Europeanization of Norwegian health policies and politics through the EEA Agreement

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1. Chapter one: Introduction

Norway is not a formal member of the EU. At the same time, Norway is an active participant in EU cooperation and has implemented much of the EU regulations into national legislation. The main pillar in Norway's relationship with the EU is the EEA Agreement, which was adopted in 1992 and entered into force in 1994. The EEA Agreement is the largest and most complex international law agreement Norway has ever entered into, and for over 25 years it has shown to have significance in most policy areas in Norway through direct and indirect, visible and less visible influence (NOU 2012:2). Since 1994, the EU has changed dramatically, and Norway has continuously sought to adapt to this change, within the EEA or through new supplementary agreements. The development has so far gone one way - towards increasingly comprehensive and binding cooperation between the EU and Norway (NOU 2012:2).
The EEA Agreement regulated cooperation in different policy areas like product standard, transportation, social benefits, but excluded agriculture and fish policies. (St.prp. nr. 100, 1992)

Welfare and health policies were supposed to be a national matter when the European Economic Community was established in 1958, but since 1992 the goal of the EU has been to strengthen the "social dimension" within the market integration (NOU 2012:2). When the EEA Agreement was negotiated at the beginning of the 1990s, it was a clear precondition that it would include the «social dimension». Thus, through the EEA agreement, Norway has adopted all EU rules in the areas of social security and welfare rights for cross-border movement of persons, as well as health, environment and safety requirements for products and services (NOU 2012:2). These regulations have had a significant impact on the formation of Norwegian health politics and policy.

The purpose of the thesis is to show how Norwegian health policy and politics were and continue to be affected by the EEA Agreement. By comparing health policy aspects in the EEA agreement when it was negotiated and health-related regulations followed after the adoption of the EEA agreement, points to the fact that Norway had to adapt to the EU in

many health-related areas on a much broader scale than it was originally intended. Therefore, the main objective of this paper is to study how Norway has adapted to the EU in the field of health after the EEA Agreement entered into force. Furthermore, the aim of the paper is to show how health policy has been Europeanized despite the fact that the EU has no common health policy.

This paper is based first and foremost on the literature review, document analysis and inputs from Norwegian health officials. The literature review reveals a remarkable knowledge gap on how and why Norway has adapted its health policy and politics to the EU. Moreover, the document analysis reveals that a process of Europeanization of health policies has occurred.

The research question of this study is ***in what way has Norwegian health policy and health administration been affected by developments in the EU and what can explain Norwegian adaptation.***

Public documents and available studies in this area disclose that Norway has adapted to the EU by taking over and complying with the EU´s legislation, as well as participating in the EU political processes and creating institutions for the management of EU-related issues on the national and international level. Institutional theories used in the discussion chapter point to the significance of the establishment and implementation of the internal market in Europeanization process (Pierson, 2000). It means that the establishment of the internal market and involvement of EFTA (European Free Trade Area) states into this market, which was the purpose of the EEA Agreement, increased the impact of regulatory mechanisms for the internal market in the health area. It was a result of removing special national rules and led to the adoption of a new common legislation.

This thesis starts with the background chapter which describes the main points of the EEA Agreement signed in 1992 and its relevance for health policies. The theory and methodology are embraced in the chapter 3 and 4 respectively, followed by the findings and discussion chapters. Methodology includes information on data collection and analysis. The chapter on findings covers findings from the literature review, public documents and laws which reveals how current Norwegian health politics and policy is affected by and adapted to the EU. These data are supplemented by information from Norwegian health officials. Finally, discussion evolves around possible explanation of why Norway had to adapt to the EU.

2. Chapter two: Background

2.1. EEA Agreement as a central premise for Norwegian politics

Norway is not a formal member of the European Union (EU) but is extensively involved in European cooperation which defines a large part of Norwegian politics (NOU 2012:2). The history of the relations between Norway and the European Community (EC) dates back to the post World War II period, when European countries wanted to secure peace through economic recovery and cooperation. The Treaty of Paris was signed in 1951 establishing the European Coal and Steel Community. Five years later, the community considered establishing a customs union which led to the Treaty of Rome establishing the European Economic Community (EEC) in 1957 (European Union, 2020). The Community ensured not only the creation of a customs union but also the common market.

In 1960, Norway, Denmark, Portugal, Great Britain, Switzerland, Sweden and Austria signed the Stockholm Convention establishing the EFTA (NOU 2012:2). Despite being a part of EFTA, Norway was interested in a closer cooperation with EC, because the conditions within EFTA were not very favorable and because Great Britain and other countries applied for the membership to the EC (NOU 2012:2). Norway applied for membership in the EC for the first time in 1962 but it has not resulted in any real negotiation. Only at the beginning of 1970s a concrete dialog started about the membership. Negotiations resulted in the membership of Denmark, Ireland and Great Britain, while Norway decided to hold a referendum giving people the possibility to vote for or against membership in the EC (NOU 2012:2).

Two referendums have been held in Norway, it happened in 1972 and 1994. Both times people decided to say "no" to joining the European Community (later European Union[1]). Even though Norway did not join the EC/EU, its political strategy since 1972 has been directed towards "Active European politics" (NOU 2012:2). It was an important goal for the Norwegian government to build strong relations with EEC based on the free trade agreement signed in 1973. Thus, since 1973 Norway has had bilateral agreements with the EC on the free trade of the industrial products (Regjeringen, 2018).

[1] European Union – the term EU was introduced by the Maastricht Treaty which entered into force on 1 November 1993.

Under the Single European Act, which entered into force in 1987, the then 12 EC countries laid the foundation for realization the internal market (Regjeringen, 2018). The consequences of remaining outside the internal market would be clearly negative for the EFTA-countries (St.prp. nr. 100, 1992, p. 9), because EFTA countries were of the view that this would lead to a weakening of the competitiveness of their companies vis-à-vis their EC competitors (Regjeringen, 2018). The main goal for EFTA-countries was constantly to expand the collaboration with EC (NOU 2012:2, 2012). On 2 May 1992 the EFTA countries, except Switzerland and those that earlier had chosen to join EC, signed the European Economic Area Agreement with the EC (Regjeringen, 2018). The Agreement entered into force in 1994 and regulated participation in the EC´s single market. The EC's internal market aimed to create a common set of rules in order to achieve a truly common economic market. The aim of the EEA Agreement is that the European Free Trade Association (EFTA) countries could participate in the EC´s market (St.prp. nr. 100, 1992, pp. 11-12).

The EEA Agreement has built a bridge between two existing legal orders, namely EU and EFTA. Through the development of the EEA one can see how EU has influenced the EEA/EFTA institutional structures and contributed to the homogeneity between states´ legal orders. The initiative of creating a free trade area in Europe had a purely economic nature through the extension of the EU´s internal market to the EEA/EFTA States (Lourenço, 2019).

Norway has a strong outward-looking economy. In the 1990s, four-fifths of the goods were exported to EFTA and EC areas, and approximately two-thirds of goods were imported from these areas (St.prp. nr. 100, 1992, p. 9). The government worked actively for expanded free trade. The government wanted to ensure predictable and equal conditions for international trade and economic cooperation through the EEA Agreement. Hence, the scope of the EEA Agreement had to correspond to the development in the markets on which Norwegian business life depended (St.prp. nr. 100, 1992, p. 9).

Agricultural policy was not a part of the EFTA cooperation, nor was it included as a part of the EEA Agreement. However, the negotiations on increased trade with agricultural products led to bilateral agreements between the EC and the individual EFTA countries. In the same way, bilateral negotiations were held between Norway and the EC on the extension of older agreements concerning fishery products. Thus, EEA Agreement has not included regulations

on fishery products and cooperation in the areas of fishery and agriculture resulted in bilateral agreements between Norway and EC (St.prp. nr. 100, 1992, pp. 119,130).

A customs union was an agreement to create a common customs area. This means that the countries participating in the customs union had to remove customs and other direct barriers to trade, and they had to introduce common external tariffs and establish a common trade policy with regard to third countries. In the area of customs and origins of products, the EC regulations are not integrated into the EEA obligations (St.prp. nr. 100, 1992).
The EEA Agreement mentions nothing about common health politics and there was neither any common health politics within EC.

2.2. EEA Agreement of 1994: Four freedoms of the European internal market and their relevance for health policy

Originally health policy was not a part of EU cooperation, and therefore was neither a part of the EEA Agreement. Still, through the internal market regulations the EU has become involved in a number of health policy areas, such as regulating food safety, medicines, medical equipment, professional qualifications and patient rights, non-binding cooperation and coordination of public health issues (Veggeland, 2017).

As mentioned above, the purpose of the EEA Agreement was the creation of the European unified internal market as well as promoting lasting and balanced strengthening of trade and economic relations between the contracting parties (St.prp. nr. 100, 1992, p. 12). The objectives of the internal market were to remove barriers to economic interaction; create common rules for the movement of goods, services, persons and capital; encourage equal national legislation and eliminate discrimination based on nationality (St.prp. nr. 100, 1992, p. 12). Regulation of the single market through the free movement of goods, services, persons and capital has become relevant also in the area of health policy.

It should be noted that cooperation between the EU and the EEA/EFTA States extended beyond the economic aspects of the internal market. It created certain flanking policies in order to guarantee equal rights and obligations to individuals and undertakings within the internal market with objective of reducing disparities between EEA member states. It was also aimed at broadening and strengthening cooperation with regard to education, social policy, consumer protection etc. (Lourenço, 2019).

Free movement of goods and its relevance for health policies

In the 1970s and 1980s there were some difficulties to regulate trade between countries and there were technical barriers to trade in Europe. The abolition of customs´ duties and restrictions were not sufficient to solve the difficulties, because there were other barriers to trade like national standards, requirements and regulations (NOU 2012:2). In order to solve these difficulties, it was required to implement new conditions and rules for the free movement of goods, which consequently required the establishment of EC's internal market. The EC's internal market aimed to create a common regulatory framework to achieve a truly common market. The aim of the EEA Agreement was that the EFTA countries could participate in this market (St.prp. nr. 100, 1992, p. 12). The rules on the free movement of goods were designed to enhance economic exchange within the EEA, as well as ensure competition and generate positive welfare effects (Baudenbacher, 2016).

These conditions covered competition on equal terms, establishing a common customs area (Customs Union), as well as establishing uniform requirements for product design and quality (St.prp. nr. 100, 1992).

Ensuring competition on equal terms entailed establishing common competition rules; surveillance body which had to monitor compliance with the rules; implementation of anti-dumping measures to prevent lower export prices than normal; abolition of state trade monopolies etc. (St.prp. nr. 100, 1992, pp. 13-15) .

Technical barriers to trade had to be removed in order to implement the idea of free movement of goods. It meant prohibition of all measures that prevented or hindered cross-border exchanges, as well as introduction of uniform requirements for product design and quality with regard to health, environment and safety (Baudenbacher, 2016) (St.prp. nr. 100, 1992, p. 32). According to the EEA Agreement, it had to be created a common European public procurement market with a common set of rules, including common rules for the state aid to create more predictable and equal conditions for competition (St.prp. nr. 100, 1992, pp. 13-14). As mentioned above, agricultural policy was not a part of EFTA cooperation and was neither covered by the EEA Agreement. EFTA has neither achieved duty-free access to the European Community market for fish and fish products (St.prp. nr. 100, 1992, p. 16).

According to the Article 168 of the Treaty on the Functioning of the European Union, health policy is basically a national responsibility.

> *Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organization and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them (Art.168, p.7).*

On the one hand, health policy was not covered by EC Treaty, on the other hand, health area was indirectly affected by the EEA Agreement. This unintended influence happened because of the introduction of the internal market, which involved the free movement of people, goods and services. A great amount of the health aspects such as patient rights for people working across national borders, standards for health-related product, trade with medicines and medical equipment across national borders has been affected by the regulation of the internal market and the four freedoms.

Healthcare is not something that stands alone, isolated from the wider economy, but rather is a subject to market regulation. Also, health-related goods are subject to the internal market, which means that pharmaceuticals and technology are traded across the borders, and their production, distribution and purchase are all legitimately governed by the provisions of the single market (Mossialos, 2010). For instance, according to the free movement of goods, the EC adopted new principles for the harmonization of regulations, known as “the new method". “The new method” set requirements for the health, safety and environment, which led to the establishment of standardization committees. It was decided in these committees that goods must have the CE mark for further distribution in the European market. “The new method” regulated a great number of product areas, including medical equipment (St.prp. nr. 100, 1992, p. 157). The EC has also developed more detailed community regulations in other product areas, including medicines(St.prp. nr. 100, 1992, p. 150).

When health systems seek to purchase medicines or medical equipment, we see that their scope to act is determined largely by EU legislation. European regulatory measures were adopted because European community got a legal power. All the EU legislation with EEA relevance is transposed into national rules by the EEA/EFTA States and EEA law is interpreted in the light of the interpretation given to the EU Treaties. EEA rests on the

legislative and judicial evolution of the EU itself (Lourenço, 2019). In the health sector it meant the power to adopt common European standards to regulate manufacture, marketing and sale of pharmaceuticals and biomedical devices (Mossialos, 2010). Medicines and medical devices were subjects to the rules of the single market. These have direct impact on human health which implied that the robust legal framework had to be established in order to guarantee the safety of these products. The regulations include rules for testing, trials, authorization for placement on the market, the surveillance and recall (European Commission, 2021).

Already in 1992, the EC had extensive regulations for human and veterinary medicine. The regulations have been constantly evolving since then. The provisions of the EEA Agreement concerning medicine regulations were built mainly on EC rules (St.prp. nr. 100, 1992, p. 155). From 1994, the EC had an objective of establishing a common market that would also include medicines. This means that several pharmaceutical companies could participate in the market and a joint registration scheme for the new drugs needed to be established. The regulations also included strict rules for drug advertising, as well as rules for packaging (St.prp. nr. 100, 1992, p. 156).

The most noticeable impact with the introduction of the EEA Agreement on the Norwegian side was the requirement that the Norsk Medisinaldepot ‘s (the largest supplier of pharmaceuticals and health-related products) exclusive right to import and wholesale medicines had to be abolished, so that other pharmaceutical wholesalers could also import and sell medicines in the Norwegian market (St.prp. nr. 100, 1992), (Dyrdal, 2004), (Moen, 1997). The abolition of the pharmaceutical monopoly was one of the few changes in the formal structure of the state apparatus that followed directly from the EEA agreement. The change in NMD's functioning (and the other changes in the pharmaceutical sector) has been therefore primarily linked to the development of cross-border market cooperation (Moen, 1997).

The EC also had extensive regulations in the area of food, which consists of many directives and regulations with detailed requirements for a product or product area (Lie, 2010), (Veggeland, 2016). The main objectives in this area were to introduce community provisions in areas that are important with regard to health, consumer protection and the environment. The aim of European cooperation was to harmonize food law in order to facilitate trade of

foodstuffs while protecting consumers' health (St.prp. nr. 100, 1992, p. 153). Control schemes in the food area include hygiene requirements, requirements for quality assurance, labeling regulations, analysis methods for food, product requirements etc. (St.prp. nr. 100, 1992, p. 153).

