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MASTER'S THESIS, MASTER INNOVATION SCIENCES

# Europeanization of eHealth and the role of national stakeholders: the case of the Polish healthcare system

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## Abstract

The European Commission (EC) supports the use of eHealth, and encouraged all European Member States to develop a national eHealth strategy. Due to the legislation of the EC, Poland also introduced a national eHealth strategy but a certain resistance from national stakeholders can be identified towards the use of eHealth. National resistances towards European regulations are often seen as great barriers for their implementation at the national level. This thesis asks the questions "How does the Europeanization of eHealth strategies influence the healthcare system of Poland, and how do national stakeholders shape its implementation?", in order to increase the knowledge base concerning the interplay between European and national institutions on the topic of eHealth.

This thesis differentiated the influence of Europeanization between top-down and bottom-up processes to analyse the Polish eHealth development. Top-down Europeanization is measured in terms of the alignment of policies regarding eHealth regulation. Bottom-up Europeanization is measured via the policy beliefs, resources and strategies of national stakeholders. Polish and EC eHealth documents are analysed on the process of top-down Europeanization and semi-structured interviews are performed with four different stakeholder groups: policy makers and experts, payors (medical professionals), providers and patients to gain insights in the process of bottom-up Europeanization.

The analysis of the top-down processes shows that the Polish legal system included new mandatory eHealth regulations from the EC and existing Polish regulations needed adjustment to align with the legislation of the EC. As shown, particularly financial reasons, the influence of other Member States, and the EC's soft law measures shaped the path of eHealth implementation in Poland.

The analysis of the bottom-up processes shows that difficulties emerged with the implementation of the Polish eHealth projects due to an absence of knowledge regarding project management and long-term planning at the national level and a lack of interest for eHealth from the general public. Further, a limited willingness and minor support of national stakeholders towards eHealth is identified due to a lack of stakeholder participation in the process of eHealth development. The stakeholder group of payors is mentioned as the only group that can influence the content of newly implemented Polish eHealth regulations, next to the policy makers.

The results of this thesis can be used to study a wider research field regarding the role of national resistance in the implementation of EC regulations in general, and national eHealth development in particular.

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## 1. Introduction

Globally, the current healthcare system is facing a number of serious challenges like aging, allocation of less resources in terms of finance to healthcare, and an augmented number of patients with chronic diseases. ICT-applications are playing a protuberant role in the current system of healthcare in order to overcome those challenges. It is assumed that ICT-applications can improve the integration of healthcare and social needs because they lower the administrative burden and costs, and are easily accessible due to online consultation (Kautsch et al., 2017; Skär & Söderberg, 2017). 'eHealth' is an umbrella-term for all ICT-applications and in this thesis, the scientifically accepted eHealth definition of the European Commission (EC) (Aanestad et al., 2017; Melchiorre et al., 2018) is used: *“tools and services that use information and communication technologies (ICTs) that can improve prevention, diagnosis, treatment, and monitoring of health and lifestyle to meet needs of citizens, patients, healthcare professionals, healthcare providers, as well as policy makers”* (Aanestad et al., 2017; p.11).

The EC promotes eHealth because it acknowledges the mentioned benefits and assumes that eHealth can be a solution for the current challenges within the European healthcare system (EC, 2015; Raposo, 2016). The EC started to encourage all Member States to develop a national eHealth strategy within their first European eHealth Action Plan (2004) (EC, 2017). The Action Plan of the EC is mainly built on soft law measures which are quasi-legal instruments meant to induce institutional changes at the level of Member States (Kautsch et al., 2016; EC, 2017). The formulation of such an European eHealth Action Plan at the EU level relates to the concept of Europeanization, as common in the literature on Europeanization studies (Radaelli, 2003; Carbone & Orbie, 2017), and described as the *“processes of (a) construction, (b) diffusion, and (c) institutionalization of formal and informal rules, procedures, policy paradigms, styles, and shared beliefs and norms which are first consolidated in the making of EU public policy and politics and then incorporated in the logic of domestic political structures, and public policies”* (Radaelli, 2003; p. 30). For the case of eHealth, the European Member States are induced to implement the standards as defined by the EC.

An important starting point for this thesis is the observation that Europeanisation increasingly lead to resistance from national stakeholders, for instance because of interests that do not align with the EC goals (WHO, 2016; De Raeve et al., 2017). Here, negative attitudes can be related to uncertainty or dissatisfaction about the consequences, or new responsibilities, arising for certain national actors because of the diffusion of eHealth technologies (Klöcker et al., 2016; Ross et al., 2016). Examples of such actors are healthcare providers, health insurances, and consumers (Ossebaard & Gemert-Pijnen, 2016). As these actors try to negotiate with policy makers on the national level to place their interests into the national strategy (Greer, 2009; Azzopardi-Muscat et al., 2016).

Poland is one of the European Member States that recently implemented a national eHealth strategy based on the eHealth Action Plans of the EC (Kautsch et al., 2017). Sarecka-Hujar et al. (2016) and Kautsch et al. (2017) identified numerous barriers for the implementation of eHealth in Poland such as a lack of 1) clear regulations 2) reimbursement arrangements and 3) awareness. The barriers of eHealth implementation in Poland are identified but scientific papers have not yet examined why these barriers arise, which is done by this thesis. Poland is the specific case for this thesis to examine a broader issue in terms of the role of national resistance in the implementation of European regulations in general, and the implementation of eHealth in particular.

To summarize, Poland implemented a national eHealth strategy due to the mandatory eHealth policies of the EC. This process can lead to tensions with respect to 1) the policy formulation as claimed by the EC does not align with Polish policy, and 2) the resistance of national stakeholders because they assume that their perspectives are not (enough) implemented into the Polish eHealth strategy. This lead to the following research question:

*“How does the Europeanization of eHealth strategies influence the healthcare system of Poland, and how do national stakeholders shape its implementation”?*

To answer these questions, desk research is performed and legal documents are analysed on the number and size of institutional changes relating to eHealth implementation to assess the influence of eHealth Europeanization. Further, semi-structured interviews are used with different national stakeholders involved in the Polish healthcare system to identify their opinions and interests towards the Polish eHealth strategy and how they try to influence it.

This thesis has a theoretical relevance. Studies in ‘Health Services Management’ and ‘Information Systems and Innovation Management in health informatics’ show, via Azzopardi-Muscat et al. (2016) and Klöcker et al. (2016), a small proportion of scientific papers about eHealth that took the national or supranational perspective as a starting point. According to Bach & Ruffing (2016), the interplay of national and supranational level in policy implementation within the healthcare system is increasingly relevant because the EU recently increased its aim on regulating the European healthcare sector, and is not anymore concerned only with financial policies (European Monetary Union). In health-related issues, Europeanization has been limited so far because Member States were afraid to lose control over their healthcare system. Further, no scientific literature is identified that examined the point of view and influence of the national stakeholders regarding eHealth Europeanization. A research gap is filled because this thesis takes into account the perspectives of national stakeholders to emphasize their role during the implementation of a national eHealth strategy encouraged by the EC.

This thesis has a societal relevance. This thesis reveals different perspectives on eHealth that support or hinder its implementation in the Polish healthcare system. This thesis proposes new perceptions about which strategy the Polish government should follow in case of further expanding their national eHealth strategy. Moreover, the same results are also relevant for other Member States because this thesis offers insights about which eHealth policy the Member States should implement: a national eHealth policy that is forced on the national actors via EC legislation or a national eHealth policy that also includes the opinions of its end users such as doctors and patients.

The structure of this thesis is as follows. The next section describes the theoretical framework that is used and a conceptual model is given. The third section describes the methodological way in how the conceptual model is applied in finding relevant results. Section 4 and 5 include the results regarding the influence of Europeanization on the Polish eHealth strategy. Section 6 includes the results regarding the role of its national actors. In section 7, a conclusion and in section 8 a discussion of this thesis is provided.

## 2. Theoretical framework

### 2.1 Influence of Europeanization on the national level

The literature in European Studies focuses on the process of Europeanization. Two forms of Europeanization can be identified. One form of Europeanization is called 'top-down' Europeanization (Börzel & Risse, 2003). Literature about top-down Europeanization assumes that political dynamics at the supranational level (EU) become part of the policymaking at the national level (European Member States). This process will lead to 'institutional changes' within the national policy (Schmidt, 2009). According to North (1991, p. 97), institutional change can be defined as the change of "*humanly devised constraints that structure political, economic and social interaction. They consist of both informal constraints (sanctions, taboos, customs, traditions, and codes of conduct), and formal rules (regulations, laws, property rights)*". This thesis aims on the change of formal rules to answer the research question because this thesis is interested in how European regulations are implemented at the national level.

The topic of equivalence between laws of the EU and the implementation of them within the national policy of its Member States was always a main point of interest for the Europeanization Studies (Börzel, 1999). The first literature of European Studies assumed that regulations from the EU were apolitical, and the efficiency of its implementation depended on the national administrations (Exadaktylos & Radaelli, 2009). Only later on, the literature developed an understanding that the degree of implementation relies on the fit between the European political structure and the national political structure. Accordingly, enhanced adaptation of European regulations into the national policy will happen if more similarities can be identified between the two structures (Exadaktylos & Radaelli, 2009). A pressure to adapt EU-regulations on a national level can arise if EU-decisions do not align with the existing formal rules of a Member State (a misfit exist). In contrast to informal institutions which may change only slowly, formal rules are often adjusted immediately due to the mandatory character of EU-regulations (Börzel & Risse, 2003).

Next to top-down Europeanization, another form of Europeanization can be found: 'bottom-up' Europeanization. Bottom-up Europeanization emphasizes that a mutual relation exist between the national and EU-level, and the change in institutions and policies will not occur in a passive way (Schmidt, 2009). Bottom-up Europeanization assumes that national stakeholders can influence the Europeanization process by transmitting their preferences into the way how EU-strategies are implemented, to strengthen their own national position (Börzel & Risse, 2003). The governments of European Member States, together with their national stakeholders (such as local and regional governments, business connotations and trade unions), try to make an impact on European integration to guard their geopolitical activities, and to endorse their fiscal and political interests. Further, the European Member States try to decrease the misfit between European and national regulations by determining the decisions of the EC (Richardson, 2006).

Top-down and bottom-up Europeanization are no isolated processes and both need to be examined to portray the influence of Europeanization on the national level. An appropriate way of connecting top-down and bottom-up Europeanization is to concentrate on the role of the European Member States as so-called 'shapers' and 'takers' of European politics (Börzel & Risse, 2003). This does not indicate that the EC is extraneous to European politics and nor do national governments always monitor whether national interests find their way into new EU regulations. However, national governments have a crucial role in the decision making and implementation of European regulations into national law and thereby they can have an impact in how they shape European regulations, and how to acclimatize to them (Radaelli, 2000). The integration of EU policy into national policy can be seen as a mutual relationship among political discussions at the national and European level. National actors try to negotiate with their national governments to develop new EU plans that fit their interests the most. National governments try to push at the European level for European plans that align with

the interests of the national stakeholders, while diminishing their contrary impacts at the national level (Börzel & Risse, 2003).

## 2.2 Top-down Europeanization

### 2.2.1 Influence of Europeanization: four categories

The influence of Europeanization can be observed in terms of the direction and depth of change that takes place in the national policy of European Member States. The Europeanization of national policy can appear in several ways. Firstly, fundamentals of national policy can be altered, for instance policy convergence among all Member States in terms of inflation and budgetary restraints. Further, the legal framework of the Member State can also be altered by Europeanization, for instance a change in national regulations (Börzel & Risse, 2003; Richardson, 2006). Four categories of influence of Europeanization on the national level are described in the theoretical works of Börzel (1999) and Green Cowles et al. (2000) which can be seen in table 1: absorption, transformation, inertia, and retrenchment. The individual categories relate to a different nature and degree of institutional changes within national policy.

**Table 1. Four categories to observe Europeanization**

<b>Category of Europeanization</b>	<b>Explanation</b>
<i>Absorption</i>	<p>Institutions of the Member State which are 1) implemented after the implementation of the EU-initiative and 2) match with the regulations and standards of the EU-initiative</p> <p>Institutions of the Member State, which match with the EU-initiative, are the same before and after the implementation of the EU-initiative</p>
<i>Transformation</i>	<p>Institutions of the Member State which are 1) implemented after the implementation of the EU-initiative and 2) match with the regulations and standards of the EU-initiative</p> <p>Institutions of the Member State are substituted after the implementation of the EU-initiative to match the regulations and standards of the EU-initiative</p>
<i>Inertia</i>	<p>Institutions of the Member State which match with the regulations and standards of the EU-initiative are not implemented after the implementation of the EU-initiative</p> <p>Institutions of the Member State, which match with the EU-initiative, are the same before and after the implementation of the EU-initiative</p>
<i>Retrenchment</i>	<p>Institutions of the Member State which match with the regulations and standards of the EU-initiative are not implemented after the implementation of the EU-initiative</p> <p>1) Institutions of the Member State which match with the regulations and standards of the EU-initiative before the implementation of EU-initiative, and 2) the same institutions of the Member State of point 1 are removed or substituted after the implementation of the EU-initiative</p>

With *absorption*, all national institutions are similar with the regulations and standards of the EU-initiative, but the national institutions do not include all regulations and standards of the EU-initiative. The missing regulations and standards of the EU-initiative need to be adopted by the national decision makers into the national institutions (Faist & Ette, 2007). So, the European Member States include European regulations within their national policy but they are induced to significantly alter current procedures, guidelines and institutions (Carbone & Orbie, 2017).

