

**Equal Access to Pharmaceutical Care: A Comparative Study of Legislation
Concerning Medicinal Products and Pharmacies in Finland and Norway**

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Apteekkilainsäädäntö on osa terveysoikeutta. Valtion intressinä on säädellä apteekialaa lääketurvallisuuden, lääkkeiden kohtuullisten hintojen ja kansalaisten yhdenvertaisten apteekkipalvelujen takaamiseksi. Tämä tutkimus vertailee Suomen ja Norjan apteekkijärjestelmiä, niiden kehitystä ja kummankin maan apteekkijärjestelmän taustalla vaikuttavia keskeisiä tavoitteita ja oikeusperiaatteita. Tutkimuksen vertailu on luonteeltaan funktionaalista ja se keskittyy oikeusjärjestelmien mikrotasoon.

Maiden järjestelmät ja lainsäätäjän tavoitteet ja niiden kehitys ovat samanlaiset. Kummassakin maassa apteekkitoiminta on luvanvaraista, lääkekuluja korvataan sosiaalivakuutuksella ja niissä on käytössä hintasääntely, geneerinen substituuatio sekä viitehintajärjestelmä. Pääasialliset erot liittyvät apteekkien omistamiseen, apteekkimaksuun ja käsikauppatuotteiden myyntiin apteekkien ulkopuolella.

Oikeusperiaatteita kuten ihmisarvon loukkaamattomuutta, oikeutta terveyteen, potilaan itsemääräämisoikeutta ja yhdenvertaisuutta sovelletaan myös lääkehuollon puitteissa. Nämä periaatteet näkyvät myös perusteluissa, jotka lainsäätäjä on esittänyt alaa koskevien säädösten valmistelumateriaaleissa. Resurssien niukkuuden takia hyvinvointivaltion lainsäätäjän on vähennettävä kuluja. Oikeusjärjestelmän syvemmillä kerroksilla toimivat terveysoikeuden periaatteet sekä perusoikeudet vaikuttavat lainsäätäjän terveydenhuollon säästätoimenpiteitä koskevien arvostelmien sisältöön. Julkinen keskustelu terveydenhuollon ammattilaisten, lakimieskunnan ja etujärjestöjen välillä on välttämätöntä näiden arvostelmien oikeudenmukaisuuden varmistamiseksi.

ABSTRACT

University of Lapland, Faculty of Law

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Abstract:

Pharmacy law is part of health law. The state has an interest in regulating the sector in order to ensure drug safety, equal access to pharmaceutical care and affordable drugs. This research compares the pharmacy systems in Finland and Norway, their development, and the central aims and legal principles behind the choice of pharmacy system in each country. Comparison under this research is functionalist in nature and focuses on the micro-level of the two legal systems.

The Finnish and Norwegian systems and the aims of the legislator have developed in a similar manner. In both countries pharmacy business is subject to license, pharmaceutical prices are controlled, drug costs are covered by a social insurance scheme and generic substitution and reference pricing are applied. The main differences relate to pharmacy ownership, the pharmacy fee and sale of over-the-counter drugs outside of pharmacies.

Principles such as human dignity, right to health, the patient's right to self-determination and equal treatment apply in pharmaceutical care. Legal principles are evident in the legislator's reasoning in preparatory materials for pharmacy law. Due to scarce resources the welfare state's legislator needs to reduce costs. The requirements of fundamental rights and principles of health law, working on a deeper level of the legal system, impact the substance of the legislator's valuations regarding savings in the healthcare sector. Public discourse between healthcare professionals, the legal profession and interest groups is necessary for ensuring justice in these valuations.

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1. Introduction

One of the central challenges of any state is to provide accessible healthcare services of adequate quality to all citizens. The Nordics have become an example of a welfare state model in which healthcare costs are covered by the public sector with funds collected from employers and tax payers, and in which the cost of healthcare for individual citizens is relatively low. However, due to the recession in 2009, several years of poor economic growth, and an ageing population, healthcare costs are growing in the Nordics and the pressure to contain them is rising.

The means by which the legislator can impact healthcare costs are limited. The needs of individual patients cannot be regulated, only the manner in which to organize and allocate funds for servicing those needs. One characteristic feature of health law is that the decisions which most directly impact individual patients are made by doctors on a case by case basis and in accordance with professional standards. This very personal process cannot be easily interjected by the legislator with regulation on which choices should be made in the doctor-patient relationship. Thus, regulation concerning healthcare is focused on structures and administration, professional standards, measures to protect patients' rights and legal remedies for malpractice.

One field of healthcare, however, is different in nature and has developed into a private business in most countries. The distribution of medicinal products in pharmacies works like an outsourced branch of public healthcare. Pharmacy as a field of healthcare is different from medical care in one central aspect: in addition to pharmaceutical service, distribution of medicinal products to a patient constitutes a transaction. In providing a physical product, as opposed to a service such as a medical procedure, the activity becomes concrete and its regulation can be approached in a more conventional and instrumental manner than the rest of healthcare.

There are various interests which need to be consolidated when drafting legislation relating to pharmaceutical distribution. The market for medicinal products in Norway was NOK 21.4 billion (EUR 2.6 billion)¹ in total turnover in 2014. In Finland, the total

¹ *Apotekforeningen*, Apotek og legemidler – Bransjestatistikk om apotekenes virksomhet og rammevilkår p. 57. Exchange rate for the Norwegian krone against the Euro was 8.3544 in 2014: *European Central Bank*, Statistical Data Warehouse. Available at:

sale of medicinal products was EUR 2.8 billion² in 2013. Actors in the pharmaceutical industry, including manufacturers, importers and wholesale companies, aim at securing profit for shareholders as well as capital for research and development. Pharmacy owners view themselves both as entrepreneurs as well as healthcare professionals and aim at ensuring the best service for customers while maintaining a profitable business. From the perspective of the state, pharmaceutical distribution needs to be organised in a just but cost-efficient manner. Customers and patients have an interest to ensure autonomy in regard to their treatment, the lowest possible medical expenses and easy access to pharmacy services.

Within the pharmacy sector, everyday business activities are regulated in detail. Simultaneously, pharmacists work in close cooperation with the public healthcare system and adhere to the same ethical standards as other healthcare professionals. This work aims at providing an overview of the factors which have led to such detailed regulation of pharmaceutical distribution in Finland and in Norway. Furthermore, I will use a comparative approach in order to analyse these factors and to systemise the legal principles which bind the legislator when enacting new norms in the field.

Healthcare is a central question within the welfare state and consequently the relatively new field of health law has been brought up to contribute to the discussion. However, in public discussion, the framework for providing healthcare is primarily referred to as a political question. In an environment of challenging state economy, discussion regarding healthcare is focused on resource allocation and cost-efficiency. Under such circumstances the legislator faces numerous choices between policy options which are based on political factors as well as on law. There is a distinct need for distinguishing the legal principles and the minimum legal requirements regarding human dignity and fundamental human rights from the political questions regarding healthcare when making legislative reforms as well as policy decisions in the field.

http://sdw.ecb.europa.eu/browseTable.do?node=2018794&SERIES_KEY=120.EXR.A.NOK.EUR.SP00.A
accessed on 20 April 2015.

² *Finnish Medicines Agency Fimea & Finnish Social Insurance Institution KELA, Suomen lääketilasto – Finnish Statistics on Medicines 2013 p. 2.*

2. Research Objective and Paradigm

I have started this research with the knowledge that until 2000 the pharmacy systems in Finland and Norway were very similar to each other. In 2001 the Norwegian system underwent a significant reform, while Finland has kept the main features of its pharmacy system unaltered. The central questions which this research aims to answer are as follows:

How do the pharmacy systems in Finland and Norway differ from each other today? Why are the systems different or similar? What are the central aims and legal principles behind the choice of pharmacy system in each country?

The work aims at identifying which legal principles and other considerations the legislator in Finland and Norway has taken into consideration in legislation regulating the pharmacy sector and medicinal products. Legal principles have been distinguished from political aims and policies. The research examines the demands of human rights and legal principles on the legal framework for distribution of pharmaceuticals.

Within this work I have aimed at a high level of transparency in regard to the utilized research methods and source materials as well as the social context in which I have carried out this research. The paradigm of this research is that there are certain fundamental human and social rights regarding health which bind the legislator.

The principal aim of this work is to provide an overview of the legal framework of principles and individual rights regarding pharmaceutical distribution which are common for Nordic welfare states. This aim is best served by conducting comparative research as described in more detail in section 3.4. This research objective is closely linked to the paradigm of this research. I have attempted to approach the research objective with recognisable methods of legal research which provide an accurate formulation of the topic. However, it is evident in the paradigm of the research that as a researcher I have not fully eliminated my subjective perception of the matter or the social context in which I am conducting my research, nor have I attempted to do so. The systemisation and the results of the legal comparison reached on the basis of the research paradigm highlight the role of fundamental human and social rights within the pharmacy sector and healthcare.

3. Research Methods

3.1. Formulating a Method

In order to conduct research in a productive manner which serves the knowledge interest outlined for the research, the researcher needs to formulate a method. This work is a comparative study of the pharmacy system of two countries and thus it falls within the scope of comparative law. Comparative law does not have a singular prescribed method which all researchers are required to strive for. On the contrary, comparative law research can employ and combine different methodological approaches and theories for its use. The combination of approaches should be chosen in the manner that best serves the knowledge interest of the research.

The following chapters outline the methodology used for this research within the larger context of legal science and legal research, the different methods of legal research employed to support law comparison, and the methodological choices made in the comparative research.

3.2. Fields and Methods of Legal Research

Legal science, as understood in a wide sense of the term, includes the following fields of legal research: doctrinal study of law, historical study, sociology of law, law and economics and comparative study of law.³ In this work I will practise comparative study (*Rechtsvergleichung*) as well as doctrinal study of law (*Rechtsdogmatik*).

Research can have different aims, which all warrant different methods. Aarnio uses the distinction between explanatory or non-explanatory research when describing the research method of legal science. This distinction clarifies whether or not the research is used to explain the *causal relationship* for example between two phenomena. Explanatory research aims at explaining the background of norms or court decisions by relying either on causal or finalistic explanation. Non-explanatory research does not attempt to explain *why* a certain phenomenon has come to existence or *why* it has developed in a certain manner. Instead, non-explanatory research describes and defines the phenomenon or the stages of its development as such. Aarnio makes a distinction also regarding the content of research. Legal research can be normative or

³ Aarnio, *Aulis*, Essays on the Doctrinal Study of Law p. 19.

non-normative. The nature of normative research is to present norms, that is, prescriptive utterances while the results of non-normative research are in the form of descriptive statements. Thus, the distinction clarifies whether the research aims at describing how something *should be* or if the goal is to describe how something *is*.

According to Aarnio, the traditional research objective of the doctrinal study of law is non-explanatory and normative. The aim of such research could for example be to describe how the legal system treats pharmaceutical patents and how difficult cases should be treated in court when the written acts of law are open to interpretation. This kind of research systemizes and restates norms, for example in order to present them in a more understandable or useful manner for the purposes of the research. Legal science also includes research which is non-explanatory and non-normative, for example in the form of presenting legal statutes or precedents without systemisation or restatement of norms. However, legal science cannot be explanatory and normative, because explanation as understood here cannot present norms as its result.⁴

The last combination of these two distinctions is explanatory and non-normative research. Aarnio finds the attempt to provide a comprehensive description of legal science by defining it as explanatory and non-normative to be problematic. In natural sciences, where the research target is external and objective in relation to the researcher, research is conducted through logical deduction and induction and it is by nature explanatory and non-normative.⁵ However, in legal science the researcher is part of the social reality examined in the research. Thus, in practice deduction and induction are not used for legal interpretation. This research does not attempt to derive legal principles from individual norms through induction. Aarnio has however discussed the possibility of explanatory, non-normative research in the form of finalistic explanation of the origins of legislative acts.⁶

⁴ Aarnio, *Aulis*, Laki, teko ja tavoite p. 216–219.

⁵ See Aarnio, *Aulis*, Laki, teko ja tavoite p. 222–247 for an overview of attempts by legal theorists to support the use of deduction and induction in legal science.

⁶ Aarnio, *Aulis*, Laki, teko ja tavoite p. 219–220.

Aarnio distinguishes three different phases in scientific research: description, explanation and prediction.⁷ This research has been conducted mostly at the level of description. In conducting comparative research, I describe and restate norms concerning medicinal products and the relevant pharmacy systems. In this sense my research makes use of the method of doctrinal study of law. I also make some attempts at explanation as described below. This research does not include any prediction of court decisions or of the behaviour of public authorities and officials and thus prediction as a level of research is not discussed further.

This work includes doctrinal study of law (non-explanatory and normative) to the measure that it aims at describing and systemising norms which apply to pharmacies and medicinal products. Identifying and restating the EU legislation and other international measures which are binding in Finland and Norway are also exercises in the doctrinal study of law. I will approach the task of systemisation with the research paradigm in mind. Systemisation begins with defining the relevant legislative acts and other legal sources which provide the basis for formulating and reformulating the system.⁸

During the comparative stage of research, I will examine preparatory works and policy memoranda in order to explain the legislator's choices. This kind of research, when it aims at explaining *why* the relevant norms were enacted, can be described as finalistic explanation. According to Aarnio, this method is explanatory and non-normative. Any explanatory features in my research method are in nature finalistic explanation and I make no claims of verifying my statements regarding the legislator's intent by induction. Instead, the reasoning involved in this work is more accurately described as practical inference.

Finalistic explanation focuses on examining the behaviour of the legislator or the public officials, such as courts, responsible for applying the law. This approach treats their behaviour as acts which have been carried out in order to achieve a particular goal. Finalistic explanation is in practice often used by legal practitioners and legal scientists

⁷ Aarnio, *Aulis*, Laki, teko ja tavoite p. 219–220.

⁸ Aarnio, *Aulis*, Laki, teko ja tavoite p. 272–273. Aarnio uses the work of *Alchurrón* and *Bulygin* to present the premises for systemization of norms. These premises are: 1) A certain set of problems, i.e. the topic. 2) A set of valid legal statements relevant for the topic. 3) A set of rules of inference for deriving other statements from the chosen set of legal statements.

as the initial stage of legal interpretation. For example, the purpose which the legislator has intended for a legislative act may influence the interpretation of the text of the act. However, the purpose may not be evident in the text of the act itself. In this case the goal for using finalistic explanation is to discover the *ratio* and *voluntas* of law. However, finalistic explanation can also be conducted independently and its findings can be valuable as such.⁹

According to Tuori, there is an underlying tension between the concepts of *ratio* and *voluntas* within the legal system. The *voluntas* of law refers to the will of the legislator and to the political aims which the legislator wanted to advance with a particular act of law. The *ratio* of law on the other hand refers to the principles and reasoning found in the deeper, underlying layers of legal culture. The power of *ratio* is in its “logical persuasiveness, normative consistency or rational coherence”¹⁰. Thus, *ratio* promotes consistency and predictability in legal decision-making and it is evident in tradition and the coherence of the existing system. Under modern law, *voluntas* has however gained prominence. New legislation is increasingly interventionist, that is, legislation is used for correcting anomalies or adverse effects of policies instead of creating a stable framework for a larger domain in society. This increasingly instrumental role of justice and law in society has made the legislator’s aims and policies, and thus *voluntas*, more prominent. Such a shift towards highlighting *voluntas* however calls for a corresponding promotion of *ratio*. On the other hand, *Ratio* can no longer be seen only as traditional reason. Instead, arguments of coherence, fundamental principles of modern law, morality and ethics should all be employed in the exercise of discovering the *ratio* of law. Tuori describes legal culture as a result of sedimentation to which the above arguments as well as different legal and judicial practices have all contributed.¹¹

Legislation regarding medicinal products and the pharmacy sector is by nature very instrumental. Therefore, considerations regarding *ratio* and *voluntas* are central for understanding the reasons *why* the pharmacy systems in Finland and Norway have developed in the way they have. *Ratio* is a central question for understanding the legal

⁹ Aarnio, Aulis, Laki, teko ja tavoite p. 248–254. Eckhoff, Torstein & Helgesen, Jan E., Rettskildelære p. 70, p. 99–109.

¹⁰ His introduction of *ratio* and its convincingness, Tuori uses Roger Cotterrell’s analysis of *ratio* and *voluntas* from the work *Law’s Community* (Oxford 1996).

¹¹ Tuori, Kaarlo, Oikeuden ratio ja voluntas p. 30–71.

principles which apply in the pharmacy sector. *Voluntas* can be discovered by examining the legislator's aims and choices. Aarnio distinguishes the following problems in the process of explaining the legislator's intentions. First of all, it is necessary to identify the agent who has enacted the law and whose behaviour should be examined. As the legislative process is a collective act which involves many different actors, the researcher must ask whose aims and beliefs form the basis of explanation. However, according to Aarnio, in the context of practical inference this issue has been resolved since the prevalent general use of the term "legislator" is not problematic. Under this research the parliament, government and relevant ministries in Finland and Norway comprise the legislator for each country. This research focuses on the intent of the legislator as opposed to other interest groups within the pharmacy sector, including public authorities such as the relevant national medicines authority or competition authority.¹²

The second problem concerns the manner in which the researcher discovers the motives of the agent. The motives and aims of individual actors, such as politicians, individual public officials or experts engaged in legislative drafting, can have a significant impact on the legislative process. However, examining the background of individual persons rarely brings to light the concrete aims and the particular problems which need to be addressed through legislation. The collective aims of the legislator are best explained through social and ideological history. This process needs to take into account the social and cultural environment in which the legislator acts, the prevalent ideology in civil society, and the basic principles on which the functioning of society is based. Here legal research has much to gain from the teachings of social science. Thirdly, the researcher needs to identify the concrete aims of the legislator within the special problematics of the field which the legislation is regulating.¹³

3.3. Rules, Principles and Policies

The knowledge interest of this research relates to legal principles and their role in the pharmacy system in Finland and Norway. Firstly, the research needs to identify the applicable legal principles. Secondly, in examining the legislator's choices particularly

¹² Aarnio, Aulis, Laki, teko ja tavoite p. 254–258.

¹³ Aarnio, Aulis, Laki, teko ja tavoite p. 254–258. Tuori, Kaarlo, Oikeuden ratio ja voluntas p. 32.

within a field where legislation is instrumental in nature, principles need to be distinguished from policies. Therefore, it is important to describe the theory regarding legal principles used in this research.

According to positivist legal theory, the scope valid law can be determined on formal criteria and is ultimately based on a *rule of recognition* in the form of institutional support. Dworkin finds this kind of definition to be insufficient since it excludes principles from the scope of valid law. Dworkin distinguishes between rules and principles and has based his distinction on the character of the direction they give. Rules are applied in an all-or-nothing manner where either the rule is valid or not. In case of conflict between two rules, one rule is valid and the other is not. Principles on the other hand provide argumentation in one direction but do not necessitate a particular decision. They include a dimension of weight, so in case of conflict between two principles one will prevail but the other still retains its validity. Here, Dworkin discusses principles in a larger meaning, comprising principles as well as policies as opposed to rules.¹⁴

Tolonen builds upon this distinction between rules on one hand, and principles and policies on the other. He distinguishes rules and principles in terms of their validity and their relevance. The validity of a rule can be ascertained through the rule of recognition. Tolonen however disagrees with Dworkin's notion of all-or-nothing validity. A conflict between two rules can be resolved with use of a principle such as *lex specialis derogat legi generali* where the overridden rule does not lose its validity. According to Tolonen the validity of a principle is not tied to a rule of recognition but should be identified based on its substance, value or significance. A principle is valid due to the fact that it has weight and value in the legal system and that there is institutional support for the principle. Tuori finds that in addition to the role of institutional support in verifying the validity of principles on this more superficial level, the requirement of institutional support also reaches the general principles found in deeper structures of law. From this perspective, the requirement of institutional

¹⁴ Dworkin, Ronald, Taking Rights Seriously p. 64–68.

support reflects the sedimentation of principles in the legal system. This is what, according to Tuori, gives principles their legal nature.¹⁵

Another aspect in distinguishing rules from principles under Tolonen's theory is relevance. This refers to the scope of application of a norm. Its overall validity should be separated from the question of its applicability in a concrete case. Within the defined scope of application of a rule, the decision must necessarily be based on that rule: its relevance has an all-or-nothing nature. With principles this is not the case even within their scope of application. Furthermore, the weight of a principle is contextual and differs with the concrete circumstances in which the principle is applied.¹⁶

Tolonen also discusses the question of conflicts between rules and between principles. Conflicts between rules are resolved based on formal criteria regardless of their weight, value or substance. Such criteria include for example the principle *lex superior derogate legi inferiori*. Conflicts between principles on the other hand cannot be resolved through formal considerations. They are resolved on the basis of the significance, value and weight which they are given in the context of the concrete case. According to Tolonen, this makes legal principles a parallel phenomenon with moral principles. Law can be seen as institutional morality in which the valuation of principles is restricted and guided by institutional requirements. Tolonen describes decision-making based on legal principles as an institutional valuation.¹⁷

Dworkin describes a policy as a "standard that sets out a goal to be reached, generally an improvement in some economic, political, or social feature of the community". For Dworkin, the substance of policies is in their aims in relation to society. Also the communal nature of policies distinguishes them from principles. A principle on the other hand "is a requirement of justice or fairness or some other dimension of morality". Under the rights thesis, arguments of principle intend to establish individual rights. This distinguishes principles from policies where arguments are intended to establish collective goals. It is the task of the legislator to set social policy goals and in this work the legislator is guided by arguments of policy. The rights thesis is built on

¹⁵ Tolonen, Hannu, Oikeuden kaleidoskooppi p. 30–37, p. 48–50. Tuori, Kaarlo, Oikeuden ratio ja voluntas p. 154–155.

¹⁶ Tolonen, Hannu, Oikeuden kaleidoskooppi p. 30–34, p. 50–51.

¹⁷ Tolonen, Hannu, Oikeuden kaleidoskooppi p. 30–34, p. 51–53.

the idea that a citizen's rights can only be based on rules and principles. Courts base their decisions on rules and principles and arguments of principle are thus characteristic to their activity. Dworkin's view is that rights exist prior to and regardless of the actions or decisions of public authorities and they are binding upon courts. Therefore, arguments of principle prevail over arguments of policy. However, he also finds that policies may be formulated into principles and, on the other hand, principles may be adopted as political aims. This may be seen to dilute the difference between principles and policies.¹⁸

Tolonen finds that the distinction between principles and policies is important in examining the difference between law or justice and social policy and in discussing increased goal-orientation within law. In Tolonen's view, the rights thesis categorizes only certain kind of legal principles as legal principles. The rights thesis does not sufficiently consider the relationship between interventionist legislation and self-regulating or reflexive legal mechanisms within the legal system. The amount of open and elastic legislative mechanisms is increasing, and, while their substance may depend on arguments of social policies and aims, in practice such mechanisms can establish rights to individual citizens.