Among other product areas regulated by the EEA Agreement with regard to health, environment and safety are seeds, textiles, machines, vehicles, chemicals, electrical equipment, tobacco, alcohol, cosmetic products. The EEA Agreement provides specific technical regulations for these product sectors. These rules promote free movement of goods within EEA at the same time guaranteeing a high level of protection to workers, citizens and consumers, imposing health and safety requirements and harmonization of standards for these goods. The legislation regulates testing and approval of the products and the process of placing them at the market. For example, cosmetics legislation covers a wide range of products, such as make-up, perfume, shampoo, sun lotion and other products for personal hygiene. The legislation and guidelines address rules for manufacturing and labelling of these products (EFTA, n.d.-a). Another example is that the Internal Market covers manufacture, presentation and sale of tobacco products, as well as advertising and sponsorship of such products (EFTA, n.d.-b). The same principle is functioning the same way in other product areas.

Free movement of capital, services, persons and its relevance for health

Common rules were established through the EEA agreement so that the benefits of international economic relations can also be utilized in the areas of service and capital. Barriers to cross-border capital flow had to be removed. The EEA Agreement also removed discrimination based on nationality when purchasing real estate, the establishment of a business or the purchase of ownership interests in existing companies. At the same time, currency restrictions had to be abolished and control over foreign transactions had to be strengthened (St.prp. nr. 100, 1992, p. 189). Services included financial services (insurance, banking, securities trading); transport sector (road, rail, air transport, shipping, inland waterway); telecommunications and television. The aim was to remove obstacles to service providers' access to sell their services in other EEA- countries, as well as to remove restrictions on individuals' and companies' access to purchase services abroad. (St.prp. nr. 100, 1992, p. 189).

Harmonization and integration in one economic sector have eventually led to similar integrations in other sectors. Thus, single market programme extended into social areas as well (Mossialos, 2010). The Single European Act (SEA) of 1986 had an objective to establish a single European internal market. With the SEA health services were included into European policies by establishing authority to legislate on issues of health policy connected with the internal market (Greer S. L., 2006). The subsequent Maastricht Treaty on European Union inserted health related articles into European law. For example, the article 152 obliges EU to take health protection into account in its activities (Greer S. L., 2006). Member States and EFTA states bounded by the regulations of the single market had to contribute towards a high level of human health.

Regulation of benefits in health services within the EEA must be seen in connection with the principle of free movement of persons. Free movement of persons included rules which declared that a citizen of one country could move freely to another of the EC and EFTA countries to apply for a job, establish himself/herself as a self-employed person or for studying. The most important thing was to create mutual rights that applied first and foremost to those who applied for a job, so that they could retain the rights which they earned in their home country and that these persons could be subject to the same social security rules in the country of establishment as this country's own citizens (St.prp. nr. 100, 1992, p. 250).

The rights of the workers were included into European legislation through the introduction of the Working time directive (93/104/EEC). Its objective was to improve living and working conditions of the workers. The completion of the internal market had to lead to improvement and approximation of these conditions (Greer S. L., 2006). According to the Greer (2006), the amendment of the WTD which introduced a forty-eight-hour working day limit has led to a new legislation which required clarification of the definition of the working time. The latter had a significant impact on the structure of medical services and shift arrangements in European health systems.

Rules for the free movement of persons within the EEA Agreement also included rules for mutual recognition of professional qualifications, medical professions included. These rules mainly cover occupations that require public approval or authorization given to persons who have completed a higher education of at least three years' duration (St.prp. nr. 100, 1992, p. 255). In health this has meant that EU mutual recognition law has, since 1975, slowly

extended across medicine (being consolidated by directive 93/16/EEC) (Nicholas, 2004), establishing adequate common standards which defines a doctor as a doctor and a nurse as a nurse in any of the European countries (Greer S. L., 2006). People who moved to another EU/EEA country to work in healthcare sector or for medical studies were subject to the same social rights on the same conditions as the citizens of the country.

The impact of principle of free movement of persons was also visible through the access to the social rights for EEA citizens in the case of them residing, working and/or travelling in other EEA-countries According to the EEA Agreement, a citizen of an EEA- country who resides in other EEA-countries obtains the same social rights on the same conditions as citizens of the country where they reside (St.pr. nr. 100, 1992). The EEA Agreement covers all social security legislation for the following types of benefits: medical treatment in the event of illness and birth, sickness benefits, benefits in the event of disability and occupational rehabilitation, benefits due to an occupational injury or occupational disease (St.pr. nr. 100, 1992, p. 258). According to the regulations, the country of residence's salary and working conditions must apply equally to all employees, regardless of nationality (St.pr. nr. 100, 1992, p. 258). Consequently, the national competence in several key areas of social policy has been eroded. On the other hand, inclusion of social objectives in the European cooperation could balance national policies promoting social and health protection (Mossialos, 2010).

Institutional framework for administering the EEA Agreement

European countries became dependent on each other due to the expansion of free trade between EFTA and the EC. This interdependence increased the need for international governance (St.prp. nr. 100, 1992, p. 11). Although Norway has been a member of EFTA since 1960, this free trade organization did not have its own institutional apparatus except for a small General Secretary in Geneva (NOU 2012:2). When the EEA Agreement was negotiated, it became necessary to establish bodies that could ensure that the EFTA countries could become an effective partner in the EEA cooperation (St.prp. nr. 100, 1992, p. 9). In order for the EFTA states to gain access to the EU market, institutions and procedures had to be established to ensure adaptation to the underlying EU law (NOU 2012:2) and to establish formalized and effective supervision of compliance with the provisions of the EEA Agreement (St.prp. nr. 101, 1992, p. 3). There was a system for monitoring and judicial

control in the EC, but the EEA agreement entailed the establishment of the bodies with parallel authority and tasks for the EFTA countries (St.prp. nr. 101, 1992, p. 3). It resulted in the establishment of so-called to-pillar system. Indeed, the two-pillar structure laid down by the EEA Agreement uniquely integrates two legal orders, those of the EU and EFTA. The EEA Agreement is of a special importance because it made EU and EFTA countries into a large economic bloc. The EEA has also created institutional and political counterparts which mirror those of the EU (Lourenço, 2019). One pillar consisted of the ECs institutions, which had responsibility over and tasks related to the EU Member States. This structure was reflected in the EFTA pillar, that was modeled after the EU institutions (St.prp. nr. 101, 1992). This institution-building process was regulated through the EEA Agreement and led to the establishment of two other agreements: The Agreement between the EFTA States on the Establishment of the EFTA Surveillance Body (ESA) and the EFTA Court and the Agreement on the Standing Committee of the EFTA States (St.prp. nr. 101, 1992). The ESA monitors compliance with the Agreement on the European Economic Area Agreement in Iceland, Liechtenstein and Norway, enabling those States to participate in the Internal Market of the European Union (EFTA Surveillance Authority, n.d.). The EFTA Court fulfils the judicial function within the EFTA system, interpreting the Agreement on the European Economic Area with regard to the EFTA States party to the Agreement (EFTA Court, n.d.). The standing committee is composed of ambassadors of the EEA/EFTA States and observers from ESA and Switzerland. It is divided into subcommittees which work on adoption of common positions which later are negotiated within the EU pillar and process the EU legislation which is going to be incorporated into the EEA Agreement (Lourenço, 2019). Also, an important role is played by the EFTA Secretariat, which was functioning before the EEA Agreement and is now based in Geneve and Brussel. It is not mentioned in the EEA Agreement, despite it playing quite an important role in managing the Agreement (Baudenbacher, 2016). The one based in Geneve has responsibility for the EFTA countries' relations outside EU. The one based in Brussel is the most relevant in the context of the EEA Agreement because it is responsible for the EFTA relations to the EU as well as giving support for the management of the EEA Agreement and assists the Member States in preparation of new legislation for integration into EEA Agreement as well as helps these States to elaborate inputs to EU decision making (EFTA, n.d.-c).

The ESA, EFTA Court and Standing committee had similar functions to the EUs European Commission, European Court of Justice and European external action service respectively

(EFTA, n.d.-d). Thus, the EEA Agreement operates across the two pillars. The EEA cooperation includes committees consisting of representatives from the EU and EFTA. The EEA Agreement became a platform for cooperation, discussion, and arena for the further development of the agreement. The institutional structure of the EEA is regulated by the EEA Agreement, and it consists of the EEA Council, the EEA Committee, the Parliamentary Committee and the Consultative Committee (NOU 2012:2). The EEA Council is not only an arena for political dialogue between EU and EFTA states, but it also adopts conclusions providing a common assessment of the overall functioning of EEA cooperation and takes into consideration resolutions adopted by the EEA Joint Parliamentary Committee and the EEA Consultative Committee (EFTA, n.d.-e). While EEA Joint Parliamentary body plays a managerial role and can be viewed as a forum for discussion and reaching consensus, the Parliamentary and Consultative Committees are advisory bodies, and these are not directly included in decision making processes (EFTA, n.d.-e).

2.3. Adjustments within the Central Administration

The EEA agreement obliges Norway to implement and practice rules written down in the Agreement. In order for EU / EEA law to become an applicable law in Norway, it must be implemented by the Norwegian legislature as a law or regulation on the national level. Adaptation to the EU through the EEA has affected not only Norwegian legislation but also Norwegian administrative policy (NOU 2012:2). All parts of Norwegian administration are affected to a greater or lesser extent by Norway's agreements with the EU. This includes ministries, directorates, as well as other underlying units and local governments. It is assumed that the national coordination and administration related to Norway's participation in the EEA shall be based on the division of responsibilities between the ministries and contribute to the appropriate integration of the EEA's work in the administration's ordinary activities (St. pr. nr. 100, 1992, p. 349).

According to the EEA Agreement, the Norwegian administration has the opportunity to participate in the preparation of new legislation in the EU as well as to coordinate and obtain views from Norwegian stakeholders (St. pr. nr. 100, 1992, p. 350). The scope and nature of the EEA agreement dictate that the ministries are actively involved in the work of balancing and coordinating the positions that Norway is to promote in the EEA context activities (St. pr.

nr. 100, 1992, p. 350). There had been established no separate EU / EEA ministry or directorate in Norway, but the work is handled through the existing departments on a national level. With the introduction of the EEA Agreement in 1994, a coordination committee (ministries) and special committees (only applicable to certain areas) were established in Norway, which retained responsibility for European work at that time (NOU 2012:2). The special committees shall contribute to coordination between the ministries in matters that affect several ministries (Regjeringen, 2020).

Studies like those of Graver (2002) show that all ministries are affected by EU / EEA matters, included state directorates and supervision institutions. Ministries supported by directorates, supervisors and other institutions participate in the EU committees and working groups in the policy areas for which these ministries are responsible. Directorates play the role of independent professional units (NOU 2012:2). Altogether they participate in preparation of legislation on the EU level and play the role of advisory parts. Norway can to a modest extent influence the political decision-making processes in the EU, but at the same time is bound by results and is obliged to implement and comply with them in the same way as the EU states. Thus, Norway is participating more in EU administration than in EU-politics (NOU 2012:2), which means that Norway does not have access to the political decision-making processes in the EU and does not participate in making decisions, it only participates in preparing decisions and providing inputs.

An important aspect of the EEA Agreement is that cooperation schemes and procedures are created in the way that they provide an opportunity for the development and expansion of future regulations, and their further penetrating into national legislative systems. This thesis examines the process of Norway´s subsequent adjustment to this expansion and integration in the area of healthcare after 1994.

2.4. Summary

The purpose of the background chapter was to reveal the origins and the essence of the EEA Agreement at the time it was adopted. It has shown the roots of Norway-EU cooperation and the role of EEA Agreement as the core of this cooperation. It can be used later to assess the further development of European cooperation in the health area after the EEA Agreement entered into force in 1994. Further, the chapter has presented the idea of four free movement principles as the cornerstone of the internal market functioning. The relevance of the free

movement of goods, services and persons for health regulation was also shown. It can be seen that the health area was affected by the EEA Agreement through adoption of legislation for medical equipment, pharmaceuticals, as well as legislation for the approval of medical qualifications, movement of medical doctors and nurses across borders for the work and social security rights for international workers.

In addition, the impact of the EEA Agreement on Norway´s adaptation to EU and organizational changes within national political administration caused by this cooperation was presented.

3. Chapter three: Theory – an institutional approach to Europeanization

3.1. Introduction to the theory

The aim of this chapter is to present the theory which can be further used in the analysis of Norwegian adaptation to European health policies. The chapter addresses theories used in studies of Europeanization in general and of the development of European health policies in particular.

In this way, this chapter presents established theories from EU studies and these theories will be further applied to health policy analysis in the discussion chapter. The chapter starts with the introduction of the term Europeanization. Then, the framework of historical institutionalism is presented and linked to the concept of Europeanization. Finally, based on this framework, the chapter presents a number of assumptions about factors relevant for explaining Norwegian adaption to EU health policy and law as well as possible explanations of Europeanization in the light of historical institutionalism.

3.2. Europeanization

Even though there is not a clearly defined and commonly shared definition of Europeanization, the term Europeanization indicates a process of change or evolution (Olsen, 2002). Europeanization is a change associated with the process of establishment and expansion of common European politics, and most part of studies on Europeanization have been done in the context of the development of European Community and European Union. Olsen (2002) comes up with five different definitions of Europeanization. This paper focuses on two major definitions, which in this context are the most relevant in the analysis of Europeanization of health politics and policies.

According to the first definition, Europeanization refers to institutional change, and entails the development of institutions of governance at the European level. Institutional change "signifies center-building with a collective action capacity, providing some degree of political coordination and coherence" (Olsen J. P., 2002, p. 923). Olsen (2002) says that taking an institutional perspective can help to answer both how and why the change has taken place. For

instance, political institutions and its agents respond to changes and challenges, follow-up routines and procedures, which in turn effects political outcomes and consequences (Olsen J. P., 2002). “The development of institutions can be described as the purposeful decision-making” and institutional perspective highlights the significance of structures, histories and dynamics for understanding political transformations (Olsen J. P., 2002, p. 925).

The second definition refers to Europeanization as central penetration of national and sub-national systems of governance which implies adapting national and sub-national systems of governance to a European political center and European-wide norms (Olsen J. P., 2002). In addition, institutional change includes formal-legal institutions of governance and normative order and central penetration implies adapting national and sub-national systems of governance to European political center (Olsen J. P., 2002). Both institutional change at the EU-level and central penetration can be used in the analysis of health politics, where the first one shows the development of health polices, legislation and administration at the EU level, while the latter reveals the adaptation of Norway´s health policy, legislation and health administration to European policies and laws.

