent the economic developments in a country, the log of the real GDP per capita is often used. Countries with higher economics tend to have less corruption, since significant resources are allocated to the fight against it. As Husted [Hus99] pointed out, corruption is highly correlated to power distance, uncertainty avoidance (a cultural dimension), and GDP per capita in USD (economic dimension). The GDP data for all EU countries was taken from the World Bank [Banb] in dimension per thousands, and adjusted for price changes (inflation). Furthermore, its logarithmic value was used as an explanatory value in our regression model. This index closely approximates the overall economic output of a country and its total spending – its consumer and government spending, investments, and trade deficits – and economist often use it to represent the financial wellbeing of the population of a country.

To account for the influence of income inequality, this study introduced the Gini index into the model as an explanatory variable. The idea is that higher inequality levels are an indication that more people perceive the system as unfair and corrupt. This study also expects a negative correlation between corruption and inequality – as inequality increases (higher Gini) the CPI values decrease (more corrupt). For all EU member states, the data was taken from Eurostat [Eur], and the missing values for the years before 2008 were filled with the values reported in the UN University's WIID3 database [Uni]. Some of these values have their origin, reportedly from Eurostat, but some used other studies as a data source. More information for the added missing values of the Gini index is provided in the Appendix A.

To measure the quality of the fit, the R-squared is often used. R^2 is the proportion of variance of the dependent variable that is explained by all of the predictive variables included in the multiple-regression models. It is an indicator for the predictive strength of the variables. It always increases however when more variables are included. A better measure would be the adjusted R-squared because it factors in the number of predictive variables.

Table 4.2: Summary Statistics Extended

Statistic	N	Mean	St. Dev.	Min	Max
EDI	196	0.688	0.107	0.474	0.916
GDP	196	3.410	0.402	2.392	4.553
Gini	196	0.297	0.039	0.220	0.381
VoiceandAccountability	196	1.136	0.358	0.300	1.830
PoliticalStability	196	0.754	0.418	−0.400	1.660
GovernmentEffectiveness	196	1.165	0.616	−0.320	2.340
RuleofLaw	196	1.110	0.626	−0.230	2.120
ControlofCorruption	196	1.021	0.813	−0.300	2.530

Table 4.3: Correlation Matrix Between all Variable

VAR	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
CPI (1)	1									
EDI (2)	.788	1								
GDP (3)	.799	.626	1							
Gini (4)	−.423	−.294	−.374	1						
Voice (5)	.897	.711	.802	−.406	1					
Stability (6)	.530	.302	.474	−.504	.593	1				
Effect.(7)	.929	.707	.791	−.455	.912	.548	1			
Quality (8)	.870	.677	.758	−.325	.885	.542	.885	1		
RoL (9)	.932	.747	.830	−.397	.934	.586	.935	.908	1	
Control (10)	.969	.749	.793	−.436	.920	.533	.942	.889	.942	1

As visible from the correlation matrix in Table 4.3 , voice and accountability, government effectiveness, rule of law, and control of corruption are all highly correlated with each other. It is no surprise that a country with an established democratic values and an effective, functioning institutions would have high scores for all four factors of government. They also clearly correlate with the other explanatory variables, such as EDI and the log – GDP – as well as with the dependent variable CPI. This is also to be expected. The fact that these independent variables do not appear to be independent from each other raises some concerns that multicollinearity can be introduced into the model. This would mean that the predictive power of those variables cannot be differentiated from the dependent variable, and might invalidate the results about the predictive power of any of the individual predictors. Even if this was the case, the model can still be used to demonstrate how well all variables together predict the dependent variable, CPI, which results in a high adjusted R^2 (Table 4.4 Model 1). The control-of-corruption indicator closely represents the dependent variable, CPI; therefore, it was not included in the model.

The government-effectiveness and rule-of-law indicators appear to be highly statistically significant (at the t-test). The other variables – voice and accountability, rule of law and political stability – are less reliable predictors. In Model 2, some of the less significant variables were removed, and the log – GDP – was exchanged for the Gini index. The adjusted R^2 is still high in the model, but the Gini index also appears to be insignificant. In Model 3, the log – GDP – and Gini were combined; this slightly improved the adjusted R^2; however, the GDP and Gini remain insignificant in the model.

In the final Table 4.4 Model 4, the Gini index was removed because it seems to have less predictable power, and, combined with the somewhat "unclean" method that this study used to construct its data (sourced from different studies), it likely introduces much noise in the model. Furthermore, European countries have one of the lowest inequalities in the world, and the Gini index across the EU member states does not vary much. The standard deviation across all EU states is only 0.039. However, if used in a global study however, this study suspects that the Gini index would demonstrate more significant effects on the Corruption-Perception Index (CPI). The high R^2 of Model 4 indicates a solid fit of the linear regression. E-Government and the rule of law remained highly significant (at 1%) throughout all the models. A summary of the models is presented in Table 4.4.

4.3.6 Reflections on Result of the Regression Model

The Gini sign was negative, as expected, meaning that the higher the level of inequality in a society, the higher the perception of corruption is. However, the data did not indicate statistically significant support of the index, and the Gini index and GDP appear to be poor predictors. Nevertheless, the log of GDP was slightly more significant, but not by much. The way in which the missing data for the Gini index were collected and handled could have influenced the predictability value of the index. It is also possible that the assumption that income inequality is the same as citizen inequality is wrong. Another possibility is that the Gini index is simply not a sound measure for the latter. There are studies [Hei] that have started to explore the connection between corruption and inequality; however, the data gathered so far do not extend far enough into the past to be useful in this model.

Voice and accountability appeared with a negative sign in some of the early models (excluded from Table 4.4). As mentioned, this might be because of the multicollinearity between explanatory variables or because we used Control of Corruption Index as a predicting variable in some of the early models. Another hypothesis that needs to be further investigated is that, at a high enough level, transparency could actually increase the perception of corruption, since people would be able to identify some of the governmental misdeeds. European countries score higher in this regard than the rest of the countries.

The EDI is significant in all the models. However, the coefficient is much smaller compared to other cross-national empirical studies [SE08], [Kim14] and [Elb13]. It still can be

Table 4.4: Regression Results

	Dependent variable:			
	CPI			
	(1)	(2)	(3)	(4)
EDI	0.348***	0.344***	0.342***	0.341***
	(0.057)	(0.055)	(0.055)	(0.055)
GDP	0.025		0.025	0.026
	(0.018)		(0.017)	(0.017)
VoiceandAccountability	0.013			
	(0.034)			
PoliticalStability	0.007			
	(0.012)			
Gini		−0.115	−0.104	
		(0.113)	(0.113)	
GovernmentEffectiveness	0.124***	0.122***	0.121***	0.130***
	(0.019)	(0.019)	(0.019)	(0.018)
RegulatoryQuality	0.018	0.024	0.023	
	(0.023)	(0.023)	(0.023)	
RuleofLaw	0.082***	0.100***	0.089***	0.098***
	(0.025)	(0.021)	(0.022)	(0.020)
Constant	0.031	0.147***	0.075	0.050
	(0.060)	(0.048)	(0.070)	(0.057)
Observations	196	196	196	196
R^2	0.9154	0.9146	0.9155	0.9148
Adjusted R^2	0.9122	0.9123	0.9128	0.9130
Residual Std. Error	0.0544	0.0544	0.0543	0.0542
F Statistic	290.425***	406.915***	341.208***	512.466***
Note:				*p<0.1; **p<0.05; ***p<0.01

considered a "good" predictor for corruption, but in a developed country with established e-Government, such as in the EU, it has less impact than in other developing countries.

Ultimately, all measures of corruption and governance are subjective and rely on judgments and opinions. The world governance indicators (WGIs) are meant to be used for broad cross-country comparisons and for observing long-term global trends. They are too broad to be used for any specific governance reforms; for such contexts, a specific in-depth analysis of the particular country should be performed. However, the WGIs can be used as a complementary tool for various types of efforts to establish measurers of government [KM09].

4.3.7 Problems of Detecting Institutional Corruption in the Empirical Studies

One criticism for all of the presented studies is their limitation in investigating the impact of ICT on IC, since they rely on the CPI, which has a more aggregative nature and cannot sufficiently differentiate between venal and systematic corruption. Furthermore, other measurements are already in place in developed countries, such as those in the EU, to combat the typical corruption enablers; therefore, the use of e-Government initiatives results in only marginal improvements. In these developed countries, there is already a high degree of e-Government implementations, which could explain the focus on efficiency rather than anti-corruption in these countries. However, the underlying problem of IC is not addressed and mostly overlooked. As Rodriguez [RBea10] argues, there is a need for research to provide better frameworks and strategies for fighting corruption by utilizing e-Government and ICT. This thesis separates IC from venal corruption, and attempts to provide insights and methodologies that would help in the development of such e-Government strategies.

In the case of IC, however, little research has been done in separating IC and venal corruption. The traditional controls of corruption are, after all, limited in detecting IC. In the last two decades, some academics, particularly in the US, began to talk more about "legal corruption." One example is the campaign-contribution process, which leads to monopolization of the government by both the rich and interest groups (lobbyists). Kobrak [Kob02] describes the American society as "legally corrupted." In such a context, impartiality of the institution appears to be or is damaged. The risk of capture of the institution by money interests was explained in the Chapter 3. Citizen involvement and participation are important factors for mitigating those influences. In her book, Shachter [Sch97] argues that citizens are not mere customers, but government's owners. She states that activating the public is essential for achieving agency accountability and efficiency. This can be achieved with better education and a more informed public – this is something e-Government should be able to deliver.

4.4 Literature Topics from the field of E-Government and Corruption

After establishing some of the relationship between corruption and e-Government development, this paper now explores developments regarding the subject of e-Government in scientific literature. Research on e-Government can be found mostly in the following fields – summarized best by Rodriguez et.al. [RBea10] after they performed a systematic literature examination of the relevant periodical journals between 2000 and 2009:

- Technological innovation and efficiency in public services
- Policy analysis – feedback or surveys from citizens, and/or project evaluations, complaints, and reports of misconduct.
- e-Participation and digital democracy – the relationship between citizens and government by using e-Government
- e-Services – the delivery of services to citizens over the Internet
- Transparency and accountability or open data
- Digital divide – the barriers to e-Government
- Organization theory – internal and external factors
- Citizen behavior
- Legislative architecture

While e-Government has already advanced many aspects of society, there is one challenge in which e-Government has the potential to be a game changer: how corruption is dealt with. The literature is lacking in a focus on e-Government as a remedy for corruption.

4.4.1 E-Government, Internet Adoption and Corruption

Corruption damages the effectiveness of institutions and their public trust; it erodes the incentive system for business and citizens – which stimulates the development and growth of an economy– and leads to economic inefficiency and loss [Elb13]. Transparency International (TI) welcomed the inclusion of "good governance" and anti-corruption as stand-alone targets in the new UN Sustainable Development Goals 2030 [PI]. Transparency International has long advocated for this inclusion, arguing that no other goal was reachable without first tackling corruption. The new anti-corruption goal calls for, among other things, the promotion of the rule of law; development of effective, accountable, and transparent institutions; and creation of inclusive, participatory, decision-making processes, which ensure public access to information at all levels of government. E-Government has the potential to be the tool that can accelerate the achievement of

such goals. By lowering the interaction between citizens, the private sector, and public administration, the discretionary power of the latter can be limited. E-Government also delivers more transparency and accountability by providing higher amounts of quality information to the economy and providing tools for businesses and citizens to question policy decisions or ineffective procedures [Elb13], p 114. In this context, e-Government can reduce many of the opportunities for corruption [SE08] in the following ways:

- By reducing discretion through the automatization of some services and/or the application of ICT systems, which can effectively monitor the processes and public officials in an institution.
- By increasing transparency and allowing more citizen participation, enabling them to actively control and provide reports about IC behaviors.

The study [SE08], p.299 further discussed some of the internal and external implications of fighting corruption with ICT. The study discussed closer institutional monitoring and control system for employees and processes. Also, providing more information to citizens or offering them a platform to effectively participate in decision-making and government improves the external relationship with the public. This could help in the control department, since the public would also actively monitor and report on the conduct of internal employees, thus decreasing corruption overall.

Traditional approaches in the literature on anti-corruption strategies usually target the corruption enablers, for example, increasing transparency, and thus promoting more accountability; limiting discretion and the public administration's monopoly of power; and streamlining bureaucratic processes by eliminating or reducing human intervention [MJ12]. Reducing interaction with bureaucrats by using e-services leads to a substantial acceleration of processes. In many cases, this benefit of an increase in efficiency overshadows anti-corruption considerations, which should have ideally been taken into account in the initial design phase of the project. Although increasing transparency and avoiding human interaction indirectly helps to reduce venal corruption, it is not sufficient in the area of institutional corruption (IC), where a substantial consideration of the processes is required in order to establish continued monitoring and evaluation of institutional goals. In many cases, this full control or transparency cannot be achievable or would go beyond the scope of a single ICT application. There is a need for careful global anti-corruption strategies, which should place emphasis on many or even all parts of e-governance.

4.4.2 E-Government, Transparency and Anti-corruption

Today, transparency is regarded as an essential democratic principal. The purpose of transparency is to keep the government honest and accountable. The Internet helped by providing the infrastructure for accessing government information. As a result, there are trends toward more open access and the promotion of transparency and accountability. In each aspect of fighting corruption, the government information and the citizen's ability

to monitor the government play a key role. This paper argues that they play an even more important role in designing and reforming an institution. Fan et al. [FY09] p.102 generally suggested that while transparency can cause public officials to act more "cleanly" by reducing opportunities for corruption, it can also simultaneously increase the risk of engaging in corrupt behavior. Transparency also provides the public with a tool to identify and control the people in power as well as hold them responsible. Bhatnagar [Bha] believes that providing information to citizens about the rules, institutional processes, governmental decisions and actions, and disclosure of conflict of interest enables them to monitor and control the government; however, the number of people ready to engage in this process is still relatively small. Bertot [Bea10] identifies that the combination of technology, transparency policy, and the public's desire for open government creates a unique opportunity for the creation of technologically enabled government that reinforces trust in the institutions. This is a rare alignment of technology, policy, and public demand.

It is important for future e-Government projects to be designed to target the problems presented by institutional corruption. There are arguably compelling reasons for such projects to be developed parallel to other open government or open-data projects. The data can provide deeper understanding about the procedures and processes in an institution. Goals to achieve efficiency and transparency are equally important because an institution cannot be fully effective if any form of corruption exists within it. The data can highlight the sources of influence, which can lead to "negative" inefficiencies or, in the worst case, corruption. Transparency, means not only increasing public trust, but also providing a way for faster identification of problems of corruption, since more people are involved in the oversight of the institution.