With *transformation*, a part of the national institutions do not agree with the regulations and standards of the EU-initiative and need to be substituted to match the regulations and standards of the EU-initiative. Further, national institutions also need to be implemented into national policy to take into account all regulations and standards of the EU-initiative (Faist & Ette, 2007). So, the European Member States include European regulations within their national policy but they have to significantly altering current procedures, guidelines and institutions before implementing the new European regulations (Carbone & Orbie, 2017).

*Inertia* can be seen as a lack of institutional change within the national policy of the Member States. Inertia occurs when national institutions are too different with the regulations and standards of the EU-initiative, and the national decision makers decide not to adopt the EU-initiative. Further, inertia also occurs if the regulations and standards of the EU-initiative are similar to national institutions. During the implementation of the EU-initiative, the national institutions stay the same (Faist & Ette, 2007). So, the European Member States do not include new European regulations within their national policy or alter current procedures, guidelines and institutions within their national policy (Carbone & Orbie, 2017). From a long-term perspective, inertia can lead to restrictions established by the EU (for example in trade in terms of import and export) if the national regulations do not align with the European regulations (Exadaktylos & Radaelli, 2009).

With *retrenchment*, national decision makers do not agree with the regulations and standards of the EU-initiative and do not implement a single regulation or standard from the EU-initiative into national policy. Further, national institutions that match with the EU-initiative are substituted (Faist & Ette, 2007). So, the European Member States do not include new European regulations within their national policy but they have to alter current procedures, guidelines and institutions within their national policy which do align with the new EU regulations (Carbone & Orbie, 2017). From the short-term and long-term perspective, retrenchment can also lead to restrictions established by the EU if the national regulations differ with the European regulations (Exadaktylos & Radaelli, 2009).

### 2.2.2 The misfit hypothesis

According to Chrobot (2012, p. 37), the misfit hypothesis defines that “*Europeanization matters only if there is divergence, incompatibility, or “misfit” between European-level institutional process, politics, and policies, and the domestic level*”. Héritier et al. (1996) mentioned the misfit hypothesis for the first time in their paper. They assumed that European Member States make attempts to upload their public policies at the level of the European Union. By doing so, European Member States try to diminish the total costs of adaptation and to create a level of European playground that fit their national industries the most in case of profits (Héritier et al. 1996). The assumption of Héritier et al. (1996) was modified by Börzel & Risse (2003) who included the course of EU adaptation. Börzel & Risse (2003) assumed that the European Member States, that failed to upload their public policies, will not be satisfied with the final outcome (in terms of new European regulations and standards) due to the aligning high costs of adaptation. The chief assumption made is that present and prevailing institutional trails of the European Member States are sticky and impervious to change. In case new European regulations or standards do fit within the boundaries of the path already taken, adaption will be fast and the national regulation will be initially accurate with the European regulation. European Member States only will change their public policy (absorption or transformation) if the differences between EU-initiatives and

national level are substantial. In contrast, if an European Member State needs to make vast changes within their current institutions, the adaptation to EU regulations and standards will be a lengthy process and originally incorrect. Inertia or retrenchment can take place because the costs of adoption of the EU-initiative will be too high (Börzel & Risse, 2003; Mastebroek & Kaeding, 2006).

The misfit hypothesis includes two different kind of misfit: 'policy misfit' and 'legal misfit'. A policy misfit occurs when the national regulation does not relate with the new regulations described within the EU-initiative. A policy misfit is fundamentally equivalent with compliance problems (Börzel & Risse, 2003). Directives that are set up by the EU are able to encounter the national public policy, national legal framework and national policy goals. A policy misfit leads to adaptational pressure on a national level. Hence, European Member States will make attempts to introduce their specific interests or policy approaches already in the policy formulation process at the European level to diminish eventual compliance related problems (Mastebroek & Kaeding, 2006).

This process can lead to a regulatory contest, especially among the more powerful European Member States, such as France, Germany and Great Britain which have been more successful in uploading their public policies into European regulations than the less powerful Member States (Börzel & Risse, 2003). This regulatory contest has led to European regulations that includes a varied set of preferences from the Member States. The less powerful Member States are compelled to change their public policy and institutional structures due to the mandatory European directives that mainly consist of preferences of the more powerful European Member States (Börzel & Risse, 2003).

The second type of misfit is the legal misfit. The EU-initiative can be implemented within the national policy even if there is a large policy misfit. The EU-initiative can be part of the national policy as a common practice but it is not yet written down in national regulations, also called the legal misfit (Börzel & Risse, 2000). An example related to eHealth are doctors that make use of online platforms for patients to make appointments before it is made mandatory to use such platforms due to EC legislation. A legal misfit is less direct compared to a policy misfit. Nevertheless, a legal misfit can lead to more incremental and long-term adaptations. If the policy misfit is high but the legal misfit is low, the EU-initiative can still be implemented into national policy. Yet, if there is a low policy misfit and a high legal misfit (national regulation is transposed but not applied), it will be more difficult to implement the EU-initiative into national policy (Börzel & Risse, 2003).

## 2.3 Bottom-up Europeanization

Next to top-down Europeanization, another form of Europeanization can be identified: bottom-up Europeanization. Studies about bottom-up Europeanization show that national stakeholders are able to influence the Europeanization process by transmitting their preferences into the way how EU-strategies are implemented, to strengthen their own national position (Börzel & Risse, 2003; Pierce & Weible, 2016). To analyse the used strategies from national stakeholders to translate their beliefs into national policy, the 'Advocacy Coalition Framework' (ACF)\* proved to be useful in these studies to reveal bottom-up Europeanization processes (Börzel & Risse, 2003; Sotirov & Winkel, 2016).

Within the ACF, the process of public policy is theorized as a political struggle amid advocacy coalitions of national stakeholders within a specific *policy subsystem* (Pierce & Weibel, 2016; Howlett et al., 2017). Figure 1 shows a policy subsystem which includes national stakeholders who attempt to influence the political system on the national level on a specific policy issue. National stakeholders try to influence politics, both on a national and supranational level, to represent their opinions into national policy to endorse their fiscal and political interests (Sotirov & Winkel, 2016; Grünhut, 2017). To upsurge their chance of success, national stakeholders can create so-called advocacy coalitions consisting of heterogeneous clusters of national stakeholders who share the same policy beliefs and who temporally coordinate their actions together because of their common goal (Pierce et al., 2017). In this thesis, advocacy coalitions will be called stakeholder groups. It is assumed that the stakeholder groups contest with each other to put their policy beliefs into actual policy. However, according to the ACF not all stakeholder groups will succeed in translating their policy beliefs into actual policy, which is a major reason of why certain policies are biased towards the particular policy beliefs of previous winning stakeholder groups (Sotirov & Winkel, 2016).

The *policy beliefs* of a stakeholder group can be seen as shared attitudes, opinions and interests of its stakeholders towards policy implementation or strategy framing (Pierce & Weible, 2016). Studies taking an ACF perspective assume that the rationality of individual stakeholders can be limited. Limited rationality assumes that stakeholders have an imperfect ability to revise their preferences about a specific policy. This can happen due to two reasons: 1) the accessible data about policy can be of low quality or little quantity, and 2) the integral ability of individual stakeholders to process this data is restricted (Pierce & Weible, 2016; Moyson, 2017). Because of the bounded rationality of the individual stakeholders, the ACF also assumes that individual stakeholders within the same stakeholder group can slightly differ in their opinions and interests about a specific topic. Individual stakeholders can filter novel data dependent on their belief systems, and this data can be processed in a biased way to fund these belief systems (Moyson, 2017).

The policy beliefs of the stakeholder groups can align with the current national policy or with the EU-initiative. However, Europeanization of national systems frequently leads to resistance from the national stakeholders (Börzel & Risse, 2003). In the case of eHealth, resistance could emerge for instance due to ethical issues on the micro level such as privacy issues regarding medical data exchange (Azzopardi-Muscat et al., 2016). On the other hand, positive attitudes of stakeholder groups towards eHealth Europeanization could arise, for example from a general interest and perceived usefulness of new technologies for the end users (Ross et al., 2016). Accordingly, it can be assumed that each individual stakeholder group attempts to put their own policy beliefs in the national strategy during its implementation to reflect their economic and political interests in the national strategy. The stakeholder groups will compete with each other, and public policy change will emerge due to the

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\* The ACF is a comprehensive framework consisting of stable parameters, short-term constraints, long-term structures, external events, and a policy subsystem. According to Fischer & Miller (2006), a fast and qualitative examination of the 'policy subsystem' part is sufficient to comprehend political conflict and policy change on a national level. The policy subsystem part will constitute the basis also for this thesis to examine the role of national stakeholders in the implementation of eHealth Europeanization

translation of the preferences of the winning coalition into actual policy strategy (Pierce & Weibel, 2016).

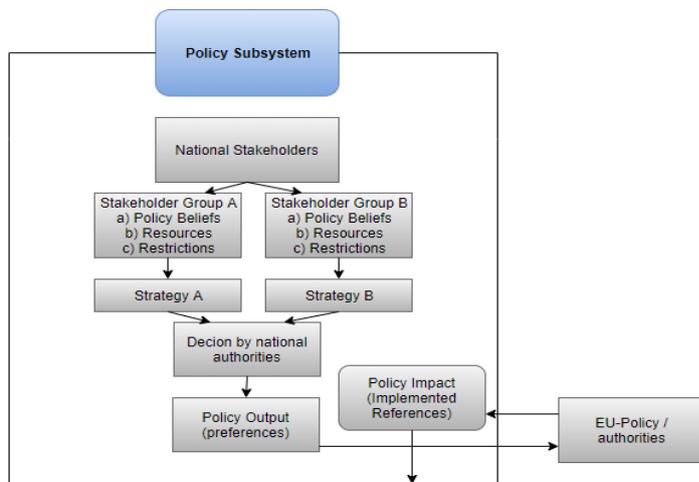


Figure 1. – The policy subsystem, own figure based on Jenkins-Smith et al. (2014)

Furthermore, studies taking an ACF perspective assume that every individual stakeholder owns a set of specific resources which can be used by the stakeholder group to achieve certain results (Moysen, 2017; Pierce et al., 2017). Stakeholder groups are generally more successful (compared with individual stakeholders) in transferring their policy beliefs into actual policy because more *resources* can be assembled. They combine the resources of the individual stakeholders which empower them to develop new strategies to make an impact on the current public policy. Stakeholder groups can apply a diverse set of resources to develop strategies to put their policy beliefs into the actual policy (e.g. creating a strong public support for the strategy).

Based on this assumption, Börzel & Risse (2003) introduced five types of resources as specified in table 2. These resources are the opposite of the *restrictions*, as for example, having extensive financial resources can be seen as a resource, but having low financial resources can be seen as a restriction for the stakeholder group. Differentiating between types of resources or restrictions allows the analysis of how specific resources or restrictions of a stakeholder group in a subsystem affect their influence and final decisions (Sotirov & Winkel, 2016).

Table 2. Resources / restrictions of a stakeholder group

Resources / Restrictions	Explanation
<i>Formal legal authority to make decisions</i>	The stakeholder group does (does not) include individuals with a position within politics (i.e. representatives, delegates) with the power to make, and influence decisions
<i>Public opinion</i>	The stakeholder group has a strong (weak) public support for its policy view
<i>Mobilizable troops</i>	The stakeholder group does (does not) have supporters that help in achieving their objectives (i.e. fund-raising campaigns, public demonstrations)
<i>Financial resources</i>	The stakeholder group owns (owns not) financial resources to invest in establishing other resources (i.e. invest in R&D for information)
<i>Skilful leadership</i>	The stakeholder group has (has not) individuals that can attract additional resources, which can be used for their strategy to put their preferences into actual policy (i.e. (political) influencers swaying public opinion, individuals with access to financial resources)

## 2.4 Conceptual model

In this part, the concepts introduced in the theoretical framework and the relations between them are visualized in a conceptual model. Figure 2 shows the conceptual model that includes three different blocks. The first block (blue) stands for the top-down Europeanization consisting the EU and national institutional status including the concepts of policy misfit and legal misfit. Top-down Europeanization will be used to identify the policy misfit and the legal misfit. The second block (yellow) is the outcome of eHealth Europeanization within the Polish Healthcare system consisting of four different outcomes (differ in scale and change of institutional change): absorption, transformation, inertia and retrenchment. The third block (grey) stands for bottom-up Europeanization consisting national stakeholder groups active in the Polish healthcare system including policy beliefs, resources and restrictions. Bottom-up Europeanization will be used to answer the second part of the research question: *how do national stakeholders shape its implementation?*

This thesis examines both Europeanization processes next to each other because the process of Europeanization is not an one way procedure. Europeanization can be seen as a compound and dynamic relationship that includes the interplay of national and supranational actors and conditions and both Europeanization processes need to be examined to depict the influence of Europeanization at the national level. Only taking into account top-down Europeanization will neglect all the involved actors on the national level that try to put their interest into the national policy of a Member State. This thesis connects the top-down and bottom Europeanization processes by focusing on the specific role of the Member States as a receiver (top-down), but also as a shaper (bottom-up) of European regulations. The implementation of EC regulations into national law is assumed to be a mutual relationship between political discussions at the European and national level. Member states play a vital part in the implementation of new regulations induced by the EC into their national legal framework, and thereby they are able to influence in how they form these European regulations. National stakeholder groups attempt to negotiate with their national governments to develop new EC regulations that include their policy beliefs the most. Aware of the policy beliefs of the different stakeholder groups, national governments attempt to negotiate at the European level for the development of EC regulations (and later on national regulations) that do align with the policy beliefs of its national stakeholders, to decrease resistance from the national stakeholder groups and the regulatory impact at the national level. Based on the interplay of both Europeanization processes, the influence of Europeanization can be examined which is described as four outcomes that differ in scale and change of institutional change (in the form of direct regulations) at the national level.