Europeanization caused changes in external boundaries of national states, leading to the expansion of Europe as a single political area. In addition, the process of Europeanization went along with the creation of European Union as a unified political organization, strengthening its position as a single political actor vis-à-vis other states and causing interdependency between its member states (Olsen J. P., 2002). According to Olsen (2002) the term Europeanization can be used in the analysis of the development of European politics and policy. It means that the term focuses on the dynamics of evolution and change on the European arena (Olsen J. P., 2002), including not only political but also economic and social changes. There are different aspects of change. In this analysis it was decided to use institutional approach, notably historical institutionalism perspective. In European integration studies, historical institutionalism has been one of the approaches most often used when scholars sought to study institutional or policy change (Christiansen, 2020). In order to explain the policy change or understand why Europeanization has taken place, one has to understand institutional structure, as well as its mechanisms and dynamics (Olsen J. P., 2002).

3.3. Explanation of Europeanization in light of historical institutionalism: institutions matter

As noted above, the historical institutionalism is oriented towards examining the way institutional structures affect change or continuity in political systems (Christiansen, 2020). In other words, an institutionalist approach indicates that processes and changes are embedded in institutions – whether these be formal rules, policy structure or norms (Pierson, 1996). Historically, institutionalism was a critique against intergovernmentalism, which was one of the prominent theories in international relations. The theory of intergovernmentalism was developed along the accelerated activity of the EC, viewing EC as a political standard of international cooperation. According to intergovernmentalism, such international institutions as EC give possibility to member-states to pursue their preferences, however putting a high value on the maintenance of their autonomy (Pierson, 1996). Intergovernmentalism also underlines the role and functions of institutions, as well as explaining the role of intergovernmental bargains (Pierson, 1996). In line with this, adaptation to the EU becomes a rational and instrumental action, which implies states´ intentional adaptation.

The main characteristic which is specific to historical institutionalism is the time aspect. It means that the historical institutionalism helps to study social processes as historical phenomena (Pierson, 1996). According to Pierson (1996) historical institutionalism indicates temporal aspects of politics, which means that historical institutionalism takes into account long-term consequences and underlines that when European integration is examined over time, the historical institutionalism helps to reveal the appearance of gaps in member-state control. By gaps Pierson (1996) meant significant divergences between the institutional and policy preferences of member states and the actual functioning of institutions and policies (Pierson, 1996: 131). Pierson´s (1996) description of gaps highlights the power of autonomous activity of EU institutions which "locks" member states into initiatives that they might otherwise not choose. In this way, rather than strengthening the autonomy of member states as intergovernmentalism does, the historical institutionalism implicitly questions the notion of national sovereignty and autonomy.

The appearance of gaps also happened in the area of health policies. For example, Greer (2006) uses a historical institutionalism to study the development of EU´s health policy. Historical institutionalism is a good tool to shed light on the role of institutional change in the

process of European integration (Christiansen, 2020). It also demonstrates how institutional arrangements in the EU were shaped by longer-term cultural and historical courses (Christiansen, 2020). At the same time these institutional frameworks lay clear guidelines on the choices and developments made. The institutional framework consists of norms, ideas, rules and practices that can both promote certain choices and limit others (Veggeland, 2016).

The evolution has been seen in the development of the EU governance, EU judicial integration, values and norms (Bulmer, 1998). According to Bulmer (1998) the historical institutionalism can be used to analyze systematic change (state's role in macro-social change), change in governance structures (the process of increasing of the EC's governance capability), and change of the norms of governance. According to historical institutionalism, institutionalization deepens integration and shapes particular outcomes. The aim of historical institutionalism is to explain European gradual transformation and thus historical institutionalism is a good framework which can help to understand "several different types of simultaneous processes of change and pattern of mutual adaptation among co-evolving institutions" (Olsen, 2002: 941).

3.4. Explanation of Europeanization: path-dependency, spill-over effect (unintended consequences) and critical juncture

Analysis of Europeanization in the light of historical institutionalism has involved several explanations to this process. Recall that answering "why" one has to understand the structure and functioning of institutions, i.e., norms, rules, practices etc. Institutional rules, norms, resources or symbols shape actors' behavior and develop endogenous institutional impetus for policy change (Bulmer, 1998). There are many different explanations presented by different scholars. This paper focuses on how historical institutionalism can shed light on Norway´s adaption to the EU in the area of health policy and law.

Path-dependency

Institutional logic is based on the idea of path-dependency which means that development of the policies and their changes, as well as possibilities and limitations are anchored in rules of the game or so-called political order (Veggeland, 2016). In this way path-dependency influences the course of policy and can be also described as accumulative policy-making

process (Bulmer, 2009) implying that integration begats integration (Greer, 2019). According to Pierson (2000) dependence refer to the causal relevance of preceding stages and path dependence means that what happened earlier will affect the possible outcomes of the events later. Along with the idea of path-dependency the idea of increasing returns was created, which means that the further trajectory along the same path increases with the movement along this path and increases the benefits of this action. Besides the benefits, it also increases the costs of exit or choosing a different alternative (Pierson, 2000).

Bulmer (1998) argues that the new strategies and policies which were adopted with the development of EU were anchored in the goals set out from the very beginning in the Treaty of Rome. Also, for example, the internal processes of decision-making in the European Commission and the committee structure of the European Parliament, or some other specific organizational features may help to explain policy outcomes (Bulmer, 1998).

Path dependency is relevant for the analysis of the health policies because integration of internal market law led to its application to healthcare services and creation of legislation that suited in health sector (Greer S. L., 2019).

The assumption based on the concept of path dependency, *is that although the Treaty of Rome did not include a common health policy, the goals set out in this Treaty have later limited some choices and enabled others thus affecting the development of EU's involvement in health policy. Moreover, although the EEA Agreement did not include a common health policy, based on the logic of path dependency, the basic logic and goals set out in the agreement have limited Norway's choices, affecting cost of alternatives, with regard to adaptations in the health area. Thus, the assumption is that EEA Agreement has limited Norway's choices and determined it's "adaptive path".*

Spill-over effects and unintended consequences

According to Pierson (1996) there is the high issue density among the anticipated consequences of Europeanization, which in turn results in a spill-over effect or unintended consequences of Europeanization. Spillover effect means that policies adopted in one area can cause changes in other policy areas. Spillover means that there is a tendency of tasks adopted to have important consequences for realm outside those originally intended, or to empower

actors who generate new demands for extended intervention (Pierson, 1996: 139). Bulmer (1998) presents the example of how the development of single market affected multiple policy issues (Bulmer, 1998) and had implications not only for economic policies, but also involved social policies and strengthened European governance. Pierson (1996) argues that the high density of political issues taken over by European governance has contributed to widespread unintended consequences not only on European level but also on domestic level of member-states. It in turn led to so-called "gaps" in states´ control possibilities which meant actually weakening of states´ control and states´ political power in decision-making.

The study of spillover effects is valuable in the health area because the integration exists and proceeds in EU health policies regardless of whether it is intended and regardless of whether regulation of health was included in the original Treaties (Greer S. L., 2019).

The assumption based on the logic of spill-over effects and unintended consequences is that *the EU's work and development of the single European Market program has "spilled over" over to health policies thus leading to gaps in member states control over health policies and to an unintended expansion of the EU's involvement in health policies. Such developments have also affected Norway through the EEA Agreement, which include the same link between internal marked regulation, free movement principles and other policy areas, as the member states.*

Critical juncture

Critical junctures are times characterized by uncertainty and the possibility of a significant change (Greer, 2008). Pierson (2004) characterizes a critical juncture as a system which implies a range of possible outcomes, consists of small events that have large consequences, characterized by the path-dependent process underlining the significance of timing and increasing the cost of changing trajectories (Greer, 2008). Explanation of Europeanization by critical juncture underlines the role of crisis in the process of European policies´ development. Crisis contributes to integration and gives more political power to EU (Christiansen, 2020). Crisis also strengthens and expands EU´s institutional position. During the history EU has been shaken by a number of crises, like for example, BSE - mad cow decease crisis, and COVID-19. The necessity to manage these crises influenced the emergence of new European policies and established new institutions. The question is whether, and if so how, such crisis

have affected health policy and law in the EU. The assumption based on the logic of critical juncture is *that crisis in the EU/EEA have opened up 'windows of opportunities' thus triggering new initiatives in health policy developments in the EU, partly beyond member states' control.*

3.5. Summary

Even though there is no shared definition to Europeanization, this paper covers two definitions of relevance for the study of Europeanization of Norwegian health policies. The first definition refers to institutional developments at the EU level; the other definition refers to central penetration of EU governance into national and local systems. This understanding of Europeanization can contribute to a better understanding of the processes where nation states adjust themselves to the developments in European institutions and policies. In the light of historical institutionalism Europeanization underlines the role of institutions (including structures, norms, values and practices) in a long-term perspective, highlighting the importance of the time factor. In this thesis, three key-explanations to Europeanization are highlighted, namely path-dependency, spill-over effects/unintended consequences and critical junctures. The further objective of this paper is to assess whether we can observe Europeanization in line with Olsen´s two definitions referred to above, and moreover to identify relevant explanations for the Europeanization process. In this way the paper will assess the development of health institutions and policies at the European level and whether and how Norway has adapted to such developments. Thus, do we observe that EU developments are penetrating Norway´s systems of health governance? How can we account for such developments?

In this chapter I have demonstrated the relevance of Historical Institutionalism theory for the study of Europeanization of health policy. I also defined key concepts from the theoretical literature and developed some assumptions about Europeanization of health policy based on this literature.

4. Chapter four: Methods and data

4.1.Introduction

Norway has been adapting to the EC / EU over a long period of time. Despite the long history of cooperation there has been done very little research on how Norway has been affected and adapted to the EU in the health area. This paper reveals the knowledge gap, which is caused by a small amount of research in the field of Europeanization of Norwegian health politics.

This study is based on a literature review, analysis of official documents, as well as a review of laws and regulations in the field. I have also contacted Norway´s representatives in Brussel and individuals who work with the EU-related issues at the major health institutions in Norway and received information of specifics of Norway's relations to the EU in the health area.

Here, I will first, show how I did the literature review and literature search on how Norway has adapted its health policies to the EU. Second, I will show how I have studied Norwegian adaptation to the EU in the health after the EEA Agreement entered into force in 1994. Finally, I present how and where I found informants to check the information.

4.2.Methods and data

I started with the literature review to map what is known about Europeanization of Norwegian health policies. For the literature review I used PubMed, Web of Science and Oria databases. In the PubMed I searched with different combinations of the following key words: EEA, EU, Europe, Norway, health, policy, politics. I filtered search by year of publication choosing articles published after 1992, i.e., after the EEA agreement was signed. In the Web of Science, I conducted an advanced search by choosing "all databases" with the various combinations of the following words filtered "after 1992": EEA, Europe, Europeanization, Norway, medicine, medical technology, health policy, health politics, cross-border. I used also Oria database for the search of the relevant literature in Norwegian language with the key words: EØS, europeisering, Europa, Norge, helse, helsepolitikk. After conducting the literature review it was revealed that there has been done few studies on how Norwegian health policies and politics were influenced by and adopted to European policies and politics.

In addition to the literature review a document analysis was conducted. The document analysis was needed to map Norway´s adaptation to the EU in the health area, more precisely adaptation through change of the old or adoption of new laws and regulations in order to comply with European legislation. The analysis included public reports, documents and laws. First, I started with the Storting bill number 100 "Consent to ratify the agreement on the European Economic Area signed at Oporto on 2 May 1992". I also used official websites to Norwegian government, parliament, Medicine Agency, Institute of Public health and Norwegian directorate of health. The focus of the search on these platforms was to find out how these institutions describe Norway´s participation in EU health politics and what is the role of these very institutions in this participation.

I used lovdata.no, which is a legal information system for laws review. It presents not only all revisions of the laws in chronological order, but also assessment of these regulations in relation to how much their revision or adoption effected previous laws in Norway. Using this platform, it was possible to track how EEA Agreement was changed after its adoption.

I have also contacted by e-mail the Norwegian Mission to the EU, based in Brussels, as well as other government representatives who work in the field of health and food safety; labor and social policy; health and emergency preparedness. Furthermore, I have sent e-mails to the Global health department at the Institute of Public health. The main goal of sending e-mails was to get information, first of all, about institutional adaptation in order to map how Norway participates in EU management of health law and policy, as well as how has adapted its national health administration to the EU participation. Moreover, I found many relevant pieces of information at the official websites of European Commission, European Parliament, DG Sante and EFTA.

4.3.Research design

This is a qualitative study, which is the most appropriate type of the study to answer my research question. Qualitative approach can be used in the studies in order to understand a political phenomenon, thus qualitative approach suits well in order to understand the phenomenon of Europeanization of Norwegian health policies. My research was based on the analysis of documents, laws and regulations to survey fields (both directly and indirectly

related to health) and timelines for the development of EU health policies and Norway´s adaptation to these policies.

The main objective of the qualitative approach is to reach validity and reliability of the studies.

"Validity refers to the "truth" of a measure: does it capture findings that present the reality ?" (Green, 2018, p. 272). This means that validity shows whether the data used in the study was suited to answer the research question. Validity can be maximized by using particular data set especially fitting for covering the topic or by justifying that the study is credible (Green, 2018). The objective of the validity in this thesis can be considered to be reached as I have been "explicit about the steps taken in the data production and analysis" (Green, 2018), I made clear assumptions about theories addressed in the analysis, and I have been aware of that the data which I used in the study was shaped by the historical and policy context which this study covers. In addition, I used literature review, official documents and laws developed over a longer period of time. These resources of data made it possible to shed the light on Norway's health policy adaptation to the EU in the long-term perspective.

So, the qualitative data and its analysis were suited well for the dealing with answering the question of this research paper. In this thesis I used primary data, such as laws, regulations and official documents. The advantage of using the primary data is that it gave possibility to provide good and politely information about Norwegian adaptations. However, the data is less suitable to say something about why the adjustments have been made.

"Reliability refers to the consistency of a measure: does it produce the same results over time?" (Green, 2018, p. 272). In other words, if other people that have had analyzed the same data would present the same findings. Reliability of my data collection is reached by the openness of my resources. In this thesis I refer openly to the resources and present the literature and documents, which are official documents that have credibility. In order to strengthen reliability of the study I checked up the literature and documents with the information I got from informants by e-mail.

However, there were some limitations and restrictions. These were related to access to informants and insufficient number of studies in this area. Few informants and few studies limited what I could tell about causes that would explain the Europeanization of Norwegian health policies. The possibly to interview informants would contribute to more accounts on Europeanization, stronger basis for legitimacy and credibility of my study as well as to answer "why" the Europeanization took place. In addition, interviews could help to map the health institutions and political practices more detailed than they are described on the official websites or in documents.

4.4.Summary

In this chapter I presented the method, data and design of the study. I argued for choosing the qualitative method and primary resources of information. I showed by what means I attempted to reach the validity and reliability in my study. Simultaneously I named the limitations and restrictions connected to the insufficient number of informants and other studies.

In the next chapter I will present findings from the study of Norwegian adaptation to the EU in the health area.