In addition to the rights thesis, Tolonen finds elements of a thesis of universalizability in Dworkin's views regarding principles and policies and he builds upon this in his distinction between principles and policies. Under Tolonen's postulate of universalizability, "cases which are similar in the relevant manner shall be treated in a similar manner"¹⁹. Principles include a different kind of requirement of universalizability than policies. For example, common goods such as public health will have a different role within the legal system if it is treated as a requirement of social policy than if it is treated as a legal principle. Furthermore, from the perspective of the *ratio* of law, an argument of policy does not have the same status as a legal principle. Tolonen bases his distinction on the idea that the requirement of universalizability applies to rules and principles but not to policies. The postulate of coherence and consistence specifies the institutional criteria for applying the principle. Tolonen finds

¹⁸ Dworkin, Ronald, Taking Rights Seriously p. 22–27. Tolonen, Hannu, Oikeuden kaleidoskooppi p. 42–44, p. 55–59.

¹⁹ Translated by K.K.

that neither his nor Dworkin's distinction of rights and policies is absolute or qualitative, but rather relative. Whether legal requirements of a goal-oriented nature are legal principles or policies cannot be derived from their substance. Such distinctions are relative and are resolved by the legal system in the form of an institutional valuation. Arguments of goal have an impact in the legal system but are restricted by certain institutional requirements.²⁰

The distinction between rules, on one hand, and principles and policies on the other ultimately deals with the relationship between law and morality. The question of distinguishing between rules and principles on one hand, and policies on the other is related to the relationship between law and politics. The way in which the distinction between principles and policies is applied in different sections of society changes in pace with social development.²¹

Tolonen also discusses the role of principles in the legal system. He describes law as a substantive system in which two basic ideas are central. The first idea relates to the consistence and coherence within the system and to conflict as their opposite phenomenon. Secondly, the development of the legal system ties conflicts to the development of society. Tolonen sees the legal system as one which is conflicted in nature and which simultaneously, by its nature, eliminates its conflicts, that is it strives for consistence and coherence. From the substantive aspect of the legal system, conflict can be described as a state of anomy. Law as a substantive system resolves and removes conflicts on different levels. Conflicts can be resolved on the level of rules, principles or theories. Conflicts between rules are resolved on the level of principles whereas conflicts of principles are resolved on the level of theories. Theories are part of the general principles of law and they are material in nature. According to Tuori, legal theories group legal concepts into networks and organize legal principles into *prima facie* orders of priority. Legal theories include normative justification for the legal institution under discussion. This deeper justification guides the manner in which the *prima facie* order of principles is defined and legal concepts are grouped. Theories also include their own understanding of the social relations which legal norms regulate. Under the substantive aspect law has an essentially wider scope than from

²⁰ Tolonen, Hannu, Oikeuden kaleidoskooppi p. 37–46, p. 59–66.

²¹ Tolonen, Hannu, Oikeuden kaleidoskooppi p. 46, p. 66.

the perspective of legal formalism. The general principles of law and particularly legal principles occupy an essential place in the legal system. Legal principles form the central substantive conception of the legal order and remove anomy and conflicts between legal norms.²²

According to Tolonen, law regulates its own change with use of universalizable norms. Law includes its own general principles regarding the criteria under which legal change is possible. These general principles form the doctrine of the sources of law. It is notable that the legal system includes very few written rules regarding sources of law and that this doctrine relies mainly on principles. In regulating change, the conflicting requirements between predictability and elasticity need to be consolidated. The doctrine of the sources of law defines the role which policy arguments have in the legal system and in changing the law. For example, the prevalent doctrine in Nordic countries recognizes real arguments as a source of law and applies a special concept of institutional universalizability to them.²³

Tuori discusses the role of sedimentation in relation to the development of law. Sedimentation begins with the normative material produced by legislative and judicial bodies in their decision-making. A legal norm on a more superficial level of law can become embedded in the deeper structures of law over time for example through court practice or jurisprudence. General principles of law embedded in the sediments of the legal system have an influence on the norms employed on the surface and the manner in which they are applied. Furthermore, legal principles are also horizontally connected with other norms functioning on the same level, and general principles of law have constant interaction with the ethical values and moral principles prevalent in society. Legal principles are applied in the context of the case at hand and are thus connected with the facts and circumstances of the case, that is, with extra-legal factors. According to Tuori, the development of the legal system is ultimately determined by external factors. However, the impact of these factors is refracted through the internal mechanisms of the legal system. The *ratio* of law and the

²² Tolonen, Hannu, Oikeuden kaleidoskooppi p. 34–35. Tuori, Kaarlo, Oikeuden ratio ja voluntas p. 158–163.

²³ Tolonen, Hannu, Oikeuden kaleidoskooppi p. 69–72, p. 85.

requirement of coherence define how the legal system responds to social development – how the legal order can change as society changes.²⁴

3.4. Comparative Law

This work utilizes the comparative method. Sections 5.2 and 7 provide descriptive overviews of the pharmacy systems of Finland and Norway respectively. These two systems are the objects of comparative analysis aiming at identifying the rights, principles and policies which form the basis for regulating pharmaceutical distribution.

Comparative law can be a difficult science to approach. Therefore, before describing the methodological choices of comparison, I have shortly addressed the field of comparative law in more general terms.

3.4.1. Comparative Law as a Science

Zweigert and Kötz on begin their definition of comparative law as “intellectual activity with law as its object and comparison as its process” and highlight the role of internationalism in distinguishing comparative law “from what lawyers normally do” within their national legal systems.²⁵ Bogdan on the other hand has constructed a definition of comparative law for the purpose of providing an overview of the field for students of law. According to his definition of the field, comparative law includes:

“the comparison of different legal systems with the purpose of ascertaining their similarities and differences;

working with similarities and differences that have been ascertained, for instance explaining their origin, evaluating of the solutions utilized in the different legal systems, grouping of legal systems into families of law, or searching for the common core of the legal systems; and

the treatment of the methodological problems which arise in connection with these tasks, including methodological problems connected to the study of foreign law.”²⁶

²⁴ *Tuori, Kaarlo*, *Oikeuden ratio ja voluntas* p. 155–157.

²⁵ *Zweigert, K. & Kötz, H.*, *An Introduction to Comparative Law* p. 2.

²⁶ *Bogdan, Michael*, *Comparative Law* p. 18.

The above definition works from multiple perspectives. Firstly, it can be viewed as an attempt to summarize the essential elements of comparative law as a science. Secondly, Bogdan's definition lists various types of research which can be grouped under the heading "comparative law". Finally, it identifies three levels of comparative law, where the first level is descriptive comparison and the second level includes analysis of the findings in a greater context. These parts of comparative law can be described as comparative research. The third level works with problems within the comparative method itself. This approach is called comparative law theory²⁷.

In defining comparative law, Husa groups comparative law together with social science. He also emphasises the role of comparative law as a cross-border exercise, which provides a reconstruction of a foreign system and thus enables dialogue between legal systems. It is characteristic for the exercise of comparative law to be international and to strive to free oneself from the constraints of one's own legal system. As national legal systems have not been insulated from each other, it is clear that there is added informational value to be obtained through cross-border comparison: Through comparative law researches can understand their national legal system better as well as draw inspiration from foreign legal systems in finding model solutions to problems arising in the national legal system.²⁸

In defining comparative law, it can be useful to coin an example of what it is not. According to Husa, the examination of foreign law is useless and without purpose from the perspective of comparative law if it is left separate of the knowledge interest of the research and if it does not serve the knowledge interest. In order to avoid the pitfall of such "ornamental" or "decorative" law comparison, I have outlined the interest and method of comparison used in this research in the following sections.²⁹

3.4.2. Uses of Comparative Law

Comparative law can be used for the following purposes. These uses of comparative law, not to be understood as exhaustive, are general education for lawyers, understanding of one's own legal system, construction in interpretation of national

²⁷ Husa, Jaakko, Oikeusvertailu p. 29.

²⁸ Husa, Jaakko, Oikeusvertailu p. 27–29 and p. 54–55. Zweigert, K. & Kötz, H., An Introduction to Comparative Law p. 15 and 21.

²⁹ Husa, Jaakko, Oikeusvertailu p. 93–94. Zweigert, K. & Kötz, H., An Introduction to Comparative Law p. 6.

rules, working *de lege ferenda*, harmonization and unification of laws, working *de lege lata*, public international law, private international law and international penal law, legal theory, pedagogical purposes and other uses such as legal history research, law dictionaries and sociology of law.³⁰

Comparative research has also been carried out in the past in order to discover the universal principles of law. According to Husa, a certain element of universalism still exists within comparative law as it aims at obtaining general knowledge of law which is by nature less bound to the state than national legal science. The findings of legal comparison can be utilised for deepening and improving normative argumentation but as such the knowledge interest of comparative law is not normative in the manner of the doctrinal study of law.³¹

This research utilizes the comparative method for two of the above purposes. Firstly, this work has elements of working *de lege ferenda*, in that it aims at providing findings which can be useful for the legislator. Secondly, the research is carried out in order to understand factors which work in the background of regulation concerning medicinal products in Finland and Norway. Thus, besides obtaining a better understanding the researcher's own legal system, the work aims at explaining and assessing the reasons behind the similarities and differences of the two systems. Reflecting these aims with the research paradigm, that there are certain fundamental human and social rights regarding health which bind the legislator, one can also perceive some sense of universalism in this research. If the idea of this sense of universalism related to health law were to be excluded altogether, this research could just as well be carried out in Finnish from a purely national perspective.

3.4.3. Interests of Comparison

Before carrying out law comparison, it is important to define the basic knowledge interests which the comparison is intended to serve. After this, the actual methods of comparison need to be established.

³⁰ Bogdan, Michael, Comparative Law p. 27–39. Zweigert, K. & Kötz, H., An Introduction to Comparative Law p. 16–18.

³¹ Husa, Jaakko, Oikeusvertailu p. 31–34.

This research has a practical-theoretical interest as it aims at producing findings which can be useful for legislative drafting or policy through increasing the informational basis regarding the research topic. The use of doctrinal study of law and more specifically of systemisation, as described above in section 3.2 supports and is also evidence of the practical interest of comparison. In contrast to the integrative approach, this research does not examine opportunities for the harmonisation of laws. Another alternative to the practical-theoretical interest would be the contradictory approach which works toward the distinction of different legal systems and cultures from each other.³²

3.4.4. Technical Methodological Choices

In light of the research paradigm and research objective, I have made a number of technical methodological choices before carrying out comparison. In most comparative research the method rarely represents a pure version of any particular technical choice. Thus, at times the comparative process includes elements of both methodological counterparts. However, the choices outlined below emphasise the overall focus of the research.

In choosing the research objective, I made a choice between the horizontal and the vertical method of comparison. In the vertical method, the comparison is carried out between legal systems which are on a different level in the scale of national-supranational law, for example between international law, EU law and national law. However, this work represents the more common horizontal method of comparison in which both legal systems are national and thus at the same level in the abovementioned scale.³³

The subject area under research is related to a concrete and limited activity within society, that is, distribution of medicinal products, which means that the comparative method used can be described as microcomparison. Research on the micro level usually deals with individual legal rules or with individual institutions within a legal system. In contrast, macrocomparison works on a greater level of abstraction. In

³² *Husa, Jaakko*, Oikeusvertailu p. 60–88. Husa has introduced a categorisation of the different knowledge interests which comparison can serve. The categorisation does not function as a prescription of the types of research available but rather provides means of describing the different underlying purposes for which comparison can be carried out.

³³ *Husa, Jaakko*, Oikeusvertailu p. 137–138.

macro research the aim is to understand foreign legal systems and legal cultures instead of examining solutions provided for concrete problems in different legal systems.³⁴

The legal systems chosen for this research are Finland and Norway which are both part of the Nordic legal culture. The reasons for this choice are manifold. Firstly, as a Finnish student of law I am in a favourable position to examine the Finnish legal system. However, this can also be a challenge when carrying out law comparison as I am also part of the social reality which I am examining. It is not uncommon for lawyers to consider their own legal system to be superior to that of others and thus they can have an ethnocentric approach to examining foreign systems. I have taken this factor into account and at least attempted to eliminate any ethnocentrism from the comparative process.

As the research paradigm is related to human rights and the legislator's aims, the research needs to be carried out on a deeper level of the legal system than on individual written rules. Thus, instead of attempting to research many different legal systems by way of multilateral comparison, I have chosen to conduct bilateral comparison. This allows a deeper examination of factors working in the background of legislative acts. In multilateral comparison the research resources would in this case only allow a surface glance at the matter.³⁵ Furthermore, the knowledge interest of this research is sufficiently served through bilateral comparison.

The main reason why I have chosen Norway as the second subject of comparison is the manner in which the Norwegian pharmacy system has developed in the past decades. In short, until 2001 the pharmacy system and the functioning of pharmacies were fairly similar in Norway and in Finland. However, in 2001 Norway introduced a law reform regarding pharmaceutical distribution and the functioning of pharmacies, whereas the Finnish legislation did not undergo a significant reform. Both systems have been amended partially in a number of ways in the past years and many of the amendments have followed similar trends in the field.³⁶ Thus, Finland and Norway provide fruitful

³⁴ Husa, Jaakko, Oikeusvertailu p. 125–127. Zweigert, K. & Kötz, H., An Introduction to Comparative Law p. 4–5.

³⁵ Husa, Jaakko, Oikeusvertailu p. 134–136.

³⁶ I will discuss these developments in more detail in section 7.

grounds for comparison as the similarities in the background of the pharmacy systems can be reflected upon the different legislative choices made at the end of the 1990s.

Furthermore, the two legal systems both fall within the Nordic legal culture. As my knowledge interest is to find out the intention of the legislator and to understand the human rights factors in the background of legislation, research within one family of legal cultures is a practical choice. Comparison between different legal cultures would be a better choice for example in researching a legal problem which has not been regulated in written legal rules in some countries or in macrocomparison.

The comparison will focus on the recent preparatory background of the current legislation regarding pharmaceutical distribution in Finland and Norway. The focus of the research is on current matters and recent developments instead of historical matters and thus it can be described as transverse comparison. The methodological counterpart for transverse comparison is longitudinal comparison which examines the historical development of a legal system or legal institution or the way a problem has been addressed throughout history.³⁷

3.4.5. Theoretical Methodological Choices

The theoretical emphasis of legal comparison depends on the knowledge interest and the nature of the subject area under research. After familiarising oneself with the source material and the legal culture under study, the comparatist will define the research objectives in more detail and make choices regarding the general theoretical framework of research. Husa has identified four alternative basic strategies for comparative research: functional comparison, structural comparison, system comparison and critical comparison.³⁸

The methodological approach chosen for this research is based on functionalism³⁹ as defined below. Functionalist comparison, represented by Zweigert and Kötz, is based on the idea that “the legal system of every society faces essentially the same

³⁷ Husa, Jaakko, Oikeusvertailu s. 130–131.

³⁸ Husa, Jaakko, Oikeusvertailu s. 144–145.

³⁹ The concept of functionalism is understood differently in comparative law than in sociology and other disciplines. Even within comparative law the concept needs to be defined. In his article “The Functional Method of Comparative Law” Michaels has discussed seven different concepts in different disciplines. In this work the concept of functionalism refers to equivalence functionalism. Michaels, Ralf, The Functional Method of Comparative Law p. 343–363.

problems, and solves these problems by quite different means though very often with similar results”⁴⁰. Thus, the functionalist approach focuses on examining the legal institutions which have been formed as responses to the same problem in different legal systems. Through this approach the researcher is more able to eliminate their own preconceptions regarding foreign law and the legal institution under review view. Furthermore, the functionalist approach provides a means to view one’s own legal system from the outside. This provides a kind of partial objectivity as researchers can treat each legal system in the same manner despite of national backgrounds.⁴¹

The functional method utilises the concept of functional equivalents in order to establish comparability between different legal systems: For instance, if system s_1 has introduced the institution i_1 as a response to problem p and system s_2 has introduced the institution i_2 as a solution to the same problem p , there is a functional equivalency between the institutions in those systems. The functions for the institutions in those systems are similar even if the legal institutions and the legal systems as such are dissimilar. According to Michaels, functionalism views an institution within a legal system as “a possible but not necessary response to a problem”, which explains the differences between legal systems also in the face of universal problems.⁴²

The common denominator for the legal institutions to be examined in this work is their function as defined in chapter 4.4.4. I have determined the substantial focus of the research with the use of functional equivalence relating to the regulation of pharmacies and medicinal products. However, as the two legal systems are within the same family of legal culture and at a similar stage of development, the process of defining this focus has been relatively unproblematic. In this case the chosen focus could have been much the same with very little consideration for method: The relevant legislation regarding pharmaceutical distribution is readily available in both systems for anyone with knowledge of Finnish and Norwegian. Nevertheless, the process used in this research is, if not entirely based on functional considerations, at least symptomatic of functionalism.

⁴⁰ *Zweigert, K. & Kötz, H., An Introduction to Comparative Law* p. 34.

⁴¹ *Michaels, Ralf, The Functional Method of Comparative Law* p. 380. *Husa, Jaakko, Oikeusvertailu* p. 149.

⁴² *Michaels, Ralf, The Functional Method of Comparative Law* p. 356–358.

The role of functionalism is more evident in the comparison carried out in this research. For the purpose of analysing of the legislator's aims and intentions, I have constructed a number of universal problems in chapter 4.4.4 which I use as *tertium comparationis* against which two legal systems can be compared. This comparison is based on the notion that the legal institutions under comparison are responses to societal needs which can be identified with reference to other possible responses which are functionally equivalent with them. With use of a problem as *tertium comparationis* I will be able to describe and explain differences and similarities of the Finnish and Norwegian responses.⁴³

This research does not apply a *praesumptio similitudinis* as understood in discussions regarding comparative law⁴⁴. In functionalism two systems s_1 and s_2 are not assumed to be similar as such, nor are the legal institutions i_1 and i_2 . However, for functionally equivalent institutions within legal systems, the institutions are assumed to be similar in terms of function as they respond to the same problem. However, while they are similar in this regard, they can still have many other similarities and differences. This research aims at discovering both and does so by examining the legal institutions of Finland and Norway through the system of functionalism. In this research I have utilised the functionalist systemisation of problems, responses and functions as described above. This allows the construction of a corresponding system from the findings and thus to better understand the underlying problems and aims within Finnish and Norwegian pharmacy legislation.⁴⁵

In my approach to comparing pharmacy legislation I examine preparatory works and the legislator's intent. I have described the exercise of discovering the legislator's intent as finalistic explanation as defined by Aarnio. Michaels has discussed the element of finalism in functionalist comparison. He describes the Aristotelian understanding of the notion of function in which the purpose of a thing, *causa finalis*, is considered inherent in its nature. According to Michaels, legal comparatists have employed this idea in the sense that they have seen the different solutions found for

⁴³ See Michaels, Ralf, *The Functional Method of Comparative Law* p. 367–369 for an overview of the use of functionalism as a *tertium comparationis*.

⁴⁴ The classic example of *praesumptio similitudinis* is the presumption of similarity presented by Konrad Zweigert in Zweigert, K. – Kötz, H., *An Introduction to Comparative Law* p. 40.

⁴⁵ Michaels, Ralf, *The Functional Method of Comparative Law* p. 370–373.

common problems as “contingent in their form but none the less required by the nature of the problem”. The function of an institution has since been separated from its cause or origin as well as from its essence in legal research. Under this research, my comparison employs elements from both the functionalist method and finalistic explanation. However, despite my interest in *why* the legislator has chosen a particular institution as the solution for a problem, I do not treat the function of the institutions under comparison as inherent in their nature.⁴⁶

3.4.6. Linguistic Considerations

Language is a vital factor for legal comparison. The source material for this work is mostly in Finnish and in Norwegian. This work has been written in English in order to enable readers representing both legal systems to benefit from its findings. The aim of this work is to identify factors which function in the background of the legislator’s work. As many of these factors are related to international treaties and human rights considerations, the findings can be of use to readers from outside of Finland and Norway as well. Furthermore, as stated above, one of the principal aims for this work is to provide a piece of comparative research which any national legislator could benefit from in its work. It serves this aim to make the research outcome available in the current *lingua franca* of legal research, in English.

When conducting comparative research, the question of translation should be taken into account. When describing and analysing a foreign legal system in English, it is important to understand the meaning which each term may have in each language. First of all, the researcher must reflect upon the meaning of legal language in the context of the legal culture which she is examining. Secondly, the terms need to be translated accurately and made understandable for the reader in the context of the language used to present the findings. Additionally, I have adopted terms which have an established use in EU law for use in this research when suitable.

The professional vocabulary in the pharmacy field has been developed from the same scientific premises internationally. Thus, translating terms from Finnish or Norwegian to English is mostly unproblematic. There are, however, some characteristic features in the pharmacy system of both countries, which do not have accurate counterparts in

⁴⁶ *Michaels, Ralf*, *The Functional Method of Comparative Law* p. 345–347.

the English language. In such cases, I will attempt to describe the terms without the use of professional terms.

Under this research I will provide a definition of a medicinal product as opposed to non-medicinal products under the EU regulatory framework. I will also use the terms “pharmaceuticals” or “pharmaceutical products” interchangeably with the meaning “medicinal products”. Similarly, I will use the more everyday terms “prescription drug” and “over the counter drug” when discussing medicinal products subject to prescription and ones distributed without a prescription respectively.

3.5. Source Materials

This work utilises primary sources such as legislative acts and regulations as well as decisions and guidelines of public authorities in Finland and Norway. In researching the aims and intentions of the legislator, the comparison will rely on preparatory materials, *travaux préparatoires*, of legislative acts to a high degree.

Eckhoff discusses the significance and weight of different sources of *travaux préparatoires* in interpretation based on the instance which has produced the material. It could be argued that the greatest weight should be given to utterances from instances closest to the actual enactment of the relevant piece of legislation, for example on the opinions of parliamentary committees discussing the law proposal. However, Eckhoff emphasises the role of professional and expert opinions in drafting acts of legislation. The underlying legal and societal reasons for legislative choices can be found primarily in the opinions adopted by the instance which has actually drafted the law proposal. These choices are based on the professional and expert discussions and opinions expressed in preparatory committee as well as in policies outlined within the relevant ministry which is ultimately responsible for drafting the text of the law. Therefore, this research focuses on law proposals and preparatory memoranda as the principal source of information regarding the reasons for which a legislative act has been enacted.⁴⁷

Some works of legal research in the field of health law, social law, competition law and intellectual property law touch upon the topic of pharmaceutical distribution.