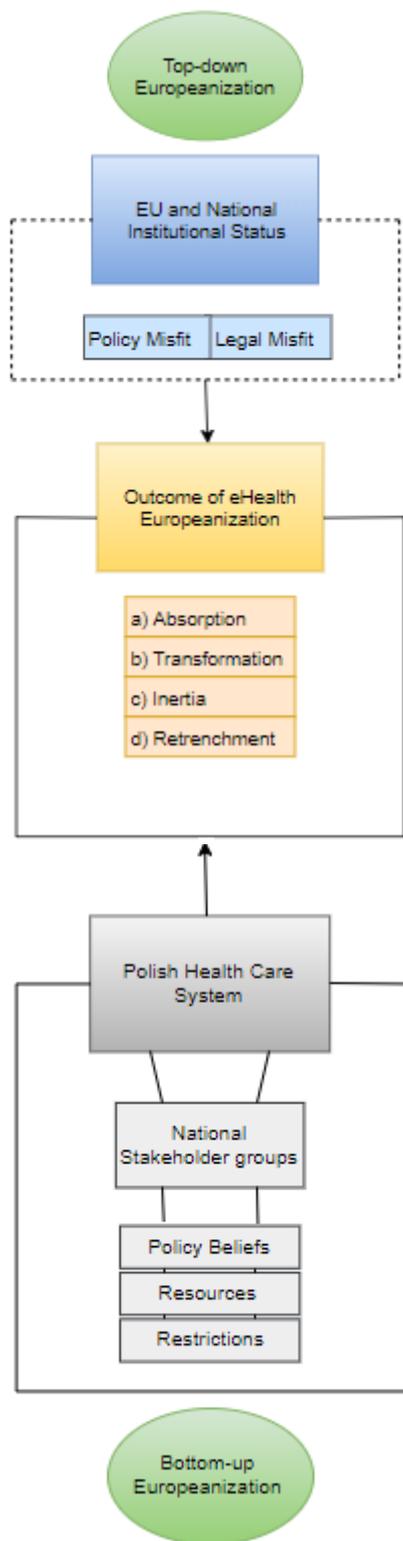


Figure 2. Conceptual model of the theoretical framework

## 3. Methodology

### 3.1 Research design

This thesis used a case study design to examine the influence of eHealth Europeanization on the Polish healthcare system, and the role that national stakeholders play in its implementation. Case studies are common in research fields such as social settings, health systems, and policy implementations as a case study design enables answering research questions starting with 'how' or 'why', limited to a single case (Stake, 2005). The data collection will be more extensive and of greater depth compared with other research designs. Due to the detailed data collection, processes, problems and policies can be examined to enhance the knowledge base of the single case (Crowe et al., 2011).

This thesis used a deductive research design because a closed set of clear concepts have been identified from prevailing theoretical work. This thesis aims at deducting conclusions from the described links and concepts within the used theoretical frameworks. If a specific theory implies a certain link between two or more concepts, a deductive research design is able to examine if the link also appears within other general conditions. Further, the research question of 'how' boils down to several categories. So, this thesis clearly assumed what was going to be analysed (Bryman, 2015).

This thesis is qualitative due to the use of interviews with the national stakeholders involved in the Polish eHealth strategy. A qualitative study opens the way to assess, comprehend, and identify the attitudes, opinions and interests (policy beliefs) of the different stakeholder groups which lead to a comprehensive collection of data to answer the research question. Qualitative research is also an appropriate method to examine new policy implementation in national health care systems which is the case in this thesis (Flick, 2014). Further, this thesis performed a document analysis to identify the established regulations regarding eHealth by the EC and Poland.

### 3.2 The case of eHealth in Poland

The Polish eHealth strategy is the case study of this thesis and an interesting case for the research problem of this thesis because of two identified barriers of eHealth development in Poland by Kautsch et al. (2016). 1) Legal barriers are mentioned as the main hindrance for the Polish eHealth development despite the implemented eHealth regulations by the Polish government. A need exist for more regulation and standards, mainly regarding the use of eHealth by end users and the sale and export of eHealth technologies. It is relevant to examine which influence the EC had on decreasing the lack of such regulations. 2) The opinions and interests of stakeholder groups were unequally considered in developing the national eHealth strategy. In particular, end users of eHealth in Poland were initially not included in the process. It is relevant to examine if their engagement increased in the last three years, and to understand potential negative consequences for the development, implementation and acceptance of eHealth if the national government neglects certain stakeholder groups.

Based on Ritz et al. (2014) and Aanestad et al. (2017), four key stakeholders are identified in relation to the national eHealth strategy of Poland:

- 1) *Policy makers and experts* consist of politicians from the Ministry of Health, academics, and consultants from NGOs. This group creates and analyses the national framework of health care services for their residents. Experts are involved in the gathering and processing of healthcare information and they advising the policy makers.
- 2) The Polish residents receive the eHealth care and are part of the *patient* group and can be represented by leaders of the civil society like the national ombudsman.
- 3) *Payers* are represented by medical professionals from medical facilities and the National Health Fund. Medical facilities as hospitals and the National Health Fund pay for eHealth services which are used by the medical professionals.

- 4) *Providers* develop healthcare and IT-services and consist of Polish enterprises that develop eHealth technologies to fulfil the needs of the policymakers, patients and medical professionals.

The time frame of the case starts at the establishment of the first regulation of the EC regarding eHealth (1995, Directive of Data Protection) till recent. At the national level, the Polish Ministry of Health ratified the 'Act of Information System in Health Care' in April 2011. This act made it mandatory for health care providers to document the medical records of patients in an electronic system for the first time. An amendment to this Act was enacted in October 2015, and allowed the use of eHealth technologies by medical professionals (Sarecka-Hujar, 2016). Further, in 2018 the Act on Professions of Doctor and Dentist was ratified which made the use of electronic signatures by medical professionals possible (Ministertwo Zdrowia, 2018). This thesis analysed very recent eHealth developments in Poland, which makes it interesting to gain a deeper understanding of how the process went, and the barriers of implementation.

### 3.3 Operationalization of concepts

This part highlights the operationalisation of the concepts derived from the theoretical framework. Table 3 includes the operationalisation of the top-down concepts, table 4 includes the operationalisation of the bottom-up concepts and table 5 includes the operationalisation of the outcome of both Europeanization concepts.

A policy misfit occurs when content of national eHealth acts is not in line with EC eHealth directives. An enhanced number of national eHealth acts that is implemented before the establishment of EC eHealth directives (do align on content) leads to a lower policy misfit and vice versa. A legal misfit occurs when EC eHealth directives are part of national policy as a common practice but are not part of national regulation. An enhanced number of EC eHealth directives that are part of common practice on a national level before the establishment of EC eHealth directives (do align on content) leads to a lower legal misfit and vice versa. It seems that, according to Falkner (2003) and Frederiksen et al. (2017), the operationalisation of the policy misfit and legal misfit did not yet received enough consideration in other papers. Difficulties emerge to perform secondary data analysis on previous material to obtain a scientifically proven operationalisation. For this purpose, this thesis took a first step to give such measurements a try and used the borderline of 50% for both misfits. More than 50% (the majority) is considered as high and less than 50% (the minority) is considered as low.

**Table 3. Operationalisation of the concepts relating to top-down Europeanization**

<b>Concept</b>	<b>Manifestation of concept</b>	<b>Measurement</b>
<b>Policy misfit</b>	Low policy misfit	Content of national eHealth Acts are in line with eHealth Directives of the EC  More than 50% of national eHealth Acts are implemented before the establishment of eHealth Directives of the EC
	High policy misfit	Content of national eHealth Acts are in line with eHealth Directives of the EC  Less than 50% of national eHealth Acts are implemented before the establishment of eHealth Directives of the EC
<b>Legal misfit</b>	Low legal misfit	Content of national eHealth Acts are in line with eHealth Directives of the EC  National eHealth Acts are implemented after the establishment of eHealth Directives of the EC

	High legal misfit	<p><b>MORE</b> than 50% of national eHealth Acts was already put into common practice before implementation</p> <p>Content of national eHealth Acts are in line with eHealth Directives of the EC</p> <p>National eHealth Acts are implemented after the establishment of eHealth Directives of the EC</p> <p><b>LESS</b> than 50% of national eHealth Acts was already put into common practice before implementation</p>
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The policy beliefs of stakeholder groups towards the national eHealth strategy are based on the analysis of the interviews, and measured by asking the individual stakeholders if their policy beliefs do align with the implemented eHealth projects part of the national eHealth strategy, and if they were missing specific eHealth projects not yet implemented.

The case could exist that the policy beliefs widely match within a stakeholder group, but on certain aspects the policy beliefs can differ between individual stakeholders. As mentioned, the ACF assumes a limited rationality of individual stakeholders. Limited rationality indicates an imperfect ability to revise preferences, and individual stakeholders within the same stakeholder group can slightly differ in their policy beliefs regarding a specific topic. To aggregate the individual policy beliefs (the same accounts for the mentioned resources and restrictions), conflicting statements from the individual stakeholders are compared and combined to draw a valid conclusion regarding the policy beliefs of the examined stakeholder groups. This could indicate that the manifestation of policy beliefs can differ within the same stakeholder group. Further, it is difficult to generalize the policy beliefs of a stakeholder group towards the entire national eHealth strategy. For this purpose, their perspectives regarding the implemented eHealth projects was examined. For example, this thesis identified a positive attitude from the stakeholder group towards a specific national eHealth project but a more neutral or negative attitude towards another national eHealth project, or they were missing the implementation of a specific national eHealth project.

**Table 4. Operationalisation of the concepts relating to bottom-up Europeanization**

<b>Concept</b>	<b>Dimension</b>	<b>Manifestation of dimension</b>	<b>Measurement</b>
<b>Policy beliefs</b>	Attitudes, opinions, interests towards the Polish eHealth strategy	Positive	<p>The stakeholder group does not miss any elements regarding a specific eHealth project part of the eHealth strategy implemented by the national government</p> <p>The policy beliefs from the stakeholder group are aligned with a specific eHealth project part of the eHealth strategy implemented by the national government</p>
		Negative	<p>The stakeholder group does miss any elements regarding a specific eHealth project part of the eHealth strategy implemented by the national government</p> <p>The policy beliefs from the stakeholder group are not aligned with a specific eHealth project part of the eHealth strategy implemented by the national government</p>
		Neutral	The stakeholder group does miss any elements regarding a

			<p>specific eHealth project part of the eHealth strategy implemented by the national government</p> <p>The policy beliefs from the stakeholder group are partly aligned with a specific eHealth project part of the eHealth strategy implemented by the national government</p>
<b>Resources / restrictions</b>	Not applicable	Not applicable	<p>The stakeholder group does (does not) includes stakeholders with a position within the political sector (ministers of the Polish Parliament) with the power to make, and influence decisions</p> <p>The stakeholder group does (does not) receives public support for its policy beliefs. A public support of more than 50% of the Polish citizens (i.e. opinion polls) can be seen as strong public support.</p> <p>The stakeholder group does (does not) has mobilized stakeholders and supporters to help them with achieving its objectives (i.e. fund-raising campaigns, raising awareness, and public demonstrations)</p> <p>The stakeholder group does (does not) owns financial resources to invest in the other resources (i.e. invest in R&amp;D for information)</p> <p>The stakeholder group does (does not) has stakeholders that can attract additional resources, which can be used for their strategy to put their preferences into actual policy (i.e. (political) influencers swaying public opinion, stakeholders with access to financial resources)</p>

The outcome of Europeanization can be measured in terms of direction and depth of change that took place in national regulation. Absorption, transformation, inertia and retrenchment are the four outcomes in theoretical papers used for the operationalisation of domestic impact of EC policy. This categorization can be used for different policy issues, for example Bolukbasi & Ertugal (2013) analysed domestic change in political economies, and Martinsen & Vrangbaek (2008) analysed domestic change in healthcare systems by using the same categorization.

Absorption and transformation are aligned on their measurements but two main differences can be identified. Absorption includes national eHealth acts that are implemented before the introduction of EC eHealth directives and transformation includes national eHealth acts that are substituted or amended due to new EC eHealth directives. Inertia can be separated into two sets of measurements. Inertia can be a 1) lack of national regulatory change and EC eHealth directives are not implemented as national eHealth acts, and 2) national and EC policy are similar and the EC eHealth directives are already implemented as national eHealth acts. Retrenchment is similar with inertia but with retrenchment, national eHealth acts that do align with new EC eHealth directives are erased from the national legal system afterwards.