4.4.3 Open Data

The US has been a leading force in opening governmental information to the public. Historically, this opening can be traced to the Freedom of Information Act, issued by President Lyndon Johnson in the USA in 1966. This law laid the groundwork for providing public access to federal government information and documents, and not just to a few lobbyists, experts, and journalists. Public administration and governmental institutions should provide information to citizens and the private sector to foster dialog and collaboration and to improve the decision-making process with respect to the needs of the local communities. In 2009, the USA launched an unprecedented process of opening all federal agencies by laying an Open Government Plan for achieving greater transparency. In 2011, President Obama expanded these efforts by launching the Open Government Partnership (OGP) at the UN. Since then, 75 countries around the globe are participating in the OGP, and have made over 2,500 commitments to ensure that their governments are more accountable and open. There are four criteria for country-OGP eligibility [Por]:

- Fiscal transparency – publication of the budget documents is the foundation of

building an open budget system.

- Access to information – the public's right, guaranteed by law, to access governmental data and information.
- Public officials' asset disclosure – disclosure of elected and senior public officials' income and assets in both the fight against corruption and accountability of the government.
- Citizen engagement – requires citizen participation in policymaking and governance.

In the US, a new open the data website was developed to disclose governmental spending (www.usaspending.gov). This website not only provides an intuitive web user interface for tracking every government transaction in the form of contracts, grants, loans, and other financial assistance on the state and county level, but also provides the data sets for every year dating back to 2000 as well as a REST API to call and create customized datasets in XML format for reuse and further analysis. There are also several similar web sites for other departments, allowing the public to monitor spending for waste or fraud.

The EU budget for spending is much more complicated, since Brussels is not responsible for the typical matters of government, such as healthcare, education, and the labor market; these are the responsibility of the national governments. At the same time, the EU shares some competences in these areas with the member states. The budget is then shared among member states using complex schemas, mainly in the form of grants and subsidies. In the EU, there are also some open-data portals that already provide the means for tracking these funds. The Cohesion data portal [Com], for example, provides Socrata Open-Data API access, along with reach-web capabilities to access and visualize the data for European structural and investment funds at an EU and a national level.

4.4.4 E-Democracy and E-Participation

E-Democracy or e-Participation refers to the collection of all forms of digital communication between government and citizens, such as information exchange, collaboration, voting, opinion polling, and policy and decision making. It is the engagement of the public through the means of ICT in the policy process [XH09]. In contrast, the term e-Consultation is used to describe the interaction between public administration and interest groups or citizens for the purpose of cost management, performance, and improvement of the institution's services. The old "silo" structure of government, which leads to intra-bureaucratic delays and conflicts, is replaced by the more efficient and citizen-centric public service. The Information and communication technology (ICT) has the capabilities to provide active and not-hierarchical information exchange. Furthermore, e-Government is not merely a modernization of public services, but also a key enabler in cooperative, citizen-oriented, modern, "Good Governance", as Hua [XH09] suggested.

E-Democracy relies on transparency. The transparency of an institution is also one of the important enablers of citizen participation. However, its implementation is not

without challenges. For starters, it is a time- consuming and expensive project, and its success is not guaranteed, as found in many of the investigated European e-Government projects [DMe14]. The report found that the success of e-Government projects depends highly on motivating the public to participate, being through national advertisement campaign or educational meetings. However, the high level of commitment required for participation is a substantial barrier for the average citizen, who is busy enough with his or her daily routine. Even for those who are already engaged, it could be a daunting task – the sheer amount of information and its unorganized delivery often require patience and work to access and analyze it correctly [Sch97]. E-Participation projects are still looking for solutions to overcome such limitations and enable citizens to participate more actively. This can be achieved by ensuring the high quality of data and Meta data, and by providing engaging and user-friendly platforms to boost collaboration between citizens and an institution. Ultimately, if the data is open and made reusable, citizens with enough ICT skills could be made use of it and become effective controller of governments. Providing more tools for manipulating the data and a more user-friendly Graphical User Interface (GUI) mean that even less-skilled citizens would be able to participate.

Kim[Kim14] also views e-Participation as a key factor in enhancing decision making by including and empowering the citizens. However, Bertot et al. [Bea10] argue that there are still no clear indicators that ICT increases citizen participation but rather brings governments closer to citizens. Citizen participation, even in developed countries, is still low and the "traditional" ways of doing business with government, such as mail and phone, are still preferred.

According to the recent e-Government survey in 2016, conducted by the UN [Sur16], Europe accounts for 50% of the top 50 countries in the e-Participation index, and although the ICT has enabled new, open channels for communication with the government in recent years, the UN survey acknowledged that e-Participation is still an evolving process. Furthermore, even though new ICT platforms have increased the capacity of the agency and enabled policymakers to collect and respond to citizens' feedback, there is a clear indication that agencies are still not willing to do so, as demonstrated in the study that evaluated 23 such platforms across 17 countries [PF16].

Husted [Hus99] explains that e-Participation can only be effective in countries with an individualistic culture. Furthermore, internal surveillance through ICT and e-Government would be more potent in collectivistic societies (southern countries).

4.4.5 Barriers to ICT-Enabled Transparency

The World Bank, in its 2016 Development Report [Ban16], has acknowledged that, on the one hand, digital technologies have increased transparency and the flow of information; however, on the other hand, they were less effective in eliminating rent-seeking behaviors and incentivizing performance in the public administration. The automation of processes is still only partly successful, with high failure rates.

Another paper by Zhang and Zhang [ZZ09] p.115 identifies e-Government as a powerful tool for increasing transparency and reducing corruption. The authors argue that e-Government reduces the chances of corruption by exposing the government to the control of its own citizens so that corrupt behaviors and processes within the institutions are discovered sooner. However, the authors have acknowledged that, to date, evidence of e-Government having an influence on corruption is mostly anecdotal. Independent reports and auditing on e-Government projects are scarce. There is a need for more public evaluation and feedback to ensure the success of e-Government initiatives. Another critique by [ZZ09] p.115 is that e-Government projects are often not designed as part of an anti-corruption objective, and positive correlation is mostly incidental. Anti-corruption agencies should work more closely with ICT teams for the implementation of more overreaching strategy.

There are no guarantees that ICT-enabled initiatives will be successful for providing more transparency. Sometimes, one initiative can have substantial success in one country but moderate or even no success in another, and although e-Government has been universally identified for removing corruption, some scholars [Hee98] see its potential to enable different kinds of corruption, as discussed in the next section.

4.5 Challenges of e-Government

There are some sceptics who argue that public officials could adapt to new e-Government systems and exploit weaknesses to continue corrupt behaviors or even create new ones [Bha]. E-Government might be a potent weapon against corruption; however, it could also lead to new corruption practices, where more tech-savvy officials find new ways to impose economic rent. In other words, it allows for corruption to shift to officials in control of the ICT-empowered processes, as expressed by the Pacific Council on International Policy [oIP02]. Some critics [Hee98] even argue that ICT can create completely new opportunities for corruption. Studies [And09] and [Gea12] found that an increase in national Internet usage is an even more important indication for reducing corruption than e-Government; however, the influx of information could also increase the perception of corruption – leading to the feeling that "everybody is corrupt". This is why it is important to find and track measurable parameters.

The UNDP's analysis of e-Government [Proa] p.3-4 identified the following challenges for its implementation:

- Integrating e-Government and "traditional" anti-corruption strategies – the use of e-Government should be part of the design objectives.
- Political commitment – e-Government projects should be backed by political leadership; this is required by the multi-stakeholder and intra-agency nature of e-Government projects.

- Providing legal support – it is covered by the Freedom of Information Act in the US and the EU.
- Technological aspects
- Interoperability between different departments and agencies
- Promoting access and use – fostering citizen participation.
- Showing evidence – so far, the evidence of e-Government reducing corruption is anecdotal; more empirical research is required, and more measurable parameters should be identified, traced, and made public.

Utilizing ICT and social media could be another tool for spreading influence and, ultimately, corruption. More governmental resources could be potentially distributed to those who have access to better technology [GJ03]. There are legitimate concerns that the development of digital governments might lead to a technological divide, where the ones with the most ICT expertise and power would be able to influence decision making. This technological divide is a new challenge, and is still mostly unexplored. It can be expressed simply as the gap between those with access to technology and those without [Bea10]. The divide includes issues such as technological literacy, usability, accessibility, and functionality so that the technology can be utilized by the broader public. Furthermore, Internet access, although growing, is still disappointing, and there are large disparities even within the member states. The digital divide is especially prominent in rural areas.

4.5.1 E-Government in the Era of Economic Crisis

One key challenge of e-governance in the EU is the diversity of the economic, political, and social systems in its member states. Also, the governmental priorities in each state are different, which makes it difficult for e-Government to meet the EU's common targets. The financial crisis of 2008 further slowed e-Government developments in the EU. The crisis appeared at a crucial period of e-Government implementation throughout Europe and caused many governments to switch political priorities, which caused a deviation from the original plans and timetables [Sid13].

4.5.2 Issues to be Solved in Order to Bring Excellence to e-Government

There are a few requirements for successfully implementing a governance-centric approach, according to Hua [XH09], such as defining a citizen-centric vision for the project and developing a process-oriented view of the institution. The technology needs to provide easy access to a variety of users with different technical backgrounds. This is especially important for the acceptance of e-Government, and is a critical factor for its success.

Along with the acceptance of the newly developed system in a given agency (by management and employees alike), the success of e-Government project also depends on citizens'

acceptance of it. In some cases, governments are inclined to provide services over the Internet because of the related efficiency and cost savings; however, citizens, especially those who are not technologically savvy, may prefer traditional phone- or person-based interactions with the institutions. More educated citizens, however, are more inclined to use technology [Ebb08].

Often, technical problems, infrastructure, software bugs, and even usability limit ICT projects. The impact varies depending on the country. Some wealthier countries are generally better equipped technologically, and have greater personal capabilities to support such ICT projects [Moo02]. The OECD tracks 15 ICT key indicators, such as trends in ICT investments, percentage of fiber connections, Broadband connectivity, on its webpage, and updates them annually [Ind]. One of those indicators, for example, is Internet access, which is still a challenge in many developing countries and even in some developed countries as well. The OECD reported broadband penetration of 95% in 2017, which is an 11% increase compared to the previous year, not all of the population have equal access to the Internet. There are only two European countries with less than 50% penetration overall – Greece and Portugal. However, there are also regions in the highest developed countries, such as Germany, where coverage is still lacking.

4.5.3 Challenges of e-Government to Tackle Corruption

There are some arguments that technology might impose specific challenges in the fight against corruption. These issues include record keeping, digital media deterioration, and software and hardware obsolescence. The secure and proper keeping of digital data is a major concern, especially when its value as legal evidence is highly dependable on its integrity – some courts are reluctant to accept digital evidence [Lem]. Although the cases of IC are not normally concerned with the legal frameworks and the ability to produce court proof, since, by definition, IC is not illegal, the record-management challenges remain the same – data loss, the format of digital records, data spreading across different systems, which makes it difficult to organize, analyze, and control. A special report about these data-management concerns was presented in 2014 at the World-Bank hosted biennial International Corruption-Hunter's Alliance meeting [Banc]. Data storage and management are important, since lost data, caused by negligence or physical corruption, can lead to loss of evidence, and can compromise the chain of custody. It was reported that many investigations into corruption have failed because of missing records caused by improper management. International standards, such as ISO 15489, can help to ensure the trustworthiness of digital records of governmental transactions.

In summary, the literature review done by Transparency International (TI) [Int13] found that, despite high expectations, the evidence of ICT's impact on corruption is limited. On the one hand, e-Governance is expected to reduce corruption by opening information to the public, automating processes, restricting discretion and limiting the gatekeepers of key services; on the other hand, there are difficulties associated with empirically evaluating the impacts. However, the connection between corruption and e-Government has only recently been explored. Further insights will be presented with ongoing research.

4.6 E-Government in Europe

The EU has been benchmarking [Mar15] the development of e-Government in its member states since 2001. This benchmark was a requirement and part of implementing the e-Government Action Plan 2011 - 2015. The newest strategy is already laid out in the e-Government Action Plan 2015 - 2020, which all member states have adopted. The benchmark provides detailed information about e-Government development in every member state [eF], and is briefly discussed in the next section. Local informational sites are also available, for example, the "Vision 2020 in Austria."

4.6.1 The Road to European Strategy for Gov 2.0

An EU e-Government strategy dates back to 2000, when the member states approved the first Europe initiative and initiated the first European policy on ICT for governments. The effectiveness of this first initiative was not analyzed; however, in 2005, the European Commission proposed new strategic goals in Lisbon, which were later previsioned as the 2006 - 2010 action plan [Mar]. The strategy included:

- access and increase efficiency on service delivery through ICT
- develop cross-border, high-impact services, such as e-procurement
- create electronic identification management (eID) for public services' electronic document authentication and archiving
- increase participation (e-Democracy) to reduce democratic deficits

In 2010, the new action plan [Mar] 2011 - 2015 was proposed in Malmö. According to this plan, there were four political priorities on which the member countries were required to focus:

- empower citizens and businesses
- reinforce mobility in the single mark – providing cross-border services
- improve efficiency and effectiveness
- develop key enablers and their interoperability, such as e-Signature and e-Identification, e-Procurement, e-Justice, and e-Health

There was no explicit mention of any Gov 2.0 toolset in the priorities of the first two action plans. Only in the third iteration and newest action plan 2016 - 2020 (called Digital Agenda) is the facilitation of interaction between government and citizens or businesses addressed for the first time [Mar].

The first two action plans (2006 - 2010 and 2010 - 2015) did not achieve their purpose to transform Europe into a digital society. This led to the newest action plan 2020 (called Digital Agenda). All these initiatives would have been more successful today, according to Sideridis [Sid13], if they had followed the original plans. Sideridis assessed that the EU has no room to delay e-Government developments any further. One of the seven flagships of the Europe 2020 strategy is the *"Digital Agenda for Europe,"* which will *"require a sustained level of commitment at both EU and Member State levels" and should "encourage the digital economy"* [Conb] p.2. However , there is still no mention of fighting corruption by using e-Government.

In summary, the European commission has been developing a strategy to utilize ICT with the main goal of providing efficient and effective public services across the member states. However, because of the way in which the European legal system is established, every member is responsible for finding its own way of achieving, and even going beyond, these high-level goals. Furthermore, although the concepts of Gov 2.0 were mentioned only indirectly, at least in the last action plan, there is already some initial level of adoption in some of the member states.

The EU makes much information available online; however, finding it requires some effort. This should not be the case. A single portal with a unified look and feel across all member states would be a useful start. It would help with the mobility of citizens to other member states, since they are familiar with the portal of their own countries. Furthermore, the fact sheets [eF] are documents that could be explored; they offer detailed information about e-Government development in a given member state. These documents are helpful starting points for exploring each EU country's e-Government vision and current offering as well as its legislative basis.