5. Chapter five: Findings

5.1.Introduction

In this part of the thesis, I firstly present a literature review on how Norway is influenced by EU policies in health area. Secondly, I present findings based on a document study, supplemented with input from employees in the Norwegian health administration, on how Norway's relationship with the EU in the field of health has developed since 1994. Findings are divided according to how Norwegian health politics was affected by four freedoms. Finally, I include findings which show that Norway had to adjust not only its policies, but also did it through organization of political institutions.

5.2. What does the gap in literature tell us? A review of the literature on Europeanization of Norwegian health policies

Since 1994 there has been an increasing interest in the study of Europeanization of Norwegian politics. A large number of studies have demonstrated that the development of Norwegian politics and policy has been clearly influenced by Norway´s involvement in European political processes. There has been done studies on the EEA Agreement´s significance for the integration of Norway into European community. One of the first books was published in 1993 by Svein S. Andersen and Kjell A.Eliassen (Andersen, 1993) where they focus on the relations between the European Union and Norway, especially lobbying of Norwegian interests in EU, Norway´s application for membership, Norwegian politics, the public sector in the EEA and the EU, administration and institutional affiliation (Andersen, 1993).

Since 1994 a large number of studies on a wide array of aspects concerning Norway's relationship with the European Union has been conducted. Most of these studies cover the topic of public administration *(Egeberg, 2003; Sogner,1995; Trondal, 2018)*, as well as the topic of EU and EEAs role in Norwegian politics *(Bårdsen, 2013; Claes, 1999; Eriksen, 2008; Fagerborg, 1991; Olsen, 2017; Sejersted, 1995; Sverdrup, 2004; Sverdrup, 2019; Stubholt, 2019).*

However, so far, relatively little attention has been directed towards the health sector, i.e., how Norway has adapted to the regulation of health in the European Union (Veggeland, 2017). Still, some studies do exist. For example, some studies have focused on how the EU

has affected regulation and governance of pharmaceuticals *(Dyrdal, 2004; Hågå, 2002; Norris, 1998; Vestlund, 2009).* Other studies focus on patients´ right to get treatment in other EU/EEA states *(Edøy, 2004; Nordeng, 2020; Ringard, 2013; Seierstad, 2009).* There are also some studies in the field of food safety *(Lie, Veggeland, 2010; Veggeland, 2016; Holm, 2009), but this topic is not within the scope of this paper.*

When searching for the literature on how Norwegian politics is affected by European cooperation one can notice that most of the studies is devoted to general surveys of Norway´s relations to the EU through the EEA Agreement *(Sverdrup, 2019; Eliassen, 2003).* A significant part of existing studies has also been devoted to more detailed surveys in specific policy areas such as: security policies, fisheries and marine policies, forest policies, energy policies, food policies, migration policies, research etc. However, as already noted, not many studies have focused on the health sector. One of the reasons could be that EU does not have a common health politics and because originally, health politics have been the responsibility of the nation states and has not been developed by the EU as a separate common policy area.

In the literature it was found only few studies on Europeanization of Norwegian health politics. The majority of studies focusing on Norway's adaptation to the EU were either about Norway´s general relations to the EU or about other policy areas than health. Those studies to be found about health policies in Europe where Norway was included, were primarily comparative and descriptive in scope and basically not about adaptations to the EU. Most of the studies on the importance of the EU for health that was found in the literature search were technical and very detailed focusing on topics such as specific pharmaceuticals, screening programmes, clinical effects of the disease control etc. Thus, these studies fall outside the scope of this thesis which focuses first and foremost on Europeanization of health *policy* and health *administration*. Studies found in the literature review do not reveal adjustments of the Norwegian health policies through for example adaptation of legislation, governance of the health services or financing methods. Some of the studies evaluate to what extend European countries comply with EU laws, directives, programmes, and practices. Still, from the literature review it appears that there is a massive gap in knowledge regarding the question of how Norwegian health politics and policy have been impacted by the EU and the EEA Agreement.

Table 1 (Appendix 1) shows studies on European health policies. The table includes studies divided into policy areas like pharmaceuticals, disease control and prevention, vaccination etc. These studies are multinational studies which cover the most part of EU/EEA countries, including Norway. However, Norway was not the main focus of the studies. From Table 1, it is seen that some of the studies are articles published in specialized medical journals. In addition, the great number of studies was published by Eurosurveillance, which is one of the largest European scientific journals devoted to the epidemiology, surveillance, prevention and control of communicable diseases, and focuses on the essence and nature of these diseases rather than on the political regulations for their prevention. Even though some of the studies focus on national policies for preventing antimicrobial resistance or immunization policy-making processes, they never reveal it as a part of common European health politics nor take Norway as the main focus of the study and that's why is falling outside this thesis' focus which is devoted to health politics and health administration.

The most relevant for the subject of European health policies are studies published in Health Policy journal which surveyed pharmaceutical policies. Many of these studies covered the topic of pricing and distribution of medicines, but the topic is too narrowed and has not focused on Norway as a primary object of the study. Also, the topic of vaccination is widely covered in the literature review. Most of the studies were focused on a specific vaccine or vaccination programme and were published in Vaccine journal and similarly to other studies included Norway only through questionnaires.

Finally, coming back to the research question, it is needed to delimit the literature search results to Norwegian health politics and its connection to EU/EEA. Preferably including studies which focus on Norway as a primary subject of the study (Table 2, Appendix 1). The literature review shows that very few studies have been conducted with the prevalence in the field of pharmaceuticals, cross-border healthcare and infection control (Table 2, Appendix 1). All of the studies are articles, most of which were published in health policy and sociology journals. From Table 2 (Appendix 1), one can notice that there was done very few studies about the relevance of Norway-EU cooperation for the development of Norwegian health policies and politics. It was also noticed that the older studies were mostly devoted to pharmaceuticals, probably because just after the adoption of EEA Agreement, Norwegian medicinal monopoly at the time was dissolved and it caused significant changes in the pharmaceutical market. We can see that the recent studies were mostly devoted to the cross-

border care and infectious control. The interests for the study of cross-border care and disease control can be related to the implementation of Patient Rights´ Directive which caused serious debates in Norway as well as lately relevant epidemic outbreaks. The literature review from the Table 2 (Appendix 1) shows the lack of studies in fields such as medical technologies, social security coordination regulations and their implementation in Norway, as well as a lack of analysis of the Norwegian health administrations' adaptation to the EU.

Based on existing literature supplemented by an analysis of public documents, the following paragraphs of this chapter will explore how the Norwegian health policies and the Norwegian health administration in practice have been adapted to the European Union – despite the fact that according to the EU Treaties (and the EEA Agreement) the EU «shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care» (Art 168 of TFEU).

5.3. Norway's adaptation to EU policy and law: a document study

5.3.1 EEA and the relevance of free movement principles for regulation of health

As noted in the background chapter, one of the main purposes of European law has been to ensure free movement of goods across borders within the European market. The free movement principle contributes to free competition. The question raised in this part of the thesis is how the internal market legislation and competition laws affect Norwegian health policies and healthcare delivery. It was noted earlier that the EEA agreement includes EU provisions related to the regulation of the internal market, including the four free movement principles. Through the adoption of the EEA Agreement, Norway has submitted itself to European rules and is obliged to implement EEA relevant EU legislation equally with other EU member-states. EU legislation has gradually included more and more legislation for the health area, leading to the establishment of what gradually appears as common European health policies. These developments also influence health policies in Norway.

The EU´s emphasis on ensuring free movement of goods means for the health sector, among other things, that the EU has a dense regulatory structure for pharmaceuticals, medical equipment, and medical devices including legislation, decisions and guidance (Geer, 2013). Through such developments the EU seeks not only competitiveness of the open markets, but

also safety and innovation (Hancher, 2010). According to the earlier mentioned Single European Act of 1986, Treaty on the Functioning of the European Union and subsequent the EEA Agreement it was necessary to ensure that products covered by the free movement of goods within the Community meet requirements that provide a high level of protection of public interests such as health and safety (EØS-avtalen, 1992)

In areas such as product regulations, approval of medicines and medical equipment, the EU has developed a comprehensive binding regulatory framework (Veggeland, 2017). In the case of approving medicinal products in European community the EFTA-states have to make the same decisions within 30 days based on the relevant legal acts (EØS-avtalen, 1992). Today most of laws regulating the production, approval and control of pharmaceuticals and medical equipment in Norway is based on EU legislation, which are incorporated into Norwegian laws such as the Law on medicines (Lov om legemidler, 1992) and Law on medical technology (Lov om medisinsk utstyr, 1995).

5.3.2 Free movement of goods: relevance for regulation of health

Pharmaceuticals

In 1988, *Council Directive 89/105/EEC relating to the transparency of measures regulating the prices of medicinal products*, was adopted on the review of pricing procedures for pharmaceuticals for human use and the inclusiveness of these pharmaceuticals in the national health insurance schemes (Official Journal of the European Communities, 1988). The implementation of the Directive required that states had to adopt economic and financial measures with the objectives of bringing public spending under control, contribute to sufficient supply, reasonable prices, more effective production of pharmaceuticals and promotion of the research. According to the Council Directive it is essential to establish a set of requirements that will ensure that national measures do not impose quantitative restrictions on imports or exports of goods (Official Journal of the European Communities, 1988). *Directive 89/105 / EEC on access to the price provisions for medicines and their inclusion in the national health insurance schemes* (the Transparency Directive) has been implemented in Norwegian law through the Medicines Regulations and the Blue Prescription Regulations (Regjeringen, 2017).

In 1993, other *Council Directives such as* 93/39/EEC, 93/40/EEC and 93/41/EEC regarding medicines were adopted which aimed at establishing procedures for the authorization and monitoring of medicinal products within the Community and the establishment of a European Office for the Evaluation of Medicinal Products. The main purpose of regulations for the approval and sale of medicines was to safeguard public health. The regulations had to ensure that the medicines that are on the market at all times did not involve a risk that was disproportionate to the benefit the medicine represents.

The EEA Committee's decision of 28 May 1999 decided on a closer connection for Norway to the EU's pharmaceutical cooperation. The decision implied that all three Council Directives of 1993 were incorporated into the EEA Agreement and the EU scheme for the authorization of medicines entailed an extension of the previous cooperation in the field of medicines. The provisions of the legal acts with some technical adaptations have become binding for Norway. Directives were integrated into the Norwegian Pharmaceuticals Act and regulations on special pharmaceutical so that Norwegian authorities would apply for the new European legislation and so that decisions on marketing authorizations in Norway would be based on other countries' assessments and recommendations.

In 2001, the Directive 2001/20/EC *on practices of conduction of clinical trials on medicinal products* was adopted establishing also of regulations for reporting unexpected and adverse effects of the medicines. Implementation of the Directive had to comply with *the Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data.*

In 2001, the directive on the introduction of a single regulatory framework for pharmaceuticals for human use which united all of the directives about pharmaceuticals was adopted in the period after 1965.

Medical devices

Norway also had to implement many new legislative acts, which applied for medical equipment and devices. Council resolution of 1985 on the “new method” demonstrated the need of harmonizing technologies and standards (St.prp. nr. 100, 1992). In order to facilitate compliance with the essential requirements and to be able to verify this compliance, it was desirable to have harmonized standards to prevent hazards associated with the design,

manufacture and packaging of medical devices (EØS-avtalen, 1992). As the result the new Directive on the product marking with "CE" was adopted in 1993, which included marking of medical equipment and was implemented in EEA Agreement when it came to force. The "CE"-mark indicated that the product was complied with European standards and that the product can be further distributed and used according to prescriptions. To secure product safety the member states´ had to adopt the same legislation. The most part of legislation for medical equipment and devices has been based on the *Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices* and *Council Directive 93/42/EEC concerning medical devices.* In 1998 a new *Directive 98/79/EC* came into force, the directive concerned *on the medical equipment for the in vitro diagnostics* which originally was excluded from the Directives of 1990 and 1993.

The first revision of the Directive on medical equipment came in 2007 to clarify existing requirements and create a legal basis for planned initiatives. It also proposes an update of the Directive on the approximation of the laws of the Member States, so that this directive complies with the Directive on medical devices, Directive on medical devices for in vitro diagnostics and Directive on medical devices containing derivatives of human blood or plasma (Revisjon av direktivene om medisinsk utstyr, 2012). Later, in 2010, the European commission decided to establish the European database for medical devices (Eudomed) in order to strengthen market surveillance by giving the competent authorities rapid access to information on manufacturers, equipment, certificates, monitoring data and data from clinical trials ((EUDAMED), 2010).

In 2017 these directives were substituted *by the Regulation (EU) No 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices*. The new EU regulations for medical devices came into force on 25 May 2017. The new EU regulations consist of two regulations: medical devices and medical devices for in vitro diagnostic. The purpose of the act was to strengthen patient safety and ensure equal implementation of the regulations in the Member States. Technical control bodies were designated by the authorities to assess whether a medical device meets the safety requirements in the regulations. If the manufacturer's documentation meets the requirements, the technical inspection body issues a certificate. The manufacturer must have this certificate to mark his product with CE.

Robust and transparent regulatory frameworks were about to be introduced to ensure that medical equipment was safe when placed on the market, while at the same time the new regulations would promote the innovation of medical equipment. Such expansion of EU legislation on medical equipment imposed stricter pre-control routines, stricter requirements for technical control bodies, strengthened regulations on clinical evaluation and clinical trials etc.

The regulations supposed a need for both legislative and regulatory changes in Norwegian legislation on medical devices. Because of such extensive changes there was proposed that a new law and regulations on medical equipment would be issued. Also, the Norwegian Medicines Agency, the legal acts entailed increased financial and administrative consequences. The regulations required increased cooperation with other Member States and the European Commission.

5.3.3 Free movement of persons and services: relevance for regulation of health

The EU´s responsibility for ensuring free movement of persons means that it coordinates the social security entitlements of migrant labor through the legislation originally adopted in the 1970s. This included access for patients to EU health-care systems beyond the country in which they live (Greer, 2013). Originally, it was focused on the realization of the internal market principle on free movement of persons and therefore was mostly devoted to the rights of the workers and their families. *The Council Regulation of 1971 on the application of social security schemes to employed persons and their families* has been implemented on both community and national levels. Coordination of social security legislation which felled within the framework of freedom of movement for workers, aimed at the improvement of standard of living and conditions of employment. It also aimed at guaranteeing within the Community equality of treatment for all nationals of Member States under the various national legislations and social security benefits for workers and their dependents regardless of their place of employment or of residence (Regulation (EEC) No 1408/71). The adoption of the directive had implications for fostering and developing cooperation between Member States in social security matters, particularly in respect of health and social measures of common interest (Regulation (EEC) No 1408/71). Norway had to implement this regulation as a part of the EEA Agreement.

The regulation has later been amended because of changes of legislations on these two levels. Major amendments came in 2004 and 2009 (see below), and these rules have become essential to achieve the aim of free movement of persons (Regulation (EC) No 883/2004).

Within the Single Market, the European community had to take care of workers´ rights and preserve their right to health and welfare benefits. With the expansion of the free movement of labor and market development there has been also expanded social rights and welfare benefits for the workers. Thus, implementation of the single market increased EU competence in the health area which in its turn gradually expanded the EU's responsibilities in the field of health.