A possibility exist that the content of a national eHealth act does align with the content of a specific EC eHealth directive but this is not the case for another national eHealth act. This would indicate cases related to absorption or transformation, and cases related to inertia or retrenchment. To aggregate the individual cases to come to a valid general conclusion, this thesis included all cases and the likelihood that different categories could be the outcome of Europeanization (also mentioned by Featherstone & Radaelli, 2003). This thesis measured the outcome apart for all relevant eHealth-

related issues for this thesis, for example the outcome of absorption has been identified in data privacy related issues and inertia has been identified in cross-border healthcare related issues.

**Table 5. Operationalisation of the concepts relating to the outcome of both Europeanization processes**

<b>Concept</b>	<b>Measurement</b>
<b>Absorption</b>	<p>Content of national eHealth Acts is in line with eHealth Directives of the EC</p> <p>National eHealth Acts are implemented after the establishment of eHealth Directives of the EC <b>AND</b> national eHealth Acts are implemented before the establishment of eHealth Directives of the EC</p> <p>National eHealth Acts are <b>NOT</b> substituted or amended</p>
<b>Transformation</b>	<p>Content of national eHealth Acts is in line with eHealth Directives of the EC</p> <p>National eHealth Acts are implemented after the establishment of eHealth Directives of the EC <b>AND</b> national eHealth Acts are substituted or amended</p>
<b>Inertia</b>	<p>Content of national Health Acts is <b>NOT</b> in line with eHealth Directives of the EC</p> <p>National eHealth Acts are <b>NOT</b> implemented after the establishment of eHealth Directives of the EC</p> <p>National eHealth Acts are <b>NOT</b> substituted or amended</p> <p><b>OR</b></p> <p>Content of national eHealth Acts is in line with eHealth Directives of the EC</p> <p>National eHealth Acts are implemented before the establishment of eHealth Directives of the EC</p> <p>National eHealth Acts are <b>NOT</b> substituted or amended</p>
<b>Retrenchment</b>	<p>Content of national eHealth Acts is <b>NOT</b> in line with eHealth Directives of the EC</p> <p>National eHealth Acts are <b>NOT</b> implemented after the establishment of eHealth Directives of the EC</p> <p><b>AND</b></p> <p>Content of national eHealth Acts are in line with eHealth Directives of the EC</p> <p>National eHealth Acts are <b>NOT</b> part of the national legal system after the establishment of eHealth Directives of the EC</p>

### 3.4 Data collection

Two different types of data were collected: one retrieved from legal documents and position papers, and one is related to in-depth information retrieved from interviews, both types of data collection are combined.

A desk research has been performed before the stage of interviews to answer the first part of the research question (how eHealth Europeanization influence the health care system of Poland). As first, the general facts regarding the key institutions, and benefits of eHealth for the current Polish health care system are identified and described. Data has been gathered and reviewed from already available sources such as published scientific and governmental papers. Further, the outcome of eHealth Europeanization on the Polish health care system can be identified by the (lack of) institutional changes within the legal institutional framework of Poland caused by eHealth Europeanization.

For this purpose, scientific articles and legal documents published by the Polish Ministry of Health are identified to get insights on the change of regulations within the Polish healthcare system. The 'Centre for Healthcare Information Systems' (CSIOZ), which is part of the Polish Ministry of Health, published a series of legal documents (CSIOZ, 2017) consisting the introduction of new acts within the Polish

healthcare system relating to the introduction of eHealth such as the 'Act on personal data protection'. The legal documents (framework of EU-standardization regulations and standards) from both eHealth Action Plans are compared with the legal documents of the Ministry of Health in Poland.

To gain deeper insights on the role of national stakeholders in the Polish eHealth strategy, 16 semi-structured interviews are performed with the four identified key stakeholders (policy makers and experts, patients, payors, and providers). The semi-structured interviews lead to a comprehensive data collection because the interviewees are able to elaborate upon their answers in detail (Bryman, 2015). A list of questions for the semi-structured interview is established from the operationalization table (section 3.3). The eight concepts of the theoretical framework are made measurable and converted into questions for the semi-structured interview. See appendix A for the set-up of the used semi-structured interview for this thesis. Supplementary questions are inquired in case of new perceptions or if additional information was needed to clarify the answer. The questions of the semi-structured interview are adjusted dependent on the stakeholders. The interviews are used to determine the policy beliefs of the stakeholders, that is whether they agree on the implemented eHealth projects, and which resources they utilized to put their preferences into the actual eHealth strategy.

Participating interviewees for the interviews are selected via non-probability sampling. Non-probability sampling is a selection method whereby elements are not selected by any chance measures (Ary et al., 2018). The form of non-probability sampling that is used in this thesis is purposive sampling: the creation of a sample of interviewees with relevant characteristics desirable to answer the research question (Bryman, 2015). In the case of this thesis, interviewees are enlisted intentionally if they fit in one of the four identified stakeholder groups and are familiar with the use of eHealth technologies or the development of the Polish eHealth strategy. However, getting access to policy makers is a difficult and lengthy process. To make this up and to guarantee a sufficiently high number of interviews, stakeholders with the same expertise such as academics and consultants from NGOs have been approached. eHealth experts are considered as useful for answering the research question because they have in-depth knowledge given their activities in gathering and processing data about the Polish eHealth development. See table 6 for the list of interviewees that participated in the interview. Supplementary interviewees within these four stakeholder groups are identified via another way of non-probability sampling: snowball sampling. The initial group of interviewees introduced and established four other respondents with relevant characteristics for the research question (Bryman, 2015).

An attempt was made to have a minimum of four interviews for every key stakeholder group. This number was able to increase if no data saturation was reached and novel topics still showed up. This thesis endeavoured for data saturation for every key stakeholder that is identified. According to Fusch & Ness (2015, p.1408), data saturation is *"the point whereby there is enough information to replicate the study when the ability to obtain additional new information has been attained, and when further coding is no longer feasible"*. The sample size can be seen as limited but the collection of data in the form of semi-structured interviews is sufficient enough to make a blueprint of which role the different national stakeholders play in the implementation of the Polish eHealth strategy. Further, all interviewees were asked about their knowledge about the other stakeholder groups (influence and resources). The relevant interviewees received an e-mail, call by phone or message via LinkedIn (including a second reminder in case of a lacking response) with the request to participate on the interview. The average duration of the interview was 45 minutes. Further, the interviewees and the interviews are made anonymously (in case the interviewee asked for such) to safeguard that the interview subjects are able to express themselves candidly.

**Table 6. The participating interviewees for this thesis**

Name	Stakeholder group	Profession	Sampling	Date	Form of interview
Bartosz Pedzinski	Policy makers and experts	Medical University of Bialystok, Public Health and IT systems	Purposive sampling	2 <sup>nd</sup> of July	Phone Call
Marcin Kautsch	Policy makers and experts	Academic: Jagiellonian University, Krakow,	Purposive sampling	10 <sup>th</sup> of July	Phone Call
Mateusz Lichoń	Policy makers and experts	Academic: Jagiellonian University, Krakow	Purposive sampling	9 <sup>th</sup> of August	Skype
Wojciech Milota	Policy makers and experts	Expert Consultant from CSIOZ and Sygnity, working on P1 project	Purposive sampling	22 <sup>nd</sup> of August	Skype
Michal Gawrys	Providers	IBM Polska, Develop eHealth solutions and contact with potential customers	Purposive sampling	17 <sup>th</sup> of July	Face-to-Face
Maciej Jakubczyk	Providers	CEO GdziePoLeK	Purposive sampling	6 <sup>th</sup> of August	Face-to-Face
Jerzy Szewczyk	Providers	Pro-Plus SA	Purposive sampling	13 <sup>th</sup> of August	Skype
Marcin Zawisza	Providers	Business Unit Manager (Health Team) at Sygnity S.A.	Snowball sampling	16 <sup>th</sup> of August	Skype
Marcin Wegrzyniak	Payors	Manager of Health Information Systems (CSIOZ) / National Health Fund	Snowball sampling	7 <sup>th</sup> of August	Face-to-Face
Andrzej Strug	Payors	A-SYST-IT systems consultant, National Health Fund	Purposive sampling	17 <sup>th</sup> of August	Skype
Piotr Soszynski	Payors	Medical IT-systems director, Medicover	Purposive sampling	23 <sup>rd</sup> of August	Skype
Wojciech Lorens	Payors	Project Manager at Medicover, IT-systems in healthcare	Purposive sampling	27 <sup>th</sup> of August	Skype
Ewa Borek	Patients	Director of Foundation WE patients	Purposive sampling	16 <sup>th</sup> of July	Skype
Dorota Kilanska	Patients	Information systems in healthcare for patients, active nurse in hospital	Snowball sampling	28 <sup>th</sup> of July	Phone Call
Wojciech Wiśniewski	Patients	Director of NGO Alivia, patient organization	Snowball sampling	30 <sup>th</sup> of July	Face-to-Face
Adrian Janus	Patients	Foundation WE Patients, field of Medical Law	Purposive sampling	21 <sup>st</sup> of August	Phone Call

### 3.5 Data analysis

The first step was to identify the implemented eHealth regulations by Poland and by the EC. The Polish eHealth documents were analysed on implemented or amended acts. Polish acts are mandatory regulations implemented into the Polish legal framework. The official documents of the EC were analysed on implemented directives. Directives are legal acts of the EC that are mandatory for all European Member States. The second step was to analyse which eHealth regulations in Poland were implemented due to eHealth legislation of the EC. The identified acts and directives were compared

on time of implementation. In case EC legislation led to the implementation of new Polish acts, the directive should have been implemented in the EU before the act is implemented in Poland. The identified acts and directives were also compared on content to analyse which aspects are in line and which are different. Based on this analysis, the Polish eHealth acts that were implemented or amended due to EC legislation were identified.

The policy misfit is identified by analysing which eHealth directives of the EC were already part of the legal system of Poland in form of an act before they were established. The identified acts and directives were compared on time of implementation and on content to analyse similar aspects. The legal misfit is identified via the interviews. Interviewees that were able to mention eHealth regulations of the EC that were implemented afterwards in the Polish healthcare system were asked if such regulations were already part of national policy as common practice before implementation. These answers were afterwards compared on similar and opposite statements.

The data analysis of the policy beliefs, resources and restrictions, identified via the interviews, is conducted via coding, using the software of NVivo. The coding process entailed three parts as described by Corbin & Strauss (1990): open, axial and selective coding. Translated to this thesis, the transcribed interviews are analysed with respect to policy beliefs towards the (different projects of the) Polish eHealth strategy. Respective statements are put together for each stakeholder group and analysed on similar and opposite statements to formulate a general policy belief of every stakeholder group towards the Polish eHealth strategy. Moreover, the transcribed interviews are analysed with respect to the resources and restrictions (formal legal authority to make decisions, public opinion, information, mobilizable troops, financial resources, and skilful leadership) of every stakeholder to put his or her policy beliefs into actual policy. The mentioned resources and restrictions by the interviews are analysed on similar and opposite statements to formulate a general assessment on the kind of resources and restrictions for every stakeholder group.

After the identification and analysis of the policy beliefs, resources and restrictions of every stakeholder group, an analysis is made to observe which policy beliefs of every stakeholder group are translated into national policy. In other words, which policy beliefs of the stakeholder groups are implemented as real standards, or even institutional changes, within the Polish eHealth strategy. This has been done by asking the interviewees from the policy makers group which opinions and interests of the other stakeholder groups are taken into account in the development of the Polish eHealth strategy. Further, every interviewee is asked about the influence of their own stakeholder group on the Polish eHealth strategy. All these statements analysed on similar and opposite statements to assess the influence of every stakeholder group on the development of the Polish eHealth strategy. At the end, a clear view emerged about the influence of top-down regulation (examining the change, or lack of change of institutions within the Polish legal framework) and bottom-up regulation (examining the preferences of the stakeholder groups that are included in the Polish eHealth strategy).

### 3.6 Data quality

Yin (2003) identified four factors that decide the quality of a case study. *Construct validity* is the degree in how much the extracted results from this thesis measured what they claim (Yin, 2003). A high construct validity was generated in this thesis due to the application of recent, peer-reviewed scientific work for the construction of the theoretical insights and for the operationalization table. *External validity* is a measure if the identified results are generalisable beyond this thesis (Yin, 2003). This thesis

used non-probability sampling. The interviewees were not randomly picked from the population which makes generalization not conceivable but this is not relevant for this thesis because a single case study is used. *Internal validity* is the extent to which the identified causal relationships are valid (Yin, 2003). This thesis used a deductive approach which can help in the explanation of causal relationships among the different concepts, based on an empirical theoretical framework. *Reliability* is the measure if the process of collecting, and analysing data can be replicated with equal results as an outcome (Yin, 2003). The language of the interviews had influence on the sample selection because this thesis actively approached English speaking interviewees. As a result, 15 interviews are conducted in English, and one interview is conducted in Polish. To increase reliability, this thesis made an attempt to distinct and well-clarify both the data collection and data analysis. Further, the interview guide is openly accessible and misinterpretations (also due to the language difference) in the conducted interviews are erased because the transcribed interviews are summarized and afterwards reviewed by the interviewees for verification.