4.6.2 Using CPI and EDI to Evaluate the Development of e-Government in EU

There are various methods used in Europe and the US for determining citizens' needs in terms of e-Government services; the most predominant of these methods is surveying the public's opinion. The recent benchmark evaluation of the EU [Mar15] has identified that the public demands more, better, and faster services. People are already accustomed to efficient and easy-to-use online services that companies such as Amazon offer, and their expectations are rising for governmental services. The taxpayer starts to demand value for money. It is imperative that governmental institutions track and measure performance to optimize delivery to their customers – citizens and businesses.

In the EU particularly, it is evident (Fig. 4.4) that countries on the lower end of the CPI (EU periphery) are trying to increase their e-Governance initiatives, and while their developments in ICT are significant (but not quite at the level of the top countries), the reduction in corruption has not caught up so far. Compared to the developing countries, the EU member countries are stable, and large increases in e-Government results in only marginal changes in the CPI. The level of ICT in the EU is also quite high; the citizens

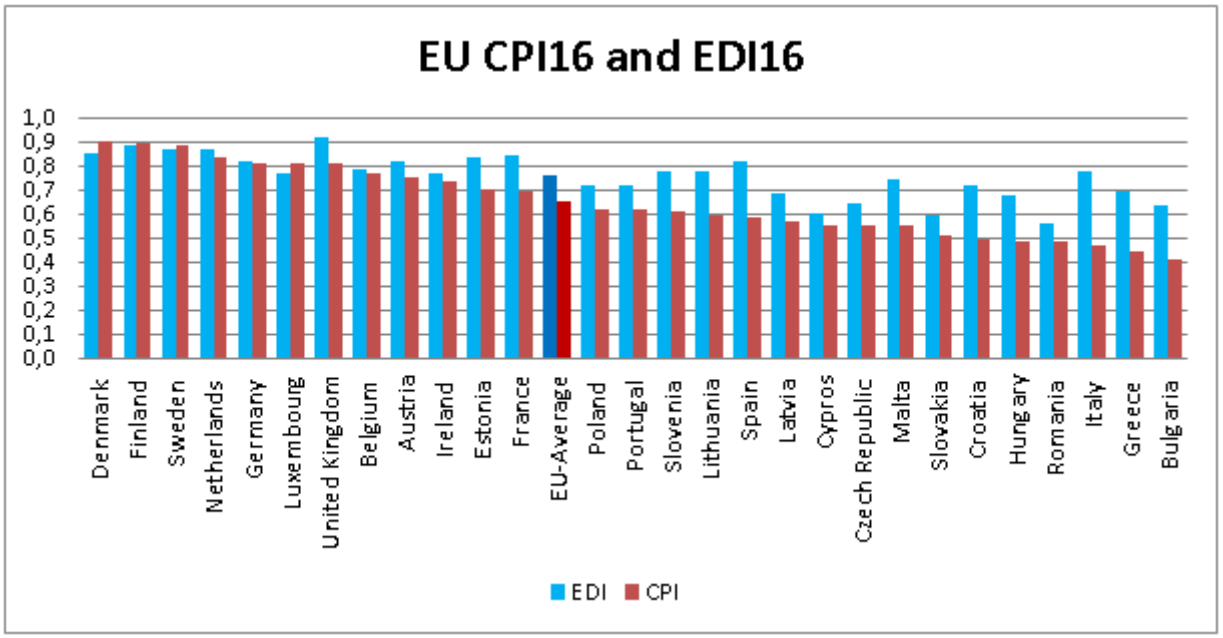


Figure 4.4: EU EDI and CPI 2016

are taking it as a mandatory service for doing business with government, and even expect some level of quality. The availability of e-Services is not considered a question anymore. The next step in e-Government will be to not only further improve the processes and services but also to start fighting against systematic corruption (IC).

The Figure 4.4 was generated using the data of the both indexes –CPI and EDI- for 2016.

4.7 Lessons Learnt

Of the many benefits of implementing e-Governance, the most prominent include the following:

- Efficiency – higher quality governmental services and reduced costs
- Transparency – higher accountability and anti-corruption
- Decision making – improved capacity of the government for optimal policies and decisions

Numerous factors are important for the success of e-Government as an anti-corruption initiative, such as technology access and penetration, literacy, and readiness of the society [Bea10]. However, not only are there technical challenges, but also organizational processes that need to be redesigned. Furthermore, legal frameworks, leadership, and political motivation are needed to complement the digital tools [DF14].

Transparency alone is not sufficient for addressing corruption. The changes need to happen in both the institutions and the individuals who can access and analyze the information. Citizen engagement in politics is another important factor for success [DF14]. There are many ways in which citizens can provide feedback and report corruption, acting on the provided information; however, there is no single solution in every case. Some e-Government initiatives simply will not achieve the same results in a different context. Media and transparency-seeking NGOs could also be important factors for keeping government accountable. There is a need to integrate e-Government with anti-corruption strategies in order to achieve real impact [DF14]. Ultimately, an anti-corruption strategy depends on many factors, and individual solutions should be applied case by case. The distinction of systemic, institutional corruption is also important to be considered in developing e-Government projects, especially in Europe and North America, where the issue is being mostly overseen by now. Corruption is rooted in political, economic, and cultural factors. E-Government might not be able to solve all of them in society; however, it remains a strong tool for mitigating some of the critical enablers of corruption and improving the government-citizen relationship and trust.

CHAPTER 5

Institutional Corruption in Health Care Industry

This thesis further presents a specific case of IC from the health-care sector, and examines how e-Government can potentially support in reforming the institutions (and industry) to achieve their "true" social missions and recover public trust. However, this chapter first briefly discusses the health industry as a whole, and identifies some of its larger issues concerning IC theory.

5.1 Big Pharma Influence

Institutional corruption provides an interesting new tool for analyzing issues in the health-care industry. As the previous chapters have already established, IC is not necessarily illegal behavior; however, some systemic practices corrupt the objectives of the institution, and thus undermine its public trust. Some authors [Rod12a] argue that large drug companies exercise a lot of influence in the healthcare sector, which may corrupt medical practices and corrode the patient trust in them. An article of the PEW Research Center [Pew] estimated that, in 2012, pharmaceutical companies spent approximately 15 billion on face-to-face sales and promotional activities, 5.7 billion dollars on free samples, and 2.1 billion on educational and promotional meetings – the top three marketing expenditures.

Society has come to expect that doctors act only in the patient's interest. After all, there is a long-established fiduciary relationship between doctor and patient. It is almost too easy to overlook the fact that doctors are their own economic entity, and can be moved by financial incentives to promote their own or third parties' interests, such as drug manufacturers, suppliers, and insurers. Third parties, such as drug manufacturers,

can offer financial incentives to doctors as part of their marketing strategies to increase prescriptions, and thus sales of their products. Such financial incentives include payments for consulting, participating in pre- and post-market clinical studies and drug evaluations, writing articles, lecturing, making speeches and participating in conferences, as well as grants for education, gifts, and free samples of products. Such a relationship presents the potential for development of conflicts of interest and biased judgment.

5.1.1 Bias and Cognitive Dissonance Theory

The current methods for dealing with conflicts of interest and correspondingly developed bias are limited to disclosure or promoting awareness to professionals (for example, physicians), providing them some ethical guidance, and letting them handle it. A medical professional (physician) could reconcile with such conflicts of interest in various ways; however, topically one might think that taking "free" gifts is acceptable, because one would remain objective, even though that might not be the case for others in the same situation.

Some academics have found these traditional strategies to be ineffective [CW13]. The biases arising from such conflicts of interest are well studied in the area of cognitive dissonance. The results demonstrated that disclosure is only partly a solution. Bias is commonplace and unintentional, and the influenced person often does not realize this bias, which makes it difficult to eradicate. The professional (for example, a researcher or physician) is able to maintain a belief in his or her objectivity, even if he or she consciously recognizes the potential conflict in obtained financial incentives, and thus remains unaware of the affect they have on his or her behavior [CW13].

Decision making also involves the emotional areas of the human brain. Many studies have demonstrated that the emotion-processing parts of the brain influence decision making, based on memories of past experiences. This processing often occurs outside of conscious awareness, and it is highly influenced by self-interest. Young [Yon09] states that *"the idea that scientists are objective seekers of truth is a pleasing fiction."*

5.1.2 "Misguided" Incentives of the Industry

While patients view doctors and health-care providers as fiduciaries, the industry and private firms of which they are composed may have different priorities – to generate profit for their shareholders. Any drug company claims that its mission is to serve the public by producing safe and effective medical products, and that these objectives are not contradictory to the other objective of every company: the ability to produce a profit. However, this goal to make a profit would take precedence in almost every case, especially when other factors arise that pose a threat to the quarterly or annual metrics. It would be naive to believe otherwise, and this could be seen in countless examples provided in this thesis as well as other authors in the literature.

The system, as it is, provides few incentives to drug companies to choose other routes than the fastest and most profitable one when creating and marketing a new drug. To

promote innovation and research in new therapies for diseases in areas with higher unmet needs, the industry is heavily subsidized by tax payers' money. The EU allocated a budget of 3.266 billion euro between 2014 and 2020 for subsidies for creating next generation medicines and treatments only as part of the Innovative Medicines Initiative (IMI 2) [Ini]. Even so, undertaking research in major therapeutic advances poses a considerable risk and requires large amounts of research, time and money, with results that are often uncertain. The most "profitable" strategy is to focus on researching products with low risks but higher returns, which can be put on the market in the least amount of time. Such products can comprise slight modifications and improvements to existing drugs that have already passed the authorization process and have a patent secured.

There are few incentives for researching new breakthrough. Professor Tom Bschor, the head doctor at the Schlosspark Clinik in Berlin and a member of the drug commission of the German medical association, is working on the new guidelines for depression treatment, where antidepressant drugs remain an important component. In an interview for the Arte documentary *"Depression – New Hope?"* Bschor stated that *"Medicaments against depression, like all psychiatric drugs, have been developed in a time span of about 10 years, 67 years ago. Since then, we have made further developments and modifications, especially in the matter of tolerance. They have not become more effective and we have not discovered brand new operating principles"* [KS]. Therefore, even though the list of medicines keeps growing, there has not been real innovation for years.

5.2 Dependency on the Industry

It would be a mistake to attribute every problem and the arising conflicts of interest to which it leads solely to the greed or immoral conduct of a few actors from the industry. While these are all problems that must be dealt with, they are merely symptoms of an institutionally corrupt system, which has evolved based on improper dependencies. If fact, almost every actor in the health-care domain is dependent on the pharma industry. Some dependency will be present, which is not necessarily unfavorable; however, it becomes a major concern when drug manufacturers influence every aspect of the health-care system. Money plays a central role – almost all activities are funded by the industry. Health-care providers, governmental institutions, and patients alike depend increasingly on drug firms to perform important activities for the functioning of the health-care system; some of these activities are identified by Rodwin [Rod12a]:

"set priorities on drug research and development; conduct the clinical trials [. . .]; monitor adverse drug reactions; evaluate drugs on the market; decide what clinical trial data to disclose; provide information about drug benefits and risks; finance continuing medical education [. . .]; and finance medical societies, conferences, journals, and other professional activities."

Awareness is increasing in academic circles, and even in society, that financial conflicts of interest are becoming commonplace. The study [CW13] discusses the most widely spread occurrences of influences by big pharma in psychiatry; however, the conclusions can be

applied to other areas in the health care domain. The field of mental illnesses (psychiatry) is more prone to bias, since there are no biological markers to help diagnose the diseases, and it is even more accepting of implicit biases under industry influence. Guild influence is likely to be even more profound than actual physical payments; however, it is more hidden from society and physicians alike, even though it may lead to biased judgment. Some of the examples in the study included the following:

- Pharma sponsoring scientific conferences and paying academic participant-speakers' fees.
- Several top medical journals are owned by medical companies, and often carry additional advertisements and opinions that might be in conflict with the authors' opinions.
- Regulatory agencies becoming dependent on drug firms.
- Clinical trials are funded by drug-manufacturing companies, who are expecting profit from their newly developed drugs; this can lead to quick and "sloppy" trials.
- Gifts, in the form of free samples, lunches, and trainings, to practicing doctors.
- Clinical practice guidelines are mostly tied to drug companies – the study [CW13] found that 59% of the authors of the guidelines had close ties with these companies, but only 7% of them believed that those ties had influenced their recommendations.

The European Medicines Agency (EMA) is already 89% funded by the industry in the forms of fees for market authorization of medical products, marketing-related services, and scientific advice and inspections [Agef].

5.3 Industry Funded Studies

Clinical studies are the most important areas in which the industry has significant influence. All medical products undergo a series of clinical trials before and after they enter the market in order to prove their effectiveness and safety. These clinical trials cost considerable amounts of time and money. However, there is a large difference between pre-market authorization clinical trials, where the company must prove that the drug meets the minimum requirements for effectiveness and safety, and post-studies, which serve more as a marketing tool to drive sales. Even though there are obligations for the company to track and report all new findings regarding the risks, benefits, alternative usage, and adverse reactions, there is not much incentive for the company to do so. This tracking and reporting can even be considered a risk of both losing authorization and market withdrawal; therefore, it is generally expected that only positive, biased studies are ever published [Rod12b].

However, these studies, which are then published in established medical journals, are doctor's primary source of information about the usage of a given drug. Some of these studies report potential therapeutic benefits in cases beyond the information investigated in the authorization process, and can encourage off-label therapies. However, the industry funds and manages the majority of these articles. It is the industry that designs and performs the studies upon which the regulatory agencies, the organizations establishing the therapy guidelines, and finally the doctors rely. Some authors [Rod13] have identified that drug companies shape a large portion of medical literature. The manufacturers actually manage the research, writing, and publishing of such studies under the names of academics who played only a small role in shaping the study. This is a process that Sismondo calls "ghost management" [Sis07]. Data are analyzed in-house, access to peer reviewers and journal editors is effectively blocked, and only optimistic results are ever published. The negative findings are not shared and disappear into the corporate vaults. The studies are then published in the best journals with the help of communications companies. Such articles, as Sismondo argues, affect the conclusions found in medical literature and use medical journals as a vehicle for marketing [Sis07].

Such *"ghost studies"* and honorary authorship present some major problems, for example, violating rigorous scientific methods by not performing truly randomized control trials nor testing a large enough population, and the company exercising considerable behind-the-scenes influence on the study's design, analysis, and journal placement. These can be seen as both a significant problem and a conflict of interest, and there is reasonable evidence to believe that drug manufacturers' pursuits to rapidly and successfully market their products prevents them from impartially evaluating the risks and benefits of their products. There are some articles [Rod12b] and [Rob13] that investigate proposals for reform strategies, which aim to mitigate biases imposed by the drug manufacturer in the conduct of clinical trials.