⁴⁷ Eckhoff, Torstein & Helgesen, Jan E., *Rettskildelære* p. 73–74.

However, legal research has produced very little literature regarding the regulatory framework of pharmacies as a field of business. Thus, the use of secondary sources is limited to some legal literature and to articles and reports regarding the functioning of the pharmacy system by state authorities, such as the Finnish Competition Authority, or by interest groups, such as the Norwegian Pharmacy Association. Pharmacy systems have been examined in economic and pharmaceutical research as well. I have utilised a number of economic reviews in this work. However, pharmaceutical research regarding pharmacies is more focused on concrete practices regarding the handling of drugs or the treatment for patients in pharmacies. Such research does not serve the knowledge interest at hand.

In developing the research method, I have mainly used Finnish works regarding legal theory. However, some of the works regarding legal theory and comparative law are international and some are Norwegian.

4. Background for Comparison

4.1. Nordic Legal Culture

This research examines the laws of Finland and Norway relating to the pharmacy sector within the context of the Nordic legal tradition.

Finland and Norway are both part of the Nordic family of law which is a special legal family within Civil Law. Nordic countries, which comprise Denmark, Finland, Iceland, Norway and Sweden, have close cultural ties and they have developed historically, politically and economically in a similar manner. Finland was part of the Swedish Empire from the thirteenth century to 1809 when it became an autonomous Grand Duchy within the Russian state. Finland gained independence from Russia at the end of 1917⁴⁸. Norway was under the control of the Danish crown until 1814 when it became part of Sweden. Norway became independent in 1905.⁴⁹

Nordic laws were historically based on old Germanic law with local variations in each country. Customary law, applied by laymen or elders, had a significant role in local

⁴⁸ Zetterberg, *Seppo*, Finland after 1917 p. 19.

⁴⁹ Zweigert, K. & Kötz, H., *An Introduction to Comparative Law* p. 277–278.

communities and legal life during the Middle Ages. The impact of the Church was significant as customary laws were written down. Furthermore, the role of the king grew both in Norway and in Sweden. In both countries, the first written laws were city and town laws.⁵⁰

In the 17th century, the idea of the nation state became more prominent. The role of the central administration and higher courts became significant in the development of the law. The influence of civil law is prominent in the Nordic countries, as particularly in the seventeenth century many Nordic legal scholars gained their education in protestant Germany. This brought with it the influence of Roman law. However, its impact was not as strong in the Nordics as in Continental Europe. Roman law was used for systemization of domestic city laws and customary law and to resolve deficiencies in the traditional local practices especially within commercial law, rather than as the primary source of law. Both within the Swedish Empire and in Denmark-Norway the centralization of power to the state led to the creation of comprehensive codes at the turn of the eighteenth century. These codifications were influenced by Roman law but were tied to the traditions of old law in construction, style and diction. In Nordic legal life Roman law was used and applied through a filter of rationality and practicality. High courts used a variety of legal sources and their decisions derogated from written law relatively often, thus influencing the development of law significantly. In the late 17th century, the influence of natural law highlighted the role of the state and of written law as the secular embodiment of universal law based on the will of God. The sovereignty and power of the state was justified through the idea that the state was in the best position to ensure the fulfilment of citizens' freedoms and rights and the interests of citizens were assumed to be in line with the interests of the state.⁵¹

In addition to using arguments regarding natural law, legal scholars began employing ideas which could be seen as the first steps toward positivism. Simultaneously, decision-making in courts started to rely more on written law. Inspired by the French Revolution, Sweden and Denmark both modernized their codes in the early 1800s.

⁵⁰ *Anners, Erik*, Den europeiske rettings historie p. 152, p. 161–162. *Pihlajamäki, Heikki & Pylkkänen, Anu*, Suomalainen oikeustiede eurooppalaisessa traditiossa p. 10–19.

⁵¹ *Anners, Erik*, Den europeiske rettings historie p. 152, p. 231–239. *Pihlajamäki, Heikki & Pylkkänen, Anu*, Suomalainen oikeustiede eurooppalaisessa traditiossa p. 25–47. *Zweigert, K. & Kötz, H.*, An Introduction to Comparative Law p. 278–280.

However, after Russia's annexation of Finland, the Finnish legal life underwent a stagnant period until the 1850s and the progressive approach taken by Czar Alexander II. However, under Russian rule, Finnish autonomy was embodied in the Finnish senate in which the role of lawyers became significant. During the late 1800s significant law reforms were introduced in nearly all areas of law in Finland. Universities began educating lawyers for purposes of the public administration and courts. The legal profession developed into its own distinct field during the 18th and 19th centuries. The role of legal positivism in Finland was emphasised through the passive struggle against periods of Russian oppression at the turn of the 20th century. Under positivist thinking, written law took a supreme position in the hierarchy of legal sources.⁵²

The Nordic legal systems are characterized by an underlying positivist tendency even today. Throughout the late nineteenth century and early twentieth century Sweden, Norway, Denmark and Iceland engaged in significant legislative cooperation and unification of commercial law. The principles of parliamentarianism and democracy were highlighted in the Nordic countries. When Norway became independent, its new constitution was based on Montesquieu's separation of powers. After gaining independence, Finland adopted results of Nordic cooperation in its legislation and joined the cooperation. For the first half of the twentieth century Finnish legal life was more conservative than in other Nordic countries. However, Finland joined the group of Scandinavian welfare states through rapid societal change and economic development after World War II.⁵³

As small nations on the northern fringe of Europe, the Nordic countries had much to gain from cooperation. Nordic countries benefited from reduced barriers to trade due to unification of laws. Due to sharing and comparing experiences, the resulting legislation was of good quality. The Nordic style of legal theory and legislative drafting, while open to influence from Continental Europe, has been reasonable and pragmatic in its adoption of external ideas and trends. Particularly during the 1930s – 1950s, Nordic legal scholars criticized positivism. The school of Scandinavian realism

⁵² *Anners, Erik*, Den europeiske rettens historie p. 240. *Pihlajamäki, Heikki & Pylkkänen, Anu*, Suomalainen oikeustiede eurooppalaisessa traditiossa p. 57–107. *Zweigert, K. & Kötz, H.*, An Introduction to Comparative Law p. 278–280.

⁵³ *Anners, Erik*, Den europeiske rettens historie p. 351, p. 365. *Pöyhönen, Juha (edit.)*, An Introduction to Finnish Law p. 4. *Zweigert, K. & Kötz, H.*, An Introduction to Comparative Law p. 280–281.

promoted the use of practical and real arguments in legal decision-making over abstraction and construction. Later on, also the analytic study of law challenged positivism and the jurisprudence of concepts. Thus, there has been a smaller tendency towards the construction of ambitiously large theoretical systems. For example, instead of carrying out immense codification projects, the legal order in Nordic countries consists of individual acts of legislation on more specified topics.⁵⁴

4.2. Sources of Law

Since Finland and Norway are part of the Nordic legal culture under the civil law family, both legal systems rely mainly on statutory law. The constitution, other legislative acts and lower level government regulations or decrees⁵⁵ are the primary sources of law. The hierarchy of national statutes, beginning with the highest, is: Constitution, act of law, government decree or regulation, decision of the Council of Ministers, decision of a Ministry and other authoritative instructions. Written sources of law are first and foremost interpreted based on the text of the statute, that is, its literal meaning. However, as more and more domains of society and life become regulated by legislation, written statutes have become more open and elastic: It is not feasible nor does it serve the purposes of the rule of law to regulate all contingencies in a casuistic manner. Open and elastic norms allow for more consideration and interpretation, which requires use of other sources of law. Their use is also necessary due to the fragmented nature of legal norms.⁵⁶

According to Aarnio, the classification of sources of law in relation to their binding force first presented by Aleksander Peczenik is the basis of the doctrine of source of

⁵⁴ *Husa, Jaakko*, Nordic Reflections on Constitutional Law p. 174. *Pihlajamäki, Heikki & Pylkkänen, Anu*, Suomalainen oikeustiede eurooppalaisessa traditiossa p. 114–117. *Zweigert, K. & Kötz, H.*, An Introduction to Comparative Law p. 280–285.

⁵⁵ This work refers to decrees in the Finnish legal system and to regulations in the Norwegian legal system. They are lower-level written norms issued by virtue of legislative acts and have an equivalent role in each legal system. However, the prevalent English term used for these written norms by Finnish and Norwegian legal scholars is different for each country.

⁵⁶ *Boe, Erik*, Innføring i juss. Juridisk tenkning og rettskildelære p. 223–224. *Eckhoff, Torstein & Helgesen, Jan E.*, Rettskildelære p. 22–24, p. 45–48, p. 54–63. *Nuotio, Kimmo; Melander, Sakari & Huomo-Kettunen, Merita (edit.)*, Introduction to Finnish Law and Legal Culture p. 55–58. *Pöyhönen, Juha (edit.)*, An Introduction to Finnish Law p. 12 and 26.

law in Nordic countries. The classification demonstrates the weight given to different sources of law as legal arguments in interpretation.⁵⁷

The first category, *strongly binding* sources of law, includes transnational legal sources which have priority over national legislation or which have been implemented in the national legal order, fundamental rights of the constitution, statutes and decrees or regulations and national custom. A decision which ignores a strongly binding source of law is illegal and should be overruled in appeal. Within this category, transnational law and the constitution are strictly binding. Deviation from statutes and national custom is possible only in case there are special grounds for bypassing the relevant strongly binding source of law.⁵⁸

The second classification is *weakly binding* sources of law. This category includes the intention of the legislator and precedents. In practice the strongest indicators of the legislator's intent are found in preparatory works, *travaux préparatoires*, such as government proposals, reports of preparatory committees and decisions of parliamentary committees. Precedents have a much smaller role in the Nordic legal culture than for instance in common law. However, public decisions of the Supreme Court and Supreme Administrative Court have weakly binding normative force. Also decisions of certain appellate courts from which there is no possibility of recourse to a higher court can have precedential value.⁵⁹

Lastly, Peczenik included the following sources of law in the group of *permitted* sources of law: practical arguments, ethical and moral arguments, general legal principles, prevailing opinion within jurisprudence and comparative arguments. These permitted sources of law are important as further argumentation for and against different alternatives of interpretation when other sources of law do not provide sufficient support for either option. Permitted sources of law are employed through consequential deliberation, whereby the evaluation is based on the possible results of

⁵⁷ Nuotio, Kimmo; Melander, Sakari & Huomo-Kettunen, Merita (edit.), Introduction to Finnish Law and Legal Culture p. 51–53. Pöyhönen, Juha (edit.), An Introduction to Finnish Law p. 25.

⁵⁸ Nuotio, Kimmo; Melander, Sakari & Huomo-Kettunen, Merita (edit.), Introduction to Finnish Law and Legal Culture p. 53–54. Pöyhönen, Juha (edit.), An Introduction to Finnish Law p. 25. Tolonen, Hannu, Oikeuden kaleidoskooppi p. 21–22.

⁵⁹ Boe, Erik, Innføring i juss. Juridisk tenkning og rettskildelære p. 234–236. Nuotio, Kimmo; Melander, Sakari & Huomo-Kettunen, Merita (edit.), Introduction to Finnish Law and Legal Culture p. 53–56. Pöyhönen, Juha (edit.), An Introduction to Finnish Law p. 28–29.

alternative conclusions. The interpreter can assess under which conclusion applicable legal principles are fulfilled to a greater extent. The options can also be weighed based on which of them yields the best moral or practical results.⁶⁰

Aarnio also categorizes sources of law as *authoritative* and *substantial*. The former refers to the institutional significance and the latter to the content of the source of law. Under this categorization, written law, *travaux préparatoires*, court decisions and jurisprudence are authoritative sources of law. They can be applied on the basis of their authoritative status. Custom, legal principles, moral and real arguments on the other hand draw their argumentative persuasiveness from their substance and therefore they alone cannot be applied as the basis of legal argumentation – their role is to work as arguments pro and contra authoritative arguments.⁶¹

Tolonen however finds that the role of principles within the sources of law is more complex than as presented by Peczenik and Aarnio. From a formal point of view, the relevance of legal principles in the legal system is weak. Rules are the primary factor which maintains and defines the contents of the law whereas principles have a secondary position. This view is prevalent in legal positivism. On the other hand, from the perspective of the substantive aspect, legal principles are part of the substance of the legal order and they are binding. The relevance of legal principles within the legal system has been described in more detail in chapter 3.3 which is also how this research treats legal principles. However, as legal positivism is part of the Nordic legal culture, the categorizations presented here are useful for understanding the basics of the doctrine of sources of law in Finland and Norway.⁶²

In Finland, EU law has primacy over national legislation. The EAA, EC and EU treaties have been incorporated with a qualified majority as an exception to the Constitution and thus have supremacy over national acts of law.⁶³ In Norway, the EAA treaty as well as other bilateral EU treaties have been implemented in the same manner as other international treaties as described in the following chapter.

⁶⁰ Nuotio, Kimmo; Melander, Sakari & Huomo-Kettunen, Merita (edit.), Introduction to Finnish Law and Legal Culture p. 53–59. Pöyhönen, Juha (edit.), An Introduction to Finnish Law p. 30. Tolonen, Hannu, Oikeuden kaleidoskooppi p. 21–22.

⁶¹ Tolonen, Hannu, Oikeuden kaleidoskooppi p. 21–24.

⁶² Tolonen, Hannu, Oikeuden kaleidoskooppi p. 22–30.

⁶³ Pöyhönen, Juha (edit.), An Introduction to Finnish Law p. 23. Scheinin, Martin (edit.), International Human Rights Norms in the Nordic and Baltic Countries p. 257–258.

4.3. Fundamental and Human Rights in the Legal System

This chapter examines the role of fundamental and human rights in Finland and Norway. The former are rights guaranteed under the constitution and latter are provided for in international human rights treaties which the state has ratified. Nordic countries implement international treaty provisions in a fairly similar manner to each other. Also, Nordic countries traditionally share similar foundational values and a common constitutional conception which includes the following elements: parliamentary system, legislative supremacy, consensual democracy, limited relevance of judicial review, elements of constitutionalism, constitutional conformity interpretation, duty to ensure fundamental rights on legislature rather than on courts. One example of differences between Finland and Norway is judicial review. Neither country has a constitutional court. In Finland, constitutional conformity of legislative acts is reviewed *a priori* by the special parliamentary standing committee, Committee for Constitutional Law (*Perustuslakivaliokunta*), whereas the role of the Supreme Court in Norway in judicial review is greater than in other Nordic countries.⁶⁴

The following chapters outline how international human rights treaties have been implemented and how fundamental rights are applied in the Finnish and Norwegian legal system.

4.3.1. Finland

Traditionally Finland has employed the dualistic model in defining the relationship between domestic and international law. Thus, the main rule is that international provisions under international treaties need to be included as part of national law. Ratification of international treaties requires approval from the Finnish Parliament (Constitution of Finland (*Suomen perustuslaki* 731/1999, CoF) CoF 94 §, 95 §)). The actual implementation of treaty provisions on the other hand can be carried out in several ways.⁶⁵

Firstly, international treaties can be incorporated into the Finnish legal system through an act of Parliament or a government decree stating that the international treaty and

⁶⁴ Husa, Jaakko, Nordic Reflections on Constitutional Law p. 172–180. Nuotio, Kimmo; Melander, Sakari & Huomo-Kettunen, Merita (edit.), Introduction to Finnish Law and Legal Culture p. 111–112.

⁶⁵ Saraviita, Ilkka, Suomalainen perusoikeusjärjestelmä p. 37–39.

its provisions are in force in Finland. According to Scheinin, wide use of the incorporation method suggests a kind of “de facto monism”. Under this method, the provisions of the treaty will have the same position in the hierarchy of laws as the ratifying act or decree. Incorporation has been the most common method of implementing international treaty provisions in the Finnish legal order⁶⁶. The second method is implementation through transformation. This entails enacting new legislation or amendments to existing legislation in order to bring domestic law to be in line with international treaty provisions. Thirdly, treaties can be implemented by reference. Under this method, special clauses in domestic legislation state that international treaties need to be taken into account, creating a domain within the domestic legal order which is in practice monistic.⁶⁷

In Finland, a rule of presumption is applied to cases where national legislation and international treaties have conflicting interpretations. Courts are allowed and required to assume that in enacting legislation the Parliament had no intention to derogate from international treaty obligations unless an intention to derogate from them is expressly stated and thus interpret domestic statutes in line with international treaties.⁶⁸

Also international human rights treaties need to be implemented – they do not have a self-executing status in Finland. Most international human rights treaties have been incorporated through an act of Parliament and can be applied directly by domestic courts and public authorities. The European Social Charter (ESC)⁶⁹ and the European Convention on Human Rights (ECHR)⁷⁰ were both implemented in this manner in Finland in 1990. Prior to the constitutional reform in 2000, pursuant to section 92 of the Finnish Constitution Act (*Suomen hallitusmuoto* 94/1919) judges and public authorities had a duty not to apply government decrees which are in conflict with the Constitution or acts of Parliament. The corresponding provision can be found in section 107 of the Finnish Constitution. In practice this meant an obligation to interpret lower-level statutes in line with the constitution and acts of Parliament.

⁶⁶ Pöyhönen, Juha (edit.), *An Introduction to Finnish Law* p. 34.

⁶⁷ Scheinin, Martin (edit.), *International Human Rights Norms in the Nordic and Baltic Countries* p. 257–258.

⁶⁸ Scheinin, Martin (edit.), *International Human Rights Norms in the Nordic and Baltic Countries* p. 260.

⁶⁹ European Social Charter, Turin 18 October 1961.

⁷⁰ Convention for the Protection of Human Rights and Fundamental Freedoms, Rome, 4 November 1950.

However, this provision did not apply in relation to international human rights treaties which had been implemented only by government decree due to their programmatic nature, such as the UN International Covenant on Economic, Social and Cultural Rights⁷¹. However, the matter has been resolved under the new Finnish Constitution.⁷²

In 2000, the Finnish Constitution was enacted after a reform process combining the four acts of law which until then had constitutional status⁷³. The constitutional reform built on the constitutional tradition of the country so far and did not constitute a drastic change in the Finnish constitution and legal life. However, it modernized the constitution and increased parliamentarianism. The new Constitution of Finland included a catalogue of fundamental rights which had been included in the Constitution Act in 1995 in connection with Finland's accession to the EEA and EU membership. The catalogue of fundamental rights reflected international human rights treaties and included civil rights and freedoms as well as social human rights. In addition to cataloguing fundamental rights, the 1995 reform aimed at emphasizing the obligation of courts and public authorities to apply fundamental rights norms in their decision-making.⁷⁴

In connection with the 1995 fundamental rights reform, the Committee for Constitutional Law discussed the application of fundamental rights and their position in the hierarchy of laws. The memorandum of the Committee (25/1993) has since defined the interpretation of fundamental rights and the manner in which they are binding upon the legislator in the legislative process. The Committee for Constitutional Law reviews whether proposed acts of legislation conform with the constitution and what their relationship is with international human rights treaties (CoF 74 §). In connection with the statement in Section 1 of the Constitution that "Finland participates in international cooperation for the protection of peace and human rights", *a priori* judicial review has made the enactment of legislation in conflict with

⁷¹ 1966 United Nations International Covenant on Economic, Social and Cultural Rights, New York.

⁷² *Christiansen, Beate S.*, Norsk rett og menneskerettighetene – utviklingslinjer, dynamikk og samspill p. 6. *Saraviita, Ilkka*, Suomalainen perusoikeusjärjestelmä p. 233. *Scheinin, Martin (edit.)*, International Human Rights Norms in the Nordic and Baltic Countries p. 259–261.

⁷³ These acts were the Constitution Act, the Act on Ministerial Responsibility (*Ministerivastuulaki* 274/1922), the Act on the High Court of Impeachment (*Laki valtakunnanoikeudesta* 273/1922) and the Parliament Act (*Valtiopäiväjärjestys* 7/1928).

⁷⁴ *Husa, Jaakko*, Nordic Reflections on Constitutional Law p. 114–118. *Saraviita, Ilkka*, Suomalainen perusoikeusjärjestelmä p. 98–101.

human rights impossible in practice. In its recommendations, the Committee also emphasized interpretation of Finnish legislation in favor of fundamental and human rights. This gives international human rights a limited status of *lex superior* in the hierarchy of laws. In addition to the Committee for Constitutional Law, the Parliamentary Ombudsman gives statements on the application of international human rights in the Finnish legal systems and has for example applied certain international treaties such as the ECHR already before its ratification in Finland.⁷⁵

The new Constitution includes the prohibition of delegating the competence to decide on measures which restrict fundamental rights with use of a decree or other decision which is on a lower level of hierarchy than an act of Parliament (CoF 80 §). Since then the legislative process has included a review of whether the proposed law includes such a delegation. Section 22 of the Finnish Constitution brings human rights on the same level with fundamental rights: “The public authorities shall guarantee the observance of basic rights and liberties and human rights.”⁷⁶

Finland’s membership in the European Union is provided for in Section 1.3 of the Finnish Constitution and EU law is directly applicable in Finland and has precedence over domestic legislation. This means that the precedents of the Court of Justice of the European Union (CJEU) as well as the special doctrine of sources of law within EU law are applied legal interpretation. The EU Charter of Fundamental Rights⁷⁷ also has direct application in Finland. Through the accession of the EU to the ECHR under the Lisbon Treaty⁷⁸ the human rights under the ECHR became directly applicable via EU law (Lisbon Treaty Art. 6.2).⁷⁹

4.3.2. Norway

Like Finland, in its implementation of international treaties Norway follows the dualistic model. Therefore, in order for public authorities and courts to be bound by provisions of international human rights treaties in their decision-making, the provisions need to be implemented as part of the Norwegian legal order. Also, the rule

⁷⁵ Saraviita, Ilkka, *Suomalainen perusoikeusjärjestelmä* p. 39–41, p. 69–70, p. 97–107, p. 233–234. Scheinin, Martin (edit.), *International Human Rights Norms in the Nordic and Baltic Countries* p. 268.

⁷⁶ Saraviita, Ilkka, *Suomalainen perusoikeusjärjestelmä* p. 38, p. 109.

⁷⁷ Charter of Fundamental Rights of the European Union (2000/C 364/01).

⁷⁸ Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community, 13 December 2007.