## 4. eHealth development at the European and Polish level

To gain an understanding about the Polish eHealth development, its perspectives, and the potential influence of Europeanization, a brief overview of the historical and current status of the Polish healthcare system and the key institutions involved in the decision-making process is required, which is firstly given by this section. Further, the perceptions and implemented regulations of the EC and Poland towards eHealth development are given which sets the scene for the analysis of the examined documents in the next section.

### **The Polish healthcare system and potential of eHealth technologies**

Since 2006, the spending of the healthcare industry in Poland doubled to approximately 110 billion zloty (25 billion euros) in 2016, which accounts for 6.8% of the Polish GDP (Nieszporska, 2017). This makes Poland one of the European Member States that spends the least amount of money on public healthcare, together with Romania, Latvia, Estonia and Lithuania (Kaplan et al., 2017). Estimations show a potential growth of the Polish healthcare industry to 140 billion zloty (33 billion euros) in 2020. The main drivers of this growth will be the fast ageing of the population and an increase of people with lifestyle related diseases such as type 2 diabetes and obesity (Nieszporska, 2017). 93% of the total expenditure in the Polish healthcare industry is used for the facility of healthcare services; 7% is used for investments in the Polish healthcare system, including the implementation of eHealth technologies (Soltysik-Piorunkiewicz et al., 2016).

As pointed out by Kautsch et al. (2017), eHealth can have a great potential for the Polish healthcare system due to three reasons: 1) Poland has the fastest ageing in the EU, 2) distances from the rural areas to the hospital can be large, and 3) number of physicians per 1000 people is the lowest in the EU. Regarding the first point, the ageing population will have a significant financial impact on the Polish healthcare system (Nieszporska, 2017). Recently, scientific research has shown that eHealth can be a possible solution due to faster access online to medical data and less duplication of medical tests (Russo et al, 2016; Iribarren et al., 2017). Regarding the second point, residents in rural areas have a lack of access to public healthcare services. It is assumed that eHealth can be a solution for healthcare in Polish rural areas because doctors have access to medical health records of all patients which allows them to consult patients online (Russo et al, 2016; Nieszporska, 2017). Regarding the third point, in 2016, 2.2 doctors and 5.2 nurses were available for every 1000 residents. eHealth can be a solution because doctors can give online consultation and spend less time on travelling. Further, electronic health records are also a measure to save time for doctors due to less paper work (Russo et al., 2016).

### **Historical development and key institutions in the Polish healthcare system**

During the second part of the twentieth century, the healthcare system of Poland went through radical reforms. Before 1999 the Semashko model was in place whereby the government finances all public healthcare for all its inhabitants (Lukasova, 2018). After 1999, the Semashko model was replaced by an obligatory health insurance model (Bismarck model) which covers all inhabitants under the umbrella of the “*National Health Fund*” (NFZ). Further, public health care amenities are now supervised by *local governments* in a more decentralized way. The *Ministry of Health* is accountable for the regulation of the Polish healthcare system. Hence, the Ministry of Health together with the NFZ and local governments, are nowadays the key institutions and control the management and funding of all aspects within the Polish healthcare system, including eHealth development (Sagan et al., 2011; Nieszporska, 2017).

The Ministry of Health, and especially the Centre for Healthcare Information Systems (CSIOZ), develops the correct policies to set up and implement an eHealth infrastructure in the Polish healthcare system, based on the eHealth Actions Plans of the EC (Szynek & Karasek, 2016; Nieszporska, 2017). They are in charge of 1) creating a regulatory environment for eHealth so eHealth technologies can be legally used by healthcare providers, 2) providing training programs for health professionals and patients to become familiar with the new technologies, and 3) creating a medical information system wherein the exchange of medical data can take place among health professionals (Kautsch et al., 2016; Szynek & Karasek, 2016).

The second key institution is the NFZ which is governed and financed by the Ministry of Health. The NFZ determines the requirements for healthcare facilities and contracts. The NFZ also decides about the reimbursement schemes for new eHealth technologies (Kautsch et al., 2016).

The third key institution are the local governments which are accountable for classifying the health requirements of its local citizens and for endorsing healthcare inside their regional borders (they receive money from the Ministry of Health). However, local governments have no influence on subjects concerning eHealth because the NFZ is in charge of signing the contracts and setting up the requirements (Kautsch et al., 2016).

### **The EC towards eHealth development**

The general healthcare mission of the EC is the overall improvement of the European healthcare system and enhancing the access to it for all European citizens. To achieve such an improvement in terms of quality and effectiveness, the EC continues to develop knowhow on healthcare systems and contribute to activities which are able to reduce costs of healthcare expenditures and ill health of its citizens (EC, 2017). An important example is the support and funding of new eHealth technologies which are more cost-effective and enhance the delivery of healthcare (EC, 2017).

To enhance the use of eHealth technologies, the EC uses mainly soft law measures in order to develop best practices, and foster cross-national partnerships and benchmarking. Despite the focus on soft law measures, the EC implemented six eHealth regulations in the last two decades that accounts for all the Member States which are described in table 7. The aim of using direct eHealth regulations was to accelerate the implementation of data protection and cross-border measures and due to the lack of legal rules regarding the interoperability of electronic health records (EC, 2017).

**Table 7. The mandatory eHealth regulations implemented by the EC**

<b>Directive</b>	<b>Year of implementation</b>	<b>Explanation</b>	<b>References</b>
Data Protection	1995	Emphasize the safety of patients with respect to processing private information, and legalized the exchange of this medical data between medical professionals	Callens, 2010; Beyleveld, 2017
E-commerce	2000	Administers information services at distance, including the purchase of medical services, and the storage, exchange and processing of medical data via electronic health records	Callens, 2010; Senftleben, 2017
Medical Device	2007	Complements the free movement of medical devices within the whole EU that match the minimum criteria of safety to receive an EC-conformity mark	Callens, 2010; Raposo, 2016
Distance Contracting	2007	The settlement of eHealth contracts can be concluded between a provider and customer at a prearranged distance	EC, 2017; Randelovic & Ljajic, 2017

Cross-border	2011	Right of the patient to 1) obtain medical treatment in other Member States, including reimbursement, and 2) have access to their own medical record	Raposo, 2016; Ibrahim et al., 2018
Electronic Signatures	1999 (amended in 2016)	Endorsing the usage of electronic signatures and make them on an equal level with hand written signatures	Callens, 2010; Bakhtiarifar & Savraj, 2018

The introduced eHealth regulations of the EC are closely related with the aims of the two developed eHealth Action Plans of the EC. The first eHealth Action Plan of the EC was for the period 2004-2010. The main aims of the eHealth Action Plan 2004-2010 can be found in table 8.

**Table 8. Main aims of the eHealth Action Plan 2004-2010**

Main Aim	Explanation
<i>Healthcare facilities and national / regional authorities show leadership</i>	eHealth can only be successfully implemented in a national healthcare system if enough financial resources are made available and if it's taken into account in the long-term development plans
<i>The decrease of market fragmentation, improve interoperability, and enhance standardisation</i>	Decrease market fragmentation via the standardisation of regulation at an EU-level because national healthcare systems in the EU highly differ in their regulatory framework
<i>Decrease legal uncertainty in implementing eHealth services</i>	Development of sustainable business models, and funding and reimbursement programs
<i>Increase the awareness of eHealth of national authorities and health professionals</i>	Development of a public healthcare portal which should functioning as a central point of access to all kinds of information on health, and eHealth in particular
<i>The protection of private medical data</i>	For eHealth technologies to get accepted by the society and healthcare professionals, it's important to build trust by decreasing the concerns aiming privacy
<i>Improving the infrastructure</i>	Increase access to high-speed internet connections in rural regions

Barriers for the implementation of eHealth in the European healthcare systems still occurred during the final stage of the first eHealth Action Plan in 2010. At that time, five barriers were identified: The lack of 1) awareness of end users about eHealth, 2) interoperability among the different eHealth technologies, 3) clear regulation for the utilisation of medical data, 4) reimbursement arrangements for eHealth, and 5) high-speed internet connectivity in rural areas (EC, 2012). These deficiencies led to a new "eHealth Action Plan 2012-2020" based on the five identified barriers after the realisation of the eHealth Action Plan 2004-2010. Three objectives have been established in the eHealth Action Plan 2012-2020 to diminish the mentioned barriers (EC, 2012; Kautsch et al., 2016).

The first objective is *improving the interoperability of eHealth facilities and services* to create better coordination of healthcare delivery and medical data exchange (EC, 2012). European regulations and standards are an accustomed method to create interoperability of ICT- technologies across European Member States. Measures include guidelines to exchange data among healthcare professionals, and coordination activities to reduce legal barriers (EC, 2017). The second objective is *financing the R&D in eHealth technologies and wellbeing to improve the access from patients and doctors to user friendly devices and services*. The EC fund R&D in eHealth technologies in three different areas (EC, 2012): 1) an IT engineering agenda for digital, tailored healthcare services, 2) novel methods to improve the analysis and sharing of medical data, 3) the development of novel digital technologies and applications wherein healthcare will be integrated with social care systems (EC, 2012). The third objective is *financing the uptake and establishing an enhanced deployment*. The EC will fund 30 billion euro for ICT-priorities such as enhancing the access to internet connectivity in remote areas and supporting the uptake of IT-applications for European citizens and SMEs (EC, 2012).

## Poland towards eHealth development

Poland started in 1997 to take regulatory measures which are relevant for, and related with eHealth. Eight measures can be identified and are explained in table 9.

**Table 9. - The regulatory measures implemented by Poland**

Regulatory measure	Year of implementation	Explanation	References
Act on Personal Data Protection	1997	Concerns the dispensation and safeguarding of medical data, and the transfer of medical data outside the Polish borders and among service providers	EUR-Lex, 2018; Masna et al., 2018
Act on Patient's Right	2008	Patient received access to their own medical documentation and medical professionals received authorization to process medical data and save it in an electronic form	Jacek & Ozog, 2012; Kubiak, 2016
Direction of Computerization eHealth Poland 2011-2015	2009	Implementation of electronic platform for: 1) the collection of digital resources about medical events, 2) the exchange of medical records between healthcare providers, and 3) eHealth eLearning for Polish healthcare professionals	Kulisiewicz, 2015; Kawalec et al., 2016
Act on Medical Devices	2010	The sell and buy of medical devices, including eHealth in European market. The medical devices need to align with requirements relating to health and safety protection. Including distance contracting.	Masna et al., 2018; Ministertwo Zdrowia, 2018
Act on Medical Activity	2011	Providing Polish healthcare (including eHealth) to all patients from the European Union	Kulisiewicz, 2015; Masna et al., 2018
Council of Ministers 157	2012	Improving the telecommunication and internet infrastructure in rural areas, promoting and creating awareness of digital literacy and telecommunication	Pomoc Techniczna, 2016; Barnard & Peers, 2017
Act on the System of Information in HealthCare	2011 (amendment in 2015)	A conversion from a voluntary system of electronic health records towards a mandatory system	Kawalec et al., 2016; Masna et al., 2018
Act of Professions of Doctor and Dentist	2018	Electronic signatures has the same value as handwritten signatures	Ministertwo Zdrowia, 2018

Poland implemented for the first time in 2011 a national eHealth strategy: the 'Polish eHealth strategy 2011-2015'. Four chief objectives of this strategy can be recognized (Kautsch et al., 2016; Ministertwo Zdrowia, 2018): 1) improve patient access to healthcare services, 2) develop a platform of electronic health record to store medical data, 3) promote the use of eHealth technologies by patients, health professionals and providers, and 4) introduce novel IT-solutions which improve the interoperability of the Polish healthcare system with other European healthcare systems.

Based on the developed objectives, the Ministry of Health established three projects to put the aims into practice (Kautsch et al., 2016; Ministertwo Zdrowia, 2018):

*Project 1* is an online platform of electronic health records to assemble, share and evaluate medical data. The introduction of project 1 should contribute to an overall improvement of the Polish healthcare system through: 1) enhanced quality and accessibility of medical data, and 2) enhanced

healthcare service for patients. Now, with the use of this platform pilots are set up including e-prescription and e-referrals but up to September 2018, the platform was not fully implemented yet. Healthcare providers are sceptical to use this central platform because they are not able to run the electronic health records in their own settings. Further, a huge problem emerged because at the same time regional platforms and a central national platform were established. So far, it is not possible to send electronic health records from the regional platforms to the national platform and vice versa.

*Project 2* is an online platform consisting of medical registers which can be accessed by entrepreneurs and fully implemented in 2012 as public information. Four registers operating in the healthcare system can be identified: 1) register of medical entities, and apprenticeships such as doctors, dentists and nurses, 2) register of public, hospital and factory pharmacies, 3) register of medicinal products registered in Poland, and 4) register of laboratory diagnostics in Poland.

*Project 3* is an IT-system associated with lecturing health professionals in terms of novel medical services, products and devices, including eHealth technologies and fully implemented in 2015. The preferred group are people aged 45+ and people who have no IT-systems in place at their workplace.

## 5. Influence of Europeanization on Polish eHealth strategy

### 5.1 The policy misfit and legal misfit between EC and Polish eHealth regulation

In this section the previously described regulations of the EC on eHealth development are compared with the introduced Polish regulations regarding 1) content and 2) time of implementation to examine which influence EC legislation has on the Polish eHealth strategy.