In order to facilitate the greater mobility of work force, European community had to establish health safety net, which could guarantee better living and working standards (Regulation (EC) No 883/2004). In 2004, the EU considered that it was important to modernize and simplify old rules for social security as well as to develop a better system for coordination across borders. It resulted in the Regulation laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems. The Regulation repeals and replaces Council Regulation (EEC) No 1408/71 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community. However, the basic principles of coordination and the most important features of the system were preserved essentially the same as before. The general starting point for coordination would continue to be that a person who is entitled to social security benefits in one Member State should not lose his right by moving to another Member State. Current coordination instruments for social security have been incorporated into Norwegian law by regulations of 2006 on the basis of a number of laws, including the National Insurance Act. In 2009, this Regulation was revised laying down more detailed rules for the implementation on the coordination on social security schemes. It also specifies the measures and procedures required for implementation of the Directive and simplifying them for all parties involved (Regulation (EC) No 987/2009). According to the Regulation, the prerequisite for the effective social security coordination is closer and more effective cooperation between the social security institutions. One of the best methods for effectivization of coordination is creation of electronic channels for communications for fast and reliable data exchange between Member States´ institutions. In order to clarify and structure the relationship between the members of the social security institutions it is vital to

set common deadlines for fulfilling certain duties or completing certain administrative tasks (Regulation (EC) No 987/2009).

However, implementation and practicing of the legislation has created controversies in Norway. In the period after 2012, there has been presented a number of Complaints against Norway´s misinterpretation of European law. Because of this misinterpretation the Norwegian authorities (The Norwegian Labour and Welfare Administration ("NAV") wrongfully demanded that 89 recipients of welfare benefits (sickness benefits, work assessment benefits or care benefits) must reside on Norwegian soil (NOU 2020: 9). This was contrary to the EEA agreement which states that everyone can move freely within the EEA area. Subsequently the EFTA Court has given its advisory assessment to Norwegian authorities, and it was concluded in an interdisciplinary working group that a misapplication of law has been made. In 2019 Norway had to implement changes into its legislation and practices. The change was that benefits could no longer be stopped or refused only on the basis that the recipient resided abroad in the EEA area (NOU 2020: 9). Thus, Norway has implemented new adjustments according to European legislation.

The term cross-border care is associated with the impact of internal market in the health area, and it includes mobility of medical goods, patients, professionals and services across national borders. However, more often the study of cross-border care has been associated with the social dimension of care, i.e., patient mobility grounded in their right to health care outside their home states *(Greer, 2013; Nordeng, 2020).*

From 1990s, cross-border care was essential not only for the welfare benefits outside the country of affiliation but has become also inherent in patients' rights to choose healthcare across borders. It commonly implies people accessing health care services outside their home state (Palm, 2010). According to European law, harmonization policies shall ensure a high level of protection of human health. Since the 1990s, there has been controversies on the interpretation of EU law in the context of the free movement of services when patients claimed treatments in another Member State as well as to be reimbursed by home health system (Greer, 2013). Traditionally, the European Court of Justice has played an important role in defining citizens' entitlements to care outside their state of affiliation (Palm, 2010). There were controversies when some Member States refused to reimburse patients for treatment in other member states. European Court viewed the action as noncompliance with

the Article 49 of EC about prohibition of restrictions on freedom to provide services within the Community (EEC Treaty). One of the best examples on how European Court evaluated such controversies can be found in the *Kohll* and *Decker* rulings. The judgment in Kohll concluded that no prior authorization was required for scheduled outpatient care in another Member State (c.f. free movement of services), while the judgment in Decker concluded that no prior authorization required for the purchase, in another Member State, of medical devices or medical products on prescription (c.f. free movement of goods).

The rulings of the European Court of Justice made it clear that healthcare was a service subject to European Union regulation and implied that EU's enormous body of law on the internal market would be applied to the previously sheltered area of health care organization and finance (Jarman, 2010). It meant that patient mobility rights expended and included more rights than previously covered by the social security rights.

ECJ helped to draw attention to the fact that health is extremely affected by the four freedoms, not least by the principle of free movement of services and persons. In order to solve the controversies connected with the free movement of services there has been adopted the Directive on Patients´ Rights in Cross-border Healthcare in 2011. According to the directive, patients can get medical treatment in other EU/EEA countries and get reimbursement for treatment received abroad in relation to what the treatment would cost the Member State if it was provided at home. The Directive has arguably contributed to important modifications of European jurisprudence on cross-border care. Norway had to implement the Directive into national law system. Implementation required to set-up National Contact Points (NCPs), as well as implementation of rules on reimbursement of costs of treatment; and the rules on prior authorization (Nordeng, 2020). In the Report on follow-up of the Patient Rights Directive Norwegian authorities have evaluated the Directive as mainly a codification of case law from the European Court of Justice that is not considered problematic for Norway. In addition, the directive was considered to be relevant and acceptable (Pasientrettighetsdirektivet: behandling over landegrensene, 2015).

However, in practice there was opposition against the implementation of the Directive among Norwegian authorities and Norway even received several complaints from ESA regarding the access to in-patient treatment in other EEA States, which raised the question about the

necessity to make changes in national law to comply with the EEA Agreement (Nordeng, 2020).

5.4. Adaptation of Norwegian health administration to the EU and EEA

5.4.1 The development of EU health administration and links to the Norwegian health administration

The establishment of DG Sante within the European Commission

The European Commission (EC) is increasingly dealing with a variety of health issues to coordinate and complement national health policies (Clemens, 2017). During the years EC has extended its capacity to pursue a certain action of EU/EEA States and surveil the EU/EEA States compliance with defined European goals. This capacity required strengthening of institutions in order to pursue policies´ implementation. The European Union (EU) has established a mandate for health, which means that EU has got an authority to carry out health policies (Clemens, 2017). Increased policy integration can be achieved through defining policy goals and guidelines as well as through reorganization of the institutional structure in order to reflect better the desired policy perspective (Ugland, 2006). In 1995 a new DG – DG XXIV (Consumer Policy) – was established in the European Commission as a separate institution dealing with consumer issues. Initially, however, the new DG did not have primary responsibility for consumer protection in the area of food safety and public health policies, and important tasks relating to the public health area remained under the responsibility of DG V (Social Affairs) (Ugland, 2006). Later, DG XXIV was renamed DG Consumer Policy and Health Protection (Ugland, 2006). The DG SANCO was established in 1999 by augmenting the existing DG on consumer protection. The responsibility for certain health policies were added including food policy, feed and animal health and public health issues from other DGs. On these specific health dossiers DG SANCO is the leading policy actor within the EC (Clemens, 2017). From end of 2014 onwards DG SANCO has been renamed and reorganized to the Directorate General for Health and Food Safety (DG SANTE) (Clemens, 2017). DG Sante has become responsible for policy making regarding the mandate for public health and health systems. Article 168 of the Treaty says that Union action shall complement national policies and shall be directed towards improving public health. It gave the legal basis for the EU to complement and coordinate Member States´ actions by establishing guidelines,

exchanging best practices, funding research and supporting health monitoring and surveillance (Clemens, 2017).

The role of Directorate Generals mostly lies in preparing laws and following up their implementation and enforcement. The mission of DG Sante is to protect the citizens´ health and monitor food safety, so DG Sante contributes to the development of food and health related legislation. The experts from the Member States (including Norway) can help enlighten the case and ensure the most appropriate legislation. Through the EEA agreement there were established formal procedures for consultation and participation of the Member States. We can see from the Table 1 (Appendix 2) that DG Sante is responsible for administering and chairing a number of committees and working groups. EEA Agreement ensures Norway's access to participate in expert committees in the preparatory phases (NOU 2012:2).

Norway's link to DG Sante

Generally, the EEA agreement means that Norway and the EFTA / EEA countries may require participation in committees under European Commission in those areas covered by the agreement. Participation in expert groups and committees under the Commission is the only formal intake Norway has in the policymaking in the EU (NOU 2012:2). Norway as EFTA/EEA country is represented through the various program committees and a heterogeneous collection of technical /scientific /legal expert committees (see Table 1, Appendix 2). It means that Norway as a participant in these committees can assists Commission in the Management and Development of EU Programs and assists Commission in preparation for new regulations. The Norwegian participants in the various types of committees are mainly officials from the central administration. Many come from the ministries, but most are from underlying directorates and supervision units (NOU 2012:2). For example, the main actors participating in European health politics on behalf of Norway are Ministry of Health and Care Services, Health Directorate, Norwegian Institute of Public health and Norwegian Medicines Agency. According to the information provided by Norwegian EU delegation in Brussels, it is not precise and very general description because there is no systematic superior overview of Norwegian participation in the various committees, nor is there an overview of who represents Norway or Norwegian bodies in the various channels.

Participation in committees is presented by Norwegian authorities as an important channel for Norwegian participation and influence. However, they do not play a prominent role in the European policy formulation in the political sense.

The development of EU agencies

The establishment of European agencies is a result of limitations of European Commission's capabilities with regard to increasing of the scope and profile of European Policies. Thus, the development of health policies within European Union has resulted in establishment of Agencies working on public health. EU agencies nowadays constitute an important part of the EU institutional landscape and are a significant component of the functioning of the EU system and policy networks (Barbieri, 2008). EU agencies are mostly confined either to the implementation phase or to the policy formulation phase. They provide data, information, and proposals (Barbieri, 2008). There is still no agreed definition of EU agency and there is no definition of it in official EU documentation (Barbieri, 2008). However, agencies can be understood as internal bodies or departments of the European Commission, or as a form of directorate or external agencies. An EU agency is an independent entity set up by the EU and assigned tasks of a technical, scientific or administrative nature to assist the EU and its Member States in their work (Regjeringen, 2017). The emergence of EU agencies is partly a result of a growing need for specialized professional competence and the desire for a clearer distinction between professional and political assessments (NOU 2012:2).

Norway's link to EU agencies

Norway's participation in agencies is partly included in the EEA agreement, partly secured through bilateral agreements with the EU. The EEA agreement does not give Norway any formal or automatic right to participate in EU agencies. Norway must therefore negotiate participation and conditions in every single agency that is created (NOU 2012:2).

Through participation in agencies, Norway contributes to the policy development in the EU in a number of areas. In addition, Norway itself benefits from such participation in that there is an exchange of knowledge and network development between Norwegian and European countries.

In the health area Norway participates in European Medicines Agency, European Centre for Disease Prevention and Control, European Food Safety Authority, European monitoring center for drugs and drug addiction, Executive Agency for Health and Consumers, European Foundation for the Improvement of Living and Working Conditions, European Research Council Executive Agency (Table 1, Appendix 2).

Norway participates in 31 EU agencies (Regjeringen, 2017). As a general rule, Norwegian board representatives have right of proposal and speech, but not the right to vote. Norwegians are also excluded from leading positions in EU agencies and had few opportunities to place national experts in the agencies (NOU 2012:2).

The European monitoring center for drugs and drug addiction (EMCDDA) was set up in 1993 to provide factual, objective, reliable and comparable information concerning drugs, drug addiction and their consequences (Regjeringen, 2017) (EMCDDA, n.d.). Today it offers policymakers the data they need for drawing up informed drug laws and strategies. EMCDDA consists of two statutory bodies management board and scientific committee. They advise and assist European Commission in the decision-making process. There are also many different working units within EMCDDA which deliver outputs like reports, briefings etc. (EMCDDA, n.d.). The National Institute of Public Health contributes with the expert advice and Norwegian drug statistics. In addition, experts from the department participate as professional advisers in some of the EMCDDA's expert groups and in professional meetings (FHI, 2017).

European Medicines Agency (EMA) established in 1995 is responsible for fostering scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health in the European Union (EU). EMA´s functioning is of great importance for health because it is responsible for evaluation of applications for marketing authorization of medicines, monitoring their safety and providing information to healthcare professionals and patients (EMA, n.d.). In other words, Agency´s evaluations of medicines provide the basis for their authorization, underpinning important decisions about medicines market in Europe. The Norwegian Medicines Agency represents the Norwegian health authorities in the EMA. The Norwegian Institute of Public Health, at the Division of Epidemiology, participates in the scientific multi-partner networks (FHI, 2017).

European Food Safety Authority (EFSA) is a European agency funded by the European Union that operates independently of the European legislative and executive institutions (Commission, Council, Parliament) and EU Member States. EFSA was established in 2002 as a response to a series of food crises to develop harmonised risk assessment methodologies on scientific matters of a horizontal nature in the fields within EFSA's remit and provides general co-ordination to ensure consistency in the scientific opinions (FHI, 2017). The main objective of the EFSA is to be a source of scientific advice and communication on risks associated with the food chain. Thus, EFSA plays an important role in development of policy aspects which contribute to public health. At the heart of the EFSA´s work is scientific expert which work on different areas of expertise related to public health, such as food, plant health, genetically modified organisms, nutrition etc. (EFSA, n.d.). The Norwegian Institute of Public Health at the Division of Environmental Medicine works closely with the Scientific Committee, which focuses on the harmonized risk assessment (EFSA, n.d.) and has representatives in the EFSA's scientific panels (FHI, 2017).

The European Centre for Disease Prevention and Control (ECDC) established in 2004 aimed at strengthening Europe's defenses against infectious diseases. ECDC works with national health authorities across Europe to strengthen and develop European disease surveillance and early warning. By collaborating with infection control experts from across Europe, ECDC can provide scientific advice to health authorities on existing and emerging infection hazards (FHI, 2017). This in turn provides a basis for the European authorities to introduce new measures or change regulations in the field of disease prevention and health. The National Institute of Public Health at the Division for Infection Control has a permanent representative in the Advisory Forum, while a number of employees from the department participate in networks, experts / professional groups and at professional meetings (FHI, 2017).

Other areas of health cooperation: research and crisis management

Norway participates also in other health areas where participation is actually voluntary and non-binding legislatively. Such areas of health cooperation are disease control and prevention, antimicrobial resistance, public health and crisis management. In practice, this means that Norway participates in areas such as research, social security and emergency preparedness. Norway participates in this co-operation both through the EEA agreement and bilaterally (Regjeringen, 2018).

Through the EEA agreement, Norway participates in the EU's research work. The work on research and technological development plays an important role in European health cooperation because the large part of the research work is devoted to medical research and development of medical technologies. Norway has participated in the framework program for research for more than 20 years on the basis of the EEA agreement since 1994. Norway and the other EFTA / EEA countries contribute to the framework programme's budget. EEA Agreement has facilitated the creation of the European Research Area (ERA) which the main objective was to develop the internal market for research that complements the internal economic market by facilitating the free movement of researchers, ideas and technologies in Europe, as well as ensuring sustainable economic growth and jobs availability. ERA is also focused on strengthening the scientific and technological base in Europe (Regjeringen, n.d.). One of the main current framework programs for research and innovation is Horizon 2020. Norway participates actively in the development of the European research area both financially and by participating in expert groups and research committees. Researchers in Norway had a strong participation in the environment and climate, energy, security, food, space research and social research programs while into a lesser extent has participated in major programs in health and ICT. However, the ambition of Norwegian government is to increase in the level of participation of just over 60 per cent compared with the previous Framework Program (Regjeringen, n.d). There is also a Reaserch Council of Norway located in Brussel, which provides assistance to research and innovation stakeholders (Forskningsrådet, n.d.).