⁷⁹ Saraviita, Ilkka, *Suomalainen perusoikeusjärjestelmä* p. 59–60, p. 234–236.

of presumption is applied in the interpretation of domestic legislation by courts, and thus interpretation in conformity with international treaties is preferred. Domestic sources of law must include clear evidence that the legislator in fact intended to derogate from treaty provisions in order to allow an interpretation which conflicts with the treaty.⁸⁰

The methods of implementation used in Norway include incorporation, reference and transformation. Similarly to the Finnish system, the Constitution of Norway (CoN) (*Kongeriket Norges Grunnlov*, 17. mai 1814) requires approval from the Parliament for international treaties (CoN 26 §). Through the method of reference, some treaties enjoy direct applicability within specified spheres of the domestic legal order. International treaties incorporated into Norwegian law by an act of Parliament can be considered an order directed at public authorities to observe the provisions of the treaties in their activities and decision-making.⁸¹

In 1999, Norway incorporated the ECHR, the 1966 United Nations International Covenant on Civil and Political Rights⁸² and the 1966 United Nations International Covenant on Economic, Social and Cultural Rights as part of Norwegian law in the Norwegian Human Rights Act (Lov om styrking av menneskerettighetenes stilling i norsk rett 21. mai 1999 nr. 30 (*menneskerettsloven*)). The preparatory committee of the Human Rights Act discussed the position of international human rights in the Norwegian legal system and proposed that the international human rights treaties which Norway has ratified should be incorporated by act of Parliament and the text of the treaty should be included in original form and as a translation in the act. The committee also proposed the inclusion of a direct statement regarding human rights in the Norwegian Constitution. Such a statement was introduced and is now included in Article 92 of the Norwegian Constitution.⁸³

⁸⁰ *Eckhoff, Torstein & Helgesen, Jan E.*, Rettskildelære p. 295–297. *Christiansen, Beate S.*, Norsk rett og menneskerettighetene – utviklingslinjer, dynamikk og samspill p. 12–13. *Scheinin, Martin (edit.)*, International Human Rights Norms in the Nordic and Baltic Countries p.205–213.

⁸¹ *Scheinin, Martin (edit.)*, International Human Rights Norms in the Nordic and Baltic Countries p.205–213.

⁸² 1966 United Nations International Covenant on Civil and Political Rights, New York.

⁸³ *Eckhoff, Torstein & Helgesen, Jan E.*, Rettskildelære p. 302–304. *Christiansen, Beate S.*, Norsk rett og menneskerettighetene – utviklingslinjer, dynamikk og samspill p. 20–29.

Article 92 of the Norwegian Constitution requires that courts and public authorities respect and ensure fundamental and human rights “as they are expressed in the Constitution and in the treaties concerning human rights that are binding for Norway”. This provision has the role of a rule of interpretation for courts but also works as a requirement for the legislator to consider the requirements of human rights and promote them through legislation. As a consequence, international human rights have a limited status of *lex superior* in the hierarchy of laws in Norway, similarly to Finland. Therefore, in the domain of human rights, the Norwegian system is not far from a monistic system.⁸⁴

The role of EU law in Norway is based on the implementation of the Agreement on the European Economic Area (EEA Agreement)⁸⁵ and the Convention Establishing the European Free Trade Association (EFTA Convention)⁸⁶ in Norwegian law. The EEA Agreement and EFTA Convention have been incorporated by act of Parliament. Therefore they are directly applicable as a part of Norwegian law. The status of EU law within the Norwegian legal system has been defined in the Act Implementing the EEA Agreement⁸⁷. However, some bilateral treaties between Norway and the EU have been incorporated with use of a government regulation and their hierarchy in the Norwegian legal system is on the level of a regulation. EU law has a special role in the sources of law in Norway. The EEA Agreement establishes an obligation for courts and public officials to apply provisions of the EU treaties in line with EU law and the precedents of the CJEU. Therefore, the special doctrine of sources of law within EU law should also be applied when interpreting Norwegian legislation based on EU treaties.⁸⁸

The following chapters discuss health law and the fundamental and human rights which have particular relevance within the field.

4.4. Health Law

⁸⁴ *Eckhoff, Torstein & Helgesen, Jan E.*, Rettskildelære p. 296, p. 304–313. *Christiansen, Beate S.*, Norsk rett og menneskerettighetene – utviklingslinjer, dynamikk og samspill p. 10–21.

⁸⁵ Agreement on the European Economic Area, 1 January 1994.

⁸⁶ Convention Establishing the European Free Trade Association, Stockholm, 4 January 1960.

⁸⁷ Act implementing the EEA Agreement (Lov om gjennomføring i norsk rett av hoveddelen i avtale om Det europeiske økonomiske samarbeidsområde (EØS) m.v. (EØS-loven)).

⁸⁸ *Boe, Erik*, Innføring i juss. Juridisk tenkning og rettskildelære p. 277–281. *Christiansen, Beate S.*, Norsk rett og menneskerettighetene – utviklingslinjer, dynamikk og samspill p. 35–37.

4.4.1. Health Law within the Legal System

In order to identify the human and social rights which, as suggested in the research paradigm, influence legislative decisions, it is necessary to determine in which area of law the topic of comparison belongs. By viewing the research topic within its position in the systemisation of laws it is also possible to examine the rights and principles which influence the legal institutions within that area of law.

Pharmacy law can be examined from various perspectives and questions related to medicinal products can be placed within different areas of law. For example, the prevention of substance abuse by imposing sanctions is a question within criminal law and the protection of an inventor's commercial interest against generic drugs is a question of patent law. Comparative law aims at viewing the legal system as a whole, and the scope of contingent problems from a functionalist perspective can span the entire legal system. Thus, comparison relating to pharmacy law covers matters which are usually dealt with within different areas of law.

However, the principal knowledge interest in this work is related to the fundamental human rights which influence the legislator's choices in regulating distribution of medicinal products and the pharmacy system as a whole. In this case, the central questions concern the relationship between individual citizens and other actors such as the state and commercial entities in pharmaceutical business. The foremost areas of law to be considered are social law and health law, while research on human rights within the national legal system is also related to constitutional law. Other areas of law which influence the structure and development of pharmacy systems include competition law, tax law, corporate law, consumer protection law and intellectual property rights.

Within the systemisation of different areas of law, health law is considered to be either a field of public law parallel with social law or as such a part of social law.⁸⁹ In any case it is beneficial to define both areas of law and to consider the general principles of both fields for the purposes of this research.

Social considerations have permeated nearly all parts of welfare state legal systems. Despite of this, the manner of regulation and decision-making within social law is

⁸⁹ *Lahti, Raimo*, Lääkintäoikeuden kehitys Suomessa p. 1010.

distinctly different from the manner in which regulation and decision-making are carried out within core areas of the legal system such as criminal law and civil law. This makes the field of social law distinct from the core areas of the legal system. Social law can be defined as the set of legal norms which regulates social security and healthcare.⁹⁰

Within the traditional areas of law, social law has the closest ties with administrative law as the implementation of legal norms in the field is carried out mostly by municipalities, state authorities and institutions which are considered to be indirectly part of public administration. Furthermore, the same legal norms of administrative law are applied in most measures of legal protection in social law and in motions to appeal the decisions of municipal or state organs. Thus, the general principles of administrative law have particular relevance within social law and health law.⁹¹

The matters which social law regulates, meaning social security and the healthcare system, call for special principles and legal institutions. Legal decision-making regarding matters of social law characteristically demands special expertise such as medical or psychological expertise instead of traditional legal expertise. Furthermore, decisions regarding individual rights are at the first instance often made by others than lawyers, for example by a doctor or a social worker. The quantity of matters at the first instance is significantly higher in matters of social security than in judicial decisions usually handled at first instance in court proceedings. Another characteristic of social law is that the legislation is in practice supplemented significantly by norms given by public authorities and officials such as interpretation guidelines provided by a state authority to its local offices. Decisions made within healthcare practice can have a significant role for an individual citizen and law can only provide a legal framework for practical situations requiring medical expertise. Thus, the ethical guidelines set by organisations of medical and other professionals provide supplementary social law norms.⁹²

In Finland the term corresponding to health law, *terveysoikeus*, has not been adopted into wider use. However, in Finnish legal literature the terms used to refer to the field

⁹⁰ Tuori, Kaarlo, *Sosiaalioikeus* p. 2–3.

⁹¹ Tuori, Kaarlo, *Sosiaalioikeus* p. 3–5.

⁹² Tuori, Kaarlo, *Sosiaalioikeus* p. 5–7.

translate as medical law or law and medicine, *lääkintäoikeus*, and healthcare law, *terveydenhuolto-oikeus*. The former term deals particularly with legal questions concerning the relationship between a patient and a healthcare professional.⁹³ The latter term is interchangeable with health law, and refers to legal matters regarding the healthcare system. The term health law, *helserett*, is generally used in the Norwegian legal research. This Norwegian term for health law covers legal questions regarding the doctor-patient relationship as well as the healthcare system.

The next chapter outlines the concept of health law used in this research and the central principles based on the understanding of health law within the Norwegian and Finnish legal systems.

4.4.2. Concept of Health Law

The following disciplines can be categorized under health law: biomedical or bio law, patient rights, reproductive law, medical law, healthcare law and medical ethics. As described above in the case of social law, health law has close ties to administrative law. Furthermore, the doctor-patient relationship and its liability matters have also been systemised through concepts of criminal law and the law of torts.⁹⁴

In Finland and Norway health law as an area of study has developed in conjunction with international human rights thinking. During the 20th century the way that the doctor-patient relationship is viewed has changed from a paternalistic approach to one which highlights the autonomy of the individual.⁹⁵ National laws have been reformed in line with this change and due to the shortcomings regarding the way in which the legal system dealt with e.g. medical liability. The speed of scientific and technological development led to new demands for regulation within the medical science and healthcare. Finland and Norway have carried out law reform projects regarding health and healthcare services also as a part of ratifying international treaties.⁹⁶

The human right to health is covered in Article 12 of the International Covenant on Economic, Social and Cultural Rights, which provides for “the right of everyone to the

⁹³ *Pahlman, Irma*, Potilaan itsemääräämisoikeus p. 3.

⁹⁴ *Warberg, Lasse A.*, Norsk helserett p. 10–20. *Pahlman, Irma*, Potilaan itsemääräämisoikeus p. 1–47. *Lohiniva-Kerkelä, Mirva*, Terveysthuollon juridiikka p. 18–20.

⁹⁵ *Warberg, Lasse A.*, Norsk helserett p. 18–20.

⁹⁶ *Pahlman, Irma*, Potilaan itsemääräämisoikeus p. 18–35.

enjoyment of the highest attainable standard of physical and mental health”⁹⁷. Article 13 of the European Social Charter imposes an obligation to the state to provide adequate assistance to “any person who is without adequate resources” and care in case of sickness⁹⁸. Also, the Convention on Human Rights and Biomedicine⁹⁹ sets requirements for the respect and protection of human dignity, self-determination, and privacy if individuals, equal access to healthcare and professional standards in the healthcare sector. International treaties do not specify standards for healthcare required from the state for every citizen regardless of the wealth of the state, nor do they impose sanctions on non-compliant states. However, they work towards putting pressure on ratifying states to establish national healthcare systems which are accessible to all citizens equally and to create a financial basis for their functioning within the means of the state.¹⁰⁰

The earliest regulations within health law concerned reproductive rights and medical ethics. During the 1970s Finland introduced reforms to modernise its legislation on abortion, medical sterilisation and the treatment of mental disease and disability. This first stage of reform worked towards eliminating defects in the freedom rights of patients. Simultaneously, the Finnish healthcare system underwent a significant overhaul and it was brought to fit the welfare state standards of the time. In the 1980s, the Finnish Patient Injury Act (585/1986, FPIA) was introduced in order to improve the legal protection of patients against medical malpractice as well as to clarify the status of healthcare professionals and the manner in which liability was distributed. Under the FPIA, compensation was available to patients without the need to establish fault or negligence on behalf of medical personnel. The FPIA was also applied to cases of violations of the patient’s self-determination when alternative forms of treatment were available. Within the field of social welfare, Finland also introduced acts concerning social welfare, child welfare and welfare of substance

⁹⁷ The United Nations International Covenant on Economic, Social and Cultural Rights, New York, 16 December 1966. Ratified by Finland in 1975 and by Norway in 1972.

⁹⁸ European Social Charter, Turin 18 October 1961. Ratified by Finland in 2002 and by Norway in 2001.

⁹⁹ Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 4 September 1997. *Pahlman, Irma*, Potilaan itsemääräämisoikeus p. 64.

¹⁰⁰ *Modeen, Tore*, Legal Aspects of Citizens’ Access and Equality within the Finnish Health Care System p. 223–227.

abusers as well as special legislation regarding resource allocation and the organization within the social welfare and healthcare system.¹⁰¹

Similarly, development of patient rights and health law in Norway proceeded hand in hand with the emergence of human rights through international treaties in the post-war period and the subsequent focus on individual rights. Other sectors of public administration were reformed in the spirit of the discussion on rule of law in the 1960s and 1970s. The 1980s saw increased discussion on patient rights. In the Medical Practitioners Act of 1980, the legislator in Norway introduced improvements to patient rights such as the right to information regarding one's health and treatment, the right to access medical records and the right to participate during treatment. However, the Act did not provide for a statutory right to self-determination.¹⁰²

The shift of legal thinking in healthcare from the paternalistic approach to one focused on the rights of the individual led to a greater need for legislation regarding patients' rights. Increasing discussion and research concerning health law by legal professionals in Finland and Norway contributed to this development.¹⁰³ In both countries, regulation regarding patient rights was scattered across multiple legislative acts dealing with different aspects of health and the healthcare system as well as in criminal law and tort law. In order to establish a model of a doctor-patient relationship based on democratic professional cooperation and patient self-determination, the matter of patient rights needed to be brought together in one act.¹⁰⁴

As the first country in the world, Finland introduced a patient's rights act in 1993. The Finnish Act on the Status and Rights of Patients (*Laki potilaan asemasta ja oikeuksista* 785/1992) covers rights of the patient to good care and treatment, to information and to self-determination, the principle of informed consent as well as measures to protect the rights of the patient such as a notice right of the patient to the head of the

¹⁰¹ Pahlman, Irma, Potilaan itsemääräämisoikeus p. 22–40. Lahti, Raimo, Towards a Comprehensive Legislation Governing the Rights of Patients: The Finnish Experience p. 208–212.

¹⁰² Kjøenstad, Asbjørn & Syse, Aslak, The Growth of Patients' Rights in Norway p. 255–262.

¹⁰³ Kjøenstad, Asbjørn & Syse, Aslak, The Growth of Patients' Rights in Norway p. 270–271.

¹⁰⁴ Lohiniva-Kerkelä, Mirva, Terveystenhäällön juridiikka p. 18–20.

healthcare unit. Also, the institution of the patient ombudsman already in use in many healthcare units became compulsory under the new act.¹⁰⁵

The Norwegian Ministry of Health and Social Affairs commissioned a draft for a Bill on Patients' Rights in 1988, which resulted in the government report NOU 1992:8 Lov om pasientrettigheter (Act on Patients' Rights). The report was criticised due to the proposal to provide a right to treatment for cases of "a serious sickness, injury or handicap". In their 1994 article, Kjønstad and Syse argued, that the distribution of healthcare services should not be allocated based on the seriousness of the medical condition as less ill patients can at times benefit from treatment even more than those who are very seriously ill. This criticism brings out the tension between the principle of need and the principle of equal access when brought into the context of factual circumstances: In order to ensure equal access, the state must also employ a standard for the allocation of resources within healthcare. Kjønstad and Syse also pointed out that the requirement of serious sickness was open to interpretation which in practice would lead to unnecessary litigation. After several years of further discussion and preparation, the Norwegian Patients' Rights Act (Lov 2. juli 1999 nr. 63 om pasient- og brukerrettigheter) came into force in 2001.¹⁰⁶

Along with this development, the doctor-patient relationship has become legal in nature. As the rights, responsibilities and liabilities within this relationship have become more clearly defined, the negative implications of regulation have also increased. The doctor-patient relationship is built on trust and confidence. A legalistic focus in this relationship can be problematic, as it becomes more open to conflict and the parties may need to focus on defending their rights and limiting their liability rather than on cooperation. This issue was also evident in the discussion regarding the Norwegian Patients' Rights Act of 2001. Furthermore, poorly drafted and implemented regulation can limit the medical professional's approach to providing care by bringing forth impersonal legal solutions rather than addressing the patient's personal needs.¹⁰⁷ This was taken into account in the Finnish Patient Injury Act by structuring the process

¹⁰⁵ *Lehtola, Pentti, Potilaan oikeusturva* p. 8–12. *Pöyhönen, Juha (edit.)*, An Introduction to Finnish Law p. 482.

¹⁰⁶ *Kjønstad, Asbjørn & Syse, Aslak*, The Growth of Patients' Rights in Norway p. 276–277.

¹⁰⁷ *Warberg, Lasse A.*, Norsk helserett p. 49.

of retaining recovery in a manner which highlights the right to compensation rather than placing blame.¹⁰⁸

The right to healthcare has been particularly challenging for the legislator both in Finland and in Norway. The legislator has paid attention to health law at a time when the “human rights train” was already passing by: The trend of codifying rights and entitlements to individual citizens preceded the health law discussion. Once the legislator started concrete work on matters relating health law, the tide had turned and it was no longer recommendable to grant new individual rights which the state and other public sector actors would then be obliged to fulfil. International conventions typically call for equal access to healthcare but they do not define standards for an individual’s right to healthcare. In Finland and in Norway, an individual only has the right for emergency treatment. In non-emergency cases, the fulfilment of the individual’s right to healthcare is contingent on prioritization and allocation of resources within the relevant healthcare unit and the overall healthcare system. The state’s participation in this process is largely financial, as policy decisions on prioritization are made in municipalities, counties and other local public sector actors. Decisions regarding prioritization in the day to day functioning of healthcare units are made by healthcare personnel such as doctors, nurses or head surgeons. In practice, through prioritization the healthcare professional evaluates which patient should be treated first and which kind of medical procedures are not only effective but also cost effective in a specific case¹⁰⁹. Due to the scarcity of resources, it has been easier for the legislator to focus on providing legal remedies and control systems to protect patient rights instead of granting specific rights to the patient under law. Such legal claims to treatment could potentially become financially burdensome and unfeasible to fulfil.¹¹⁰

In relation to health law, it is important to note that legal remedies and control systems have a very different practical relevance than for instance in private law or even in other areas of administrative law. Even in cases where the right to treatment is explicit and the law provides for remedial legal protection, restitution may of little

¹⁰⁸ *Pahlman, Irma*, Potilaan itsemääräämisoikeus p. 37–41.

¹⁰⁹ *Warberg, Lasse A.*, Norsk helserett p. 30–35.

¹¹⁰ *Modeen, Tore*, Legal Aspects of Citizens’ Access and Equality within the Finnish Health Care System p. 229–232. *Kjønstad, Asbjørn & Syse, Aslak*, The Growth of Patients’ Rights in Norway p. 259–274.

relevance or not possible in practice. For example, in case a patient in immediate need of medical assistance is denied treatment, the consequence for the patient can be as severe and as irreversible as death or permanent disability. This is why ethical considerations and professional ethical standards have a special role in health law. Medical ethics examines conflicting and congruent interests of the healthcare professional, patient and society in a critical manner and professional standards based on ethical considerations reduce the need for detailed regulation. For example, Article 4 of the Convention on Human Rights and Biomedicine calls for the use of ethical standards in situations which are not covered by provisions of law.¹¹¹

However, relevant rights within health law cannot be left to rely only on ethical standards. Within a welfare state, social human rights and the principles of health law should be evident also in written law¹¹². This is the case in the Finnish Constitution as well as the Norwegian Constitution where many of the rights relevant to health law have the status of fundamental rights. The underlying constitutional values relevant to health law include respect for human dignity, the rights and freedoms of the individual and justice. In addition to the fundamental rights described in the following chapter, these underlying principles have a role in interpreting legislation regarding health.¹¹³

Legislation regarding pharmaceutical care is part of health law and the principles of health law apply in the field. As I have described in the Introduction to this research, the distribution of medicinal products includes a transaction from the health professional to the patient. Pharmacies function as private businesses and the recipients of their service and products are not only patients but customers. Thus, the pharmacy sector can be regulated more directly and in a more interventional manner. Since the transaction is tangible, also its value can be determined more easily. Furthermore, the actors are separate from each other. In healthcare, the expenses and income of the healthcare are public sector expenses and income. However, in the pharmacy sector the expenses and income are allocated to the proprietor of the

¹¹¹ *Modeen, Tore*, Legal Aspects of Citizens' Access and Equality within the Finnish Health Care System p. 229–232. *Kjønstad, Asbjørn & Syse, Aslak*, The Growth of Patients' Rights in Norway p. 259–274. *Pahlman, Irma*, Potilaan itsemääräämisoikeus p. 87–88, p. 116. *Mikkola, Matti*, Social Human Rights of Europe p. 22. *Tuori, Kaarlo*, Lagstiftningsstrategierna inom social- och hälsovården p. 11–12.

¹¹² In his 1993 article regarding strategies for legislation within the social and health sector, Kaarlo Tuori argues in favor of including social human rights in the catalogue of fundamental rights proposed for the Finnish Constitutional Act. *Tuori, Kaarlo*, Lagstiftningsstrategierna inom social- och hälsovården.

¹¹³ *Pahlman, Irma*, Potilaan itsemääräämisoikeus p. 104.

pharmacy and state expenses consist of reimbursement of medicine expenses for citizens. Also, the citizen carries the costs of their pharmacy purchases to a greater extent than in healthcare: as a rule, the pharmacy establishment runs on its revenue from sales whereas a healthcare unit is funded mostly by the public sector.

All of the abovementioned factors lead to a greater ability of the state to monitor its expenses relating to pharmaceuticals. The state also has a greater selection of mechanisms with which it can impact the sale and prices of medicinal products. The state can for example impose tax-like payments on pharmacies whereas the same would not increase the states revenue if imposed on hospitals run on public funds.

Despite the differences between the pharmacy sector and healthcare, the same principles of health law apply to the sale of medicinal products and to the profession of the pharmacist. Pharmaceuticals have an essential role in healthcare and in preventive care. Thus, the state must take the principles of health law into consideration in its legislation concerning medicinal products and the pharmacy sector. The next chapter outlines the central principles and fundamental rights which impact the legislator's decision-making in the field and which have been used in determining the specific focus of this research.