When it comes to legislation, it can be observed that the EC influences the Polish eHealth development, especially regarding general data protection, cross-border healthcare, and electronic signatures. The same accounts for the European regulation regarding the implementation of electronic health records and E-registration. Those two eHealth technologies are originating from the EC because it is mentioned as one of their priorities within the European healthcare system.

The first point of interest is *data protection*. The EC introduced the Data Protection Directive in 1995. This directive is related to eHealth because it gave permission for healthcare professionals to process and share personal data of patients within and between Member States via specific guidelines. The EC made it obligatory for all European Member States to incorporate this directive into their regulatory framework. As a result, Poland introduced the Act on Personal Data Protection two years later in 1997. This act included guidelines about the registration of medical data, and comprises the right for all healthcare providers to share medical data among each other, both on a national and European level. The Data protection Directive formed the base for the E-commerce Directive.

The second point of interest is *Electronic health records*. The EC introduced the E-commerce Directive in 2000. This directive is important for eHealth development because it aims on doctors and healthcare providers that share and transfer medical data among each other via electronic health records. Those actors have to follow mandatory standards that are included into the E-commerce directive in terms of the storage and exchange of medical data. The EC made it obligatory for all European Member States to incorporate this directive into their regulatory framework. As a result, two regulatory reforms can be found in the Polish healthcare system that do align with the E-commerce directive. Poland introduced the Act on Patient's Rights in 2008 based on the Act on Personal Data Protection of 1997: All healthcare providers and doctors received the possibility to share and transfer medical data via an electronic form. This act is amended in 2014 (Act on the System of Information in HealthCare) which made it mandatory to store all medical data in an electronic form. Poland also implemented regulations to create an IT-infrastructure to permit the interoperability of electronic health records that are shared by doctors and healthcare professionals and providers, based on the E-commerce Directive. Poland started in 2009 with developing such a national IT-infrastructure to exchange medical data among Polish healthcare providers and doctors.

The third point of interest is the *free movement of medical devices*. The EC introduced the Medical Device Directive in 2007. This directive relates to the free movement of medical devices within the whole EU. All medical devices, including eHealth technologies, should match minimum criteria of safety and managerial requirements to receive an EC-conformity mark. These medical devices can be sold and bought throughout the whole EU. Further, the EC introduced the Distance contracting Directive in 2007 as well. This Directive states that eHealth contracts can be arranged on distance. Poland introduced the Act on Medical Devices in 2010 that combines both directives. This act states that in case Polish manufacturers introduce new medical devices into the Polish or European market, these medical devices need to align with specific health and safety requirements set-up by the EC. Further, this act also states that Polish providers and buyers of eHealth technologies can conclude their contracts on distance.

The fourth point of interest is *cross-border healthcare*. The EC introduced the Cross-border Directive in 2011. Patients received the right to obtain medical treatment and reimbursement schemes for eHealth technologies in foreign Member States, and the right to have access to their own medical

record. The last point does align with the Act on Patient’s Rights’ established in Poland that state that a Polish patient should receive the right to information about their health condition, and access to the their own medical documentation. The Polish Act on Medical Activity was introduced shortly after the Cross-border Directive. This Act states that the provision of eHealth is also acceptable in the context of cross-border healthcare which aligns with the regulations of the EC. The Act on medical activity indicates, from the perspective of Polish law, to provide health care benefits with the same requirements (including eHealth) to patients residing in Poland from another Member State.

The fifth point of interest is *electronic signatures*. The EC introduced the Directive of Electronic Signatures in 2016. This Act is relevant for eHealth because eHealth technologies frequently ask for the application of electronic signatures. The EC recognized electronic signatures with this act on the same level with written signatures. The Polish Medical Profession Act states that a medical professional should examine its patients in person to make an assessment of their health. These standards discouraged medical professionals to use eHealth technologies. The Act on the System of Information in Healthcare was implemented afterwards which stated that the use of electronic signatures was legal in case of chronically ill patients. Since April 2018, the Act of Professions of Doctor and Dentist replaced the Polish Medical Profession Act and electronic signatures became equivalent with handwritten signatures.

Table 10 gives a brief overview regarding which Polish eHealth regulations are implemented by which specific EC eHealth legislation on the basis of content and time of implementation.

**Table. 10 Comparison of the Polish and EC eHealth legislation**

EC Legislation (year of implementation)	Polish regulation (year of implementation)
Data Protection Directive in (1995)	Act on Personal Data Protection (1997)
E-commerce Directive (2000)	Act on Patient's rights (2008) & Act on the System of Information in Healthcare (2014)
Medical Devices Directive (2007) & Distance contracting Directive (2007)	Act on Medical Devices (2010)
Cross-border Directive (2011)	Act on Medical Activity (2011)
Directive of electronic signatures (2016)	Act on Professions of Doctor and Dentist (2018)

Based on the comparison and analysis of the European and Polish directives and regulations, which resulted in the five points previously described, the policy misfit and legal misfit can be identified. As previously stated, a policy misfit is in place if existing Polish regulations does not relate with the new regulations proposed by the EC. As a result, the regulations of the EC can lead to the introduction of new or amended Polish regulations. Based on the content analysis, a high policy misfit is identified: Less than 50% (zero out of six) of the direct eHealth regulations, described in the eHealth Action Plans, had been implemented within the legal framework of Poland at the moment they were established. All six eHealth directives of the EC were included afterwards in six different acts in the Polish legal framework due to the mandatory character of the EC legislation.

The second type of misfit is the legal misfit which assumes that the eHealth regulations established by the EC were already part of the legal framework of Poland but not yet written down in national

regulations. Based on the results, a high legal misfit is identified: Less than 50% (zero out of six) of the mandatory eHealth regulations of the EC were already put into practice by the Polish stakeholders before they were implemented into the Polish legal system. Three reasons for a high legal misfit were identified: the Polish culture, a lack of eHealth advocate groups, and a lack of interest for eHealth from medical professionals. The Polish culture is mainly based on Imperial Russia which indicates that the Polish government and citizens do not have trust in organisations that control them as the EU. The fact that Polish people are still very cautious and do not want to start new things regarding eHealth before clear regulations are part of the Polish legal framework, was for instance emphasized as a major reason for a high legal misfit by several interviews. As evidenced by multiple interviews, eHealth is not a topic of interest for the general public which makes eHealth not a priority for the Polish government. The Polish government does not have strong advocate groups that support and promote the development and use of eHealth, or stimulate the Polish government to increase its efforts to encourage the use of eHealth technologies by the end users such as doctors and patients. One interviewee mentioned a related argument about the lack of interest regarding eHealth by medical professionals as a major reason for the high legal misfit. The implementation of new eHealth technologies can increase the average workload of medical professionals, especially in the beginning of the process. Medical professionals do not want to spend extra time to get familiar with the new eHealth technologies. If the current process of providing medical services is sufficient, and no mandatory regulations are in place that oblige them to use eHealth technologies, no reason exists for them to change their current way of providing healthcare.

## 5.2 Specific mechanisms of influence and reasons of change

Next to the influence of direct EC legislation on the Polish eHealth strategy, three other mechanisms of influence were identified which were not taking into account in the theoretical framework of this thesis: 1) the EC's financial influence, and 2) influence of other Member States, and 3) the EC's soft law measures.

The first mechanism is the EC's financial influence. A big percentage of the public investments in the Polish eHealth strategy are derived from European funds, which went directly into the development of project 1. The EC funded a total of 600 million zloty so far in the Polish eHealth strategy. As evidenced by multiple interviews, the funds of the EC were even the main reason to start the development of project 1. The EC gave Poland instructions in how to invest this money and for what purpose: Poland was obliged to follow the developed standards of the EC. Further, one interviewee mentioned that the majority of IT-investments in Polish hospitals for the last ten years are financed by the EC. Polish hospitals do not invest in new IT-equipment if it is not financed by the EC. Polish hospitals are often in huge debts. In case a budget is available, investments will be made in new medical devices and not in eHealth technologies. Hence, the distribution of European funds can be seen as one of the most influential instruments of the EC to initiate and support the implementation of the Polish eHealth strategy.

The second mechanism is the influence of other Member States. The collaboration of the CSIOZ with eHealth actors of other European Member States on the topic of eHealth development has also been identified as evidenced by multiple interviews: an influence on the Polish eHealth strategy on a state level. Poland started such collaboration to not lack behind other Member States in terms of the interoperability of eHealth technologies and cross-border healthcare. Poland is trying to catch up, and observes the eHealth implementations within the healthcare systems of other European Member States. One interviewee mentioned that within the last two years, the CSIOZ collaborated and exchanged knowledge and practices with eHealth experts from Denmark, the Netherlands, Sweden and Estonia. For instance, multiple meetings with experts from other countries were organised to analyse how they finance the development and implementation of new eHealth technologies into their healthcare system, centres of medical registers of other countries (such as the Netherlands, Sweden and Estonia) were visited by the CSIOZ to gain knowledge on how to set up a national framework for the exchange of electronic health records on a national and international level.

The third mechanism is the EC's soft law measures. Multiple interviews mentioned that the EC does not have the power to fully control the healthcare systems of individual Member States with direct regulations. Poland and all other European Member States are all different in the way of providing healthcare which means that the EC cannot equally regulate health in the same way in all Member States. The EC is only able to regulate more general parts within the European healthcare system like patient rights, safety, privacy, and equal healthcare. The EC cannot regulate how Poland delivers its healthcare, and specifically eHealth. One interviewee mentioned that due to this reason, indirect regulations embodied as soft law measures are the best effort for the EC to put influence on the Polish eHealth development such as promoting enhanced interoperability of ICT-technologies across European Member States to improve the cooperation and exchange of medical data between different national healthcare facilities and professionals. Two interviews mentioned that such soft law measures are useful for the Polish eHealth strategy because it is easier to follow certain predeveloped guidelines for eHealth than to develop them on its own. Such soft law measures give guidance and enough freedom for Poland to invest in specific eHealth projects that align with the eHealth strategies of other Member States.

## 6. The role of national stakeholders in the implementation of eHealth

In this part, the policy beliefs, resources and restrictions of the four identified stakeholder groups regarding eHealth development in Poland are given.

### 6.1 Policy makers and experts

#### *Policy beliefs regarding Polish eHealth strategy*

From the analysis of documents and the expert interviews, it becomes clear that the interest of the Polish government towards eHealth development can be considered as low. Four major reasons can be identified:

The first reason is *a lack of planning long-term eHealth strategies*. As emphasized by two interviewees, long-term eHealth development strategies were not prioritized by the Polish government because of a tendency to focus on short-term strategies (i.e. time frame between the elections). The implementation of large-scale eHealth projects within the Polish healthcare system induces changes that enquire a longer time-frame to successfully implement the different eHealth projects. The Ministry of Health is currently developing a new eHealth strategy starting in 2020 but the previous eHealth strategy is not fully implemented yet and no real eHealth breakthroughs were set regardless two pilots for E-prescription.

The second reason is *a lack of eHealth advocate groups*. As mentioned by one interviewee, the Polish government had a low willingness to invest in the Polish eHealth strategy because they did not had powerful eHealth advocate groups that stimulated the Polish government to encourage the use of eHealth in the Polish healthcare system or to induce the implementation of the different eHealth projects.

The third reason is *a lack of interest for eHealth from the general public*. According to multiple interviewees, Polish citizens were in general unaware of the benefits of eHealth due to a lack of eHealth documentation. For this purpose, the general public is not interested in the Polish eHealth development which makes eHealth not a priority for the Polish government. One interviewee even mentioned that eHealth covers just a small part of the governmental plans and investments are made in fields that can gain votes such as improving the labour market.

The fourth reason is *the low turnover of the eHealth niche*. One interviewee, which was confirmed by the Polish eHealth documents, stated that the turnover of the Polish eHealth niche can be considered as 1% of the total Polish healthcare spending. Such a low turnover gave the Polish government a low motivation to develop the Polish eHealth projects, and the majority is still in the implementation phase.

Despite the low motivation to implement the different eHealth projects, the Polish government had a strong interest in the successful implementation of eHealth project 1 within a short time-frame due to *the risk on returning the received EC funds*. As observed in multiple interviews, Poland received European funds to finance its eHealth projects which will be refunded if the eHealth projects do not align with the European standards or time-frame of implementation. The CSIOZ included stakeholder management, such as patient associations and IT-providers, via the 'interoperability council' in 2016. This council introduced two E-prescription pilots in 2018 as a result.

#### *Influence on the Polish eHealth strategy*

From the analysis of expert interviews, it becomes clear that the stakeholder group of policy makers has the most influence on the Polish eHealth strategy, but mainly in a negative way.

As evidenced by multiple interviews, the Ministry of Health finances the Polish healthcare system and makes all the final decisions regarding the development of the Polish eHealth projects. The Polish eHealth strategy is set-up by the Ministry of Health and the CSIOZ works on the implementation of the

established eHealth projects. Newly introduced decisions and regulations from the Ministry of Health, related to eHealth, are hardly negotiable for the other stakeholder groups.

Nevertheless, according to one interviewee, the Ministry of Health has always been generally weak in Poland compared with other Ministries. The ministry of Health has a limited amount of financial resources available for national healthcare (6.8% of GDP) which makes it difficult to invest in the Polish eHealth projects. Due to the European funds, enough money is made available but the Polish parliament is obliged to follow the EC standards which reduces its influence.

Multiple interviewees mentioned the Polish government as a negative influence that hindered a successful implementation of the Polish eHealth projects due to three major reasons.