There was established EU´s coordination mechanism for civil preparedness and crisis management which involved, among other things, the creation of a voluntary reserve of national capabilities in high readiness, called the European Emergency Response Capacity (Regjeringen, 2018).

The Mechanism aims to strengthen cooperation between the EU Member States and 6 Participating States (European Comission, 2021) giving the European Commission possibility to play a key role in coordinating the disaster response worldwide. Norway has national experts who work in the European Commission with social security, crisis management and emergency preparedness (Regjeringen, 2018).

Also, the COVID-19 pandemic demonstrated the need for coordinated EU level action to respond to health emergencies. It revealed gaps in foresight, including demand/supply dimensions, preparedness and response tools. A European Health Emergency Preparedness and Response Authority (HERA) is a central element for strengthening the European Health Union with better EU preparedness and response to serious cross-border health threats, by enabling rapid availability, access and distribution of needed countermeasures. In one of the reports written by Norwegian prime minister it is said: "HERA to a large extent will address issues relating to the development and production of pharmaceuticals in emergencies and it will be vital in terms of national preparedness for Norway to participate in this work" (Regjeringen, 2021). It indicates importance of such cooperation and even Norway´s willingness to participate in this. Even though the establishment of HERA is only in the proposition phase, European Commission has actively prepared the COVID Recovery plan for European community (European Comission, n.d.). Throughout the crisis, Norway has actively promoted European cooperation on access to pharmaceutical products (Regjeringen, 2021). The close cooperation Norway has with the EU on dealing with the pandemic has also been a decisive factor for getting it in place so-called Covax collaboration with the EU which ensured access to Covid-19 vaccines (Regjeringen, n.d.).

5.4.2 Adaptions to the EU within the Norwegian health administration

Table 2 (Appendix 2) covers information on administrative adjustments to European health policies in Norway. The matters related to the EU-Norway politics are mainlined within established administrative structures. However, there has been established special units or representatives within national administrative structures whose primary area of work is focused on European cooperation in order to support and provide better approximation between Norwegian and European policies.

Norway's delegation to the EU

The Norwegian EU delegation in Brussels is Norway's largest foreign service mission. Its task is to safeguard Norwegian interests vis-à-vis the EU institutions and member states in Brussels in all areas that affect Norway's cooperation with the EU (Regjeringen, 2020).
The EU delegation represents the Norwegian authorities vis-à-vis the EU. The delegation

works on the basis of a series of instructions and overall objectives for European policy. The EU delegation plays an important role in the coordination of the Norwegian authorities' work towards the EU institutions. The Delegation maintains regular contacts with Norwegian authorities and with all important players in Norwegian society. It prepares analyses and reports on developments in Norway. Another important task of the Delegation is to provide information about EU institutions and policies to both the government and the wider public. EU Commissioner for Health and Food Safety works to strengthen Norwegian bilateral conditions, as well as to learn more about what Norway is doing in areas of security in health and food (Regjeringen, 2020)

Through the years, the delegation has developed into one knowledge-intensive, specialized and network-oriented organization. The great number of special councils and subject areas has expanded sharply in the years with the EEA agreement. Many more people have been employed in the delegation's administration which means that the scope and relevance of European cooperation have become even bigger (NOU 2012:2). The EU delegation work is divided into many subject areas. Most relevant in the health area is the delegation for health, work and social policy. There are three delegates from Norway. One of the delegates is placed in the Council for health and food safety and works on Health co-operation in the EU, patient mobility, health professionals, e-health, medicines and medical equipment, public health - including infection control, drugs, nutrition and food safety. The second one is working under Council for health preparedness and crisis response focusing on EU cooperation on health preparedness and crisis response, purchasing cooperation and the Health Safety Committee. The area of responsibility of the last delegate is Labor Market Policy, free movement of workers, labor law, health / environment / safety in the workplace, social policy, coordination of social security rights, equality / non-discrimination in working life (Regjeringen, 2020).

Special Committees

Generally, the division of responsibilities between the ministries are arranged according to their subject area, and this also applies in the EEA matters. However, there were also established The Coordinating Committee for EEA Affairs and other Special committees which contribute to coordination between the ministries in matters that affect several ministries. Special committees play an important role in the ongoing design and coordination of Norwegian European policy (NOU 2012:2). Special committees issued a great number of

strategy documents, action plans, work programs, guidelines, etc. to strengthen the administration's EU / EEA work and to ensure that the administration contributes to early political priorities in European policy, strengthen coordination internally in Norway, improve implementation, ensure that the administration has sufficient competence, and ensure that the work on European policy takes place in openness and is designed in dialogue with affected parties (NOU 2012:2).

The most relevant in the health politics are Special committee on Health and Special committee on social security. EEA-relevant proposals that are being worked on in, or that have been put forward by the Commission or the Council, shall be assessed and followed up in the committees. The ministry of Health and care services is responsible for the health-related subjects and has ensure that all aspects concerning a case are covered (Regjeringen, 2020).

The European Consultative Committee

The European Consultative Committee is the body in Norwegian Parliament (Storting) responsible for consultations with the Government on European Union (EU) and European Economic Area (EEA) matters. The Committee principally considers EU legal acts (directives and regulations) that are to be dealt with in the EEA Committee (Stortinget, n.d.).

5.5. Summary

The chapter on Norway´s political and institutional adjustments in the context of European health policies and politics demonstrates how Norway has been gradually integrated into EU health regulation and governance. I referred to the tables in the Appendix 1 and Appendix 2, which cover literature review and institutionalization of health policies respectively. The purpose of the Appendix 1 was to show the literature gap, while the goal of the Appendix 2 was to show European health institutions and connections between them and Norwegian central administration. However, it is not an exhaustive list and there are many other EU bodies and structures in which Norway participates in the field of health.

The fact that Norwegian health policy was shaped by the EEA Agreement points to the relevance of path-dependency theory. Development of European health institutions and penetration of European laws into Norwegian national legislation can be explained by the spill-over effect revealed earlier in this paper.

This chapter confirms the conclusion from the literature review, that there is need for more studies on these processes. More studies must be encouraged both with regard to the causes behind the changes and the possible effects of the changes for the health sector, including institutional adjustments as well as changes in health policy areas such as pharmaceuticals, medical devices, patients´ rights in particular.

6. Chapter six: Discussion and conclusions

6.1. Introduction

In this chapter I aim to answer my research question, namely ***in what way has Norwegian health policy and health administration been affected by developments in the EU and what can explain Norwegian adaptation.*** The purpose of this chapter is to discuss the findings based on the analytical framework presented in the theory chapter. Based on the findings I will first discuss to what extent and how we see the process of Europeanization of Norwegian health policies. This part has two dimensions: one dimension is related to the development of European health institutions (health policy, law and administration) and the other dimension is whether European governance has penetrated into the Norwegian system of governance, including policy, law and administration. Further, I look at the Historical Institutionalism and the development of Norwegian health policies in the light of this theory. At the end I present the explanations of Europeanization of Norwegian health politics, more precisely the process of Norwegian adjustments to European health policies through path-dependency, spillover and critical juncture.

6.2. Europeanization of health policies

Olsen´s (2002) definitions of Europeanization are used in this analysis to assess Europeanization of Norwegian health politics and policies.

Europeanization understood as the development of EU health institutions

By institutions we mean both administration and legislation. Europeanization can be characterized as a historical process which developed common political administration and common legislation in aftermath of the establishment of the EU. Europeanization as a development of institutions of governance on the European level included also development of European institutions which covered health politics. “The EU institutions exercise a substantial and growing influence over the health services of member states” (Greer, 2006:135). It had implications on the designing of member states´ health politics and policy.

With the development of EU and increasing the number of areas covered by EU politics, there has been developed a complex administrative system with strong administrative capacities, which eventually mobilized more power. European commission is one of the key institutions on the line with European Parliament and European Court of Justice. European Commission is responsible for proposition, enforcement and implementation of EU policies. It is organized into policy departments (Directorate Generals) which support European Commission in development, implementation and management of the EU law and policies. DG Sante (DG Health) can be viewed as a ministry of health in the EU. DG Sante is one of the most important actors within health politics and health systems (Greer, 2019). One of the evidences of institutional change in health area is steadily increasing role of the European Commission and the European Court of Justice in the designing of health politics, where the first one prepares and implements legislation while the second one explains and clarifies this legislation in the context of European law. Also, the development of institutions is seen through the establishment of European Agencies such as EMCDDA, EMA, EFSA and ECDC. These agencies assist European Commission to perform specific tasks. For example, EMA plays the main role in the process of approval and authorization of medicines on the EU basis.

The common legislation in the EU was established exactly through the functioning of European administration because the more issues were proposed for discussion on the EU´s agenda the more solutions EU needed to come up with and the more legislation was developed based on these issues. Legislation developed gradually and regulated steadily more policy areas, which included also health area.

An institutional adaptation of Norway indicates adaptation within the framework of the EU development and EEA Agreement. According to the findings earlier in this paper, through the EEA Agreement Norway was granted the right to take part in working, expert groups and committees under the European Commission and European Agencies. Even though Norway does not exercise political power to take decisions, it takes part in preparation of legislation. A significant characteristic of this adaptation is that by signing EEA Agreement Norway is obliged to implement EU laws into national legislation without a possibility to change it either through the taking part in preparation stage or after the legislation was adopted on the EU level. The establishment of institutions played also a significant role in Norway´s adjustment to European health politics as we have seen that Norway developed numerous connections to

the agencies and is often bidden by the decisions taken by European Commission and European Court of Justice.

Europeanization understood as the central penetration of European developments in the Norwegian systems of health governance

Europeanization as a central penetration implies the change of national (systems of governance (central administration, politics, legislation, decision-making process) as an act of adjustment to the development of European institutions. It has been found that Norway has adjusted itself to European politics and policies by taking over European legislation and incorporating it into national legislation as well as by implementing EU-issues in the daily work of central administration. Even though there any special directorate or institution has not been created in Norway which can illustrate the penetration of EU institutions on the national level, there have been established special units within the national administration which work with EU-Norway politics. There were also created Norway´s delegation to the EU and special committees which indicates that EU politics has taken a significant part of Norwegian politics and is no longer viewed as a separated area of the international politics but rather is sought to be incorporated in the ordinary political processes on daily basis.

Two main characteristics of central penetration in Norway is that through the EEA Agreement Norway has become Europeanized on equal terms with the EU member states, and that there the political decision-making process has been changed in Norway. It had implications for the domestic health policies considering that Norway had to implement EU legislation which covered health in the same way as other European states, like, for example, policies on pharmaceuticals and medical devices guaranteeing the same European quality, safety and standard. At the same time decisions made in the health policy area, especially decisions concerning the introduction of new legislations or regulations, were no longer made on the national level and no longer taken by national authorities. Norway has been linked to the EU´s decision making process i.e., by taking part in the earliest stages of the process, however, EU has increased its role as a supplier of premises for Norwegian health policies. Thus, the governance of health in Norway has to some extent changed its form, at least in the areas where EU has expanded influence and authority.

6.3 A historical institutionalist account of the Europeanization of health policies

Historical Institutionalism underlines the role of institutions in the development of European politics highlighting the long-term perspective. According to Historical Institutionalism the growing involvement of institutions had a significant impact on the process of treaty reform, thus the increasing power of European institutions had ability to develop health politics in the context of European Union, locking member states into initiatives that they otherwise would not choose (Christiansen, 2020). It creates so-called gaps according to the "reality and expectations" of the states. These gaps have been caused by a path-dependency and spillover effects.

6.3.1. Path-dependency, spill-over effects and unintended consequences

Path-dependency means that what happened earlier in politics will affect the possible outcomes of the events later (Pierson, 2000). This implies that decisions at one point lay down guidelines for decisions later. These decisions enable some options, while making other options impossible or difficult to achieve. The notion of path-dependency illustrates also, that the development is often not straightforward but shaped by historical events (NOU 2012:2).

In the case of Norway-EU cooperation it means that when Norway has chosen to sign the EEA Agreement it automatically has chosen to follow the trajectory of European politics. There has been seen a parallel development of EU and Europeanization of Norway through EEA Agreement. It happened because the objective of EEA Agreement was to make it possible for Norway to participate in the EU marked. By signing the EEA Agreement Norway had to implement EU laws and with the evolution of EU politics and legislation Norway was automatically influenced by it through the Agreement. It is called path-dependency because Norway couldn't follow completely different way than the EU. With the greater degree of Norway´s involvement and Europeanization it has become much more expensive to choose something away, for example if Norway would decide not to implement some laws. Norway is woven into this form of affiliation and there are both costs and uncertainties related to changing it. In literature it was described as once as one has started down a particular track, the costs of reversal are very high, and deep involvement make it difficult to reverse and

return to the start point and every step forward makes it harder to go back and change (Greer, 2008:18). Norway´s relations with the EU have been reactive in all years. It means that when the EU developed cooperation in new areas Norway followed most often after (NOU 2012:2).

The EU governance has been a subject to considerable evolution (Bulmer, 1998). The political dynamics of transition from the Single Act to the Maastricht Treaty and the Amsterdam Treaty is associated with development of European governance, institutions and transition to European Union. Later judicial integration into EU political processes influenced the development of European health politics and increased the role of European Court of Justice in the health area. Judgments of the ECJ in the late 1990s are examples of what the Member States seemed to experience as the "gaps in member-state control". For instance, Kohll & Decker case described in the findings chapter, had consequences for patients' rights to get treatment across the borders, which eventually led to the drafting of the Patient Rights Directive (2011). Norway's adaptation in this case was through the implementation of the Patient Rights Directive. The Patient Rights Directive was based on the idea of free movement rather than health considerations. At the time when the Directive was about to be implemented Norwegian law and practices were already adapted to the developments in the EU/EEA and the implementation itself didn't cause extraordinary changes in the area. Therefore, if Norway had decided not to implement the directive there would be more costs than benefits. However, the Directive was to some extent modified on a national level and there was bigger room for national adaptation. In addition, Norway itself has chosen to go further than was required by the Directive. For example, Norway removed the requirement of the prior approval of treatment places and therapists in other EU countries in order to cover the costs of treatment.

According to the Pierson (2000) spill-over effect means that policies adopted in one area can cause changes in other policy areas, initially not intending to provoke them. Spillover effect in the analysis of health policies indicates that objectives related to the internal market and four freedoms have become important for the later development of health policy. Norway as a member in the EEA had to adjust not only to the legislation which regulated four freedoms, but also later legislations developed based on the initial one. The findings chapter revealed the relevance of four freedoms for health.