4.4.3. Social Human Rights as Fundamental Rights

Health law deals with the following rights: human dignity, the patient's right to self-determination, right to privacy, right to health, access to healthcare and equal treatment. These rights represent the social rights family of human rights. It is characteristic of social rights that their fulfilment is carried out collectively and gradually. The state is obliged to commit to fulfilling and promoting these rights according to its level of development and available resources.¹¹⁴

The following rights relevant to health law are fundamental rights in the Finnish and Norwegian legal systems. Equality of individuals under the law has been ensured in CoF Section 6 and in CoN Article 98. The fundamental right for equal treatment is central for ensuring justice in the health sector. The right to privacy has been ensured in CoF Section 10 and CoN Article 102. Both the Finnish and the Norwegian constitution ensure the right to life, personal liberty and integrity (CoF 7.1 §, CoN 93 §,

¹¹⁴ *Mikkola, Matti, Social Human Rights of Europe p. 2–5.*

94.1 §, 102.2 §). These rights form the foundation of the principle of self-determination. Social human rights ensured in CoF Section 19 ensure the “right to receive indispensable subsistence and care” for those without sufficient means and a requirement for the state to guarantee “adequate social, health and medical services and promote the health of the population”. The Norwegian Constitution does not include a corresponding provision. However, CoN Article 104 includes an obligation for the state to ensure “necessary economic, social and health security” for children. Together with the right to life, rights relating to social assistance and healthcare ensure the minimum requirements for the fulfilment of human dignity.¹¹⁵

Since social human rights are strongly connected to resources, equal treatment has a central role in the fulfilment of all social rights. Equal treatment can be promoted in different ways. Under the first example, labour market old age pension, the social benefit rises with an individual’s labour earnings. Another option is to treat everyone similarly irrespective of their situation which has been the case with child benefit in Finland. The third option is to distribute benefits based on need.¹¹⁶

In Finland and Norway, the most significant manner in which the state promotes equal treatment in relation to medicinal products is reimbursement of medicine expenses under national social insurance schemes. In both countries the system employs the two latter forms of equal treatment. Firstly, the rates at which costs are reimbursed are the same for everyone. However, medicinal products are included within the scope of reimbursement according to the medical purpose and need which they serve. Furthermore, individual exceptions can be made when necessary and social assistance for medicine expenses is available for those who otherwise could not afford their necessary medicinal products.

In relation to social rights the state’s obligations can work on several levels. On the first level, the state must respect a relevant right or freedom. This is more applicable to civil and political rights – however, human dignity requires respect on behalf of the state. No-one should be subjected to inhumane treatment. An example under health law would be the abolishment of forced castration of the mentally disabled in Finland in

¹¹⁵ *Pahlman, Irma*, Potilaan itsemääräämisoikeus p. 103–104. *Saraviita, Ilkka*, Suomalainen perusoikeusjärjestelmä p. 339.

¹¹⁶ *Mikkola, Matti*, Social Human Rights of Europe p. 9.

1970¹¹⁷. The next level of the state's fulfilment of social rights is protection. For example, the right to health requires that the state has sufficient institutions of pharmacovigilance in place to protect its citizens from deficient medicinal products. This is done through the requirement of a market authorization for all medicinal products which is followed up with meticulous reporting and supervision processes for the products which have been placed on the market. Thirdly, the state has an obligation to ensure the fulfilment of social rights such as minimum income and emergency healthcare. Lastly, depending on the nature of the obligation defined in the relevant international convention or national act of law, the state may be obliged to promote the relevant social right. Promotion makes the nature of the obligation progressive and it sets a requirement for the state to strive for and to achieve progress in the relevant field. One example of this is promotion of public health through allowing the sale of nicotine replacement products in retail stores and kiosks in Finland for the purpose of lowering the threshold to quit smoking.¹¹⁸

4.4.4. Functionalist Comparison of Pharmacy Legislation

Regulation concerning the pharmacy sector and medicinal products needs to take into account of fundamental rights ensured in the constitution as well as the underlying principles of health law. However, the central question which the state has to answer when regulating the pharmacy sector and medicinal products is: *"How can the state ensure equal access to pharmaceutical care for all citizens?"*

This question can be divided into three different and at times conflicting aims. Firstly, the state must ensure that all citizens have reasonable access to pharmaceuticals in that they are available without unreasonable delay or effort. Thus, the state will for instance need to ensure that the pharmacy network is comprehensive enough that individual citizens do not need to travel long distances or wait a long time for their medicine. Secondly, the state must ensure that all citizens have sufficient means to afford to pay for their necessary medicines. Thirdly, the state must ensure that the pharmaceutical care which the citizens receive is effective, appropriate and safe. The focus of this research is on these questions.

¹¹⁷ Pahlman, Irma, Potilaan itsemääräämisoikeus p. 25.

¹¹⁸ Mikkola, Matti, Social Human Rights of Europe p. 23–25.

The legal institutions with which the state regulates these three questions of access, price and effective care are interlinked and impacted by each other and the remaining rights relating to health. With this in mind, I have chosen the following institutions as the main topics of comparison: (1) pharmacy ownership and management; and (2) price control mechanisms and reimbursement of medicine expenses. This research describes and to some extent explains the legislative framework and institutions as well as their origins, development and function for Finland in chapter 6 and for Norway in chapter 7. Even though these functionally equivalent institutions have been chosen based on certain central rights and principles relevant to the pharmacy sector, during the comparison of the institutions other factors relating to the pharmacy sector have also been highlighted from time to time.

Before examining the two main topics of comparison, I have described a number of matters which are central for building an overall understanding of the retail sale of pharmaceutical products. These topics are common to Finland and Norway and many of them are regulated by international treaties or on EU-level. These topics are central from the perspective of safety and effectiveness. However, they are less political in nature as the specific norms under the topics are defined more by technical and scientific requirements than by questions of resource allocation.

5. Introduction to Pharmacy Legislation

This research will deal with pharmacy legislation in Finland and Norway in the following manner. First, this chapter 5 will introduce the international and European regulatory framework which is applicable in both countries. This chapter will also describe features of pharmacy legislation which are common to the distribution of medicinal products in Finland and Norway. In order to provide a holistic view of the level of detail with which medicinal products and the behaviour of actors on each level of the distribution chain are regulated, this chapter discusses topics such as pharmacovigilance, professional standards and hospital pharmacies. The knowledge interest of this research is in the choices made by the legislator regarding the sale of medicinal products to the public. Thus, this research will not discuss these individual topics in detail.

Chapters 6 and 7 will provide an overview of the pharmacy systems of Finland and Norway respectively. These chapters will focus on relevant permits required for pharmacy businesses and price control mechanisms for medicinal products as well as regulatory matters with a unique impact on the pharmacy market in each country.

5.1. Ethical Standards

The International Pharmaceutical Federation (*Fédération internationale pharmaceutique*, FIP) has adopted the “Statement of Professional Standards – Code of Ethics for Pharmacists” regarding the main principles which should be included in the codes of ethics of national pharmaceutical organizations¹¹⁹. The statement places pharmacists first and foremost into the context of the overall health system. It emphasizes their role as “expert[s] on medicines” and the aim of helping patients maintain and achieve good health, whether remunerated or not. The statement also takes into account the significance of pharmacists in other roles than in a clinical relationship with patients, for example in developing new medicinal products, education and policy development. The principles cover topics such as integrity and honesty, professional autonomy, the patient’s best interest, confidentiality of patient information, regulatory compliance, respect for cultural diversity and professional development.

The Association of Finnish Pharmacies has adopted a “Code of Ethics for Pharmacy Activity” and established a “Board of Professional Ethics” which issues statements and guidelines on questions of professional ethics in the pharmacy sector¹²⁰. The Norwegian Pharmacy Association (*Apotekforeningen*, former *Apotekerforeningen*), the Norwegian Association of Pharmacists (*Norges Farmaceutiske Forening*, NFF) and the Norwegian Association of Pharmacy Technicians (*Farmasiforbundet*) adopted “Branch Standards for Pharmacies” in 2003.¹²¹

5.2. International Treaties

¹¹⁹ FIP Statement of Professional Standards – Code of ethics for pharmacists. FIP, 2014. Available at: www.fip.org/statements.

¹²⁰ Apteekkitoiminnan eettiset ohjeet. Code of Ethics for Pharmacy Activity. Suomen Apteekkariliitto. Available at: <http://www.apteekkariliitto.fi/apteekkityo/eettiset-ohjeet.html>.

¹²¹ Bransjestandarder for Apotek. Branch Standards for Pharmacies. Norges Apotekerforening, 2003. Available at: <http://www.apotek.no/om-apotekforeningen/bransjestandarder/dokumentet-bransjestandarder.aspx>.

Medicinal products and the pharmacy sector are impacted by provisions of numerous international treaties. Pharmaceutical patents are subject to the TRIPS Agreement¹²² which provides for a 20-year patent protection period for new medicinal products. Patent protection aims at incentivizing research and innovation by providing protection from competition and thus enabling the patent holder to charge higher prices during the protection period.¹²³

Many of the international treaties concerning medicinal products regulate narcotics and psychotropic substances¹²⁴. The Council of Europe is also working on the recent MEDICRIME Convention¹²⁵ which covers counterfeit drugs.

The impact of these treaties is that national legislation concerning medicinal products and their distribution must ensure protection of relevant patents and trademarks as well as refrain from establishing barriers to trade under the relevant treaties. Thus, national health policy and the national pharmacy system need to be formulated in accordance with these treaties.

International human rights and social rights treaties in the Finnish and Norwegian legal systems, as well as their impact on pharmacy legislation, are discussed in chapter 4.3.

5.3. European Union Legislation

EU legislation differentiates between medicinal products for human use and for veterinary use. For the purposes of this research it is sufficient to outline the legislative framework only regarding medicinal products for human use. Medicinal products are regulated by the EU Directive 2001/83/EC on the Community code relating to medicinal products for human use (“Directive on medicinal products” for the purposes of this research) and by the EU Regulation 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and

¹²² Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994. Annex 1 C: Agreement on Trade-Related Aspects of Intellectual Property Rights.

¹²³ Ho, *Cynthia M.*, Access to Medicine in the Global Economy p. 5–6, 68–70.

¹²⁴ The principal treaties regulating narcotics include the 1961 United Nations Single Convention on Narcotic Drugs, the 1971 United Nations Convention on Psychotropic Substances and the 1988 United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.

¹²⁵ The Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health, Moscow, 28 Oct 2011. Finland has signed the Convention on 28 October 2011. Norway has not signed the MEDICRIME convention. Available at: <http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=211&CM=8&DF=18/11/2014&CL=ENG> Accessed on 9 May 2015.

veterinary use and establishing a European Medicines Agency (“Regulation on centralized procedure” in this research). The provisions under the Directive have been implemented in national law in Finland and Norway (FMA 21–21c §, FMR 9–10f § and NMA 8 §, NMR chapters 2–6).

The European Union has enacted legislation concerning the manufacture, wholesale, entry into the retail market and classification of medicinal products, and pharmacovigilance. EU legislation has left pricing and the inclusion of medicinal products in national health insurance systems subject to the Member States' national legislation (Art. 4.3, Directive 2001/83/EC).

In the following chapter I will briefly summarize the EU framework regarding medicinal products and the scope of legislative choice left for Member States regarding distribution of medicinal products.

5.3.1. Definition of Medicinal Product

The Directive on medicinal products for human use defines a medicinal product as:

“Any substance or combination of substances presented for treating or preventing disease in human beings.

Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product.”¹²⁶

Finland and Norway both define medicinal products in a similar manner in Section 2 of the Norwegian Medicines Act (Lov om legemidler m.v.: *legemiddelloven*, 4. desember 1992 nr. 132, NMA) and section 3 of the Finnish Medicines Act (*Lääkelaki* 10.4.1987/395, FMA). The directive is applied to medicinal products produced industrially on the internal market¹²⁷. Special provisions regarding immunological medicinal products, radiopharmaceuticals and medicinal products derived from human blood or human plasma in the Directive are excluded from the following review.

¹²⁶ Directive 2001/83/EC on the Community code relating to medicinal products for human use, Article 1, subsection 2.

¹²⁷ The directive excludes e.g. medicinal products manufactured in pharmacies.

5.3.2. Marketing Authorization

Any medicinal product intended to be distributed to consumers in the internal market must have a market authorization. The Directive on medicinal products sets forth an authorization procedure for placing a medicinal product on the market in a Member State. The Directive defines the procedure and requirements, including documentation, clinical data and deadlines, for marketing authorization requests. Applicants must be established in the European Community.

There are three distinct cases and procedures for obtaining a marketing authorization. The first case applies for medicinal products not yet placed on the market in any Member State and which do not have a marketing authorization in place or pending in any Member State. In such cases, the request is submitted to the competent authority of the relevant Member State. For Finland, the competent authority is the Finnish Medicines Agency, Fimea (*Lääkealan turvallisuus- ja kehittämiskeskus*). The Norwegian competent authority is called the Norwegian Medicines Agency (*Statens legemiddelverk*). Under the Directive, the competent authority has the right to grant a marketing authorization for the market within the Member State.

In the second case, the applicant already has a market authorization for the medicinal product in one of the Member States (reference state). In such cases, a mutual recognition procedure is applied. Under this process, the applicant informs the reference state authority of its intention to apply for additional marketing authorizations and receives an assessment report from the authority. The applicant then submits its application along with the documentation received from the reference state to the competent authority of each relevant Member State. The Member States will then grant marketing authorizations for their respective markets. However, it is possible that a Member State has reason to suppose that the product may pose a threat to public health or that Member States issue diverging decisions on the matter. In such cases, if they cannot agree upon a joint decision, the entire matter or any remaining questions will be submitted for community level review.

The Regulation on centralized procedure for medicinal products sets forth a centralized procedure for obtaining market authorization for certain medicinal products listed by the Commission. Under the centralized procedure, the applicant

applies for market authorization from the Commission for the entire internal market. If the authorization is granted, the medicinal product can be distributed subject to the same conditions in all Member States.

Final decisions regarding marketing authorizations under the mutual recognition procedure and the centralized procedure are made by the Standing Committee on Medicinal Products for Human Use (the Standing Committee) working under the European Commission. The European Medicines Agency (EMA) is the community level supervising body for medicinal products. The Committee for Medicinal Products for Human Use (the Committee) is responsible for reviewing marketing authorization requests and for drafting opinions of them on behalf of the Agency for the Standing Committee.

5.3.3. Exceptions to Marketing Authorization Requirements

Article 10 of the Directive on medicinal products provides for a simplified procedure for generic drugs. A generic drug is a medicinal product which has the same pharmaceutical form and is bioequivalent with, and which has the same qualitative and quantitative composition in terms of active principles as a medicinal product authorized in a Member State or within the Community¹²⁸. Generic drugs are subject to a lighter review process. If the applicant can demonstrate that its product meets the requirements of Article 10, the applicant does not need to provide toxicological or pharmacological test results or results of clinical trials for the market authorization process.

Additionally, homeopathic and traditional herbal medicinal products are exempt from the marketing authorization process and are instead subject to a simplified registration process (Art. 13 and 16a, Directive 2001/83/EC)¹²⁹. For a product to qualify as a traditional herbal medicinal product, the applicant must prove that it has been in use for 30 years or more, including 15 years within the Community. The competent EU authority responsible for the registration process and supervision is the Committee for Herbal Medicinal Products under the EMA.

¹²⁸ Judgment of the European Court of Justice C-368/96.

¹²⁹ The registration procedure is applied only to traditional herbal medicinal products which are meant to be used without supervision or prescription by a medical practitioner, which are administered in a specified strength orally, externally or as an inhalant and which have not been deemed harmful under normal conditions of use (Art. 16a.1 and 16e, Directive 2001/83/EC).

5.3.4. Special permission for compassionate use

Article 83 of Regulation 726/2004 allows Member States to make an exception to the marketing authorization procedure for the purposes of compassionate use. This means that Member States can provide a special exception for introducing unauthorized medicinal products to the market for a specific person or a specific group of patients on humane grounds. The aim of the exception is to facilitate the use of new or extraordinary medicinal treatments for patients with a life threatening, chronic or seriously debilitating disease. The Regulation requires that the patient cannot be treated with an authorized medicinal product and that the exempted product is either the subject of a marketing authorization application or undergoing clinical trials. The exemption under Article 83 also covers situations where there are plans to use an authorized medicinal product for a target group or a therapeutic purpose other than the permitted use under the marketing authorization¹³⁰.

5.3.5. Manufacture, Import and Wholesale

The Directive on medicinal products for human use requires that Member States require authorization for manufacture and import of medicinal products. The Directive defines minimum requirements for the standards to be applied to such authorizations.

According to article 77 of the Directive, wholesale of medicinal products is also subject to authorization. However, in case the entity engaging in wholesale is in possession of an import or manufacturing authorization, such authorization also covers wholesale.

5.3.6. Classification of Medicinal Products

Title VI of Directive 2001/83/EC classifies medicinal products under two categories: medicinal products subject to medical prescription and medicinal products not subject to medical prescription. The Directive allows Member States to define three subcategories of medicinal products subject to prescription. In defining subcategories, the Member State shall take into account, for example, the risk of adverse effects, misuse and abuse of the medicinal product. (Art.70, Directive 2001/83/EC)

In Norway prescription drugs have been classified into groups A, B and C based on the level of their addictive effects (NMR 7:3 §). Group A includes highly addictive medicinal

¹³⁰ Guideline on Compassionate Use of Medicinal Products, Pursuant to Article 83 of Regulation (EC) No 726/2004 p. 4.

products, whereas prescription drugs in group C do not include any risk of addiction. The Norwegian Medicines Agency maintains a list of medicinal products subject to prescription in Norway. Prescription drugs have not been categorized in any such manner under the FMA. However, both in Finland and in Norway prescription drugs have been classified for purposes of their respective national health insurance systems¹³¹. Both countries also utilize the international Anatomical Therapeutic Chemical Classification System (ATC) in deciding maximum wholesale prices for medicinal products and in defining the therapeutic purpose of use for prescription drugs reimbursed under national health insurance.

Medicinal products which, according to their marketing authorization, are not subject to prescription are called over-the-counter drugs. Marketing authorizations for products with a different dosage or package size of the same medicinal substance can have different conclusions regarding prescription even if they are covered by the same marketing authorization. For example, smaller packages with a low dosage of certain anti-inflammatory painkillers which are usually subject to prescription may be sold over the counter. Fimea maintains a list of dosages and package sizes for medicinal products which can be sold over the counter¹³². The Norwegian Medicines Agency can exclude certain dosages and package sizes according to Section 7.6 the Norwegian Medicines Regulation. On the other hand, for some medicinal substances all dosages and package sizes are authorized as non-prescription drugs. Homeopathic and traditional herbal medicinal products which are subject to registration are also sold over the counter.

Pharmacies also sell a variety of other products, such as cosmetics, nutritional products and other products which are not medicinal products subject to marketing authorization or registration. They may however be covered by regulation concerning medical devices, biocides, CE-marking, food safety and consumer protection and subject to supervision by relevant authorities. EU and national legislation concerning medicinal products does not apply to these other products and they may be freely sold in retail stores. However, they constitute a significant source of revenue for

¹³¹ Regarding national health insurance and medicinal products see section 6.3.7.3 for Finland and section 7.2.4.3 for Norway.

¹³² The list is available online at: http://www.fimea.fi/download/22526_Itsehoitovalmistelista.pdf.

pharmacies and may serve as ancillary means of advancing health. This research will refer to such products jointly as non-medicinal products.

5.3.7. Prescription Drugs Subject to Additional Restrictions

Article 71 of Directive 2001/83/EC defines the criteria by which medicinal products should be classified further. According to the Directive, drugs can be subject to prescription, special prescription or restricted prescription. Member States can apply restricted prescription to a medicinal product which is reserved only for treatment in a hospital environment or which should be diagnosed in a hospital or special diagnostic institution or which can cause very serious adverse reactions and thus requires prescription by a specialist and special supervision throughout the treatment.

Special prescription can be applied to a medicinal product classified as a narcotic or psychotropic product or which includes the risk of substance abuse or addiction (Directive 2001/83/EC: Art. 71.2). Narcotics are subject to several international treaties and their use, distribution, handling and storage are heavily regulated. International treaties on narcotics and psychotropic substances have also been adopted in EU legislation¹³³. Medicinal products can also be subject to doping regulation. The Finnish Criminal Code (*Rikoslaki*, 39/1889, FCC) and the Norwegian Criminal Code (Almindelig borgerlig Straffelov, *straffeloven* – strl. 22. mai 1902 nr. 10, NCC) both include provisions on narcotics and doping substances. (FCC 44:5a – 8 §, chapter 50; NCC 162 §, 162b §)

The Finnish Narcotics Act (*Huumausainelaki*, 373/2008) provides for an authorization process for manufacturing, import, export and handling of narcotics. The Act also defines additional requirements for data collection, maintaining records, notification duty, storage, transportation, disposal, supervision, sanctions and various other aspects of handling narcotics. The Finnish Government Decree on substances, products and plans which are classified as narcotics 543/2008 provides a list of substances and products which are subject to the Finnish Narcotics Act. The Government decree 705/2002 lists medicinal products which are classified as doping products in Finland.

¹³³ Examples of this include the Directive 92/109/EEC on the manufacture and the placing on the market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances as well as the Regulation 273/2004/EC on intra-Community trade in drug precursors and the Regulation 111/2005/EC on extra-Community trade in drug precursors and their implementing Regulation 1277/2005/EC.

Chapters 8 and 8a of the Norwegian Medicines Act govern narcotic drugs and substances which can be used for manufacturing narcotics. The Norwegian Narcotics Regulation (*Narkotikaforskriften*, 14. februar 2013 nr. 199) provides for detailed practices and control mechanisms which must be applied in the manufacture, transportation, storage, industrial use, import, export and sale of narcotics. The Regulation includes a list of substances which have been classified as narcotics. Medicinal products classified as doping substances have been listed in the Regulation on Doping Substances (*Forskrift om hva som er dopingmidler*, 30. april 1993 nr. 318).

5.3.8. Pharmacovigilance

Directive 2001/83/EC title 9 and Regulation 726/2004 chapter 3 lay out detailed requirements for pharmacovigilance in Member States. Pharmacovigilance refers to the activities and processes for quality control and safety of medicinal products. EU legislation includes strict pharmacovigilance obligations on marketing authority applicants and holders as well as on manufacturers, importers and wholesale companies. From the perspective of pharmacies, pharmacovigilance sets standards for the way medicinal products are distributed, handled, manufactured and stored inside the pharmacy. However, pharmacies also have an obligation to monitor the quality of the products which are delivered to them and to report on matters of drug safety to the national medicines agency. In practice reporting covers data on reclamations from the pharmacy or the customer and on any adverse effects that the pharmacy becomes aware of. Under the EU framework the Pharmacovigilance Risk Assessment Committee working under the EMA is responsible for assessing and monitoring drug safety (Directive 2001/83/EC Art. 27.1).