The first reason is *a lack of knowledge within the CSIOZ*. As evidenced by two interviewees, the biggest barrier for the development of the Polish eHealth projects is mentioned as the placement of the wrong experts at the CSIOZ. The CSIOZ has a lack of knowledge regarding project management and newly announced European eHealth standards which led to too big scoped and ambitious eHealth projects. Both interviewees continue that the received EC funds are not well-spent on the right eHealth projects due to a lack of experience of conducting such eHealth projects by the Polish government and the lack of power that the CSIOZ has to implement big eHealth projects like project 1.

The second reason is *a lack of published eHealth documentation*. Multiple interviews emphasized that the Polish government did not delivered any documentation regarding the benefits that different stakeholders attain by the implementation of eHealth technologies. Without such documentation, the resistance towards eHealth development cannot be lowered which hindered the implementation and use of eHealth. One interviewee mentioned that in case such documentation exists, the stakeholder group of payors can be convinced to use eHealth which will ease the development of the eHealth projects in general.

The third reason is *a lack of stakeholder management*. Two interviewees mentioned that the Polish government drafted its own eHealth Action Plan, based on EC legislation. The policy beliefs of other stakeholder groups, and especially the end users, were not taken into account and they were obliged to follow it (an exception is the previous mentioned interoperability council). Forcing the Polish eHealth strategy on the national stakeholders led to an enhanced resistance towards the eHealth projects from doctors and patients. The two interviewees also assumed to include stakeholder management in the upcoming Polish eHealth strategy. If policy beliefs of the end users do align with the content of the eHealth projects, it will enhance the uptake of the eHealth projects and use of eHealth in general.

## 6.2 Payors

### *Policy beliefs regarding Polish eHealth strategy*

From the analysis of expert interviews, it becomes clear that the opinions of the payors towards eHealth development can be considered as negative. Five major reasons were identified:

The first reason is *a lack of general knowledge regarding eHealth*. As emphasized by multiple interviews, doctors are not aware of the benefits that eHealth can deliver. A common fear exists that doctors are not needed anymore in the near future due to advanced eHealth technologies, which can be seen as a subjective fear.

The second reason is *an increase of work load*. According to one interviewee, the introduction of new eHealth technologies will increase the work load of the medical staff, especially in the short term. Doctors will lose time with gaining new knowledge and monitoring patients via IT-systems.

The third reason is that *doctors do not want to be controlled*. One interviewee mentioned that current IT-systems can be checked on the made decisions of the doctors such as the received prescription of the patient and total time of consultation. This can be seen as an ethical control and doctors prefer not to be controlled.

The fourth reason is *a lack of interest of hospitals*. Two interviewees emphasized that Polish hospitals in general have debts and are currently not able to introduce and use new eHealth technologies. If a budget is available, hospitals prefer to invest in new medical devices or employees. One interviewee mentioned that hospitals do not introduce new eHealth technologies because the hospitals will be visited anyway.

The fifth reason is *a low salary in the public healthcare system*. According to multiple interviews, Polish doctors are obliged to work part-time in the public healthcare system with lower salaries compared to the private healthcare system. Doctors do not take into consideration the uptake and use of new eHealth technologies due to the lack of incentives.

As emphasized by multiple interviews, the medical staff had a sceptical and negative attitude towards eHealth because of the induced changes. Nevertheless, it seems like this situation is slowly changing if the use of eHealth will become a habit. Further, multiple interviews also mentioned that doctors that are just graduated do support the implementation of new eHealth technologies into the Polish healthcare system. They are already aware of eHealth via their studies and using new technologies such as Skype and other apps in their personal life.

### *Influence on the Polish eHealth strategy*

From the analysis of expert interviews, it becomes clear that the stakeholder group of payors is the second group with considerable influence on the Polish eHealth strategy. Multiple interviews mentioned that the influence of payors on the Polish healthcare system increased within the last decade. Three major reasons for their influence were identified.

The first reason is *a strong negotiation position*. As evidenced by two interviewees, hospitals and medical centres are big employers in local communities which gives them a strong negotiation position. It seems like hospitals bring the discussion to the political level in case the Polish government induces changes such as decreasing the number of hospitals or enhanced performance checks. Two other interviewees mentioned that the stakeholder group of payors can also organise strikes if they do not align with new developments in the Polish healthcare system. Recently, Polish doctors organised a strike related with eHealth on a national level. They disagreed with made propositions in the Amendment of the Data protection Act, which is now reconsidered by the Polish government.

The second reason is *the Telemedical Working Group*. Multiple interviews emphasised that the stakeholder group of payors is in a good relationship with the Ministry of Health due to the fact that high management positions are mainly performed by doctors. The same interviews mentioned that this relationship led to the Telemedical Working Group. The telemedical working group consulted the development of the first Polish eHealth strategy regarding interoperability and electronic health records. They also negotiated the implementation of the Act of Information System in Health Care, which officially allowed the use of eHealth technologies in the Polish healthcare system.

The third reason is *the Family Doctors Association*. One interviewee mentions the Family Doctors Association as an active player in public health consultation. In case the Ministry of Health is trying to introduce a new legal health issue, it seems like this has to be consulted with the Family Doctors Association who can resist the new regulations. The same accounts for the implemented Polish eHealth acts which are consulted by this association.

## 6.3 Patients

### *Policy beliefs regarding the Polish eHealth strategy*

From the analysis of expert interviews, it becomes clear that the stakeholder group of patients is highly interested in eHealth development because Polish patients are aware of the known benefits of eHealth. However, their opinion about the Polish eHealth strategy is negative, one major reason was identified.

This reason is *a lack of patient participation*. As evidenced by multiple interviews, the policy beliefs of patients are not taken into account within the development of the Polish eHealth projects. The Polish government considered such approach as sufficient because not a centric type of patient perspectives can be identified that can benefit the different interests of the patient organizations. This led to a Polish eHealth strategy that did not benefit the general patients' perspectives. Two interviewees mentioned two specific examples: *medical registers* and *E-prescription*.

One interviewee emphasised that the stakeholder group of patients is highly interested in medical registers which are systems that can measure and compare medical data between hospitals. However, such medical registers are not implemented yet in the Polish healthcare system due to negative opinions (regarding extra work pressure) of medical professionals, which were taken into account in the Polish eHealth strategy.

Another interviewee emphasised the negative opinion towards the pilots of E-prescription in which the stakeholder group of patients is highly interested in. These pilots did not include patients' functionalities such as data about allergies or health interactions, and cost containments. 40% of the Polish expenditures on drugs is paid by the patients themselves and E-prescription could deliver information on how to save money on private drugs spending.

### *Influence on the Polish eHealth strategy*

From the analysis of expert interviews, it becomes clear that the stakeholder group of patients has no influence on the Polish eHealth strategy. Two major reasons were identified.

The first reason is *a lack of financial resources*. As evidenced by two interviewees, the stakeholder group of patients has low financial resources, which can be used for the promotion of eHealth and their interests, because most patient organisations are willing to stay transparent. Due to their transparency, the Polish government was not able to align their motives with a profit-driven purpose, but with a centralised purpose on eHealth development and fulfilling patient needs.

The second reason is *unpublished documentation regarding the new Polish eHealth strategy*. Multiple interviewees mentioned the 'WE Patients Foundation' as a large Polish patient association that puts effort on the patients' accessibility towards eHealth. The main goal of this foundation is to build patient coalitions and to deliver evidence related to patient needs to policy makers. This foundation is represented at multiple eHealth councils, forums and discussion panels. The Polish government collaborated in 2017 with different stakeholder groups on the new eHealth strategy (implementation date in 2020), including the perspectives of the patient group. Nevertheless, this document is not officially published and implemented thus, the current Polish eHealth strategy is in place which not includes the policy beliefs of patients.

## 6.4 Providers

### *Policy beliefs regarding the Polish eHealth strategy*

From the analysis of expert interviews, it becomes clear that the opinions of the providers towards eHealth development can be considered as optimistic. Two major reasons were identified:

The first reason is *a likelihood on higher sales and profits*. According to two interviewees, the stakeholder group of providers is interested in the Polish eHealth strategy and involved in the implementation phase of the eHealth projects. Their interest endured due to the fact that they can increase their sales and profits. Providers are involved in the development of project 1 to be included in the development of the whole Polish eHealth infrastructure afterwards, which increase their profits on a long-term as well.

The second reason is *regional eHealth projects*. One interviewee mentioned that the stakeholder group of providers is working on regional eHealth projects due to profit-related issues as well. The regional governments have a higher budget for eHealth development than the national level since 2014. Another interviewee emphasized that Polish hospitals (big clients) are managed by regional governments which gives an extra incentive for providers to start developing regional eHealth projects.

However, one negative aspects is also mentioned by the stakeholder group of providers towards the Polish eHealth strategy: *a lack of clear eHealth regulations*. Multiple interviews mentioned that clear guidelines and regulations, related to the sale of eHealth technologies, are lacking for the stakeholder group of providers. It seems like providers have difficulties with the sale of eHealth technologies on the Polish market because clear legislation regarding reimbursement schemes and minimum product requirements is lacking.

### *Influence on the Polish eHealth strategy*

From the analysis of expert interviews, it becomes clear that the stakeholder group of providers has a moderate influence on the Polish eHealth strategy. Two major reasons were identified.

The first reason is *the lobby process*. Two interviewees emphasised that the 'GP eHealth Association', consisting of general practitioners such as IBM, HP, and Asseco, did influenced the Polish eHealth development. They have connections with policy makers which were invited at their organized lobbies. Via these lobbies, providers tried to secure their spot in the development of the Polish eHealth projects. Multiple interviews mentioned two annual lobby conferences. The 'Telemedical Foundation' lobbied with the Polish government regarding the reimbursement of eHealth technologies. After three years of lobbying, a reimbursement scheme was finally implemented for the first eHealth technologies in 2018. At the 'Connecting Ton', the CSIOZ shares new eHealth developments with the providers and multiple agreements were set, for example the Polish government would not aim on the delivery of end users solutions such as new applications for doctors.

The second reason is *financial resources*. Multiple interviews mentioned that the stakeholder group of providers has huge financial resources which make them able to hire eHealth experts that support them in the development of eHealth business plans, and to promote their eHealth technologies to the public. Their financial resources are also used to include the policy makers into their lobby process.

However, according to one interviewee, the stakeholder group of providers has hardly any influence on Polish eHealth regulations. There is no room for negotiation for the providers' side regarding newly introduced eHealth regulations from the Ministry of Health. The Polish government implements a new regulation and the providers need to follow it up, often within a short time frame.

## 7. Conclusion

European healthcare systems face several challenges related to aging populations and scarce financial resources. eHealth can be seen as a solution because of less administrative paperwork and online consultation. The EC recognized these benefits and made it mandatory for Member States to design a national eHealth strategy. Such adaptational pressure can lead to a mismatch between national and European regulations. Poland also introduced a national eHealth strategy but a certain resistance from national stakeholder groups (patients, providers, payors and policy makers) can be identified towards the Polish eHealth strategy because national policy does not align with their policy beliefs. This led to the following research question: *“How does the Europeanization of eHealth strategies influence the healthcare system of Poland, and how do national stakeholders shape its implementation?”* Desk research was performed on Polish and EC eHealth documents to identify Polish regulatory changes regarding eHealth due to EC legislation. Semi-structured interviews are performed with actors from the stakeholder groups to identify their policy beliefs and how they shaped the development of the Polish eHealth strategy.

The analysis of the eHealth documents revealed a high policy misfit on the one hand, and a high legal misfit on the other hand. Regarding the former, the EC established mandatory eHealth regulations and none of these EC regulations were already in place within the Polish legal framework at the moment they were established. All eHealth directives of the EC were included afterwards in new and amended Polish acts. Regarding the latter, the results of the interviews show that none of the established eHealth regulations of the EC were already put in practice by Polish stakeholders at the moment they were established. The soft law measures and financial influence of the EC, and the influence on a state level are other identified factors that draw the path of eHealth development in Poland.

Furthermore, this thesis revealed that the stakeholder group of *policy makers* has the most influence on the Polish eHealth strategy. This is because the Ministry of Health and their internal eHealth organisation, the CSIOZ, control all factors concerning decision making during the technological development of the Polish eHealth projects. The major reasons leading to a delayed or insufficient implementation of the Polish eHealth strategy have been the lack of knowledge and financial resources of the Polish government, lack of long-term planning and lack of priority for eHealth development by the general public.

The stakeholder group of *payors* consisting of medical professionals, is the second group with considerable influence on the Polish eHealth strategy. Interestingly, they show mostly a negative attitude towards eHealth due to a lack of knowledge of eHealth benefits and the potential increase in workload related to spending extra time on learning the new systems. This group is characterised by strong associations of medical professionals which make them able to resist the developed eHealth standards of the Polish government. These associations also play a consultant role during the development of new Polish eHealth regulations.

The stakeholder group of *providers* has a moderate influence on the Polish eHealth strategy. Providers are generally more optimistic about the eHealth strategy due to the potential of increased sales. They have financial resources, big associations, and contacts with policy makers that are included in the lobbying process. The technological part of eHealth development in Poland is a main point of

discussion within these lobbies. Nevertheless, providers are not included in the negotiations about the implementation of new eHealth regulations and are dependent on the policy makers.