5.4 Limits of the Clinical Study

Even the most rigorous, randomized trials have their limitations. A prime example is the controversial anti-alcoholism therapy with Baclofen – a medicament that has approved for the treatment of multiple sclerosis since the 70s. It has demonstrated practical results in suppressing alcohol cravings, and grew in popularity among patients and doctors. The French authorities were put under pressure to allow temporary Baclofen prescriptions during the trails. A camera team recorded the study, and it resulted in a documentary[Jau13]. However, the clinical trial indicated that the results of Baclofen were insignificant compared to placebo treatments – most of the patients had positive results at the end of the trial. This is often the case in clinical studies, especially in behavioral ones, because the patients can speak to somebody, be heard, and there is someone to take care of them. Beliefs and autosuggestions played a significant role in this trial, but it could be inferred for many other similar trials. The effect of Baclofen on alcoholism was ultimately not proven. A study could not account for the unpredictable nature of human behavior. Even with all its limitations, the rigorous scientific method of

clinical trials is far more reliable than any other means of uncovering knowledge that exist today.

5.5 Inefficiency of Regulatory Agencies

The role of regulatory agencies is to evaluate the findings from the abovementioned studies, and they serve as guarantors of the safety of the public's health. These agencies can be captured by industry influence, which weakens their effectiveness. Apart from capture, there are other factors that can result in agency inefficiency in achieving its goal of safeguarding public health. An interesting case presented the debate over the safety of Selective Serotonin Reuptake Inhibitors (SSRI) antidepressants by a health analysis in Britain [McG07]. Of course, there are challenges in approving new drugs, which carry certain risks as their clinical side effects will be better understood over time. The matter is far from ideal when the initial research and clinical trials are conducted or funded by the company that is expected to market the drug. Even more striking is that when the same agency (Medicines and Healthcare products Regulatory Agency - MHRA in this particular case) is responsible for both approval and post surveillance of the drug's use, there is certain "motivation" for the agency to obscure its own oversights. A tactic of "will to ignorance" becomes a survival strategy for the institution. Purposeful strategic ignorance can explain why regulators do not raise alerts, even when they have access to data aggregates over decades [McG07]. More transparency in the agency's work and public surveillance can help to mitigate some of those issues.

CHAPTER 6

Case Study: Off-Label Prescription and E-Government

This paper has already established that the pharma industry has much influence, which could lead to IC in the medical literature and in the health-care system as a whole. Some approaches regarding how this could be limited by traditional institutional reforms or other political (legislative) means were also discussed. To better illustrate the role of e-Government and the solutions it can deliver in this regard, the following chapter examines the case of off-label prescription through the lens of the IC framework and identifies innovative e-Government tools that might be easier and faster to implement than changing the political and industry status quo.

6.1 Off-Label Prescription - Background

Governmental legislations, at both state and EU levels, aim to authorize any medical product according to its clinical trials and the evidence of its safe and effective usage. These legislations and regulatory agencies have the most important mission to safeguard public health and authorize the use of medical products only in the terms that the drug manufacturer described and proved for safety and efficacy. This information, which is an important part of the authorization process, is included in theSummary of Product Characteristics (SmPC) from which the patient information leaflet is derived, and provides a detailed description about approved usage, dose, and target group, based on the results of the performed randomized clinical trials. However, once the drug is authorized, the agencies have limited influence and do not regulate how a drug is prescribed this is trusted to be in the competence of the doctors. Sometimes doctors can decide to prescribe a drug outside the terms established in the SmPC, and this is often referred to as an “off-label” prescription or off-label use.

Off-label use refers to the use of a drug in other therapies in a way that deviates from the specified and scientifically proved uses, and it is not covered in the SmPC of the drug. Such therapies can include not only using a drug for another therapeutic indication but also using different dosis, frequency, duration, or prescribing the drug to another patient group (for example, children) [Wea17]. Off-label use can vary in definitions, but the most recognized one, which is adopted in this work, is the definition used in the report of the Belgian Health-Care Knowledge Center: the *"unlicensed use of an authorized medical product"* [Van]. In other words, off-label use occurs when a physician prescribes a drug for a different therapeutic purpose than the approved one.

6.1.1 Why Off-Label Prescriptions Are Made

Off-label prescriptions are not necessarily inappropriate, and they have their uses as part of medical practice. In many cases, they are even necessary in order to meet patients' individual needs, especially in cases where patients have already exhausted all approved options, or in cases of rare (orphan) diseases. A well-informed healthcare professional (doctor) can offer an off-label prescription if he or she is aware of reasonable evidence, for example, that is found in medical literature, in professional guidelines, or from own experience, about the benefits that might outweigh the risk of using a drug off-label for a particular case (patient). There might also be no adequate alternative therapy or no other licensed drug available, but declining to treat would pose even greater danger to the patient than an off-label prescription.

In many cases, however, the off-label drug is prescribed out of ignorance – the doctor is not aware of prescribing off-label, or prescribes irrationally without taking into consideration the potential risks. For a medicine to be authorized, its benefits should heavily outweigh any associated risks of side effects. However, many of the off-label prescriptions lack significant scientific support, and can place the patient at risk without adequate knowledge of their potential side effects [Rod13]. Doctors can also find additional information in medical journals that suggest other uses for a drug, where the authorization process is slow and still outdated. This represents a conflict of interest, as Chapter 4 of this thesis establishes, since many of those studies and articles are funded by the same drug companies that manufacture the drug.

6.1.2 Marketing Authorization

Every drug, before entering the EU or any national market, must undergo a rigorous authorization process. The medical product can be authorized either centrally (Market Authorization (MA)), by the European Commission (EC) in accordance with Regulation 726/2004, or nationally, by the competent agency of the member state in accordance with Directive 2001/83/EC. Not all medical products are authorized centrally; the majority of these products still undergo individual national-authorization procedures, although the advantages of the central procedure are becoming apparent, and drug manufacturers are starting to favor it for newly developed drugs. Every member state still has its

own national-authorization procedure, but accepts all centrally authorized drugs. For example, in Austria, the regulatory agency responsible for MA is the Austrian Medicines and Medical Devices Agency (AGES).

In the central procedure, the EC authorizes the marketing of medicines in all EU countries. It bases its decision on the scientific assessments of the EMA, ensuring that all medical products are safe and conform to high standards of safety and efficiency. All applications for the marketing authorizations are submitted to the EMA, and the decision to grant authorization is made after careful analysis of the drug's benefits and risks This analysis is performed by the agency (EMA), especially its Committee for Medicinal Products for Human Use (CHMP), which works closely with the EC and other National Competent Authorities (NCA) from the member states. Every member state has representative experts in CHMP, and the purpose of the committee is to assess the presented evidence for the efficacy and safety of the drug and to prepare scientific reports for the commission, which in turn can authorize or reject the application.

The submitted market-authorization document should consist of three parts to be assessed by the competent authority: quality of the pharmaceutical, non-clinical tests, and clinical trials. Only the clinical trials are made public in summarized form in the European Public Assessment Reports (EPAR), and, as of October 2016, includes all submitted clinical data. Since not all medicines are authorized by the EMA, some reports can be only obtained from the respective national authority. Therefore, the ability to access the EPAR through a central portal and central medicine repository would be beneficial.

As part of the MA procedure, the EMA can additionally require post-studies for further investigations of a drug's efficiency or to identify new areas for application (so called extensions), which can cover off-label uses. However, once the MA is granted, it is difficult to initiate such studies because there is no legal obligation for the drug manufacturer to do so.

6.1.3 Measurements in the EU to Encourage Marketing-Authorization Holders to Conduct Post- MA Studies

Although legislation does not explicitly regulate the use of off-label prescriptions, the new directive 2010/84/EU recognizes it, and requires that theMarket Authorization Holders (MAH)s provide all available information on pre- and post-clinical trials and marketing, including new information about any use outside the terms in the authorization, and the (possible) side effects. To provide incentives for applying for new indications of already authorized drugs, one extra year of market protection is granted, along with other incentives introduced in Pediatric Regulation 1901/2006/EC and Orphan Medicinal Product Regulation 141/200/EC [Wea17].

However, this additional year of market protection only applies to the new indication if the drug is well established (after the eighth year of its ten-year market protection). One year is also a short period, and might not cover all the investments for research and trials of the new indication. This is especially the case when the new indication

often impacts only a small population, such as children or patients with rare diseases. Nevertheless, extending the market protection can present dangerous possibilities to the MAHs to constantly apply for new indications and effectively keep generic drugs off the market [Van] p.15.

6.1.4 Pharmacovigilance

Even though the EU legislation addresses off-label prescriptions only indirectly and views it as an exemption from the rigorous MA procedure, there is increasing interest in it from the EU pharmacovigilance. Pharmacovigilance is the set of rules and procedures for monitoring the safety of every medical product post MA in Europe. Marketing-Authorization Holders are already obligated to report the side effects for every use of the medical product – authorized or off-label. Doctors, hospitals, and patients can also report side effects, and all such effects are collected in a database.

6.1.5 Member States' Policy Options for Off-Label

The EU has no major administrative responsibility for the health-care sector. Its major responsibilities include providing guidelines, and harmonizing the legislation across member states to provide and guarantee the free movement of safe and effective medical products and to boost the competitiveness and productivity of the pharmaceutical sector. The actual responsibilities to protect the health of its citizens and provide them with health-care services lie within the mission of every member state. Member states are allowed to form their own policies related to off-label use as long as they do not undermine the EU pharmaceutical legislations. Member states also have full autonomy to decide how to organize and spend resources for health care. For example, member states can use the reimbursement policy for promoting or restricting off-label prescriptions. However, supporting off-label use based on economic or cost considerations is not allowed.

The regulatory agency only regulates drug approval, not drug prescription. The latter is in the competence and responsibility of the treating health-care professionals (doctors). The most widely spread view across the health-care sector is that off-label prescribing remains the individual responsibility of the doctors, and no policy measure can counteract that [Van]. To date, doctors are not obligated to specify or register off-label prescriptions; however, they are required to inform their patients of such uses, and are liable for their decisions. This represents a concern for every doctor who is aware of the current legislation.

Later in this chapter, the possibilities of an ICT solution are explored – an expert system based on the advancement of machine-learning algorithms can be created that evaluates the doctor's diagnosis and prescription, and is able to determine off-label use and provide this information to the patient as part of the traditional e-health services. This thesis would argue that such a solution would be better than any new legislation requiring doctors to specify the off-label prescription themselves, since, in many cases, such prescriptions are part of routine medical practice, and a doctor might not be aware

of the existence of the authorized treatments. Such a system would have no impact on the administrative burden of doctors; however, it may provide them with valuable information when evaluating the risks and benefits of a given therapy.

6.1.6 Steps Taken by the EU Regarding Off-Label

The commission in the framework of the EU Pharmaceutical Committee discussed the issue of off-label use because of the significant cases of this type of use and the increased number of related questions by various stakeholders. A resolution was adopted in the European Parliament based on the report on the Implementation of the Council Recommendation (2009/C 151/01) on patient safety, specifically with the following implications regarding off-label use [Ros13]:

- (in paragraph 13) called on the EMA to draw a list of off-label uses and called member states to ensure that patients and health-care professionals are informed when medicine is used as off-label;
- (In paragraph 52) called the EMA to develop guidelines regarding off-label use.

And while the commission views the EMA as an important player in this matter, its view is that drafting such a list will not be representative, since different member states have authorized different medical products. To collect more information about the issue before the EMA actions, a study was ordered by the commission in 2014.

The results of the study were published in 2017. Based on a systematic literature study and interviews with stakeholders and experts, the study found significant off-label prescription practices in hospitals in many European countries [Wea17]. The results of the study were also presented in front of the expert group on Safe and Timely Access to Medicines for Patients (STAMP), providing advice and expertise to the commission concerning implementation of EU Pharmaceutical legislation. [Hea17]

6.1.7 Statistics and the Extend of Off-Label Use

The data from the report [Wea17] suggested significant off-label use in the pediatric department within hospitals – in the range of 13% and 69% (from 32 studies), and in range of 2% and 100% in outpatient settings (12 studies). The figures for the adult population follow a similar trend – in inpatient settings, the range was between 7% and 95%, and in outpatient settings, it was between 6% and 72% (covering data from six member states). The data for Austria obtained from hospitals (Prandstetter 2009) indicated that 33% of children were treated off-label. There were no other studies for different patient groups available for Austria.

The figures obtained from the literature for the report [Wea17] are generally high, with the majority of studies reporting levels of 20% or higher for the use of off-label medication and more than 55% when looking at the percentage of doctors prescribing off-label.

However, the reported figures differ considerably between and within countries. Other estimations [Van] suggest the off-label use to be up to 80% of all drugs used in pediatrics and at least 50% in oncology.

The main areas of off-label usage were found to be in children and for treatment of orphan diseases. The pregnant and elderly, according to the stakeholders of the report, are groups that may need special attention. There are many areas where considerable off-label use was identified with the most mentioned being oncology, hematology, psychiatry, and rheumatology [Wea17] p 47.

6.2 Off-Label Prescription and Institutional Corruption

Some could argue that unregulated off-label prescription undermines the mission of regulators, such as the EMA, to protect patients by authorizing only medical products proven to be safe and effective. It also undermines the medical principles of drugs being prescribed only after careful, evidence-based evaluation of their risks and benefits. The current legislation fails to address it and lacks the means to track and manage off-label prescriptions, and thus presents a possibility for corruption of the regulatory agencies' designed mission, which is to regulate the industry and promote public health [Rod12a]. The mission of regulatory agencies, such as EMA is to regulate the drug market in order to protect patients from ineffective or dangerous treatment. The mission of the EMA is stated clearly on its website: *"to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health in the European Union (EU)"* [Ageg]. The EMA further defines its goals to protect and help humans in four major points [Ageg]: *"1) Facilitate development and access to medicines; 2) Evaluate applications for marketing authorization; 3) Monitor the safety of medicines across their life cycles; and 4) Provide information on human medicines to health-care professionals and patients."*

Off-label prescribing undermines both this mission and the idea that physicians should use medication only after careful evaluation of its benefits and risks. Some authors are calling for more transparency and systems that can track, evaluate, and manage the use of off-label drugs [Rod13].To achieve its goals, the EMA must promote medical innovation by granting drug companies easier access to the shared market. This is achieved by making the authorization process more streamlined, effective, and faster. However, this mission does not and should not contradict the mission of protecting public health. After all, those missions can be viewed as shared by the regulators and industry together, and even as supplementary to one other. Furthermore, this thesis will show that e-Government initiatives have the potential to help maintain these goals. Measurable parameters are needed to identify deviations from institutional goals. Such parameters can, for example, be the annual ratio of off-label to on-label use for a given therapeutic indication. A list of the top priority off-label cases can be periodically monitored, and policies and decisions would be made to address such issues in cooperation between regulators, insurers, industry, and the practicing professionals (doctors). A periodical

evaluation of the number of these issues being resolved can ensure that the institution is correcting its course and staying true to its mission to protect public health. Transparency, deliberation on regulatory decisions, and education of the public should improve and restore trust in the health-care system as a whole.