5.4. Professional Standards and Regulation

Sections 6 and 7 describe the main features of pharmacy systems in Finland and Norway respectively. In addition to the main features outlining the system, ethical standards, international conventions and EU legislation, the domestic law in both countries includes detailed regulation on medicinal products. In order to fully understand the pharmacy sector, it is important to be aware of the professional and regulatory requirements which impact the everyday business in the retail sale of

pharmaceuticals. This section summarizes certain domains of regulation which otherwise are excluded from the scope of law comparison.

5.4.1. Professional Standards and Special Regulation

There are special requirements for the professional qualifications of pharmacy personnel in Finland and Norway. These requirements are set in the Finnish Act on Health Care Professionals (*Laki terveydenhuollon ammattihenkilöistä* 559/1994) and the Norwegian Act relating to health personnel etc. (Lov om helsepersonell m.v.: helsepersonelloven – hlspl. 2. juli 1999 nr. 64). These acts for example define the level of education required for the use of the professional title pharmacists and set special obligations relating to confidentiality. Furthermore, both the Finnish Medicines Act and the Norwegian Pharmacy Act include a requirement of sufficient personnel in order to fulfil the pharmacy's service obligation and to ensure drug safety (FMA 56.1 §, NPA 4:3 §).

Pharmacies in Norway have an obligation to sell any medicinal product introduced into the domestic market if this is necessary for the pharmaceutical care of the patient (NPA 6:2§). In Finland, the capacity of pharmacies to provide necessary products has been ensured through a requirement for a sufficient stock and offering in the pharmacy (FMA 55.1 §). Pharmacies also have an obligation to provide information and guidance to patients on medicinal products and their prices and if necessary instruct the patient to consult a doctor (FMA 57 §, NPA 2:8 §). Regulation also sets standards for the facilities of the pharmacy both for purposes of general drug safety, in house manufacturing and customer service (FMA 56.2 §, FMD 15 §, NPA 5:5 §, NPR 21 §). Pharmacy opening hours must be sufficient to ensure sufficient service in the area and opening hours can be restricted on Sundays (FMA 55 §, NPR 25 §, NPA 5:2 §).

Marketing and advertisement of medicinal products to healthcare professionals and to the public is carefully regulated (FMA 91–94 §, NMA chapter 7). Activities such as online sale, dose-dispensing of medicinal products to individual patients and electronic prescription are also covered in relevant legislation, supplemented by government decrees and regulations.

Privacy and data protection are critical questions in the health sector. Pharmacies have a strict confidentiality obligation and their processes and facilities need to ensure the

protection of personal and sensitive information. This also includes the perspective of data security. Pharmacies need to have protocols in place not only for processes in their everyday business but also in exceptional circumstances. Pharmacies' data systems often also constitute personal data registers. Data protection and personal information are covered in the Finnish Personal Data Act (*Henkilötietolaki* 523/1999) and the Norwegian Personal Data Act (Lov om behandling av personopplysninger (*personopplysningsloven*) 14. april 2000 nr. 31).

Hospital pharmacies work in connection with hospitals and their purpose is to ensure the pharmaceutical care and distribution of medicinal products inside the relevant hospital. Hospital pharmacies are usually publicly owned and they may distribute medicinal products to other public healthcare units. Hospital pharmacies play a role in the professional field in pharmacy as well as in the pharmaceutical market. However, the manner in which their role in the market has been resolved in relation to other public sector actors and to privately owned pharmacies is not central for the knowledge interest of this research. (FMA 61–66a §, NPA 1:3 § subsection c, 2:5§)

It is not necessary for the purposes of this research to outline the processes for supervision, sanctions and administrative processes for appealing decisions of supervising bodies in the pharmacy sector. The Finnish Medicine Agency (Fimea) and the Norwegian Medicines Agency are the supervising bodies regarding medicinal products and pharmacies. The appellate body for decisions of the Norwegian Medicines Agency in questions relating to pharmacy licenses is the Appeal Board for Pharmacies (*Apotekklagenemnda*) under the Norwegian Appeal Board for Health Personnel (*Statens helsepersonellnemnd*). In Finland, the Fimea's decisions regarding pharmacy licenses can be appealed in the relevant administrative court.

6. Legislative Framework of Pharmaceutical Distribution in Finland

6.1. Finnish Medicines Act

The principle legislative act governing medicinal products and their distribution is the Finnish Medicines Act. The Act implements EU-legislation regarding manufacturing, import and wholesale of medicinal products as well as pharmacovigilance and marketing authorizations. Chapter 6 of the Act concerns pharmacies and retail of

medicinal products. The FMA also covers pharmaceutical care in hospitals, health centres and in social care centres as well as direction and supervision of pharmaceutical care.

The Finnish Medicines Decree (*Lääkeasetus* 24.7.1987/693, FMD) has been issued based on the FMA and it provides more detailed provisions regarding the topics covered by the FMA.

6.2. Development of Pharmacy Legislation in Finland

6.2.1. Background and History

The first pharmacies in Finland were founded in Turku and in Vyborg in 1689 under a royal privilege. Pharmacy privileges were personal save for the privilege issued to the Royal Academy of Turku in 1755 which ultimately developed into the Helsinki University pharmacy. Pharmacy privileges were personal, assignable and subject to inheritance. During the 1800s several committees discussed the development of the pharmacy system and considered numerous alternatives from complete freedom of establishment to a state-owned pharmacy network.¹³⁴

The Finnish Act on Pharmacies (*apteekkilaitoksesta annettu laki* 4/1928) and the Finnish Pharmacy Goods Act (*apteekkitavaralaki* 374/1935) were enacted during the early years of Finnish independence. Under the Act on Pharmacies, the system functioned on the basis of the principle of personal ownership subject to a pharmacy license. These two acts governed the pharmacy sector until late 1980s and were amended several times during their existence. The development of the Finnish pharmacy system was influenced by changes in society, world events and advances in medical science and the pharmaceutical industry. For example, prohibition in 1920s increased turnover while the depression in 1930s was a difficult time for pharmacies. The Second World War called for a complete reorganization of distribution chains. After the war, the pharmacy system and legislation was adapted to suit the rapid development of new pharmaceutical innovations and industrial manufacturing of medicinal products.¹³⁵

¹³⁴ Kärkkäinen, Reijo & Purasmaa Reijo, *Lääkelaki* p. 18.

¹³⁵ Kärkkäinen, Reijo & Purasmaa Reijo, *Lääkelaki* p. 19–20. Peltonen, Markku, *Apteekki suomalaisessa yhteiskunnassa* p. 105–107.

6.2.2. Development of the Finnish Medicines Act

The Finnish Medicines Act was adopted in 1987. The FMA replaced the two main legislative acts regulating medicinal products and the pharmacy sector, the Finnish Act on Pharmacies and the Finnish Pharmacy Goods Act. Both acts were out of date and patched with numerous small amendments over several decades. The chief aims for enacting the new Finnish Medicines Act was to bring together regulation concerning medicinal products and pharmacies under one legislative act, to modernize the terminology used in the legislation and to clarify certain ambiguities and structures in the existing legislation. The new Act did not change the main features and structures of the Finnish pharmacy system.¹³⁶

The Act has been modified and revised several times. The first major amendments to the FMA were made in 1993 in connection with Finland joining the European Economic Area and with Finland's EU membership in 1995. The next significant amendments were adopted in the 1990s when the pharmacy market faced increasing criticism due to the high level of regulation regarding pharmacy ownership and lack of competition among pharmacies. Certain features of the pharmacy permit system were simplified and made more flexible. However, unlike in Norway the main structure of the Finnish pharmacy system has not been changed in the past decades.

After the enactment of the new Finnish Medicines Act, discussion regarding the pharmacy sector has become more focused on the prices of medicinal products and competition within the sector. The legislator has been concerned about the limitations for competition in the field due to the pharmacy license system on one hand and due to asymmetric information between the consumer, healthcare professionals and the pharmacy. It is clear that the market for medicinal products does not function in normal way: It is often the doctor and not the patient who chooses the medicinal product on behalf of the patient¹³⁷.

The most significant changes that have been implemented in the Finnish pharmacy system after the enactment of the FMA have been in the field of price regulation. In 2002 generic substitution was introduced in Finland and in 2008 internal reference

¹³⁶ Finnish government proposal HE 87/1986, p. 3.

¹³⁷ HE 165/2001 p. 11.

pricing was adopted in order to reduce public subvention costs for medicinal products. In 2005 retail sale of nicotine replacement products was permitted outside of pharmacies.¹³⁸ In adopting these methods, Finland has followed the general trend of Northern European countries.

6.3. Main Features of the Finnish Pharmacy System

6.3.1. Retail Sale of Medicinal Products

The sale of medicinal products to the public is only allowed for pharmacy establishments. Pharmacy establishments are defined as pharmacies, subsidiary pharmacies, pharmacy service points and pharmacies engaging in online sale (FMA 38 §). The sale of homeopathic and traditional herbal medicinal products is permitted also outside of pharmacies, unless otherwise stated in the relevant registration (FMA 38a §). The sale of nicotine replacement products is permitted outside of pharmacies, e.g. in retail stores and kiosks (FMA 54a §).¹³⁹

6.3.2. Pharmacy Ownership and Management

In Finland the exercise of pharmacy activities is subject to a pharmacy license, which covers pharmacy ownership and management. Fimea is the competent authority responsible for issuing pharmacy licenses. The number of pharmacies in Finland is limited by the pharmacy license system: on its own proposal, Fimea decides on the establishment of new pharmacies and other pharmacy establishments, number of pharmacy establishments and their geographical distribution on the basis of local demand and the requirement of equal access to healthcare. In cases reduced local demand Fimea can decide on the discontinuation of the license for a pharmacy establishment, if demand is sufficiently met by other pharmacy establishments in the area. Municipalities can propose the establishment of a new pharmacy establishment or amendments to the location of existing pharmacy establishments in their area. (FMA 40 § and 41 §)

In addition to the establishment of a new pharmacy, licenses become open for application when a pharmacy owner is granted with a new license for another

¹³⁸ HE 107/2005.

¹³⁹ Heiliö, Pia-Liisa et al., *Narikka Jouko (edit.)*, Sosiaali- ja terveystalvelujen lainsäädäntö käytännössä p. 508.

pharmacy, retires or decides to discontinue their pharmacy business, or when a pharmacy owner loses their pharmacy license or otherwise becomes ineligible for holding a pharmacy license. Section 43 of the FMA defines the criteria of eligibility for license holders and the factors which Fimea shall take into account when choosing the best out of several candidates. Firstly, a pharmacy license can only be granted to a citizen of an EEA state who is a certified Master of Pharmacy. The law also requires that the license holder has full legal competence and has not been declared bankrupt. Among several candidates, the pharmacy license shall be granted to the person who can be considered to have the best overall capability to run a pharmacy establishment.

The factors to be taken into consideration in assessing overall capability include the applicant's previous work at a pharmacy or in other pharmaceutical services, previous pharmacy ownership, relevant studies, management skills and other activities. Thus, a doctoral degree in pharmacy, a certified course in business administration and for example a significant position of trust in a professional organization such as the Finnish Pharmacists' Association can work as an advantage in the application process. (FMA 43.3 §)¹⁴⁰

The pharmacy license is personal and non-transferable (FMA 44.1 §). The license holder must manage the pharmacy personally, although the law provides for special conditions such as illness (FMA 44.2). Each pharmacy owner runs their business as a sole proprietor and their business is taxed accordingly¹⁴¹. Thus, pharmacy chains in which each pharmacy is under common control of one pharmacy group are not permitted in Finland.

A pharmacy license holder can only own and run one pharmacy at a time. Pharmacy owners can however apply for any pharmacy license which has become available. If a pharmacy owner is issued with another pharmacy license, the former license expires and it is opened for application (FMA 44.1 §). The Finnish Medicines Act provides for a transitional period during which one person can own and run two pharmacies when a pharmacy owner has been issued with a new pharmacy license and the old pharmacy

¹⁴⁰ HE 107/2005 p. 15.

¹⁴¹ The central tax legislation for sole proprietors comprises the Finnish Act on the Taxation of Business Profits and Income from Professional Activity (*Laki elinkeinotulon verottamisesta*, 360/1968) and the Finnish Act on Valuation of Property for Taxation (*Laki varojen arvostamisesta verotuksessa*, 1142/2005).

has not yet been sold (FMA 46 §). Pharmacy owners have the right to own and run their business until the age of 68 (FMA 45 §), which is the latest age of retirement in Finland.

Section 50 of the FMA defines the cases in which Fimea will revoke a pharmacy license. These include bankruptcy, legal incompetence, loss of certification as Master of Pharmacy, inability to run a pharmacy due to illness or substance abuse, criminal conviction of two years in prison or more, significant abuse of the pharmacy license, failure to react to a written warning under FMA Section 51 or other obvious incompatibility for exercising pharmacy business. Fimea can issue an oral or written warning under Section 51 of the FMA in cases where the license holder has infringed the provisions of the FMA or another regulation issued under the FMA, has acted erroneously, negligently or inappropriately but which do not warrant prosecution in court.

6.3.3. Subsidiary Pharmacies and Pharmacy Service Points

A pharmacy owner can be issued with a license to up to three subsidiary pharmacies (FMA 52.1 §). Subsidiary pharmacies are owned and managed by the license holder of the main pharmacy and they provide the full scope of pharmaceutical services to the public. Pursuant to Section 54 of the FMA, Fimea can decide to turn a subsidiary pharmacy to a pharmacy, if the turnover of the subsidiary pharmacy grows to a level which corresponds to at least half of the average turnover of private pharmacies in Finland. This can be done at earliest five years after the establishment of the subsidiary pharmacy. In case the turnover of the subsidiary pharmacy is larger than that of the main pharmacy, Fimea can issue the pharmacy license of the new pharmacy to the holder of the original license of the subsidiary pharmacy without an application process.

Subject to a permit from Fimea, pharmacies can also establish pharmacy service points in sparsely populated areas (FMA 52a §). Service points are not required to be run by a pharmacist. Therefore, the pharmacy is required to have a plan regarding the selection of medicinal products available and the manner in which prescription are distributed drugs through the service point. The pharmacy must also have measures in place for ensuring drug safety. (FMR 21 §)

6.3.4. Pharmacy Fee

In order to level out the differences in profitability between larger urban pharmacies and small pharmacies operating in sparsely populated areas, the state collects a pharmacy fee from all license holders. The fee is based on the Act on the Pharmacy Fee (*Laki apteekkimaksusta* 148/1946, Pharmacy Fee Act) and it is calculated based on the pharmacy's turnover excluding value added tax and certain other exclusions. Turnover from in house pharmaceutical manufacturing, sales to public healthcare units and nicotine replacement products available outside of pharmacies is excluded. Also the sale of non-medicinal products is excluded but only up to an amount corresponding to 20 percent of total turnover after the exclusion of in house manufacturing and sales in healthcare units. (Pharmacy Fee Act 1a §)

The pharmacy fee is progressive: Pharmacies with an annual turnover below EUR 871,393 do not pay any fee. The percentage of turnover payable, starting at 6.10 percent, increases in tiers with the highest pharmacy fee being for businesses with a turnover over the limit of EUR 6,243,857: For them the fee is EUR 537,406 and 11.20 percent for turnover exceeding the limit (Pharmacy Fee Act 2 §). Turnover from subsidiary pharmacies, service points and online sales are included in the turnover. However, the Pharmacy Fee Act provides for different reductions from the turnover depending on overall turnover for the license holder and turnover from each subsidiary pharmacy. The aim for these reductions is to ensure that the pharmacist is not disincentivized from developing its subsidiary pharmacies and service points due to increases in the pharmacy fee.

The effects of the pharmacy fee on the pharmacy market have been subject to significant debate. On one hand, the pharmacy fee is seen as an impediment to competition and one of the factors maintaining a higher price level for medicinal products. On the other hand, the pharmacy fee restricts larger pharmacies from engaging in aggressive price competition and ensures that all pharmacies across the country have more or less the same price level. Thus, smaller pharmacies in rural or

sparsely populated areas can maintain a price level that keeps the pharmacy business profitable.¹⁴²

During the 1990s and early 2000s there have been several calls and proposals to eliminate the pharmacy fee in Finland. In 1991, the Pharmaceutical Competition Committee recommended its discontinuation¹⁴³, in 1997 the Working Group on Pharmaceutical Costs proposed that the government should remove the pharmacy fee “at its earliest convenience”¹⁴⁴ and in 2007 the III proposed to abandon the pharmacy fee in stages¹⁴⁵. However, these proposals only led to gradual adjustments in the pharmacy fee such as the exclusion of non-medicinal products from the calculation and measures to incentivize the upkeep of subsidiary pharmacies in sparsely populated areas. In its policy papers from 2003 and 2011, the Ministry of Social Affairs and Health highlighted the aim of a comprehensive pharmacy network which reaches also sparsely populated areas as one of the main priorities of Finnish policy concerning pharmaceutical care¹⁴⁶.

In recent years, the Finnish Competition and Consumer Authority (*Kilpailu- ja kuluttajavirasto*) has highlighted the problems which the pharmacy license system and pharmacy fee pose on competition¹⁴⁷. The Ministry of Social Affairs and Health Committee for developing the pharmacy sector and other pharmaceutical care on the other hand has stated that the central aim of pharmaceutical care is related to public health and “therefore the competition aspect cannot be the primary starting point in developing [pharmaceutical] activity”. This does not exclude the possibility of promoting healthy competition through improving efficiency and quality. The Committee also found that the type of business entity does not necessarily have an impact on the quality and development of the pharmacy. However, it pointed out that

¹⁴² *Finnish Ministry of Social Affairs and Health, Apteekkitoiminnan ja muun lääkehuollon kehittäminen* p. 10.

¹⁴³ *Finnish Ministry of Social Affairs and Health, Lääkealan kilpailutoimikunnan mietintö 1991:49* p. 64–66.

¹⁴⁴ *Finnish Ministry of Social Affairs and Health, Lääkekustannustyöryhmän muistio 1997:11* p. 51–52.

¹⁴⁵ *Finnish Ministry of Social Affairs and Health, Apteekkityöryhmän muistio*. p. 55–56.

¹⁴⁶ *Ministry of Social Affairs and Health, Lääkepolitiikka 2010* p. 15–16. *Ministry of Social Affairs and Health, Lääkepolitiikka 2020* p. 18–19.

¹⁴⁷ In particular, Authority’s finds the discretion of Fimea in issuing licenses based on the demand for pharmaceutical services in the area where the pharmacy is located and restrictions on the type of business entity under which pharmacies can be run to be problematic for competition. *Finnish Competition and Consumer Authority, Lääkehuollosta lääkemarkkinoihin* p. 30–38.

under the current license system pharmacies pay their taxes in Finland whereas the three largest pharmacy chains in Norway are under foreign control and in half of them the main shareholder is a holding company with its seat in a tax haven. The Committee's proposal is to develop the pharmacy sector on the basis of the current framework of pharmacy licenses and pharmacy fees.¹⁴⁸

6.3.5. University Pharmacies

The pharmacy privilege of the University of Helsinki dated back to the privilege issued to the Royal Academy of Turku in 1755. In 1953, the University of Helsinki was permitted to establish subsidiary pharmacies in selected large cities in Finland. These days the University of Helsinki is allowed 16 subsidiary pharmacies (FMA 52.3 §). Also the University of Eastern Finland has the right to run one university pharmacy in Kuopio (FMA 42 §). University pharmacies are not allowed to establish pharmacy service points but they can engage in online sale (FMA 52a.5 §, 52b §). The purpose of the pharmacy privilege is to provide a training facility for pharmaceutical education and research to the universities (FMA 42 §). They for example provide in house manufacturing of medicinal products to privately owned pharmacies. However, since the pharmacy fee collected from the universities is allocated from the state directly to the relevant university, pharmacies have become a significant source of income for the universities. Furthermore, the effective lack of a pharmacy fee gives university pharmacies a competitive advantage in the market.¹⁴⁹

6.3.6. Medicinal Products outside of the Pharmacy

In 2005, Finland freed the sale of nicotine replacement drugs to retail stores and kiosks which also sell tobacco products (FMA 54a §). The reasoning for releasing these products to sale outside of pharmacies was that products which help citizens to quit smoking should be readily available to anyone who needs them. Furthermore, increased competition would bring down prices. Together these effects would reduce the threshold of attempting to quit. This would lead to cost-efficient improvements in public health and savings for the state. In considering the proposal, the legislator acknowledged the significance of guidance for the patient from pharmaceutical

¹⁴⁸ *Finnish Ministry of Social Affairs and Health, Apteekkitoiminnan ja muun lääkehuollon kehittäminen* p. 9 – 12.

¹⁴⁹ HE 244/2010 p. 2. *Peltonen, Markku, Apteekki suomalaisessa yhteiskunnassa* p. 139–140.

professionals. However, the benefit of improved access, even where guidance was not available, was seen as sufficient reason to release nicotine replacement products for sale outside of pharmacies. Also, lack of pharmaceutical guidance and control was not seen to pose a significant risk in terms of drug safety.¹⁵⁰

The permit process for selling nicotine replacement products is similar to that of tobacco products and it is administrated by municipalities (FMA 54a.2 §). As a consequence of the 2005 reform, nicotine replacement products were also released from price control (FMA 37a §).

6.3.7. Price Regulation and Reimbursement under the National Health Insurance System

6.3.7.1. Wholesale Prices

According to Section 37a of the Finnish Medicines Act the wholesale price of each medicinal product, including all rebates, must be the same for all pharmacies. Wholesale prices for medicinal products can be updated by the market authorization holders every two weeks to the university pharmacies and the Association of Finnish Pharmacies (*Apteekkariliitto*). In connection with Finland's accession in the EEA, the requirement of a "reasonable wholesale price" was removed from the marketing authorization criteria¹⁵¹. However, price control is allowed under EU law for the purposes of national social insurance schemes. Thus, Finland applies a maximum wholesale price for all prescription drugs which can be reimbursed under the Finnish health insurance system.¹⁵²

Chapter 6 of the Finnish Health Insurance Act (*Sairausvakuutuslaki* 224/2004, FHIA) covers price control of medicinal products from wholesale prices to generic substitution and internal reference pricing. The Pharmaceuticals Pricing Board working under the Ministry of Social Affairs and Health decides on granting reimbursement status to each medicinal product under the health insurance system and on a reasonable wholesale price for the product (FHIA 6:1 §). This reasonable wholesale price works as a maximum price for the product and thus the wholesale price can

¹⁵⁰ HE 107/2005 p. 5–12.