There is a clear process of spill-over in the development of relations between four freedoms and legislation which covered health policy areas. The free movement of goods resulted in legislation which covered health-related products and these products have become a major part of the internal market (Greer, 2019). In this way the free movement of goods led to harmonizing requirement for medicinal product, rules for licensing, regulations for medical devices etc. As we have seen in the previous chapters, Norway had to adapt to these legislations by implementing it into national law as for example laws on medicines and medical devices. One of the objectives of free movement of goods was to contribute to competition and we have seen earlier that Norway had to adapt to it by dissolving national pharmaceutical monopoly.

Free movement of persons and services had implications also for the health care sector. The objective of the free mobility of people resulted in the movement and regulation of healthcare workforce in Europe, movement of patients and other workforce which preserved their rights to health care and social benefits under the social security law. In the context of persons´ movement Norway had to incorporate European social security legislation into its national law and facilitate possibility of free movement of patients.

In 1980-90s the main objective of the EU was realization of the internal market. The aim was to remove the restrictions of four freedoms. Since member states had different health related rules and standards for products and services which imposed a barrier for the free movement, EU started to develop common health rules (concerning product standards, medicines, medical equipment), and rules related to the free movement of persons and services (Social security coordination, mutual approval of qualification, patient rights). Thus, there was a spill-over from the internal market to the health area. This spill-over effect was not intended, but Norway was affected because it became a part of EEA. Norway was thus affected by these spill-over effects which contributed to its further Europeanization.

The implementation of the Social Security Coordination was another example of Norway seeming to have lost control, especially when Norway had to adapt in the area of Social Security Coordination. The NAV (The Norwegian Labor and Welfare Administration) scandal is a vivid example of Norway experiencing “control gap” caused by wrong interpretation of European law by Norwegian authorities. It is a case, which can be explained by both path-dependency and spill-over effects.

NAV has over time misinterpreted Article 21 of Regulation (EC) 883/2004 of the European Parliament and of the Council (the Insurance Regulation) (NOU:2020). This Regulation entered into force for Norway on 1 June 2012 and laid the basis for the free movement of persons and capital across the borders, but according to the National Insurance Act, short-term benefits (sickness benefits, care allowance and work clearance allowance) cannot normally be paid to persons residing outside Norway. However, it follows from the provisions of the EEA Agreement and the Regulation of EC, that payments of such cash benefits cannot be stopped on the sole ground that the recipient lives or resides in an EEA country other than the country that pays the benefit (NOU:2020). As a result of NAV's understanding of the Social Security Ordinance, a significant number of people have received unlawful repayment claims, and some have been convicted of social security fraud because they have not informed about staying abroad and NAV viewed it as that NAV has been provided an incorrect information. It was determined to change its practice for the payment of benefits for short-term stays abroad within the EEA area. The change was that benefits could no longer be stopped or rejected (NOU:2020).

6.3.2 Critical juncture

We have seen in the theory part that critical juncture characterizes the times of crises, instability and when countries have many options to deal with problems. It was also noted that EU has acquired more power in the times of crises through mobilizing forces for common European problem solution. Mad cow crisis and Covid-19 crisis are examples of crises which had impact on the development of European health policies. They had also a significant impact on the Norway´s adjustment to European policies. There has been a closer co-operation between Norway and the EU during the crises. This cooperation was primarily aimed at the crisis management but later resulted in more long-term co-operation and the introduction of political processes that were preserved even after the crisis was over.

Many studies have shown that crisis situations increase the likelihood of political reforms (Olsen, 1989). The Mad cow (BSE) crisis caused changes in the division of responsibilities between the various institutions (European commission's expansion of competences), contributed to the creation of new bodies (DG Sante) and changed existing practices and the way things were organized in European politics (Veggeland, 2000). Thus, the Mad cow crisis

has helped to politicize food policy throughout the Europe. Food policy was moved from the agricultural arena becoming a health policy matter. In addition, the European Parliament and the Commission have been given increased competence and capacity for decisions in the field of health. BSE crisis contributed to the development of food safety policies which aimed at the preserving public health through setting requirements and standards for the food products. Moreover, BSE was followed by the establishment of health-related agencies and not least DG Sanco (now: DG Sante). The crisis created more room for acting for the EU institutions and made in possible to take such initiatives which caused significant changes. Later we have seen how Norway adjusted by harmonizing its food policies and took part in developing of EU food legislation though participation in expert and working groups in the EU.

COVID-19 crisis has proven that in the times of crises EU has possibility to extend its areas of influence. It can be seen through the response of European Union to COVID-19. There are at least 10 areas of policies affected by the Commission's response including public health, travel, research and innovation, transportation, jobs and economy etc. (European Comission, n.d.). It shows that crisis paves the way for political change not only in the health area, but also in other areas of social and political life. There were created new platforms for cooperation like Global Health Summit and based on the lessons of Coronavirus there were launched the negotiations concerning establishment of European Health Union (European Comission, n.d.). COVID-19 crisis showed again that Norway don't stay outside European handling of the crisis and have chosen to take part in the mutual handling of the crises. It was a national choice because Norway´s contribution happens on the voluntary basis. Thus, Norway has taken part not only in the development and distribution of vaccines, but also Norwegian experts did the research on the disease and vaccines (Regjeringen, 2021). Now we see that Norway is going to introduce a vaccine passport in order to become a part of European public health campaign. It can be supposed that Norway will be one of the pioneers on the work with establishment of the European Health Union based on the Norway´s previous interests in health cooperation.

6.4. Summary and conclusions

The main objective of this chapter was to show in ***what way Norwegian health policy and health administration has been affected by developments in the EU and what can explain Norwegian adaptation.*** Thus, this chapter reveals the path of Europeanization of Norwegian

health policy. It was demonstrated that Europeanization can be seen both in terms of development of health institutions, including policy, law and health administration, at the EU-level, and in terms of Norway´s institutional adjustments and penetration of EU developments into Norway´s systems of health governance. The chapter showed that there was a significant implication of EU´s institutional development and Norway´s adaptation to these institutions for the reduction of Norway´s state control over its own health policies. Path-dependency reveals the significance of Norway´s decision to become a part of the EEA and its influence on the further political trajectory of Norway. Spill-over effect reveals the significance of four freedoms for the development of health policies and indicates the development of health policies defined as unintended consequences. At the end, critical juncture has shown the role of crises in the development of health policies and establishment of its new dimensions.

To sum up we can look again at the Article 168, which says that *the Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organization and delivery of health services and medical care*. This study demonstrated that with the development of European Union there has been smaller room for national action. It included also reduction of state control over the health sector. It was caused by the development of new EU legislation which covered steadily more common policy areas which in turn has limited the possibilities of countries to choose their own political course. If we look at the conditions of the EEA Agreement which Norway has signed in 1992, we can see how little health policy was covered by it at that time (see background chapter). There has been a strong development of European politics which proliferated through different policy areas and different levels of governance. Norway has taken its first step towards Europeanization of national health policies when it signed the EEA Agreement. Europeanization of Norwegian health politics can be explained through the path-dependency, penetration and critical juncture approach. Moreover, the paper shows that Norway decided to deepen its cooperation with the EU in some of the policy areas, even though it was not the requirement of the EU or the EEA Agreement. As noted above, Norway took voluntary initiative when the Patient Rights Directive was implemented and when the cooperation in the wake of COVID-19 crisis was established. Even the latter was not something that followed directly from the EEA Agreement, it still was natural to cooperate on because of the previous common policies on medicines.

Even though it can be proved that Norwegian health politics was Europeanized through the EEA Agreement very little research in this area is still done. One of the limitations of this paper is that not so many studies on Europeanization of Norwegian health policies which could be a good ground for the discussion and checking up the facts have been done so far. At the same time, it was not possible to find a sufficient number of informants in order to draw conclusions based on their information and claims. However, information provided by them was enough to prove that the suggestions about Europeanization of Norwegian health policies presented above were valid. The main objective reached by the paper is showing the difference between how Norwegian health politics was influenced by the EU at the time when the EEA Agreement was signed and how it has become Europeanized in the years that followed. However, further research in the area should be strongly encouraged especially in the wake of current developments caused by the COVID-19 where the need for cooperation and common approaches towards health governance has been raised.

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Appendix 1

Table 1 – Health policy literature review where Norway has been studied along with other European countries. These surveys don't cover Norway as a primary objective of the study. The literature review is organized according to the health policy areas.

(a) Pharmaceuticals:

Name of the work	Authors, year	Type of publication	The main topic
Impact of changes in the methodology of external price referencing on medicine prices: discrete-event simulation.	Vogler, Sabine, Peter Schneider, and Lena Lepuschütz (2020)	*Cost effectiveness and resource allocation*, Article	The study of the policy of external price referencing (EPR) and its impact on medicine prices. The survey conducted in all European countries where the EPR is applied. Norway is included but is not a primary subject of the study.
Liberalization and integration of drug distribution in the EU 28 and Norway	Písek, J., & Pícha, K. (2018)	*Ceska a Slovenska farmacie: casopis Ceske farmaceuticke spolecnosti a Slovenske farmaceuticke spolecnosti*, Article	The paper describes systems of pharmaceutical distribution and their specifics in individual EU countries and Norway.
Overview of external reference pricing systems in Europe	Rémuzat, C., Urbinati, D., Mzoughi, O., El Hammi, E., Belgaied, W., & Toumi, M. (2015).	*Journal of market access & health policy,* Article	The study aimed to provide an overview of ERP systems, both on processes and potential issues in 31 European countries. Norway included.
Policy interventions related to medicines: Survey of measures taken in European countries during 2010-2015.	Vogler, S., Zimmermann, N., & de Joncheere, K. (2016).	*Health Policy,* Article	This study aimed to survey pharmaceutical policies that were implemented in European countries between 2010 and 2015. Norway included along with other 31 European countries.
Tendering for outpatient prescription pharmaceuticals: What can be learned from current practices in Europe?	Dylst, P., Vulto, A., & Simoens, S. (2011).	*Health policy,* Article	To explore the current status (2010) of tendering programs for outpatient pharmaceuticals in the European countries and how these programs operate.

(b) Disease control & prevention

Targets for the reduction of antibiotic use in humans in the Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) partner countries	D'Atri, F., Arthur, J., Blix, H. S., Hicks, L. A., Plachouras, D., & Monnet, D. L. (2019).	*Eurosurveillance,* Article	Study of measures to limit the overuse and misuse of antibiotics. Norway responded to questionnaire which was sent by European Centre for Disease Prevention and Control.
Presence, characteristics and equity of access to breast cancer screening programmes in 27 European countries in 2010 and 2014. Results from an international survey	Deandrea, S., Molina-Barceló, A., Uluturk, A., Moreno, J., Neamtiu, L., Peiró-Pérez, R., ... & Salas, D. (2016).	*Preventive Medicine,* Article	Evaluating rganised, population-based breast cancer screening programmes within European countries, plus Norway.
National Advisory Groups and their role in immunization policy-making processes in European countries.	Nohynek, H., Wichmann, O., D'Ancona, F., & Gatekeepers, V. N. (2013).	*Clinical Microbiology and Infection,* Article	The role of National Immunization Technical Advisory Groups (NITAGs) in the decision-making and recommending processes. Norway is a part of the study.
National policies for preventing antimicrobial resistance - the situation in 17 European countries in late 2000.	Therre, H. (2001).	*Eurosurveillance,* Article	A survey carried out within Member States of the European Union and Norway studies national surveillance of microorganisms resistant to antibiotics.
Towards a cancer mission in Horizon Europe: recommendations.	Berns, A., Ringborg, U., Celis, J. E., Heitor, M., Aaronson, N. K., Abou-Zeid, N., ... & Voest, E. (2020).	*Molecular Oncology,* Article	The study argues that meeting cancer research targets will require harmonization of EU and national priorities and policies, improved research coordination at the national, regional and EU level and increasingly efficient and flexible funding mechanisms.

(c) Vaccination

Immunisation of healthcare workers in the Nordic countries: Variation in	Dub, T., Søborg, B., Andersen, P. H., Gudnason, T., Nøkleby,	*Eurosurveillance,* Article	The sudy assesses current policy for immunisation of healthcare workers and

recommendations and practices and a lack of assessment.	H., Lindstrand, A., ... & Nohynek, H. (2021).		the availability of vaccine coverage data. Includes information on if and how Nordic countries (Norway included) implemented European directives aimed at the reduction of employees' potential exposure to infectious diseases and offering immunisation free of charge.
European survey of hepatitis B vaccination policies for healthcare workers: an updated overview.	De Schryver, A., Lambaerts, T., Lammertyn, N., François, G., Bulterys, S., & Godderis, L. (2020).	*Vaccine,* Article	Electronic survey on HBV prevention in healthcare workers in the European Union (included Norway). Survey conducted after EU Council Directive (2010/32/EU) on sharps injuries was adopted.
Mandatory and recommended vaccination in the EU, Iceland and Norway: results of the VENICE 2010 survey on the ways of implementing national vaccination programmes.	Haverkate, M., D'Ancona, F., Giambi, C., Johansen, K., Lopalco, P. L., Cozza, V., & Appelgren, E. (2012).	*Eurosurveillance,* Article	**The Vaccine European New Integrated Collaboration Effort (VENICE) network, conducted a survey among the VENICE project gatekeepers to learn more about how national vaccination programmes are implemented, whether recommended or mandatory.**
National Differences in Requirements for Ethical and Competent Authority Approval for a Multinational Vaccine Trial under the EU Directive 2001/20/EC.	Van Doorn, E., Hak, E., & Wilffert, B. (2015).	*Vaccines,* Article	Obtaining approval for a multinational vaccine trial from an ethics committee and the national competent authority of different Member States of the European Union (EU) is challenging under clinical trial Directive 2001/20/EC because of the differences in the implementation of the directive in national laws of Member States. This study illustrates differences in requirements for ethical and competent authority approval. Norway is one of 5 European countries included in the survey.

Influenza A(H1N1)pdm09 vaccination policies and coverage in Europe.	Mereckiene, J., Cotter, S., Weber, J. T., Nicoll, A., D'Ancona, F., Lopalco, P. L., ... & O'flanagan, D. (2012).	*Eurosurveillance,* Article	The Vaccine European New Integrated Collaboration Effort (VENICE) project conducted a survey to collect information on influenza A (H1N1) pdm09 vaccination policies and vaccination coverage in the European Union (EU), Norway and Iceland.
Vaccination policies for health-care workers in acute health-care facilities in Europe.	Maltezou, H. C., Wicker, S., Borg, M., Heininger, U., Puro, V., Theodoridou, M., & Poland, G. A. (2011).	*Vaccine,* Article	The aim of this study was to evaluate existing policies regarding recommended and mandatory occupational vaccinations for health-care workers (HCWs) in Europe.
Hepatitis B immunisation programmes in European Union, Norway and Iceland: Where we were in 2009?	Mereckiene, J., Cotter, S., Lopalco, P., D'Ancona, F., Levy-Bruhl, D., Giambi, C., ... & O'Flanagan, D. (2010).	*Vaccine,* Article	European Union (EU) Member States (MSs), Norway and Iceland, participated in a survey seeking information on national hepatitis B vaccination programmes. Details of vaccination policy, schedule, population groups targeted for vaccination, programme funding, vaccine coverage and methods of monitoring of vaccine coverage were obtained.