6.2.1 Organization and Economy of Influence

To better understand where influences can take place, the connections between the legislative and executive branches of the EU must first be examined. The EU citizens vote for their representatives in both the national and the EU parliaments. The legislative process is a somewhat complicated procedure of negotiations between the EU Parliament and the Council of Ministers, and, specifically for this study's case, its configuration Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) consistent of the relevant ministers of each member state. The proposal for legislation comes from the EU Commission, which is also the responsible executive authority for the implementation of said policies and the budget. The office of the commissioner for Health and Food Safety and its administrative support from the Directorate-General for Health and Food Safety (DG-SNATE) are responsible for the implementation of EU law for the protection of people's health. An oversimplified view is presented in Figure 6.1.

Having established the surface for influence, the lobbying can be broadly divided into two distinct levels: national and EU. This paper concentrates more on the lobbying at an EU level, since the lobbying and the established regulation at a national level can differ between the member states. Some authors suggest that, there are sectors, such as health care, where a large part of the lobbying is done at a national level, as demonstrated in chapter 10 of [Coe09]. Transparency International established a three-dimensional framework to grade the lobbying regulation system in the member states and the EU – transparency, integrity, and equality of access. In its last published report in 2015, the average score of 19 countries and the three EU institutions was 31%. In Brussels, the highest rating was awarded to the European Commission – 53%, because of the implementation of the EU Transparency Register and disclosing the meetings of commission office members and director-generals with lobbyists. These rulings do not apply to the EU Parliament and the less transparent European Council, which accordingly achieved scores of only 37% and 19%, [Mul]. According the report, the pharma lobby spent "official" estimates of 40 million euro. This thesis used the official dataset of the EU Transparency Register, and searched for the mention of "pharma" in the reported goals for a total of 4,423 organizations from the register. The search yielded 66 organizations that reported annual costs related to activities covered by the register lower figure reported was 24.286.113 Euro and 28.314.062 Euro the higher bound. It should be noted that these figures are provided by the organizations themselves, and there is no meaningful way to check their accuracy. The report of TI for 2015 estimates that the pharmaceutical sector realistically spent 91 million [Coe09] p.15. Looking at meetings of the European commission with organizations from the register, and searching for "off-label" and "authorization" did not return any meaningful results regarding off-label

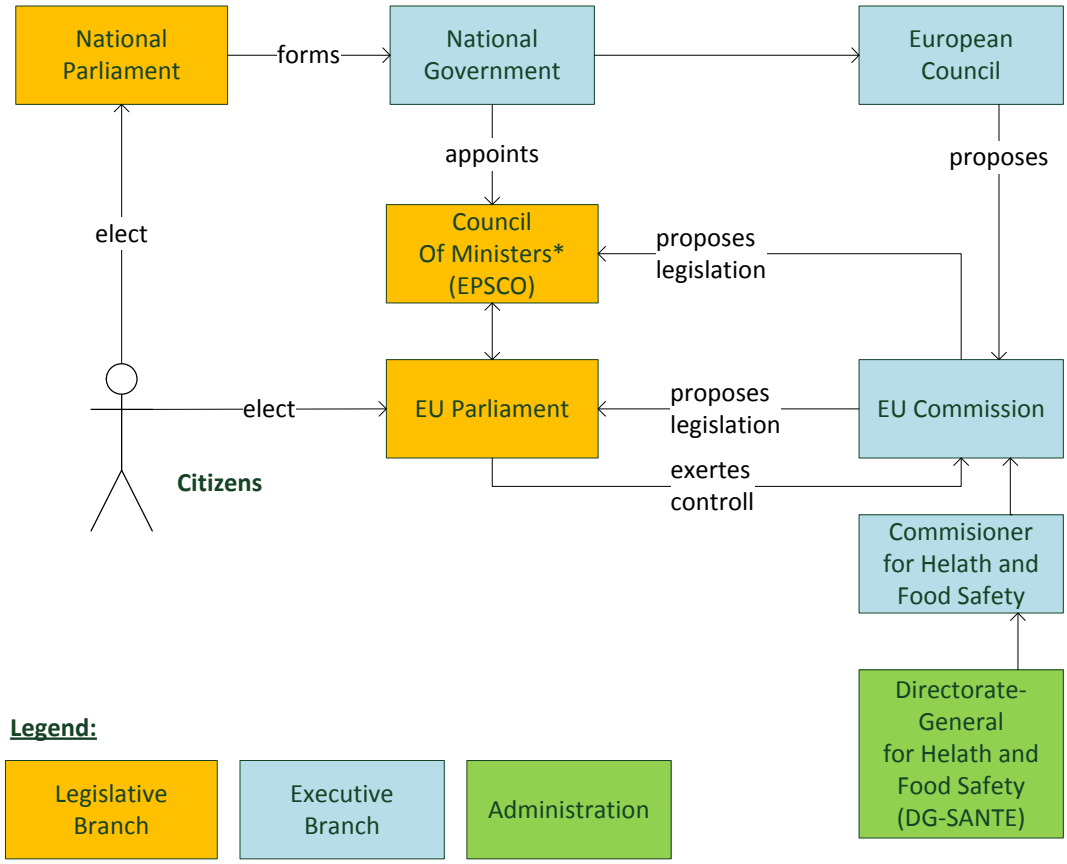


Figure 6.1: EU Institutions

use and MA. However, only the subjects of the meetings, not the meeting proceedings, are protocolled and made public. Also, the practice of publishing the subjects of the meetings began after 01.12.2014, whereas the last regulation regarding clinical trials and market authorization (536/2014) was discussed and adopted much earlier – on the 16th of April 2014. Further, EMA and its special committees are the major advisory and assessment authorities in the process of market authorization, as apparent from [Elb]: *"Exclusive responsibility for preparing the Agency's opinions on all questions concerning medicinal products for human use should be vested in a Committee for Medicinal Products for Human Use"*

The Figure 6.2 presents the structure of the EMA and its connection to the EC and multiple expert and advisory groups, some of which can be traced to be directly linked to the industry.

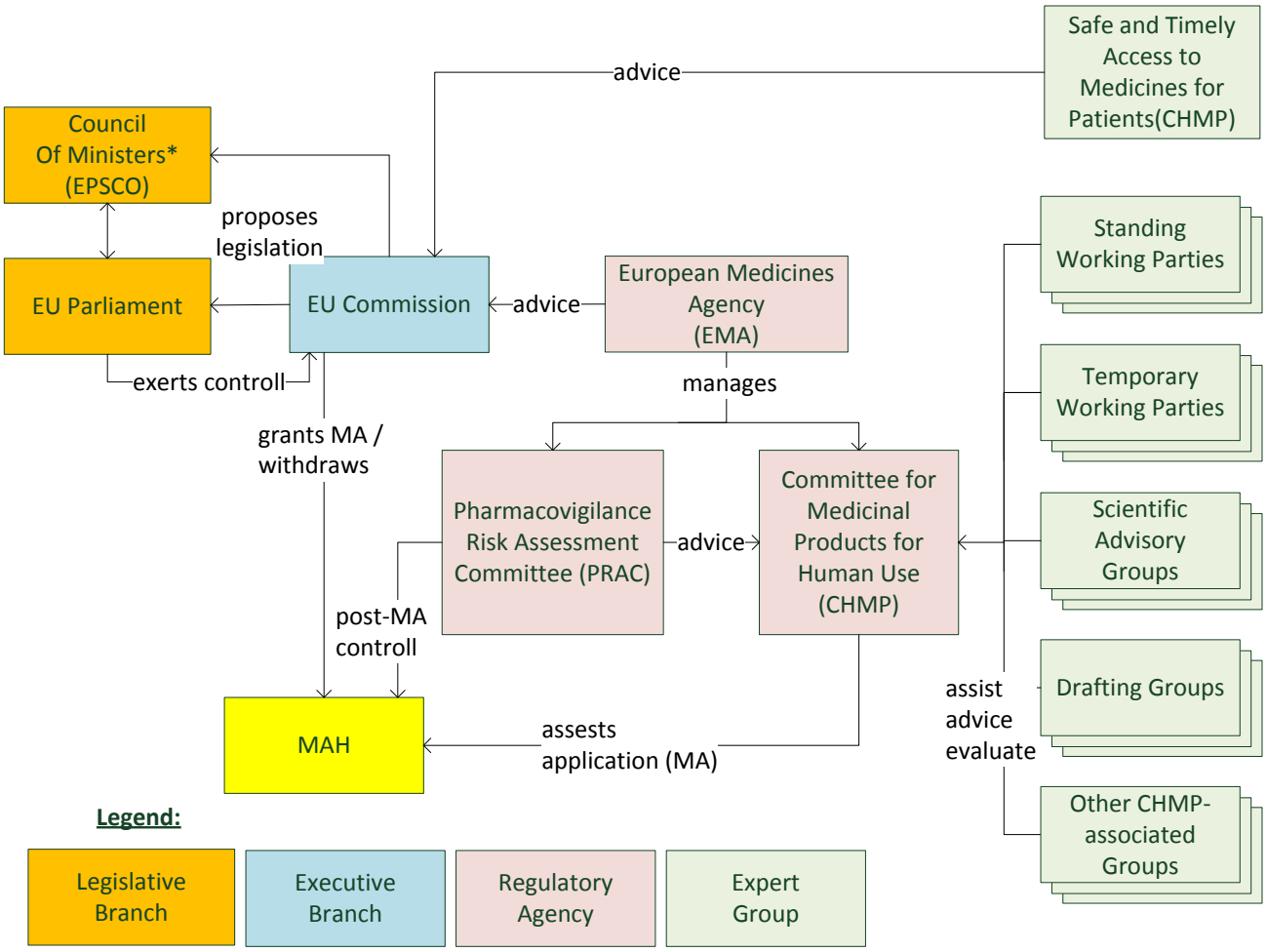


Figure 6.2: EMA Organisation and Connection with EU Institutions

6.2.2 Analysis of the Advantages and Disadvantages of Off-Label Prescriptions

Off-label prescription is not an issue itself, but the absence of adequate support data sometimes can be an issue. Proof of safety and efficiency is often lacking [Van]. Radly at el [RS06] p. 1023 in their research found that *"15% of the drug mentions reported herein lacked scientific evidence for the indication they were used to treat. Among off-label mentions, most (73%) lacked evidence of clinical efficacy."* After all, the evidence, which is provided for one clinical indication or patient population shouldn't necessarily apply to another. There are certain expectations for evaluation of the efficiency and efficacy of a drug. Breaching these expectations could undermine trust in the health-care system. Mistrust and skepticism about the practices in medicine are ever increasing. A prime example is the increasing resistance to vaccinations, which could be quite harmful in the long term.

The main disadvantage for the industry as a whole is that off-label prescriptions may discourage manufacturers from performing rigorous studies. This poses a significant risk of health damage to patients and lawsuits. Furthermore, although a drug manufacturer may not be liable for the off-label use of its products, the negative press and poor public image could be damaging in terms of revenue or potential threats for the company. These risks are rarely taken into consideration despite their potential to negatively impact a company. The freedom of doctors to prescribe drugs also has important advantages. It promotes innovation in clinical practice, and provides more tools to doctors to best meet the diverse requirements of their patients. In many cases, it is even unavoidable when conventional therapies have either failed or posed even greater risk for the patient, or when no such therapies are available for certain groups or "orphan" conditions.

6.2.3 Identify the Key Stakeholders

The key actors in the economy of influence can be grouped into different categories. The categorization done in the report to the European Commission [Wea17] provides three levels of categorization of the main stakeholders, which this thesis expands on:

- On a regulatory level, there are the EU legislative and regulatory agencies, such us the EC, the EMA, their advisory and expert groups, such as CHMP and STAMP, and their counterpart institutions at member-state levels.
- On a health-care level, there are insurers, patient and doctor organizations, health-care experts, and providers of practice guidelines. An insurer can play a significant role in the control of off-label prescriptions in terms of reimbursements. The insurer can ask doctors to justify the usage of a given drug and refuse reimbursements if the drug is prescribed off-label. However, this can be a complex process to manage, and physicians often do not need to justify their decisions. Furthermore, it is difficult for insurers to recognize off-label prescriptions. Sometimes, a state legislation can also prevent an insurer from declining reimbursement.

- On professional and patient levels, there are the health-care professionals (doctors) for primary and secondary care, hospitals and clinics, who provide the health-care services directly, and patients, who receive them.
- On an industry level, there are the drug companies. For any solution to be plausible, the profits of the pharmaceutical industry cannot be reduced. In fact, the opposite is required. Through technical innovation in ICT and smart organization, the costs for MA and the time for trials and authorizations of new indications for existing products should be reduced. Identifying these new indications from the clinical practice would increase profits by allowing the company to expand to other previously closed markets (in member states where the drug was not authorized or reimbursed on the grounds of being off-label).
- On scientific and academic levels, there are academics, researchers, centers for performing clinical trials, and medical journals. For-profit private organizations and experts can perform this research, or it can be conducted in the academic circle.

The connections between stakeholders can be drawn by considering the directions of the influences and money flows. The most important, but not exclusive, connections are drawn in Figure 6.3.

Not all influences are shown of the Economy of Influence Map in order to not overload the diagram. For example MAH can also directly influence other institution without mediation from lobbyist. Drug companies have good amount of political power, especially in the countries, where they are important contributor for the economy and labor market. The legislator, executive branch and regulator have the power to influence all stakeholders, so those connections are also omitted. Omitted are also the "influence" connection from the other stakeholders (beside the MAH) to the legislator and executive branch, since everyone is theoretically able to lobby the government for their interests.