¹⁵¹ HE 101/1993 p. 3.

¹⁵² HE 165/2002 p. 18.

always be set to be lower than that in order to meet competition from more affordable products. In assessing the reasonable wholesale price, the Board considers the costs of using the drug against the benefit for medical care in comparison with alternative care options. The price is benchmarked with corresponding products in Finland and in other EU Member States. Also the manufacturing, research and development costs can be taken into consideration when applicable. The Board also consults the Finnish Social Insurance Institution (*Kansaneläkelaitos*, KELA) during the process. The wholesale prices are set for a period of five years and for three years in case of a new active substance. The Board may also amend the reasonable wholesale price on its own initiative for example when a new cheaper generic product becomes available in the market or the medical purpose of use for the product becomes wider.¹⁵³

The requirement of the same wholesale price for all pharmacies was adopted in 2005 in order to eliminate the effect of rebates on pharmacies' practices in distributing medicinal products and carrying out generic substitution. The aim was to increase transparency in pricing and to ensure that consumers benefit from all rebates. According to the legislator, pharmacies should not receive indirect rebates in for example in the form of overpriced advertisement space or compensation for favorable shelf placement of specific products. The requirement of unified prices also eliminated volume and other rebates which until then had provided an advantage to larger pharmacies. Furthermore, the elimination of rebates also ensured that pharmacy personnel base their recommendations to the customer solely on the customer's medical needs.¹⁵⁴

6.3.7.2. *Pharmacy Profit Margin and Retail Price*

The retail price for consumers consists of the declared wholesale price, the pharmacy's profit margin and value added tax. In Finland the maximum profit margin allowed for pharmacies is defined in Government Decree 713/2013 (*Valtioneuvoston asetus lääketaksasta 17.10.2013/713*). The profit margin limit is applied to all medicinal products and defined separately for prescription drugs and over the counter drugs.

¹⁵³ Martikainen, Jaana & Rajaniemi, Sinikka, EU-maiden, Islannin ja Norjan lääkekorvausjärjestelmät p. 103–104. HE 175/1997 p. 14.

¹⁵⁴ HE 107/2005 p. 5–14.

The profit margin is calculated based on the wholesale price and consists of a fixed amount per package and a multiplier for the wholesale price. They are both defined for different wholesale price ranges. The multiplier is regressive: For example, for OTC drugs with a wholesale price below EUR 9.25 the fixed profit is EUR 0.50 and the multiplier is 1.5. For OTC drugs with a wholesale price over EUR 420.47 the fixed profit is EUR 47.68 and the multiplier is 1.125. Thus, the pharmacy's profit margin percentage is higher for inexpensive products and lower for costlier ones (FMA 58 §, Decree 713/2013 3 § and 4 §). In Finland, a lower rate for value added tax is applied to medicinal products. Value added tax for medicinal products is 10 percent (Finnish Value-added Tax Act (*Arvonlisäverolaki*, 1501/1993) 85a:1 § subsection 6). It should also be noted that due to the pharmacy fee, in practice the profit margin for certain medicinal products may not cover the distribution costs of the pharmacy. This is the case in particular for large pharmacies.

6.3.7.3. *Reimbursement under the National Health Insurance System*

The Finnish health insurance scheme reimburses the cost of prescription drugs which have been included in the reimbursement scheme in full or in part. Reimbursements are paid through the Finnish Social Insurance Institution, KELA, as expenses under the Finnish health insurance scheme which is funded in half with returns on the healthcare payments by the insured and in half by the state. In order to be included, a reasonable wholesale price needs to be defined for the medicinal product. (FHIA 5:1.1 §) Furthermore, granting reimbursement status for the medicinal product should support rational pharmaceutical care. Reimbursement status is not granted to products which have an insignificant value in medical care or the purpose of which is to treat illnesses with mild symptoms or which is used only temporarily.¹⁵⁵

Reimbursement is possible also for over-the-counter drugs which have been prescribed on medical grounds and which have reimbursement status (FHIA 5:1.2 §). Also costs for clinical nutritional preparations and basic ointments with reimbursement status can be reimbursed in case of a severe disease or chronic skin disease respectively (FHIA 5:2 §).

¹⁵⁵ HE 175/1997 p. 13. HE 100/2008 p. 5–10.

The basic rate of reimbursement is 35 percent of the retail price (FHIA 5:4 §). Special reimbursement is possible for severe and long-term diseases in two tiers. Under the higher special reimbursement medicine expenses are covered fully for costs exceeding EUR 3 per product. The lower special reimbursement rate is 65 percent of the retail price. (FHIA 5:5 §) If the total amount which the patient has paid for reimbursable drugs exceeds EUR 612.62 during one calendar year, the costs exceeding EUR 1.50 per drug are covered fully (FHIA 5:8 §)¹⁵⁶. The Finnish social assistance scheme can cover medicine expenses which are higher than insignificant on social grounds (Finnish Act on Social Assistance (*Laki toimeentulotuesta*, 1412/1997) 7b § subsection 4).

The medical conditions for which special reimbursement is available have been defined by government decree¹⁵⁷. In order to qualify for reimbursement the patient must provide a doctor's statement regarding the diagnosis and need for pharmaceutical treatment to KELA which also confirms the patient's right to special reimbursement. For certain diseases with expensive treatments, the medical conditions and purposes of use for which basic reimbursement status is granted have been defined by government decree¹⁵⁸. This can mean that reimbursement status is granted for a specific medicinal product only for patients whose disease has developed to a certain stage or who have a certain variant of the disease. In those cases the patient also needs to demonstrate by doctor's statement that their disease and use correspond with those defined for reimbursement.¹⁵⁹

The marketing authorization holder of a medicinal product has a right to terminate the reimbursement status with prior written notice to the Pharmaceuticals Pricing Board.

¹⁵⁶ As of 1 January 2016, for patients who are 18 years of age or older, the right to reimbursement begins after the drug costs of the patient exceed EUR 45 during the calendar year. The basic reimbursement rate will be 40 percent and the special reimbursement rates will remain the same. According to HE 330/2014, the chief aim of the amendment is to reduce costs under the Finnish health insurance scheme. However, the amendment is designed to impact patients in a just manner. The costs covered by the patient rises for individuals with low yearly drug costs. On the other hand, the increased basic reimbursement rate serves to mitigate costs for individuals whose drug expenses do not reach the yearly limit of EUR 612.62.

¹⁵⁷ Government decree 25/2013: Valtioneuvoston asetus lääketieteellisin perustein vaikeiksi ja pitkäaikaisiksi arvioitavista sairauksista, joiden lääkehoidon kustannuksista sairausvakuutuslain 5 luvun 5 §:n 2 momentin perusteella korvataan 65 tai 100 prosenttia 17.1.2013/25.

¹⁵⁸ Government decree 490/2001: Valtioneuvoston asetus merkittävistä ja kalliista sairausvakuutuslain 9 §:n 4 momentin mukaan korvattavista lääkkeistä ja sairauksista, joiden hoitoon ne korvataan

¹⁵⁹ *Martikainen, Jaana & Rajaniemi, Sinikka*, EU-maiden, Islannin ja Norjan lääkekorvausjärjestelmät p. 104–105. HE 330/2014 p. 4.

The product's reimbursement status, as well as its maximum wholesale price, ceases to apply at the beginning of the next quarter following termination.¹⁶⁰

6.3.7.4. *Generic Substitution*

Finland adopted generic substitution in 2002. Before that, only generic prescription was possible. This meant that the doctor could prescribe a specific active substance instead of a medicinal product under a specific trademark. In those cases the pharmacy had an obligation to choose the least expensive readily available product. In practice, generic prescription was very rare and pharmacies did not keep a varied stock of generic medicinal products. Thus, the market share of generic drugs in Finland was low in 2002.¹⁶¹

The adoption of generic substitution was justified with the aim to provide healthcare and pharmaceutical care in a rational manner. According to the legislator, reimbursement of medicinal products reduced the patient's and the doctor's incentive to prefer inexpensive products. This irrationality was enhanced through the lack of information which patients had regarding prices in the market. The legislator found that the pharmacy was the most rational instance for making the decision to provide a generic drug instead of the original medicinal product as pharmacies were in the best position to follow price levels and developments in the pharmaceutical market. In the government proposal for the legislative act to amend the FMA, the legislator argued that generic substitution would bring direct savings for consumers and to national health insurance and it would additionally increase price competition between the original medicinal product and generic drugs. The legislator cited successful savings in medicine expenses for example in Norway and Denmark. Generic substitution was seen to be in line with EU practice as well as the aims of maintaining competitiveness of the pharmaceutical industry and of promoting public health: Decreased medicine expenses would free up funds for financing the development of innovative medicinal products.¹⁶²

Fimea maintains a list of substitutable generic medicinal products and parallel imported medicinal products. Together with the original product they form a

¹⁶⁰ HE 100/2008 p. 6.

¹⁶¹ HE 165/2002, p. 12.

¹⁶² HE 165/2002, p. 11–19.

substitution group which at minimum will comprise the original patented product and one generic product or parallel imported product (FMA 57 c §).¹⁶³

The pharmacy has an obligation to substitute the prescribed medicinal product to a generally available product within the substitution group with the lowest price or to one which costs up to EUR 1.50 more than the most inexpensive product where the product costs less than EUR 40. For products which cost over EUR 40 the price difference to the most inexpensive product can be up to two euros. The prices are updated on the first day of each quarter based on prior price notification by each marketing authorization holder. The lowest price, including value added tax, among products in the substitution group on that day will be applied as the lowest price for the substitution group during that quarter. (FMA 57 b §) In addition to providing information on the properties and proper use of the prescribed drug, the pharmacy has an obligation to advise the patient on the prices of the generic drugs in the same group (FMA 57.1 §). The pharmacy's informational obligation regarding medicinal products and their prices also extends to over-the-counter drugs.¹⁶⁴

The price needs to be flexible in order to make it feasible for pharmacies to provide either the product with the lowest price or one with a price close to the lowest to customers without delay. Firstly, pharmacies are not obliged to immediately stock the cheapest medicinal product in the market if it is not readily available. Sometimes generic products of a specific manufacturer have the lowest price only for the time that it takes for other manufacturers to respond to the price reduction. When the wholesale prices are updated the product with the most inexpensive price can change and vary. It would be counterproductive to oblige pharmacies to always stock every possible generic product from each available manufacturer for the same original medicinal product. Instead, they will need to have a selection of the most common generic products available and they can order product with the absolute lowest price for customers who request it and are ready to wait for the product to be shipped.¹⁶⁵

The doctor prescribing the medicinal product is allowed to prohibit generic substitution on medical or treatment-related grounds. For example, the patient's

¹⁶³ HE 165/2002 p. 20.

¹⁶⁴ HE 165/2002 p. 17.

¹⁶⁵ HE 165/2002 p. 14.

allergy to one of the non-active substances in the generic product can establish sufficient medical grounds. In practice the requirement regarding treatment-related grounds is fulfilled in cases where the proper medical treatment of the patient warrants the concise use of a product from the same manufacturer with the same packaging, for example for patients with dementia or a mental health condition. Also, in line with the principle of self-determination the patient may prohibit generic substitution without stating any purpose for such decision. In these cases the pharmacy is not allowed to substitute the medicinal product to a generic one (FMA 57 b.3 §). In many cases generic substitution can support the patient's right to self-determination. Firstly, the asymmetry between the pharmacy and the patient regarding prices is balanced through the pharmacy's obligation to inform the patient. Secondly, the patient's willingness to accept pharmaceutical care increases as the threshold to purchase and use the product reduces with price.¹⁶⁶

6.3.7.5. *Internal Reference Pricing*

Finland adopted internal reference pricing in 2008. Under this system, reimbursement from the Finnish health insurance is only granted up to a reference price. The chief reason for adopting reference pricing in Finland was to accelerate and widen price competition already established through generic substitution. Based on experiences in other European countries, generic substitution and reference pricing support each other. Drug costs were expected to grow due to aging population, the development of pharmaceutical care and new medicinal products and the increased use of pharmaceutical care in treating illnesses. Thus, the internal reference pricing system was seen as necessary to ensure the sustainability of drug reimbursements under the Finnish health insurance system.¹⁶⁷

The Pharmaceuticals Pricing Board decides on the establishment of a reference price group which includes products in the same generic substitution group¹⁶⁸. The Board does not have discretion in the matter but all substitution groups in which the products fulfil the relevant criteria will also be subject to reference pricing: The reference price group must include at least one generic product and all medicinal

¹⁶⁶ HE 165/2002 p. 13–18.

¹⁶⁷ HE 100/2008 p. 9-12.

¹⁶⁸ Since 2008, medicinal products subject to analogous process patents have also been included in the reference price system. HE 100/2008 p. 15–19.

products in the group must have reimbursement status (FHIA 6:18 §). Thus, reference pricing is not applied for medicinal products for which only the original product and a parallel imported product are available.¹⁶⁹

The Board determines a reference price for the group for each yearly quarter based on prior price notifications by marketing authorization holders of the products in the group. The reference price will be the retail price, including value added tax, of the most inexpensive product added with EUR 1.50 for product under EUR 40 and with EUR 2.00 for products with a retail price of EUR 40 or more (FHIA 6:19 §). Thus, small differences in prices will not impact the level of reimbursement for the patient or the price covered by the patient. In connection with confirming the reference price, the Board decides a maximum wholesale price for the entire reference price group. Individual product inside the group can have any wholesale price below the maximum price. The incentive to keep prices low comes from the combination of generic substitution and reimbursement only up to the reimbursement level based on the reference price.¹⁷⁰

As in generic substitution, the patient has the right to forbid substitution to a lower price product. However, if the product is included in a reference price group, the patient is reimbursed only up to an amount based reference price. Furthermore, the price which the patient covers above the reimbursement level of the reference price is not included in the calculation of the patient's yearly drug costs under Section 5:8 FHIA.

7. Legislative Framework of Pharmaceutical Distribution in Norway

Two central legislative acts regulate pharmaceutical distribution in Norway: the Act relating to medicines etc. called Norwegian Medicines Act and the Norwegian Medicines Pharmacy Act (Lov om apotek: *apotekloven* – *apotl.* 2. juni 2000 nr. 39, NPA). These acts outline the fundamental principles relating to pharmaceuticals, their production, distribution and use. There are several regulations based on the Medicines Act and Pharmacy Act such as the Pharmacy Regulation (*apotekforskriften* (26. februar 2001 nr. 178)) and the Medicines Regulation (*legemiddelforskriften* (18. desember

¹⁶⁹ HE 100/2008 p. 30–31.

¹⁷⁰ HE 100/2008 p. 14–30.

2009 nr. 1839)) which cover the pharmacy sector and pricing of medicinal products in more detail. The Norwegian National Insurance Act (Lov om folketrygd: *folketrygdloven – ftrl. lov 28. februar 1997 nr. 19, NNIA*) is relevant to the field of pharmaceuticals as it defines the social subsidies relating to medical and pharmaceutical costs.

7.1. Development of Pharmacy Law in Norway

7.1.1. Background & History

Also in Norway, pharmacies first functioned under a royal privilege, the first of which was issued in 1595 for a pharmacy in Bergen. Pharmacy became an independent profession in Norway based on a royal decree in 1672 which separated pharmacy from the medical practice and made the pharmacy privilege subject to inheritance. This decree formed the regulatory basis of the pharmacy privilege in Norway until the enactment of a Pharmacy Act in 1909.¹⁷¹

As in Finland, the development of the Norwegian pharmacy system was influenced by prohibition in the 1920s and other social and scientific developments. The pharmacy system was discussed throughout the decades and also a state monopoly was proposed in the 1920s as well as after the Second World War. Inheritance of the pharmacy privilege was discontinued by 1954. In 1953, a state monopoly was established for import and wholesale of medicinal products in the form of the Norwegian Medicines Depot (*Norsk Medisinaldepot, NMD*).¹⁷²

Due to its privilege based structure, though out its history one of the pharmacy sector's priorities was to maintain privileges. During the 20th century and particularly after the Second World War the greatest change facing the pharmacy sector in Norway was that manufacturing of pharmaceuticals moved from pharmacies' in house manufacturing to industrial manufacturing. This, along with the threat of proposals to reorganize pharmacies in the 1950s, 1960s and 1970s on the basis of public ownership, put pharmacists on the defence. Pharmacies needed to justify their existence on a privately-owned basis through emphasising their role as service providers taking care

¹⁷¹ Johannessen, Finn Erhard & Skeie, Jon, *Bitre piller og sterke dråper – Norske apotek gjennom 400 år 1595–1995*, p. 8–23.

¹⁷² Johannessen, Finn Erhard & Skeie, Jon, *Bitre piller og sterke dråper – Norske apotek gjennom 400 år 1595–1995*, p. 181–183, 233–234.

of tasks which were best carried out in private pharmacies. The Norwegian Pharmacy Association also argued that private ownership incentivized efficiency in the sector. By the 1980s the trend in relation to public ownership had turned and thus the challenges facing the sector became different.¹⁷³

7.1.2. 1980s–1990s: Pressure for Change

The role of pharmacies in providing information and guidance on medicinal products and their use as part of the healthcare system was highlighted from 1985 onwards when pharmaceutical guidance and counselling was permitted in pharmacies. This also increased the contrast between the business perspective and healthcare perspective in the discussion regarding the development of the pharmacy sector.¹⁷⁴

In the 1980s, the Norwegian pharmacy system was very similar to the Finnish system. Pharmacy ownership was subject to a personal license granted to a certified Master of Pharmacy.¹⁷⁵ The Norwegian Board of Health Supervision (*Statens Helsetilsyn*) was responsible for drafting a national plan for the pharmacy network in which it determined the need for pharmacy licenses based on population and geographic factors.¹⁷⁶ Free establishment, pricing and competition were considered incompatible with the interest of the state.¹⁷⁷

Norway also applied a yearly pharmacy fee. The fee amounted to 0–4 percent of the turnover for medicinal products. Smaller pharmacies and less profitable pharmacies could be granted relief from the fee. Pharmacies which were either making a loss or were not profitable could also receive pharmacy assistance. The aim of the pharmacy assistance was to ensure availability of pharmacy services in sparsely populated and rural areas. It also served to ensure the economic independence of pharmacies and to eliminate influence of other market actors in choices made in pharmaceutical care. The pharmacy fee was directed into a pharmacy fee fund from which pharmacy assistance was paid. The fund was also used for financing other measures within the pharmacy

¹⁷³ Johannessen, Finn Erhard & Skeie, Jon, *Bitre piller og sterke dråper – Norske apotek gjennom 400 år 1595–1995*, p. 278–279. *Hamran*, *Riktig medisin?* p. 128–130.

¹⁷⁴ *Hamran*, *Riktig medisin?* p. 121.

¹⁷⁵ Ot.prp. nr. 29 (1998–1999) chapter 9.1.4.1.

¹⁷⁶ Ot.prp. nr. 29 (1998–1999) chapter 9.1.3.2.

¹⁷⁷ *Hamran*, *Riktig medisin?* p. 126.

and health sector. Approximately half of the pharmacies in Norway either received pharmacy assistance or had been granted relief from the fee.¹⁷⁸

The protected status which pharmacy owners had in the form of the license system and possibility to receive pharmacy assistance was based on the idea that pharmacies served a purpose within the healthcare system. Pharmacists saw the system as a way to ensure that the aims of pharmaceutical care were not compromised by short-sighted profit seeking. However, in 1987 the Norwegian Competition Authority (*Konkurransetilsynet*, former *Prisdirektoratet*) issued a report in which it found that the system did not encourage efficiency. It found that pharmacy assistance left pharmacy owners unaccountable and ensured a steady minimum wage level for them regardless of the quality of management. The fact that the amount of pharmacy assistance was tied to pharmacists' wage level meant that in negotiations with the Norwegian Association of Pharmacists the result was not critical to approximately half of the employer organization's (Norwegian Pharmacy Association's) members. Furthermore, the Competition Authority considered that interest groups were too deeply involved in decisions regarding pharmacy licenses and seniority was prioritized over efficiency. It found that the state should aim to correct these anomalies in the market and to promote competition.¹⁷⁹

In 1988, The Norwegian Association of Pharmacists published the report Pharmacy towards the year 2000 (*Farmasien mot år 2000*)¹⁸⁰ as a response to the Competition Authority's arguments. The report emphasized the need for pharmaceutical expertise in regulating and managing the sector. The report started a series of researches and committee reports regarding the pharmacy sector in the next ten years. Also the Norwegian Directorate of Health (*Helsedirektoratet*) which was responsible for pharmacy policy under the Ministry Social Affairs (*Sosialdepartementet*) also supported the basis for the existing license system. One of its central arguments was that the new tasks relating to drug safety and guidance required more resources from pharmacies and cooperation with other healthcare units, and short-sighted economic thinking could jeopardize their fulfilment. The Directorate of Health, the Norwegian

¹⁷⁸ Ot.prp. nr. 16 (1996-97) p. 1–3. *Hamran*, Riktig medisin? p. 66, p. 145.

¹⁷⁹ *Hamran*, Riktig medisin? p. 126.

¹⁸⁰ *Norges Farmaceutiske Forening*, Innstilling fra utvalget farmasien mot år 2000.

Association of Pharmacists and the Norwegian Pharmacy Association all saw the Competition Authority as an external actor which lacked the professional expertise to assess the pharmacy sector and its special features.¹⁸¹

In the late 1980s, the need for pharmacy assistance from the fund exceeded the budgeted amount during several consecutive years. This resulted in increased pressure from the government to reduce costs. The Ministry of Social Affairs started to move towards the opinion that the license system provided a readily distributed market in which competition did not work¹⁸². In order to avoid such situations in the future the Norwegian Pharmacy Association proposed that the funds from pharmacy fee fund would be used more effectively within the pharmacy sector. Under the system of the time, the state guaranteed pharmacy owners' loans for acquisitions, new establishments and renovations. Thus, investments were subject to the control of the Norwegian Board of Health Supervision¹⁸³. The Pharmacy Association argued that better management and use of the pharmacy fee funds for investments would improve efficiency. Better use of available technology would also increase efficiency. However, the Pharmacy Association also emphasized the special nature of the pharmacy business and the role of the pharmacy as an information and service provider. Their view was that the license system, pharmacy fee and pharmacy assistance ensured a nation-wide service network and worked towards better drug safety. Pharmacy professionals found that pharmacies could provide patients rational pharmaceutical care most efficiently, if the economic basis of the activity was ensured by law. This would allow pharmacies to carry out projects to promote drug safety and public health which would not be profitable in an ordinary business environment.¹⁸⁴

7.1.3. Law Reform of 2001

7.1.3.1. Preparation

Despite the pharmacy professionals' efforts to argue in favor of the existing system, preparation of a comprehensive law reform was started in 1994. The Ministry of Social Affairs and Health (*Sosial- og helsedepartementet*) established two public committees,

¹⁸¹ *Hamran*, Riktig medisin? p. 121–142.