(d) Others:

E-Health Adoption Gaps in the Decision-Making Process.	Lobont, O. R., Vatavu, S., OLARIU, D. B., Pelin, A., & Codruta, C. H. I. S. (2019).	*Revista de Cercetare si Interventie Sociala*, Article	Statistical analysis of the complex decision-making process related to the adoption of eHealth. Norway is included but is not the main subject of the study.
Access Governance for Biobanks: The Case of the BioSHaRE-EU Cohorts	Kaye, J., Briceño Moraia, L., Mitchell, C., Bell, J., Bovenberg, J. A., Tassé, A. M., & Knoppers, B. M. (2016).	*Biopreservation and biobanking,* Article	This article analyzes the access governance arrangements of the original five biobank members of the Biobank Standardisation and Harmonisation for

			Research Excellence in the European Union (BioSHaRE-EU) project in 5 countries, Norway included. Findings suggest potential areas for harmonization across biobanks.

Table 2 – Literature review of Norwegian health policies

(a) Pharmaceuticals

Whatever happened to the Norwegian Medical Need Clause? Lessons for current debates in EU pharmaceutical regulation.	Brooks, E., & Geyer, R. (2016).	Sociology of health & illness, Article	Norway was forced to abandon its Medical Need Clause (MNC) when it joined the European Economic Area. his article reviews Norway's experience with its MNC in light of contemporary debates in European health policy.
The impact of European harmonization on Norwegian drug policy.	Norris, P. (1998).	Health Policy, Article	This paper describes the previous arrangements and the impact of European harmonisation on them.

(b) Cross-border healthcare

The implementation of European Union (EU) rules on cross-border care: moving towards convergence?	Nordeng, Z., & Veggeland, F. (2020).	Health Economics, Policy and Law, Article	Article studies the implementation of the European Union (EU)'s Patients' Rights Directive in Germany and Norway.
"Then I went to a hospital abroad": acknowledging implications of stakeholders' differing risk understandings related to use of complementary and alternative medicine in European health care contexts.	Salamonsen, A., & Wiesener, S. (2019).	BMC complementary and alternative medicine, Article	The aim of this article is to explore and discuss the existence and possible consequences of differing risk understandings among stakeholders maneuvering in the complex landscape of Complementary and alternative medicine (CAM) practice and CAM regulation contextualized by European public healthcare systems.

(c) Infection control

Mapping of control measures to prevent secondary transmission of STEC infections in Europe during 2016 and revision of the national guidelines in Norway.	Veneti, L., Lange, H., Brandal, L., Danis, K., & Vold, L. (2019).	Epidemiology & Infection, Article	The article reviewed preventive control measures for secondary transmission of Shiga-toxin producing Escherichia coli (STEC) in humans in European Union (EU)/European Free Trade Association (EEA) countries to inform the revision of the respective Norwegian guidelines
Legal aspects of prevention in Norway.	Tellnes, G., & Andresen, E. T. (2006).	Journal of public health policy Article	This paper addresses three questions: What relevant legislation on prevention currently exists? What are the perspectives of ongoing activities and their intentions? What are the strategic issues?

Appendix 2

Table 1 – European intuitions in which Norway participates, which in turn has a significant effect on the formation of Norwegian health policies

European Commission

The European Commission is the executive of the European Union. The Commission is steered by a group of 27 Commissioners, they take decisions on the Commission's political and strategic direction. The Commission is accountable before the European Parliament. President and vice-president steer and coordinate work across the Commission. The Commission is organized into policy departments, known as Directorates General (DG). DGs are responsible for drafting bills and following up their enforcement and implementation (European Commission , n.d.-a).

DG Sante

The mission of this Directorate General is to protect the citizens' **health** and monitor food safety. It also monitors implementation of the related laws (European Commission , n.d.-b).

EU complements policies of national governments in the areas of antimicrobial resistance; vaccination; blood, tissues and organs; health workforce; cancer; rare diseases; tobacco; nutrition and physical activity; medicinal products for human use; medical devices; cross-border healthcare; digital health; communicable diseases; non-communicable diseases; alcohol; mental health; health data; heath research etc (European Commission, n.d.-c). The European Commission needs specialist advice from outside experts as a basis for policymaking (NOU 2012:2, s. 170). The experts work in committees and expert groups who assist DGs in preparing and implementation of laws (NOU 2012:2, s. 171).

Norway has several national experts working in the European Commission on health issues. There are experts, who are called seconded national experts (SNE). The SNEs are hired out by Norwegian government to European commission for some period of time and they have the same tasks as the Commission´s permanent employees. Norwegian government has no instructional authority over SNEs (NOU 2012:2, ss. 170-177). There are also national experts which represent Norway in the Commissions committees and working groups. They are subordinated national departments or directorates (European Commission , n.d.-o). There are also pure technical and scientific committees which participate on the basis of their professional competence, independently of political guidelines (NOU 2012:2, ss. 170-177).

Because Norway has signed EEA Agreement, Norwegian EFTA experts can participate in DG Sante on the issues related to Digital Health, European Reference Networks, Animal Health and Welfare (EFTA, n.d.).

Committees under DG Sante

Variety of the committees indicates the scope of EU cooperation in the health sector.

Scientific Committees
When preparing policy and proposals related to consumer safety, health and the environment, the Commission relies on independent Scientific Committees to provide it with sound scientific advice and draw its attention to new and emerging problems (European Commission, n.d.-d).

Scientific Committee on the Consumer Safety (SCCS)	Scientific Committee on Health, environmental and emerging risks (SCHEER)

SCCS´s working groups: - Working group on cosmetic ingredients - Working group on nanomaterials in cosmetic products - Working group on methodology ((European Commission , n.d.-e)	SCHEER´s working groups (most relevant for health): - Working group on breast implants - Working group on electronic cigarettes - Working group on Tobacco additives - Working group on Weight of evidence (European Commission, n.d.-f)

Other committees. Among them programme committees which assist Commission in the Management and Development of EU Programmes, as well as standing committees which inform the Commission on the planned measures (NOU 2012:2, s. 171).

The EU4 Health Programme Committee	Works on establishin a new and reinforced programme for Union action in the field of health, called the 'EU4Health Programme' (the 'Programme'), for the period 2021-2027. The Programme should emphasise actions in relation to which there are advantages and efficiency gains from collaboration and cooperation at Union level, and actions that have an impact on the internal market. (Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a EU4Health Programme for the period 2021-2027). (European Commission, n.d.-g)
Standing Committee on Plants, Animals, Food and Feed	This committee delivers opinions to the Commission on the drafted measures which the Commission plans to adopt. Management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material. Laying down procedures in matters of food safety (European Commission , n.d.-h)
Committee on Medical Devices	Works with the Union´s regulatory framework for medical devices in order to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation, which in its turn can ensure the smooth functioning of the internal market as regards medical devices (Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices) (European Commission, n.d.-i).
Committee of the third Programme of Community action in the field of health (2014-2020)	The main objective of the committee is promotion of good health at Union level is also an integral part of 'Europe 2020: A strategy for smart, sustainable and inclusive growth' ("the Europe 2020 Strategy") (European Commission, n.d.-j).
Tobacco Products Committee & Tobacco Products Regulatory Committee	Work on the legislation on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products (European Commission, n.d.-k).
Standing Committee on medicinal products for human use	Work with Community´s procedures for the authorisation and supervision of medicinal products for human (European Commission, n.d.-l).

Committee on the approximation of the laws of the Member States relating to medical devices	Working on measures for the smooth operation of the internal market related to medical devices (European Commission, n.d.-m).
Committee on serious cross-border threats to health	Assists Union´s action in order to complement national policies to cover monitoring, early warning of, and combating serious cross-border threats to health (European Commission , n.d.-n).

Expert groups and other similar entities:

Comission´s advisory panel on Covid-19; EU4Health Steering group; European Alcohol and Health Forum; European workforce for health expert group; Expert group on clinical trials; Expert group on food hygiene and control of food of animal origin; Expert Group on General Food Law and Sustainability of Food Systems; Expert Group on Health Information; Expert Group on Safe and Timely Access to Medicines for Patients; Expert Panel on effective ways of investing in health; Group of experts on tobacco policy; Health Security Committee; Health systems performance assessment; Medical Device Coordination Group; Pharmaceutical Committee; Scientific Committee for Health, Environmental and Emerging Risks; The Cross-border Healthcare Expert Group; Working Group on European Databank on Medical Devices (European Commission, n.d.-p).

European Commission and its agencies

The European Commission delegates the implementation of certain programmes to executive agencies (European Commission, 2020). Agencies´ mandate is placed within networking and information exchange, monitoring based on diverse data sets, non-binding guidance and risk assessments, early warning and response mechanism, cooperation with Member States´experts (NOU 2012:2, ss. 175-177).

EMA - European Medicines Agency

The mission of the EMA is to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health in the European Union (EU). National authorities – provide experts – these take part in EMA´s scientific committees, working parties and other groups (European Medicines Agency, n.d.-a).

EMAs committees

Committee for Medical Products for Human use (CHMP): responsible for authorization of medicines in EU; evaluates medicines authorized at national level referred to EMA for a harmonized position across the EU (European Medicines Agency , n.d.-b).

Working parties and other groups at CHMP. Standing working parties: Healthcare Professionals Working Party; Biologist working party; Patients´working party; Quality working party; Safety working party; Scientific advice working party. There are also temporary working parties, drafting groups, scientific advisory groups and other CHMP-associated groups (European Medicines Agency , n.d.-c).

Pharmacovigilance Risk Assessment Committee (PRAC) Responsible for assessing and monitoring the safety of human medicines. Assessing all aspects of risk management of human medicines. Provides recommendations on questions on pharmacovigilance and risk management systems, including the monitoring of their effectiveness (European Medicines Agency, n.d.-d).

Committee for Advanced Therapies (CAT) Responsible for assessing the quality, safety and efficacy of advanced therapy medicinal products (ATMPs) and following scientific developments in the field (European Medicines Agency, n.d.-e).

Working parties and groups. Associted groups: European Medicines Agency / CAT and Medical Devices' Notified Body Collaboration Group; Drafting groups – experts; Scientific advisory groups – on oncology (European Medicines Agency , n.d.-f).

Committee for Orphan Medicinal Products (COMP) Responsible for recommending orphan designation of medicines for rare diseases (European Medicines Agency, n.d.-g).

Working groups at COMP: patients and consumers working party; scientific advisory group (European Medicines Agency, n.d.-h).

Paediatric Committee (PDCO) Responsible for activities on medicines for children and to support the development of such medicines in the European Union by providing scientific expertise and defining paediatric needs (European Medicines Agency, n.d.-i)**.**

The current PDCO working groups are Formulation Working Group; Non-clinical working group; modelling and simulation working group (European Medicines Agency , n.d.-j).

EFSA – European Food Safety Authority

EFSA is a European agency funded by the European Union that operates independently of the European legislative and executive institutions (Commission, Council, Parliament) and EU Member States (European Food Safety Authority, n.d.).

Scientific committee: The Scientific Committee develops harmonised risk assessment methodologies on scientific matters of a horizontal nature in the fields within EFSA's remit where EU-wide approaches are not already defined. It provides general co-ordination to ensure consistency in the scientific opinions prepared by EFSA's Scientific Panels. It also provides strategic scientific advice to EFSA's management (European Food Safety Authority, n.d.).

Networks: Emerging Risks Exchange Network; Risk assessment of nanotechnologies in food and feed (European Food Safety Authority, n.d.).

Working groups: Chemical mixtures; Copper; Emerging Chemical Risks etc (European Food Safety Authority, n.d.).

EMCDDA – European monitoring center for drugs and drug addiction

The EMCDDA was set up to provide 'factual, objective, reliable and comparable information concerning drugs, drug addiction and their consequences (European Monitoring Centre for Drugs and Drug Addiction , n.d.-a).

Units:

- Scientific coordination – scientific committee
- Public health unit
- Risks to public safety and security unit
- Communication
- Reitox and external partners unit (RTX)
- Communication unit
- ICT (European Monitoring Centre for Drugs and Drug Addiction, n.d.-b)

ECDC - European Centre for Disease Prevention and Control

ECDC is an EU agency aimed at strengthening Europe's defences against infectious diseases. The core functions cover a wide spectrum of activities: surveillance, epidemic intelligence, response, scientific advice, microbiology, preparedness, public health training, international relations, health communication, and the scientific journal *Eurosurveillance* (European Centre for Disease Prevention and Control, n.d.-a).

UNITS:

- Digital transformation services
- Scientific methods and standards
- Public health functions
- Resource management services
- Disease programmes (European Centre for Disease Prevention and Control, n.d.-b)

Table 2: Institutional adjustments to European health policies in Norway

EU Delegation to Norway	The Delegation of the European Union (EU) in Oslo is one of around 140 diplomatic representations of the EU around the world. The Delegation in Oslo was founded in 1987 as the Delegation of the European Commission and was for many years responsible for the official relations between the EU and Norway and the EU and Iceland. The Delegation maintains regular contacts with Norwegian authorities and with all important players in Norwegian society. It prepares analyses and reports on developments in Norway. Another important task of the Delegation is to provide information about EU institutions and policies to both the government and the wider public (Regjeringen, 2020). EU Commissioner for Health and Food Safety to strengthen Norwegian bilateral conditions, as well as learn more about what Norway is doing in months of security in health and food (Regjeringen , 2018).
Special committees (government) **The most relevant here:** Special committee on Health Special committee on social security	The special committees shall contribute to coordination between the ministries in matters that affect several ministries. EEA-relevant proposals that are being worked on in, or that have been put forward by the Commission or the Council, shall be assessed and followed up in the committees. The special committees meet as often as necessary to be able to consider promoting Norwegian positions on proposals that are under preparation, or have been submitted in the EU, and on adopted legal acts. The ministry responsible for the subject shall, with the help of the special committees, ensure that all aspects concerning a case are covered (NOU 2012:2, s. 150).
Stortinget (Parliament) The Delegation for Relations with the European Parliament	The delegation meets the corresponding delegation from the European Parliament to debate and discuss issues of current interest relating to European politics and parliamentary cooperation between the Storting and the European Parliament (Stortinget, n.d.-a).
The European Consultative Committee	The European Consultative Committee is the Storting body responsible for consultations with the Government on European Union (EU) and European Economic Area (EEA) matters (Stortinget, n.d.-b).

European Reference Networks European Reference Networks (ERNs) are virtual networks involving healthcare providers across Europe. They aim of ERN is to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. There are 24 ERNs. The first one was launched in 2017. Ministry of health and care services takes part on behalf of Norway. Norwegian members in these networks are Bergen Hospital Trust and Oslo University Hospital (European Commission, n.d.-r).