6.2.4 Identify the Drivers of Off-Label Use

The largest challenge of modern medicine is scientific proof. For this purpose, all people should be identical and able to react the same way to a medicine or therapy. However, people are not the same, and as Diter Sicard, former President (1999 - 2007) of the French governmental advisory council on bioethics issues (CCNE), said in an interview (translated): *"real medicine starts where it is powerless; where there are no medicaments, medical apparatus, or operations; no chemotherapy and no infusion, because it is there where it can remember its purpose – to help people"* [Jau13]. Major problem of clinical trials often is the exclusion of significant groups, such as children, pregnant women, the elderly, patients with complicated medical conditions, and other patients who might already be using other medication that can interact negatively with the tested drug. Yet physicians need to treat these patients who are faced with the lack of therapeutic alternatives. A clinical trial also cannot cover all possible circumstances, nor can it

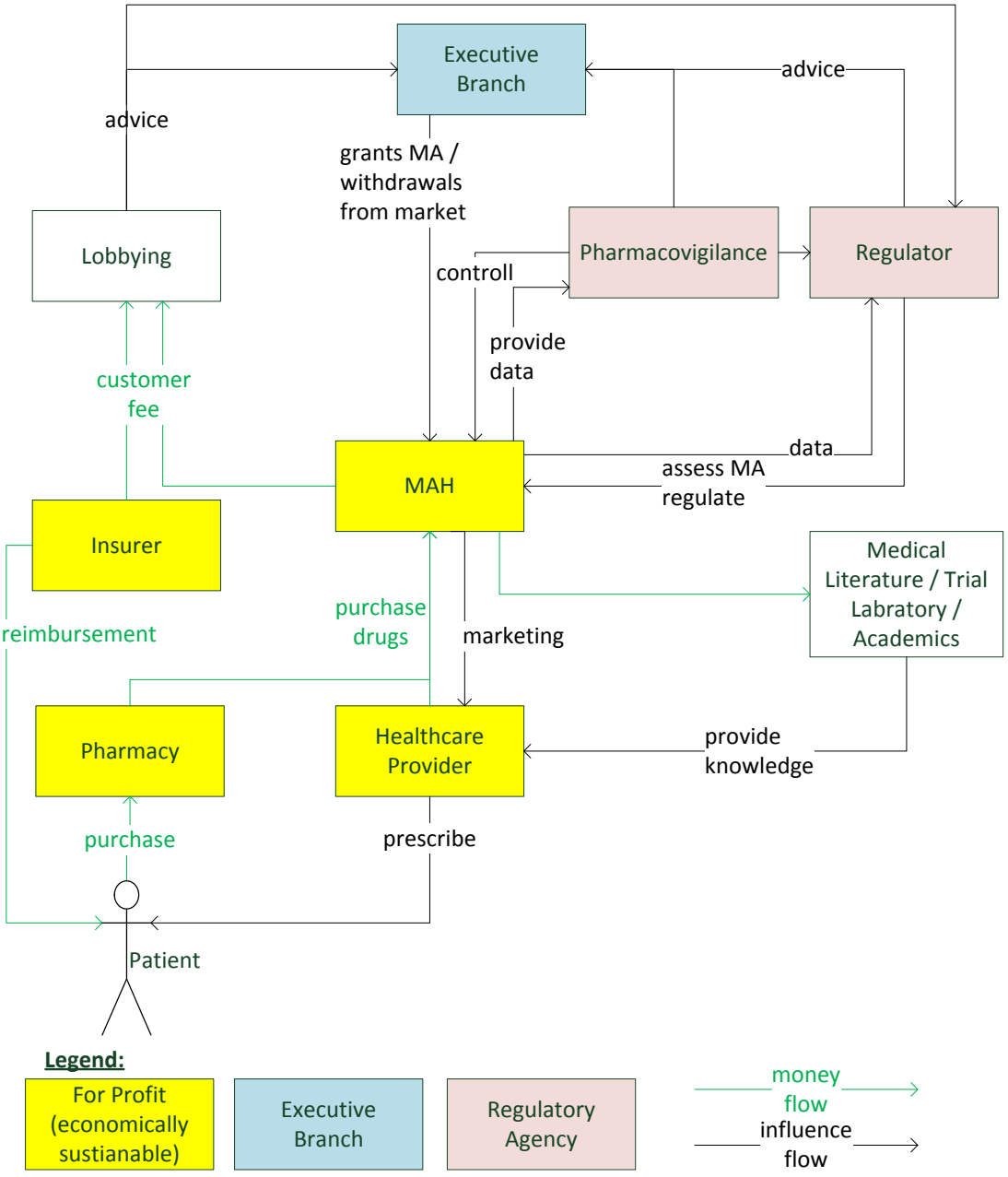


Figure 6.3: Main Stakeholders in Healthcare Domain and Economy of Influence

provide information about the effectivity and safety of the tested drug for different purposes or even for patients with different conditions. Additionally, extensive trials are costly and time consuming, and manufacturers have a profit incentive to rapidly enter the market. Off-label prescriptions can be made to treat similar problems to those tested in clinical trials, and the prescriptions can have some theoretical basis. For example, an antibiotic that works on certain microorganisms can be used to treat problems caused by other, similar microorganisms. The next section of this thesis examines the drivers per different level of stakeholders.

Drivers on Professional and Patient Level

Doctors can make off-label prescriptions because there are no other available authorized alternatives, or because the patient has exhausted all other authorized means. There is a significant lack of authorized medicaments for some patient groups, such as children and pregnant women. Sometimes doctors can justify such practices by suggested in medical articles, post-authorization studies indicating benefits, or professional guidelines, which are still not aligned with the regulatory approval. Off-label prescriptions could already be part of the established routine medical practice. Off-label prescriptions also provide more options for the prescriber, and can be appropriate depending on a patient's needs and considering the balance of risks and benefits of different therapies. Economic reasons could also be drivers, when hospitals are trying to organize their resources. On a patient level, the main drivers of off-label use are the availability of therapy options and the cost of medicaments. Some off-label drugs are reimbursed in comparison with their more expensive authorized counterparts. Some patients can experience adverse reactions or side effects to the authorized drug, or its effectiveness is insufficient for the particular patient. Also, patients trust the prescriber. Ignorance is a crucial factor when discussing off-label use. There are cases where prescribers are simply not aware that their prescription is off-label and that another authorized drug might exist. Prescribers are subject to irrationality and can act on false assumptions, for example, lowering the dosage to prevent side effects, or trusting their own personal experience from previous, similar cases.

Drivers on the Health-Care and Insurer Level

Insurers are mainly concerned with pricing and reimbursements. The main concern on the health-care level is the cost of medicine. In many cases, authorized drugs have higher price tags than off-label products. In some member states, the affordability of medicine is a key issue, and the cheaper product is often reimbursed regardless of label.

Drivers on the Industry Level

Market authorization is a complicated, costly, and time-consuming process. There is little incentive and higher costs to apply for new indications for already authorized products. Furthermore, there is an associated risk of potentially discovering new risks during new trials, which might lead to the drug being withdrawn. The potential patient group for new indications is often too small to recoup the costs for new trials, and the incentive to begin a new trial is low, since this group is already using the product. There is

also concern that approval for a new indication would increase the bargaining power of countries to reduce the cost of the medicine. There are also no legal requirements for MA of new indications, even if sufficient scientific evidence is presented, and it is entirely up to the MAHs to decide to apply for one. There is also no requirement for the MAHs to monitor and report on the efficiency and risks of off-label use.

Drivers on the Regulatory Level

On the regulatory level, the main issue is the lack of legal basis to require market authorization for new indications from the MAHs after the drug has been permitted on the market. Regulatory agencies can request post-authorization studies, but only for the authorized indications, and only as part of the authorization procedure.

The industry is a major funder; it is also a primary provider of research and expertise in the field. The pharma industry is vital for the health-care system, and is a key contributor to the economy for some member states, thus the legislator is challenged to find a balance between protecting public health and corporate and economic interests. The public might not be willing to finance public trials.

6.2.5 Requirements of the stakeholders

By taking into consideration the drivers of off-label prescriptions, some of the most important requirements for management and tracking of off-label use should be deducible. The report for the EU commission [Wea17] has identified many of these requirements by conducting interviews with experts and involved stakeholders throughout Europe. All stakeholders agree that the ability to make off-label prescriptions offers more and better options for treating the individual needs of patients, and the issue should be addressed at a prescriber level rather than implementing stricter regulation.

Two major concerns that remain are the liability of doctors and the requirement of informing patients about off-label treatment. Solutions are needed to reliably assist doctors and to inform patients about their prescriptions. The insurers would benefit from information about the relevance of some off-label therapies to properly manage the costs and sustainability of the health-care system. However, economic reasons should not be the driving factor for reimbursement policies. At that level, aggregate information about medical practices instead of individual cases should be sufficient for better annual planning and identifying budget problems that can then be jointly addressed in cooperation with the competent authorities. Regulators, health-care experts, doctors' associations, and medical-guideline providers could use the information for the frequency of given off-label therapy to better adapt the legislations, update medical guides, and set more adequate reimbursements rules to be more closely aligned to medical practice. Governments may use the information to negotiate prices with manufacturers. The safety and efficacy of off-label prescriptions are yet to be determined. Having sufficient information about the frequency of a given off-label use could be the trigger for deeper investigations. If the frequency is high enough, even the drug manufacturer could be persuaded to conduct the necessary trials, or if not, publicly funded trials and academic investigations could also

be initiated. It remains important that drug manufacturers and MAHs receive statistics, which could possibly incentivize them to seek MA for the new therapeutic indications. The creation of better incentives can be encouraged at the legislation level.

6.3 Proposed Solution – ICT and e-Government

Off-label prescription presents a controversial case. As discussed, the stakeholders have a number of concerns and, sometimes, contradicting expectations, and there is no agreement regarding how to approach this issue. There are no easy answers because off-label prescriptions can only be analyzed on a case-by-case basis. In some cases, it could be lifesaving, while in others, it presents a significant risk; however, there are many cases in between where its effects are unknown. Information and Communication Technology (ICT) can assist in this particular area by doing what it does best – providing the means to collect and analyze data to better support all the stakeholders in their decision making. E-Government and ICT are potentially valuable tools to track and provide the necessary data that will allow for a better understanding and management of off-label use. Another important goal is to restore public trust in the institutions by finding ways to minimize the damaging influences in the system. Increasing transparency for the patient and providing awareness for the key stakeholders – medical professionals, insurers, manufacturers, and other regulatory authorities – are important first steps in this process.

6.3.1 Tracking Off-Label Use

The best-case scenario would be to identify all off-label prescriptions and create a database in which they can be evaluated and categorized based on their outcome. Off-label uses, which prove to be high risk with small efficiency, can then raise red flags, which would initiate the drug's re-evaluation by scientists and regulators, and inform doctors and health-care professionals about the potential dangers. On the other hand, discovering a new indication for existing drugs could lead to new clinical trials, and could accelerate their approval for the new indication. To achieve better tracking of off-label use, doctors should indicate the purpose of every drug prescription by providing diagnostic and symptoms codes. Keeping records of patients is already a requirement for every health provider. This first prerequisite for implementing such a system is already widely implemented. Various Electronic Health Record (EHR) systems are currently being utilized to digitally collect and store patients' health information [Wika]. This data are exchanged through networks between health-care providers to improve and accelerate the treatment of patients for reimbursement and cost reasons, and for management, monitoring, and statistic purposes. The data from such EHR systems can be utilized as the test sets needed for identifying off-label use.

Having an electronic record is only part of the solution. The instances of off-label use must also be identifiable in those records. Thus, the second requirement for tracking would be the development of an expert system, which would carry out those tasks. This

thesis explores, at a high level, one possible implementation of such a system as a national or EU e-Government project. This system will be referred to as the System for Tracking Off-Label (STOL). Figure 6.4 presents an overview of the main tasks of the proposed STOL.

A diagnosis must be linked to the prescribed medication, and must be uniquely identified not only on a national level, but most importantly, internationally. Using only nationally recognized codes may suffice for the pilot implementation of national-scale use or if the country still has not adopted an international classification system for its health-care management. The most widely used classification system for diseases is maintained by the World Health Organization (WHO) International Classification of Diseases (ICD) classification system, which provides a system of diagnostic codes for classifying diseases, symptoms, and other related health conditions, and allows for the sharing of health information using a common language [Prob]. The ICD system is translated into 43 languages and is used in more than 100 countries to report mortality rates. Twenty-seven countries use modifications of the current version 10 (ICD-10) for reimbursement and resource allocation in their health systems, including Austria, Germany, France, the UK, Sweden, the Netherlands, and the Czech Republic [Wikc]. Version 11 is currently in development, and is expected to be approved by WHO in 2018.

The core functionality of STOL is the identifier that matches a prescribed drug with its authorized therapeutic indication as reported in the drug's SmPC (the market authorization can be granted either nationally or centrally by the EC and the EMA). The expert system should be programed to consider not only the therapeutic indication, but also additional factors that can result in marking a drug for off-label use, such as patient age, sex, target population (group), dosing frequency and duration, and methods of administration. Also, the drug's Anatomical Therapeutic Chemical (ATC) code and chemically active ingredients can facilitate the distinguishing of proprietary and generic versions of the prescribed drug. If the system is integrated with the EHR systems used by health-care providers, the identifier can answer queries and deliver real-time information about the drug to the doctor. The system could be easily expanded into an expert recommendation system to provide prescription support for doctors.

An additional component that can also be optionally developed, is a classifier, which can group the off-label uses based on various factors, such as the level of scientific support for a given prescription. The assessment of the level of scientific support can be achieved using the analytics created from the usage of STOL. For example, it can track how many times an off-label drug was used in similar condition to other doctors in the clinical practice, and offer recommendations based on the statistical evidence. While such a naïve approach might be rather easy to implement, it will not necessarily reflect the "true" scientific evidence for the efficacy and risks of the off-label use. It can also pose the risk of recommending dangerous therapy, and thus spreading a potentially harmful practice among doctors. A better, but more time-consuming approach would be to build a recommendations system, with knowledge evaluated by experts and based on evidence from officially enforced medical compendia and journals, where such off-label indications

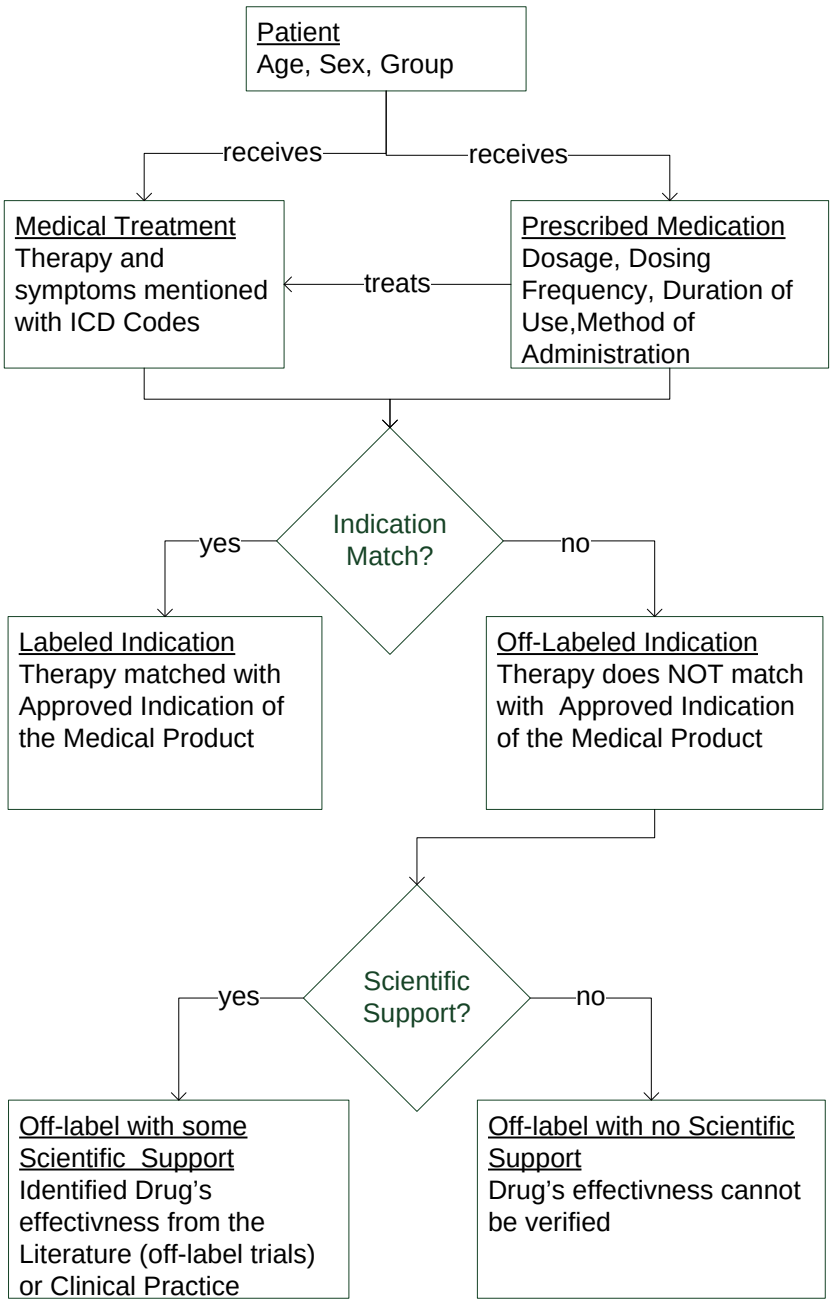


Figure 6.4: Process Overview of Off-Label Identification

are already being reported, and preferably clinically tested. Such information would be valuable to practicing health-care professionals (doctors).