The stakeholder group of *patients* had no influence on the Polish eHealth strategy and their policy beliefs are not included in the Polish eHealth strategy. A lack existed of strong patient organisations and financial resources. Recently, patient organisations emerged and they started to collaborate on Polish eHealth development. Their position is slowly changing and the policy makers started to invite them at eHealth conferences and councils at the national level to share their policy beliefs.

To finalize, from a top-down perspective, the influence of EC legislation on the Polish healthcare system led to induced regulatory changes (new or amended Polish Acts), including a high policy misfit and a high legal misfit. From a bottom-up perspective, Polish stakeholder groups who negotiate with the national government to include their policy beliefs into the Polish eHealth strategy were identified. The stakeholder groups of policy makers and payors were able to translate their policy beliefs into the development of new Polish eHealth Acts. Based on the analyse of both perspectives, this thesis revealed that the outcome of eHealth Europeanization on all relevant eHealth related issues can be seen as the category of *transformation*.

## 8. Discussion

In this part, this thesis is evaluated based on three different points. First of all the results are interpreted. This is followed by the limitations of this research, and relevant recommendations for future research.

### 8.1 Interpretation of the results

Based on the first part of the research question of this thesis, this thesis made use of different theories from the Europeanization studies as a basic structure to conduct the research, which are in general difficult for enacting causality. Nevertheless, a difference between the developed eHealth policy at the European level and the developed eHealth policy in Poland can be identified. This raises questions about the efficiency and execution of eHealth Europeanization in its European Member States. As already stated, the Europeanization of national process is often influenced by the large European Member States as the UK, France and Germany and hereby the Europeanization of healthcare (including eHealth) is mainly based on soft law measures. The eHealth priorities of the larger Member States can differ from the small, and less influential Member States which also have limited resources (Klöcker et al., 2016). Together with the non-mandatory character of the eHealth Actions Plans of the EC, Poland puts less effort and priority on its national eHealth development, also because of the lack of eHealth advocate groups that pressure them and the low interest at the public level.

In the case of Poland, the results show a passive adoption of European regulations, and an effective usage of European standards to reach the minimal targets regarding eHealth development. Albeit the current low influence of the EC on national healthcare policy, the theories of European Studies have their benefits to increase the knowledge about the expansion and progression of this policy area in the European Union. Attaining an increased knowledge base concerning the interplay between European and national institutions is relevant because of the enhancement of European objectives whereby the national healthcare systems of the European Member States are more and more framed regarding fiscal considerations with the conceivable adaptations of national healthcare systems to achieve European health targets.

Based on the second part of the research question of this thesis, this thesis intended to examine the resistance and affection of the four biggest stakeholder groups concerning eHealth development in the healthcare structure of Poland. Within this fairly uncharted field of research, this thesis introduced some factors that have influence on the policy beliefs of policy makers, payors, patients, and providers on the implementation of a national eHealth strategy in Poland. Further, this thesis delivered new empirical results regarding the factors that lead to the resistance in the direction of the enactment of eHealth in the Polish healthcare structure, which are: 1) the development of the Polish eHealth strategy was done with a lack of participation of the stakeholder groups of providers, patients and payors, 2) a lack of financial resources, 3) the eHealth projects are too big scooped and ambitious, 4) a lack of people with the right knowledge that are working on the development of eHealth projects at the CSIOZ, 5) a lack of eHealth documentation that is available regarding eHealth development in general, including the possible benefits for the stakeholder groups.

Based on these factors, the Polish government can change the way how it operates its national eHealth strategy. Currently, the Polish government mainly drafts its own Action Plan, based on EC legislation, regarding eHealth and its end users (for example the medical professionals and patients) are obliged to follow it. Forcing such a specific strategy on their national stakeholders can lead to

enhanced resistance towards eHealth implementation. The Polish government could conduct a strategy that includes the policy beliefs of the four stakeholder groups to create an encouraging environment around eHealth technologies.

Another point for the Polish government is to deliver more information and documentation about why all stakeholder groups should need eHealth technologies, and what benefits it will give for all stakeholder groups. By following such a strategy, a lowering in the resistance will emerge towards the implementation and use of eHealth technologies in Poland, especially by medical professionals. Such a change of strategy can already be seen in Poland. The CSIOZ started with including stakeholder management: all the opinions, interests and needs of the different kind of stakeholders in the Polish healthcare system such as professional associations, patient associations, and IT-providers are taken into account in the development of an eHealth infrastructure. This process started in 2016 but so far a new Polish eHealth strategy, including such stakeholder management, is not published or implemented.

## 8.2 Limitations of the research

Although the choice of methodology to increase the validity and reliability of this thesis, specific limitations can be identified. The first limitation concerns that this thesis only aims on four different, Polish stakeholder groups within a single, limited time frame for answering the research question. Due to the character of the case study design, the results cannot be generalized to other European Member States as Poland due to the substantial difference of the circumstantial setting of the healthcare systems of the European Member States in terms of size, financing, reimbursement schemes etc. Notwithstanding, because of the data triangulation of desk research and semi-structured interviews, wide-ranging and comprehensive observations are made that gives a new perception of the influence of the EC on the Polish eHealth strategy and the role of its national stakeholders to put their interest into national policy.

The second limitation is the low response rate of the interviewees that received a message via email or LinkedIn to participate in the interview. After sending the reminders, 11 interviewees replied and were willing to conduct an interview. To increase the sample size, new interviewees were contacted via direct phone calls or visits at their office. Due to this method of applying interviewees, a sufficient number of interviewees participated in the in-depth interviews to gain insights in the Polish eHealth development to create varying and robust results. Further, all interviewees were asked to the policy beliefs, resources and restrictions of the stakeholder group they belonged to, but also to the policy beliefs, resources and restrictions of the other stakeholder groups if they possessed the knowledge, to increase the input for the results.

As last, one stakeholder group exist of both policy makers and eHealth experts. The access to policy makers is a difficult and long-lasting process. Due to the aforementioned, eHealth experts are included in the same stakeholder group because the number of policy makers was too low to create valuable results. Nevertheless, in many cases such as eHealth, experts and policy makers can differ in their opinion regarding specific topics because of a discrepancy in interests. Experts are mainly involved in the gathering and processing of information and the policy makers are the group with the power and influence to change the policy. To mitigate this effect, the eHealth experts are not asked for their personal opinion about the Polish eHealth strategy but only about their knowledge about the stakeholder group of policy makers and their influence on the Polish eHealth strategy.

### 8.3 Recommendations for future research

This thesis gave a new meaningful, innovative context regarding the Europeanization of national healthcare systems, especially aimed on eHealth development. Future research can examine if other (relatively) small Member States with a lack of resources, face opposite or similar resistance towards the Europeanization of the national eHealth strategy from the national stakeholder groups. Possibly, a cross-national study can even be set up. Another focus point for future research is if the policy beliefs, resources and restrictions of the four examined stakeholder groups in the larger European Member States equal or differ from the stakeholder groups of the smaller Member States. This because the larger Member States have more influential power on the decisions of the EC, which make them able to upload more interests from the national level into European strategies, which could possibly decrease the resistance from their national stakeholders.

Further, an additional research design can be applied, for example 'process tracing', in which the policy beliefs, resources and restrictions of the Polish national stakeholder groups are evaluated at multiple points in time to increase the validity and reliability of this research. This is especially the case because of the government elections every four years with a potential change within the Polish parliament, the fast development of eHealth technologies, and changes in the priorities of the EC regarding eHealth development.

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## Appendix A: Set-up of the interview

### Introduction

First of all, thank you for taking part in this interview. The time frame of this interview will be approximately 40 to 50 minutes. Does it suits you if I record our interview? For me it will be easier to transcribe and summarize the interview by recording the interview. Afterwards, I would like to send you the summarized interview which can be checked on inconsistencies and additional information can be added. The given information will be used to answer the research question of my master thesis. You can remain anonymous if you wish.

### Summary of thesis

The national healthcare systems in the European Union (EU) are facing a number of serious challenges like aging and an increased number of patients with chronic diseases. eHealth technologies are playing a protuberant role in the current system of healthcare in order to overcome those challenges. The European Commission (EC) encouraged all Member States (including Poland) to develop a national eHealth strategy. This eHealth strategy of the EC is mainly built on soft law measures due to the difficulties of creating and the high costs of developing such an imposing project. Further, a contradiction in attitudes, beliefs, opinions and interests about eHealth implementation within the national healthcare systems can exist between the different national stakeholders. Understanding eHealth Europeanization in a national healthcare system asks because of the contradiction in beliefs, also for an examination of the point of view of the national stakeholders that will make use of eHealth. The research question of the thesis will be: *“How does the Europeanization of eHealth strategies influence the healthcare system of Poland, and how do national stakeholders shape its implementation”?*

### Questions

*“Can you give a little introduction of yourself based on your background and profession, and your relation with eHealth”?*

*“Can you shortly summarize the most important historical changes in terms of eHealth implementation in the Polish healthcare system since the introduction of the first Polish eHealth strategy in 2004”?*

*“Are you familiar with the current Polish eHealth strategy?”* (If yes can you tell something about it, if no, I will give an explanation).

*“The current eHealth strategy of Poland contains three projects. Can you shortly summarize every project in a couple sentences (such as why it is implemented, the main goals etc.)”?* (I will introduce the projects one by one, see table below).

Project	Explanation
Project 1	Online platform consisting of electronic health records to assemble, share and evaluate personal medical data
Project 2	Online platform consisting of medical registers which can be accessed by entrepreneurs
Project 3	IT-system associated with lecturing health professionals in terms of novel medical services, products and devices, including eHealth technologies

*“From your own perspective, did you supported or had any concerns about a specific project as a whole, or certain elements of a specific project?”*

*“Based on the three projects that are set up as part of the current Polish eHealth strategy, do you miss any elements in terms of eHealth development in Poland which are not taken into account into the Polish eHealth strategy?”*

Four relevant stakeholder groups (a group of people with the same profession, interests and opinions) are identified for answering the second part of the research question (how do national stakeholders shape the implementation of the Polish eHealth strategy?): Policy makers & experts, providers, payors and patients. Stakeholder groups can apply a diverse set of resources to develop strategies to put their policy beliefs into the actual policy.

*“Did you joined a stakeholder group of (mark the profession of the interviewee, i.e. if the interviewee is an eHealth provider, a stakeholder group of providers) with common opinions and interests according to eHealth development in Poland and took measures together to include your view regarding eHealth development in the Polish eHealth strategy?”*

**If the answer of the last question is yes, ask the following six questions about used ‘resources’, otherwise continue with the following question:**

*“Which assets (resources) did your stakeholder group (replace stakeholder group by the profession of the interviewee in the following six questions) had to put their view on eHealth development into the Polish eHealth strategy?”:*

- 1) *“Does your stakeholder group includes individuals with a political position (regional politics / local government representatives / ministers of the Polish Parliament) with the power to make, and influence decisions in terms of the Polish eHealth strategy? How were or were they able to put the view on eHealth development from your stakeholder group into the Polish eHealth strategy?”*
- 2) *“Does your stakeholder group has a strong / weak public support (from Polish citizens) for its view on eHealth development in Poland? This shows itself in which way?”*
- 3) *“Is your stakeholder group able to clarify / summarize the 1) eHealth Action Plans of the EU, 2) the views of eHealth development in Poland of the other stakeholder groups, and 3) your own views regarding eHealth development in Poland?”*
- 4) *“Does your stakeholder group has supporters to help them with implementing your views into the Polish eHealth strategy (i.e. fund-raising campaigns, public demonstrations)? This shows itself in which way?”*
- 5) *“Does your stakeholder group has financial resources to invest in the other mentioned resources (i.e. invest in R&D for information, swaying public opinion?”*
- 6) *“Does your stakeholder group has individuals that can attract additional resources, which can be used for their strategy to put their views on eHealth development into the Polish eHealth strategy (i.e. (political) influencers swaying public opinion, stakeholders with access to financial resources)?”*

*“Are there any resources not mentioned that your stakeholder group applied to put their view of eHealth development into the Polish eHealth strategy?”*

*“Are you aware of any other stakeholder groups (replace stakeholder group by the three other identified stakeholder groups) that applied specific assets (the six assets from above) to put their view on eHealth development into the Polish eHealth strategy? Are you aware of them and are you able to mention them?”*

*“In general, are you aware of actors, public (policy makers and experts) and private (doctors, providers, patients), who supported (or were against) the development of the Polish eHealth strategy at the national level? This shows itself in which way, and which specific points exactly and why?”*

The EC developed two eHealth Action Plans so far which included guidelines for the European Member State in terms of developing a national eHealth strategy. Those guidelines are so-called 'soft law measures' which means that the EC gives specific future aims in terms of eHealth development in the EU, and the Member States are able to freely develop their own eHealth strategies to fulfil these aims.

*“What is the influence of EC legislation, and the targets of the eHealth Action Plans of the EC on the national eHealth strategy in Poland, and Polish legislation”? Are you able to mention examples about introduced regulations of the EC which are followed up by Poland in terms of eHealth development?*

This was the last question of the interview, thank you for your time. I will try to transcribe the interview as fast as possible and I will send back the summarized interview. If I finished my Master Thesis, I will send you the full product in case of interest. Do you have any questions for me or would you like to elaborate on a specific topic or question?