6.3.2 Concept Overview of STOL

The information about all medical products authorized for European or single, national markets is already stored on various databases, some of which are maintained by the Agency (EMA) and others by the respective national authorities. Currently all sponsors and MAHs are required to update such databases with all related information from the SmPC of their medical products (already authorized or in the process of being authorized).

The centrally authorized medical product and its therapeutic indications and chemical substances, among other information, are currently submitted and updated by the sponsors and MAH in the Extended EudraVigilance medicinal product dictionary (Extended EudraVigilance Medicinal Product Dictionary (XEVMPD)) – also known as Article 57 – database using Medical Dictionary for Regulatory Activities (MedDRA) codes to describe the drugs indications. MedDRA is an internationally validated medical terminology dictionary (thesaurus), which is used by the pharma industry and regulatory authorities during and post the regulatory process. It provides a host of medical terminology, and is globally used in ICT applications for identification and categorization of medical terminology. MedDRA can be used to derive all authorized purposes of a medical product from those databases. Then, when attempting to identify off-label use, one can simply check whether the prescribed drug was used according to the indications provided in its SmPC. If not, this would indicate an off-label use.

MedDRA is not a taxonomy; it is limited only to the medical regulatory domain. National healthcare typically uses a different medical classification system for management and billing purposes, based either on national modification of the ICD, or possibly operates some other coding systems. In any case, the information from regulatory databases (using MedDRA) and national databases (using other standards) must be matched. After extraction, transformation, and loading of the data from the source databases, a mapping must be done between the MedDRA and nationally used terminology (likely the ICD-9 or ICD-10 national modification). This would require expert judgment, and presents challenges of its own. The ICD has evolved over the last 30 years to accommodate the needs of various stakeholders, such as hospitals, health-care providers, insurance, and government, and could be quite complex, while MedDRA is relatively simple, and is aimed mainly for use in the regulatory domain and pharmacovigilance [Cona]. There are some positive reports for the automation of such mapping [DJ]. The mapping of MedDRA and the ICD is an interesting topic for further research, which goes beyond this thesis. Therefore, for the purposes of the thesis, it will be assumed that this mapping could be done. The overview architecture of the proposed mapping in this thesis's theoretical STOL is illustrated in Figure 6.5.

Stakeholders can continue to use their traditional e-Government portals EHR systems,

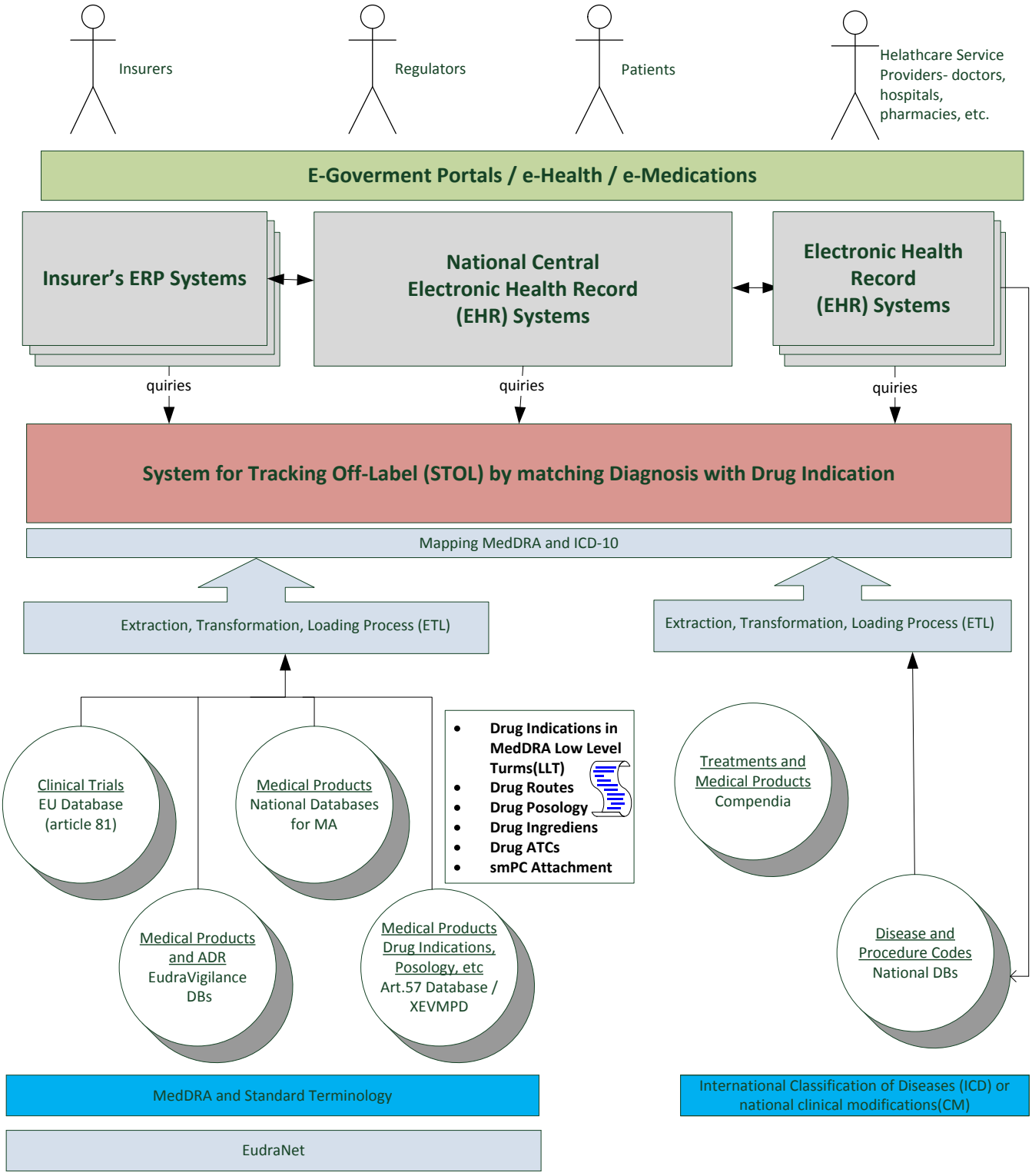


Figure 6.5: Concept Overview of STOL

which will be able to query the STOL whenever identification of off-label drugs is required. This would enable the development of new features of the existing applications, and the establishment of new or the enhancement of existing processes in the health-care system by providing valuable data to facilitate decision making. The STOL database for off-label drug therapies would be an important tool for analysis. Patients could also be enabled to receive more detailed information about their prescribed medicine through their usual e-health and e-medication portals. In Austria, for example, such portals are the GESUNDheit.gv.at and the web portal of the central record-keeping system, the Austrian Elektronische Gesundheitsakte (ELGA), and insurers provide patients with information for all reimbursed dugs on their web portals.

6.3.3 Databases Used as Source for STOL

The previous section briefly discussed the XEVMPD or Article 57 database, from which all related information for authorized medical products can be extracted. The MAHs and sponsors in the EU and European Economic Area (EEA) are responsible for registering the medical products and updating the information for the EMA, which uses the electronic format referred to as Article 57 or the eXtended EudraVigilance Product Report Message (XEVPRM). *"The aim of the submission of data is to establish a complete inventory of all medicines authorized for use in the EU and EEA, including medicines authorized centrally via the EMA and those authorized at national level"* [Agea].

Every member state would also have some sort of national database containing all authorized drugs. Since there is not much publicly available information for such national databases, this thesis concentrates more on the information provided by the EMA – XEVMPD (Art. 57) database. However, it is reasonable to assume that such databases would have a similar design, and exporting data from them could also be implemented in a similar fashion. Such an approach would be taken if the proposed STOL project needs to be implemented only at a national level because of various technical or political reasons, such as the lack of compliance by the EMA to provide the necessary interfaces and data.

Since 2014, there is a new EU regulation No 536/2014, which regulates clinical trials, and aims to streamline the application procedure via the EU portal as a single entry point. The assessments of applications are divided into two parts: in the first part, the assessment is jointly performed by all concerned member states, and in the second part, each concerned member state has the opportunity to assess individually [Heaa]. Article 80 and 81 require the establishment of a new EU portal to be the single entry point for submission and data concerning clinical trials. All of the submitted information about the application, the clinical trials, and the assessments are stored in the EU database. The new regulation also aims to increase the transparency of the outcomes of the clinical trials by giving the general public access to these outcomes [Heaa]. The EMA is the controller of the EU database and has the responsibility to avoid duplication between the EU database and already existing EudraCT and EudraVigilance databases. The EU database contains information submitted in accordance with the regulation, and

these data and documents are hyperlinked to other EMA-managed databases. The full specifications and functional requirements for the EU database are available [Agee]. The production version is expected to go live in October 2018, and, by October 2021, the old directive on clinical trials 2001/20/EC should no longer be applicable.

6.4 Pharmacovigilance

Since medical products cannot be tested for all possible effects and groups of patients, dosage, and durations of treatment during the pre-market clinical trial phase, constant monitoring for the safety of medicine, called pharmacovigilance, throughout the EU is established during the lifespan of the medical product. The major aim of pharmacovigilance is to reduce the number of Adverse Drug Reactions (ADR) in the EU.

The key tool for pharmacovigilance activities is the EudraVigilance Database, which collects and analyzes information about ADR to medicine that has already been authorized. I (ICSR)s, which provide information on suspected side effects and ADRs, are exchanged electronically between the EMA, national authorities, MAHs, and sponsors of clinical trials [Ageb].

The system includes data-collection and data-warehouse and analysis systems, and reports are accessible via the adrreports.eu portal [Agec]. A restricted set of data is also available to the general public. The data of the EudraVigilance Database is only one tool that the EMA and national regulatory agencies use to monitor a drug after it has been authorized. Other tools include post-authorization studies, clinical trials, and new toxicology data [Add].

The Data from of EudraVigilance can be utilized to Link Off-Label with Side Effects. Since most of the incidents (ICSRs) of adverse drug reaction are recorded in EudraVigilance, it can also be used to link such ADRs with off-label prescriptions. As the public doesn't have full access to the database, the internal architecture of the database cannot be known with full details. It is expected however that every ADR which is caused by off-label prescription can be marked as such. The off-label could be identified, by comparing reported in the ICSR prescription, with the authorized information (SmPC) for the medical product (such us therapeutic indications, administrable dosage, etc.). This information is already available in the system (as part of XEVMPD submission) or it can be delivered from other databases, such as EudraCT or the in the future the newly developed EU Database. Some of the architecture of EudraVigilance can be derived from XEVMPD Data-Entry Tool (EVWEB) user manual [Aged] The EMA is working closely with European pharmaceutical-industry associations by hosting meetings with the Joint Implementation Working Group (IWG) and representatives of the industry to define new business requirements, new functionalities and implementation of additional information requirements for XEVMPD [Agea].

6.5 How the 2020 EU e-Government Strategy Enables the Creation of System for Tracking Off-Label

All the technical prerequisites for exchanging medical records in the EU are currently available; if not completely technically achieved in all member states, they are at least already established as a clear e-health strategy, and are in stages of active development in all member states. The countries in Europe have already implemented various degrees of national EHR systems and exchange networks for different health-care stakeholders. The adoption of the cross-border care directive 2011/24/EU, which requires patients to be able to receive healthcare across the EU, and which states that health-care professionals can work in different countries, posed the inevitable need for tighter integration of national EHRs and e-health services at an EU level [Heab]. In 2010, it was already established as part of the Digital Agenda for Europe that, by 2015, pilot projects for secure online access of patients to their own medical records should be ready, and that, by 2020, there should be widespread e-health services(Key Action 13). Also, steps should be taken to harmonize the interoperability of patient-data records for electronic exchange across all member states by 2012 (Key Action 14) [ELa]. The groundwork already seems to be laid. Furthermore, a pilot project for tracking off-label use does not need to be done at an EU level. Every member state can use its own infrastructure, depending on its maturity, to facilitate such a service.

6.6 Advantages of Proposed Solution

Typical stakeholders in the health-care domain can continue to use their EHR and Enterprise Resource Planning (ERP) systems for record keeping and exchange, reimbursements, management, and control. Additionally, they will be able to differentiate off-label use in real time, but more importantly, the data from STOL would enable various investigations and studies to be performed. The data should be made anonymous in order to prevent privacy issues, and can be utilized for faster identification of new or the spreading of improper clinical practices. More importantly, researchers would have some means to assess the safety and efficacy of a given drug for its new uses. This could provide a level of evidence for using the drug off-label; however, the drug must ideally undergo randomized clinical trials and the authorization process. Such studies could enable the shortening of the procedure and significantly reduce its cost.

For doctors, such a system could provide guidance based on the available evidence. Doctors can examine different potential therapies used in similar situations and make therapeutic decisions based on more information. Legally, it is also difficult to change the SmPC, since it is the property of the MAHs; however, professional guidelines can be more flexible to include new scientific evidence. Ensuring that the patient is well informed about off-label use can also mitigate a fair amount of the liability issues that doctors face when making off-label prescriptions.

The realization of STOL would also increase the awareness of doctors and patients

regarding possible alternatively available therapies. There is a risk of promoting decisions based solely on budgetary and economic reasons, not only for the health-care system but the patient as well. It can be argued that this is already the case; however, more informed decisions supported by an evidence-based system could be beneficial both for the health-care system and patient alike.

An information system based on matching the indication with the prescribed medicine would not drastically increase the existing administrative burden on practicing physicians, since this information is required to be entered in the EHRs. Depending on the software that doctors are using, integration with STOL will require some adaptation for existing systems. The System for Tracking Off-Label (STOL) could be used as a standalone system as well; however, this would increase the administrative burden on doctors. Different strategies need to be considered regarding how STOL can be integrated into existing ICT in the health-care system, which would depend on the existing national infrastructure.

For patients, on the other hand, the system would provide them with more transparent information about their medications and therapies. This would enable more detailed and careful deliberation about the therapy between doctors and patients. It would also contribute to more general acceptance of public funding for medical research and trials.

6.7 Limitation of Proposed Solution

The proposed solution may be difficult to implement in every context because of the various levels of regulation and the availability of guidelines for applying off-label therapies in different member states, as well as the different level of maturity of e-health adoption in each country.

Patient resistance because of privacy-related issues should be considered. Patients may be concerned with who has access to their data. For example, health-related information can be used by insurers or employers to influence their decisions regarding the patient. To date, in Austria, the patient has an option to opt out of the central record-keeping system, ELGA, and has options to manage different health-care providers' access permissions to their record. An information campaign and public deliberation would be an important part of such a project.

Furthermore, it can be argued that full transparency on prescriptions could undermine the patients' trust in the therapy, in doctors, and in the health-care system as whole. Further discussion would be needed with doctor and patient groups; however, the solution could be implemented without necessarily disclosing the off-label information to the patients, and only making it available to health providers, who then can find traditional ways of explaining and discussing the prescription decision with their patients.

There could also be resistance from doctors because of the perceived extra administrative effort involved in documenting (protocol) patients' diagnoses and related medications, and potentially the need to argue their decisions in written form. However, this is already a requirement and "best practice" with the majority of health-care providers.

The integration of doctors' already existing ITC patient-record systems could reduce this burden.

Resistance from the industry or budgetary and political considerations could prevent project realization. The industry rarely supports disturbances in the status quo. Discussions with all stakeholders would be able to address many of the concerns.

6.8 Where the Proposed Solution Could Be Implemented

The implementation of STOL may be difficult in some EU countries because of missing legislation and technical infrastructure in the e-health domain. Austria has many factors that would make such implementation possible in a relatively short term:

- The e-Government and e-health infrastructure is relatively well established. There is already an established electronic system for exchange of patient information between different health-care providers, such as doctors, hospitals, and pharmacies. The Austrian electronic medical record system ELGA is a central system for storing e-diagnostic findings (e-Befund) and e-medication, and provides a clinical history of the patient to all connected health-care providers, such as hospitals, authorized doctors, caretakers, and pharmacies. The technical challenge of linking a diagnosis with the prescribed medication can be alleviated if doctors indicate the medication for their diagnosis.
- The Austrian medical record system (ELGA) is also currently further developed to provide citizens with access to their own clinical finding, indications, and prescribed medications. Currently, a list of reimbursed medications is also available from the portals of the Austrian Social Insurers (for example, the Austrian national health insurance organizations- WGKK and SVA). Health-care providers and doctors already provide their prescription to insurers electronically. The reimbursement is done transparently for the patient.
- Currently, the prescribers in Austria are obligated to indicate off-label prescriptions, justify their use, and inform the patient (according to article 55 AG). If they fail to do so, the treatment may be regarded as unauthorized (article 6, 88, and 110 StGB). Prescribers are liable for their prescriptions and could profit from a system that indicates such uses.
- The insurers are public, and reimbursement policies cover almost all medicaments, including off-label prescriptions, as long as the appropriate justification is provided by the prescribing doctor. Currently, this is rarely the case, since doctors are not obligated to report the disease for which a medicament is used. Since insurers are not profit-oriented, there is little risk of starting a trend to refuse reimbursements for off-label therapies. Insurers would benefit immensely from such information to better organize their decision making and policies.

CHAPTER 7

Critical Reflection, Summary and Future Works

I started writing this thesis with the goal of demonstrating IC in Europe. The example of the use case about the health-care industry and big pharma was a prime opportunity to do this. The damaging behavior of corruption is well explored and documented in the academic works. There are many activities of big pharma that are rooted in their consolidation of market power, short termism in decision making, and the growing pressure to increase profits in the drug industry, which result in dubious market practices that undoubtedly have a negative impact on the industry's reputation, and consequently on the health-care system in Europe as a whole.

However, there were many difficulties in applying the framework to identifying IC in Europe. Although some of the sources of influence have been identified, there are only few that can indicate, with enough evidence, the impact of these influences, nor can they describe how these influences work in greater detail. It cannot be implied that there is no such influence; however, it is well hidden in the complicated bureaucratic structure of EU institutions. The transparency level of these institutions is improving; however, in comparison with the USA, transparency in the EU is not yet at a level where in-depth studies can be performed. One of the biggest challenges of the approach was the over-reliance on American literature about IC, since the American system is vastly different from the European one. However, the lack of major studies about IC in Europe was the reason for taking such an approach. The main differences between the US and the EU, which, in my view, are the most influential for the impact of this work, are as follows:

- Money – the US system has been heavily reliant on money for a long time. Although

money certainly played a large role in European politics and regulation, it is not as apparent, traceable, researched, and visible to the public and even to scholars as it is in the US political environment.

- Transparency – this might not be obvious to the general public, and even though much EU data has been made available in recent years, it still substantially trails behind the level of transparency achieved in the USA since its establishment in 1966 with the Information Act. The drive and demand for more transparency in the US might have something to do with the innate sense of mistrust that the majority of Americans hold toward their government.
- Research in the area of IC – in the US, there is at least decade-long research in different disciplines about IC, which is lacking in Europe because of the previous two points.
- Complexity of the structure of the EU – the EU is not a federal state as in the USA, where the federal government has much central power, and, more importantly, the responsible institutions and their inter-connections are easier to recognize and investigate. Only two political parties are presented in the US, compared to the diverse structure in European politics.

Because of these factors, IC terminology and issues as a whole are largely still unrecognized in the field of European institutions and scholar circles alike. From my informal discussions with academics attending the International Conference for e-Democracy and Open Government 2017 in Krems, corruption was mentioned only by American participants. In fact, a simple search for "corruption" in the proceedings of the conference [PE] will yield only two results. Corruption is considered to be something illegal that police should take care of. This is also the impression I was left with after other talks with officials from the Austrian e-Government agency (BRZ) and the federal ministry of finances (BMF). Of course, this is anecdotal evidence, and a much broader study could and should be performed across not only governmental institutions and scholars, but also e-Government providers at national and European levels.

Interestingly, the problems of IC across different industries are largely the same universally (in all industrialized countries in Europe and America), as it becomes even more apparent from the off-label case study. However, if we assume that money plays a lesser role in the EU compared to the USA, then it becomes more difficult for the study of IC to identify the economy of influence in no uncertain terms. Furthermore, although many other influences can be attributed to IC, money is by far the easiest to track and identify, since it is the only quantifiable one. With the amount of evidence provided by US authors, money is certainly a factor in driving IC; however, it was difficult to find many sources for tracking money in pharma in the European scenario. The lobbyist database is still not granular enough, and its voluntary nature and the lack of external auditing damage its credibility. Of course, the absence of solid evidence for the role of money (or at least not on the same scale as in the USA) in European institutions does not mean that there

is no such influence or that it is insignificant. Further investigations and research are required in this area than my limited capacity can achieve for the purposes of this thesis.

E-Government solutions could play an essential role in solving or reducing some of the forces of corruption presented in this thesis or, at the very least, uncovering some of the dynamics of those forces to enable us to improve and continuously correct the deviations arising from them. There is little doubt that there is a clear connection between e-Government development and corruption reduction; multiple empirical studies, and one conducted especially for Europe in this thesis, have proven this. Inequality (of wealth and citizens) and its link to corruption is the next hot topic, and there are already works from transparency international that investigate it. The historical data still do not date back far enough; however, this will change in the next few years, and more scholars start investigating this connection.

Transparency and opening governmental data are unanimously agreed to be the way forward for a modern and informed society. There are significant challenges ahead that still require major solutions. The quality of data and provided tools are still not sufficient. However, there are many legitimate privacy concerns that must be addressed to establish an open-information society. Full transparency and privacy are unfortunately conflicting concepts. It is possible that the data, which only a select few can exploit, could be the next currency for rent-seeking behavior. Issues such as the technological divide and surveillance state will continue to be substantial challenges and the subjects of future studies.

There are different ideologies on how to address problems in society and economics. I myself am not a proponent of solving every issue with stricter regulations. Regulations are indeed important; however, my opinion is that they can be easily exploited, are prone to political and economic influences, and can be easily obstructed or delayed. After all, the human mind, with enough incentives, would find a way around it. A technical approach that benefits all the involved parties could prove to be much more effective. Of course, some technical approaches are inevitably bound to legislative and judicial restrictions. Nonetheless, a technical solution provides a means to "bend" or circumvent some of the established rules of the status quo and even accelerate the adoption of beneficial policy. I would argue that in the same way as a lobbyist would "game" the system to create benefits for its clients, an e-Government strategist would also be able to circumvent some of the "corruption" forces in the system and create a publicly beneficial application, which could even help to reform the system. Caution is needed, since such an application could be turned into a different source of IC. Sometimes, the best intentions lead to catastrophic results. To accelerate the adoption of such solutions, they should benefit all the relevant stakeholders, including the industry, since the industry plays a major role in the system. Even if such solutions are found, there would still be considerable risk of industry or political resistance, since it is far easier to maintain the status quo than introduce risky and disruptive policies or e-Government projects. A certain amount of

"lobbying" to set such projects afloat would require having the industry on one's side.

List of Figures

List of Tables

Acronyms

ADR Adverse Drug Reactions. 105

ATC Anatomical Therapeutic Chemical. 100

CHMP Committee for Medicinal Products for Human Use. 87, 94

CPI Corruption Perception Index. 53–56, 58, 59, 61, 62, 65, 75, 76, 112

CRM Customer Relationship Management. 42

EDI e-Government Development Index. 53–56, 58, 59, 62, 63, 75, 76, 112

EEA European Economic Area. 104

EHR Electronic Health Record. 99, 100, 102, 106, 107

ELGA Elektronische Gesundheitsakte. 104, 107, 108

EMA European Medicines Agency. 4, 6, 82, 87, 89, 90, 92–94, 100, 102, 104, 105, 112

EPAR European Public Assessment Reports. 87

ERP Enterprise Resource Planning. 106

FDA Food and Drug Administration. 24

GDP Gross Dpmestic Product. 55, 61–63

IC Institutional Corruption. 2–6, 10, 14–29, 31–33, 35–39, 41, 46, 47, 49, 53, 65, 67, 73, 76, 79, 85, 109–111

ICD International Classification of Diseases. 100, 102

ICSR I. 105

ICT Information and Communication Technologies. 3, 4, 27, 28, 42–45, 50, 51, 53–55, 65, 67, 69–75, 88, 95, 99, 102, 107

MA Market Authorization. 86–88, 92, 95, 98, 99

MAH Market Authorization Holders. 87, 88, 95, 98, 99, 102, 104–106

MedDRA Medical Dictionary for Regulatory Activities. 102

NCA National Competent Authorities. 87

NPM New Public Management. 42, 43

OAS Organization of American States. 49

OECD Organization for Economic Co-operation and Development. 49, 73

OGP Open Government Partnership. 68

RE Random Effect. 55

SmPC Summary of Product Characteristics. 85, 86, 100, 102, 105, 106

SSRI Selective Serotonin Reuptake Inhibitors. 84

STAMP Safe and Timely Access to Medicines for Patients. 89, 94

STOL System for Tracking Off-Label. 6, 100, 102–104, 106–108, 112

TI Transparency International. 49, 66, 73, 91

UN United Nations. 41, 53, 54, 61, 66, 68, 70

WDIs World Development Indicators. 55

WHO World Health Organization. 100

XEVMPD Extended EudraVigilance Medicinal Product Dictionary. 102, 104, 105

APPENDIX A

Appendix: EU Countries Gini Index Sources 2006 - 2014

Table A.1: Gini Index 2003-20014

Country	2003	2004	2005	2008	2010	2012	2014
Austria	27,4	25,8	26,3	27,7	28,3	26,6	27,6
Belgium	28,3	26,1	28,0	27,5	26,6	26,5	25,9
Bulgaria	24, 0[1]	26, 0[1]	25, 0[1]	35,9	33,2	33,6	35,4
Croatia	29, 0[1]	30, 0[1]	30, 0[1]	33, 71[2]	31,6	30,9	30,2
Cyprus	27, 0[2]	30, 1[3]	28,7	29,0	30,1	31,0	34,8
Czech Republic	24, 6[4]	27, 53[3]	26,0	24,7	24,9	24,9	25,1
Denmark	24,8	23,9	23,9	25,1	26,9	26,5	27,7
Estonia	34, 0[1]	37,4	34,1	30,9	31,3	32,5	35,6
Finland	26, 0[1]	25,5	26,0	26,3	25,4	25,9	25,6
France	27, 0[1]	28,2	27,7	29,8	29,8	30,5	29,2
Germany	28, 0[1]	28, 0[1]	26,1	30,2	29,3	28,3	30,7
Greece	34,7	33,0	33,2	33,4	32,9	34,3	34,5
Hungary	27, 0[1]	29, 98[3]	27,6	25,2	24,1	27,2	28,6
Ireland	30,6	31,5	31,9	29,9	30,7	30,5	31,1
Italy	32, 9[7]	32,9	32,7	31,2	31,7	32,4	32,4
Latvia	36, 53[3]	36, 77[3]	36,2	37,5	35,9	35,7	35,5
Lithuania	35, 46[3]	35, 2[3]	36,3	34,5	37,0	32,0	35,0
Luxembourg	27,6	26,5	26,5	27,7	27,9	28,0	28,7
Malta	27, 0[7]	27, 0[7]	27,0	28,1	28,6	27,1	27,7
Netherlands	27, 0[1]	30, 74[3]	26,9	27,6	25,5	25,4	26,2
Poland	34, 91[3]	34, 91[5]	35,6	32,0	31,1	30,9	30,8
Portugal	37, 8[7]	37,8	38,1	35,8	33,7	34,5	34,5
Romania	30, 0[1]	31, 0[1]	31, 0[1]	35,9	33,5	34,0	35,0
Slovakia	29, 9[4]	26, 8[5]	26,2	23,7	25,9	25,3	26,1
Slovenia	22, 0[1]	24, 6[5]	23,8	23,4	23,8	23,7	25
Spain	31, 0[1]	31,0	32,2	32,4	33,5	34,2	34,7
Sweden	25, 4[6]	23,0	23,4	24,0	24,1	24,8	25,4
United Kingdom	34, 0[1]	33, 1[5]	34,6	33,9	32,9	31,3	31,6

Notes:
[1] *Eurostat*
[2] *European Commission*
[3] *Word Bank 2016*
[4] *Transmonee 2005*
[5] *OECD StatExtract*
[6] *Sweden CSO 2005*
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