¹⁸² Ot.prp. nr. 29 (1998–1999) chapter 9.3.2.

¹⁸³ NOU 1997:6 Rammvilkår for omsetning av legemidler p. 65.

¹⁸⁴ *Hamran*, Riktig medisin? p. 169–170 and p. 203.

named after their chairs, to discuss the pharmacy sectors and medicinal products. The first committee, called the Grund Committee, was to evaluate the reimbursement system under national social insurance. The second committee, called the Strøm Committee, reviewed the general framework and requirements for retail sale of medicinal products.¹⁸⁵

The committee reports were published in 1997¹⁸⁶. The Ministry received a total of 89 statements from interest groups commenting the reports. The Strøm Committee report was used as the basis for the government proposal Ot.prp. nr. 29 (1998–99). The law proposal was sent for comments in 1998 and discussed in the Parliament during spring 2000 and approved in March 2000¹⁸⁷.

The health policy objectives defined as the basis of the 2001 reform in NOU 1997:6 corresponded with the aims defined in the national health policy plan at the end of the 1980s¹⁸⁸. According to the report, the primary objective of the Norwegian pharmacy system is to provide the best pharmaceutical service to the public. This requires that the pharmacy sector is developed together with other branches of healthcare. The sector should be organized in a way that ensures reasonable access to effective and high quality medicinal products at a low price which is consistent across the country. The special features of the pharmacy sector in contrast to other fields of business were taken into consideration in the reform. These included the role of pharmaceutical care as part of medical care and other forms of healthcare and as an alternative to them, the risk of misuse and adverse effects and the impact of drug costs on the patient.¹⁸⁹

The Strøm Committee discussed the ways in which competition on the pharmaceutical market derogated from a perfectly competitive market. Some of the factors were structural. The asymmetric information between patients and other actors in the sector weakens the patient's negotiation position and makes their behavior irrational. Third party financing of purchases in the form of reimbursements from the national

¹⁸⁵ Ot.prp. nr. 29 (1998–1999) chapter 2.1.

¹⁸⁶ The Grund Committee report was published with the headline NOU 1997:7 Piller, prioritering og politikk and the Strøm Committee report is called NOU 1997:6 Rammevilkår for omsetning av legemidler.

¹⁸⁷ Parliament decision Besl. O. nr. 70 (1999–2000) and opinion of the Social Committee Innst. O. nr. 52 (1999–2000) Innstilling fra sosialkomiteen om lov om apotek.

¹⁸⁸ St.meld. nr. 41 (1987–1988) Helsepolitikken mot år 2000.

¹⁸⁹ Ot.prp. nr. 29 (1998–1999) chapter 3.1. NOU 1997:6 Rammevilkår for omsetning av legemidler p. 9–13, p. 99–100.

social insurance scheme reduce the incentive of patients and doctors to choose the cheapest product. Due to these factors the Committee saw public supervision and guidance to be necessary in order to ensure the quality of medicinal products and pharmaceutical care. Furthermore, price control reimbursement policies could be designed to encourage price competition and to ensure consistent prices across the country.¹⁹⁰

At the end of 1995 there were 250 privately owned pharmacies, 78 subsidiary pharmacies and 1,250 pharmacy sales points in Norway. This was significantly less than in other Nordic countries. According to the Committee, a greater number of pharmacies was necessary in order to establish more competition. This would then lead to greater pressure for pharmacies to lower costs and work efficiently. The majority of the Committee saw the pharmacy license system as a barrier to entry into the market. Furthermore, the license policy and pharmacy assistance among other features of the existing system¹⁹¹ reduced the entrepreneurial risk in the sector and did not incentivize renewal and development. The only source of uncertainty in the sector was related to the development of the regulatory framework, pharmacy fee and profit margin control. On the other hand, the Committee acknowledged that pharmacies take on many professional tasks which can be in conflict with their economic interests either voluntarily or required by law.¹⁹²

The Strøm Committee was divided on how the establishment of pharmacies should be organized. Six of its members¹⁹³ were of the opinion that there were no strong economic or health policy arguments that a public authority should decide on the number and location of pharmacies. Their view was that drug safety and other professional standards could be ensured also within a system based on free establishment. The other six members¹⁹⁴ disagreed and found that the establishment of pharmacies should be subject to regulation due to the pharmacies' role as information and service providers. Furthermore, free establishment would not ensure

¹⁹⁰ NOU 1997:6 Rammevilkår for omsetning av legemidler p. 14–16, p. 102–115.

¹⁹¹ For example, the Norwegian Board of Health Supervision determined the purchase price in pharmacy acquisitions according to certain standards. The buyer had an obligation to purchase the pharmacy's inventories and equipment. If a buyer could not be found, the state had an obligation to purchase the pharmacy.

¹⁹² NOU 1997:6 Rammevilkår for omsetning av legemidler p. 24–25, p. 61.

¹⁹³ These members were Strøm, Johnsen, Nestvold, Skarheim and Wesenberg.

¹⁹⁴ These members were Dalen, Eide, Hensrud, Johannessen, Krey-Jacobsen and Øydvin.

a comprehensive pharmacy network in sparsely populated areas. They also argued that the price elasticity of pharmaceuticals was very inelastic and thus competition would not reduce prices in any significant manner.¹⁹⁵

7.1.3.2. *Main Objectives and Changes*

One of the aims of the reform was to change the license system so that more pharmacies could be established in Norway. In the Government proposal Ot.prp. nr. 29 (1998–1999), the Ministry of Social Affairs and Health argued that pharmacy sector has not renewed itself in the same pace as other institutions in society. Any changes in the sector had been based on the existing values and opinions of the pharmacy profession. The Ministry's view was that the sector had not been subject to significant impulses for change and renewal.¹⁹⁶

The Strøm Committee's proposal of free establishment would permit pharmacy chains. The Committee argues that pharmacy chains would have a stronger negotiation position towards wholesale companies and that this would improve pharmacies' ability to negotiate lower prices. The Strøm Committee's proposal of free establishment was not adopted as such. Ownership was made possible for individuals without a degree in pharmacy and to corporations. However, each pharmacy was to be managed by a Master of Pharmacy. Pharmacy ownership and management were separated into two different license processes. After the reform, pharmacy chains were allowed. By promoting flexibility in ownership, the legislator aimed at increased development, competition and efficiency in the pharmacy sector.¹⁹⁷

The reform also updated safety and quality criteria to fit the new framework where pharmacies were not owned by pharmacy professionals. The reform also provided for special means for the public authorities to ensure that the pharmacy network would cover sparsely populated areas.¹⁹⁸

The Strøm Committee had discussed the sale of non-prescription drugs outside of pharmacies. The Committee was split on the matter as were the interest group

¹⁹⁵ NOU 1997:6 Rammevilkår for omsetning av legemidler p. 108.

¹⁹⁶ Ot.prp. nr. 29 (1998–1999) chapter 9.4.2.3.

¹⁹⁷ Ot.prp. nr. 29 (1998–1999) chapters 14.2. and 14.3. NOU 1997:6 Rammevilkår for omsetning av legemidler p. 27–29.

¹⁹⁸ Ot.prp. nr. 29 (1998–1999) chapter 1.1.

statements received during consultation. At this stage the government did not propose to release over the counter drugs for sale outside of pharmacies.¹⁹⁹

The 2001 reform introduced generic substitution in Norway as a means to increase price competition. However, the reference price system was left unaltered pending further evaluation.²⁰⁰

7.1.4. Development of Pharmacy Law after 2001

The Norwegian Medicines Act and the Norwegian Pharmacy Act have been amended several times since the 2001 reform. These amendments have mainly been introduced in order to develop individual topics relating to medicinal products and the pharmacy sector and to resolve smaller problems arising from the application of the new Acts.

The restrictions on pharmacy ownership were specified in 2002 based on the Government proposal Ot. prp. 61 (2000–2001) in order to ensure competition and prevent circumventions to ownership restrictions²⁰¹. This amendment also imposed an obligation to wholesale companies to provide price and sales data to supervising authorities for use in evaluating the success of price control measures²⁰². The amendment also discontinued the pharmacy fee system. The Ministry of Social Affairs and Health was of the opinion that the pharmacy fee caused distortions in competition. The pharmacy fee was replaced with a neutral sales fee on medicinal products which is covered by pharmacies in the wholesale price and charged from wholesale companies.²⁰³

After the 2001 law reform and removal of the pharmacy fee, the Ministry entered into agreements concerning pharmacies in sparsely populated areas with the largest pharmacy chains in Norway. Under the agreements, the pharmacy chains undertook to establish and maintain pharmacies in municipalities where an earlier main pharmacy had discontinued its business. The framework was in place between 2001 and 2011

¹⁹⁹ Ot.prp. nr. 29 (1998–1999) chapter 4.5.

²⁰⁰ Ot.prp. nr. 29 (1998–1999) chapter 5.1.3.

²⁰¹ Ot.prp. nr. 61 (2000–2001) chapters 2.2.2., 2.2.4. and 2.3.4.

²⁰² Ot.prp. nr. 61 (2000–2001) chapter 3.1.4.

²⁰³ Ot.prp. nr. 61 (2000–2001) chapter 3.3.

after which the scope of the pharmacy network has been determined on market conditions.²⁰⁴

The Government proposal Ot. prp. 29 (1998–1999) stated that promotion and advertisement of medicinal products should be investigated and clarified in the future. Marketing and advertisement were addressed with Ot. prp. 55 (2001–2002) which was enacted in 2003.²⁰⁵

In 2003, a reference price system was introduced. Its aim was to support the functioning and efficiency of generic substitution. In connection with the reference price, also the rebates in wholesale prices given to pharmacies were also regulated in order to ensure that customers would benefit from the rebate²⁰⁶. The market share of generic products within prescription drugs in 2003 was approximately 15 percent. The law proposal aimed at introducing measures to increase price competition in advance of the upcoming breakthrough of generics in the pharmaceuticals market. Introducing such measures any later, after generic products had established their role in the market, could cause a significant market disruption.²⁰⁷ The means for the government and the Ministry of Health and Care Services (*Helse- og omsorgsdepartementet*) to regulate prices and manage the reference price system were specified further with another amendment in 2008.²⁰⁸

The Norwegian Pharmacy Act was amended also in 2009 in order to improve the act based on experiences gained since the law reform. For example, restrictions on opening hours were removed from weekdays, regional restrictions on distance orders were removed, marketing restrictions of drugs inside the pharmacy were simplified and practical issues within the license processes were resolved.²⁰⁹

7.2. Main Features of the Norwegian Pharmacy System

²⁰⁴ *Dalen, Dag Morten ja Steinar Strøm*, The pharmaceutical market in Norway s. 53–54. St.meld. nr. 18 (2004–2005): Rett kurs mot riktigere legemiddelbruk s. 74.

²⁰⁵ Ot.prp. nr. 29 (1998–1999) chapter 4.6.5. Besl. O. nr. 57 (2002–2003). Ot. prp. 55 (2001–2002).

²⁰⁶ Ot.prp. nr. 16 (2002–2003) chapter 1.1. and 1.2.

²⁰⁷ Ot.prp. nr. 16 (2002–2003) chapter 2.1.4.

²⁰⁸ Ot.prp. nr. 58 (2007–2008) chapter 2.4 and Besl. O. nr. 9 (2008–2009).

²⁰⁹ Ot.prp. nr. 91 (2008–2009).

7.2.1. Pharmacy Ownership and Management

7.2.1.1. Pharmacy License

In Norway, ownership of a pharmacy business is subject to a pharmacy license from the Norwegian Medicines Agency (NPA 1:4 ja 2:1). However, the pharmacy license is not personal in the sense that it needs to be issued to an individual. In addition natural persons, the license holder can be a company or corporation. A single company or person can hold several pharmacy licenses and thus pharmacy chains are permitted in Norway.

The applicant has to prove sufficient economic means to engage in the pharmacy business in an economically responsible manner and in accordance with the requirements set by law and regulations. Due to the standards and special service obligation applied to retail distribution of medicinal products, the above requirement also includes providing unprofitable services to customers. The applicant must also prove with sufficient likelihood that the pharmacy business will reach a high enough volume in order to sustain the minimum level of specialization and drug manufacturing standards required by law (NPA 2:2 subsections a and b). The pharmacy permit can include special conditions regarding services, opening hours and other factors in order to ensure local or regional fulfilment health policy objectives. For example, the Agency can set an obligation to maintain a subsidiary pharmacy or pharmaceutical sales point. However, this kind of enforcement to run a business is an exceptional measure applied only in cases fulfilling specific geographic, demographic and economic criteria relating to pharmaceutical services in the area. In these cases the Agency can compensate the license holder with public funds.²¹⁰

Pharmacy ownership is restricted to individuals who are not engaging in industrial pharmaceutical manufacture and who do not have the right to prescribe medicine to patients. Similarly, companies which engage in industrial pharmaceutical manufacture or in caring diseases or which have a person with a prescription right in their management cannot be granted with a pharmacy license. The NPA extends this restriction to indirect ownership. This is to avoid any conflict of interest between the

²¹⁰ Ot.prp. nr. 91 (2008–2009) chapter 10.3. *Legemiddelverket*, Retningslinjer for bruk av apotekloven § 2-8 og for driftstøtte til apotek.

commercial benefit of selling medicinal products and servicing the patients' medical needs (NPA 2:3). A pharmacy license can be granted to a municipality, regional administration or a company owned by either of the aforementioned on special grounds (NPA 2:4).²¹¹

The pharmacy license usually gives the license holder a right to establish or own a pharmacy within a specific municipality (NPA 2:7). The license allows the license holder change the location of the pharmacy within the municipality. As a rule, in case the pharmacy owner wishes to move the pharmacy into a facility located in another municipality, even if it is nearby, a new pharmacy license is required. However, according to clause 3 of the Norwegian Pharmacy Regulation (apotekforskriften (26. februar 2001 nr. 178), NPR) the pharmacy license can define an alternative geographical area in case it is necessary due to the natural customer base of the pharmacy.

The conditions under which the pharmacy license can be revoked are similar in Norway as in Finland. The pharmacy license can be revoked for example if professional standards under Section 2:8 of the NPA are not met or if the license holder no longer meets the eligibility criteria under Sections 2:2 and 2:3 NPA. Other conditions include neglect of reporting obligations required by law or decision of a public authority, failure to cooperate with supervising authorities and closing of the pharmacy due to danger to health or safety. Revocation is also possible if, under prevalent conditions, the license holder becomes legally incapable of pharmacy ownership. (NPA 2:8 §)

Sections 2 and 3 of the Norwegian Pharmacy Act authorize the Ministry of Health and Care Services to further regulate the right to receive a pharmacy license in case it is necessary from a competition policy viewpoint and limit the right in case it is necessary for the responsible distribution of professional pharmacy services in the country. Clause 13 of the NPR caps the market share of pharmacy ownership to 40 % of the total turnover of non-hospital pharmacies in the country. This requirement can be overlooked in order to ensure sufficient supply of medicinal products in the area.

²¹¹ Ot.prp. nr. 29 (1998–1999) chapter 10.1.4.4.

7.2.1.2. *Management Permit*

Each pharmacy in Norway must be run and managed by a pharmacist. Management is subject to a management Permit granted by the Norwegian Medicines Agency (NPA 1:4 §, 3:1 §). The management permit concerns the person who is responsible for the operative management of a specific pharmacy and possible subsidiary pharmacies and it requires the permit holder to be personally present and involved in the pharmacy in order to carry out the day to day running of the pharmacy business (NPR 15 §). Prior to receiving the management permit, the pharmacy license holder must prove that the pharmacy facilities meet the requirements for running a pharmacy establishment and that the pharmacy has the required capability for in house manufacture of medicinal products (NPA 3:3 §).

The pharmacist is responsible for ensuring that the pharmacy business is carried out in accordance with relevant legislation, regulations, decisions of public authorities and the requirements of good pharmacy practice and manufacturing practice for medicinal products (NPA 3:6.1 §). The pharmacists must follow the pharmacy owner's instructions to the extent that they are in line with relevant professional standards (NPA 3:6.2 §). The pharmacy license holder decides all significant and extraordinary matters concerning the pharmacy as well as hiring and dismissal of pharmacy personnel based on the recommendations of the pharmacist, provided that the pharmacy owner has not authorized the pharmacist to make such decisions independently. (NPA 3:6 §).

One person can hold only one management permit at a time. The pharmacist must meet certain eligibility criteria concerning the applicant's professional skills and civic constitution. The pharmacist must hold a certified Master's degree in Pharmacy, a minimum of two years' work experience after graduation and the competency of a pharmacist provisor. The Norwegian Medicines Act also requires a clean criminal record as well as suitability for managing a pharmacy business (NPA 3:2 §). The applicant is unsuitable in case they have been convicted to prison for an economic or financial crime for 3 years or more, in case of serious substance addiction and irresponsible exercise of their rights and obligations as a pharmacist (NPR 17 §).

7.2.2. Subsidiary Pharmacies and Pharmaceutical Sales Points

The pharmacy license can also include a right to own and the management permit can include a right to run a subsidiary pharmacy (NPA 3:4 §). The pharmacist managing the pharmacy is accountable the subsidiary pharmacy and its functioning. However, the pharmacist has an obligation to designate a person who is responsible for managing the subsidiary pharmacy. This person must be qualified as a pharmacist provisor.

Pharmacy license holder can also have a license to maintain a pharmaceutical sales point in areas without a pharmacy. The requirement is that there is no pharmacy or subsidiary pharmacy within 10 kilometres of the sales point (NPA 2:7.1 § subsection a). The pharmaceutical sales point can only distribute over-the-counter drugs and other products which are not subject to prescription or classified as medicinal products (NPR 57 §). The pharmacy is required to make a list of products available at the sales point in cooperation with the municipal doctor (NPR 58 §).

7.2.3. Medicinal Products outside of the Pharmacy

In 2003 the Norwegian Ministry of Health and Care Services released certain OTC drugs for sale outside of pharmacies (NMA 16.4 §). The government regulation on the sale of non-prescription drugs (*forskrift om omsetning av reseptfrie legemidler*, 14. august 2003 nr. 1053, generally called the LUA regulation (*legemidler utenom apotek*)) provides detailed regulation on the distribution of medicinal products in retail stores. For example, medicinal products must be placed so they are distinguished from other products and are not available to children under the age of 18 (LUA regulation 10 §). According to the regulation, the Norwegian Medicines Agency can restrict the number or size of packages which can be sold to an individual customer (LUA regulation 11 §). Products available outside of pharmacies include traditional herbal medicinal products, nicotine replacement products and specific non-prescription drugs listed by the Norwegian Medicines Agency (LUA regulation 1 §). The aim of permitting sale of certain medicinal products outside of pharmacies was to improve access to medicine and to increase price competition.

7.2.4. Price Regulation and Reimbursement under the National Health Insurance System

7.2.4.1. Wholesale Prices

One of the state's central aims concerning medicinal products is to ensure that medicinal products are affordable to citizens. As in Finland, citizens can have expenses for pharmaceuticals reimbursed by the Norwegian national insurance scheme (*folketrygden*), regulated by the Norwegian National Insurance Act (NNIA). Thus, it is in the interest of the state to influence drug prices for two reasons: Firstly, low prices ensure that as many citizens as possible will purchase their medicine without need of assistance. Secondly, when prices for medicinal products are low, the state's expenses under the national insurance scheme remain reasonable.

Prices for medicinal products have been regulated in Norway since 1928. In connection with Norway's accession in the EEA, direct price control has been applied only for prescription drugs from 1995 onward²¹². Thus, unlike in Finland, prices are limited irrespective of the drug's reimbursement status. Price control for medicinal products in Norway includes a cap for the price on all prescription drugs and mechanisms to stimulate further price competition. Since veterinary medicinal products and OTC drugs can be priced freely, the state attempts to influence their prices through alternative means. One of the legislator's aims in liberating pharmacy ownership in 2001 was to lower consumer prices through enabling synergies for pharmacy chains and through increased competition. Also the sale of certain non-prescription drugs outside of pharmacies under the LUA-regulation is expected to increase price competition for OTC drugs.²¹³

Price control in Norway covers the wholesale and retail level of the value chain for medicinal products. Importers and wholesale companies negotiate their prices with pharmaceutical manufacturers freely to establish the wholesale purchase price (*grossistenes innkjøpspris*, GIP).²¹⁴ Price control for prescription drugs is covered in

²¹² NOU 1997:6 Rammvilkår for omsetning av legemidler p. 10 and p. 55.

²¹³ *Helsedepartementet*, Høringsnotat: Forslag til forskrift om omsetning av visse reseptfrie legemidler utenom apotek kohta "Konsekvenser for prisutviklingen". *Martikainen, Jaana & Rajaniemi, Sinikka*, EU-maiden, Islannin ja Norjan lääkekorvausjärjestelmät p. 72.

²¹⁴ *ECON Analyse*, Evaluering av apoteklovet og indeksprissystemet p. 68. *Martikainen, Jaana & Rajaniemi, Sinikka*, EU-maiden, Islannin ja Norjan lääkekorvausjärjestelmät p. 72.

Section 6 of the NMA and chapter 12 of the NMR. The Norwegian Medicines Agency determines the highest permitted wholesale price for each medicinal product (*apotekets innkjøpspris*, AIP, also referred to as *maksimal AIP*). In its deliberation the Agency takes into consideration the market price of the medicinal product in Sweden, Finland, Denmark, Germany, the United Kingdom, Netherlands, Belgium and Ireland. In special cases the AIP price can be set to be higher than in the reference states if this is required to ensure that the product remains available in Norway. The value of the product within medical care, the price level of corresponding products and manufacturing and development costs are also taken into consideration in determining the AIP. The Norwegian Medicines Agency readjusts the wholesale price for the most commonly sold products on a yearly basis. For other products the AIP price can be reviewed upon request of the marketing authorization holder or on the Agency's own initiative. As a rule, such reviews are not made more frequently than one year after the latest review.²¹⁵

7.2.4.2. *Pharmacy Profit Margin and Retail Price*

The profit margin which pharmacies can charge for prescription drugs is capped. The Norwegian Medicines Agency determines the maximum profit margin for pharmacies which consists of a fixed amount in NOK and a percentage of the wholesale price (NMR 12:3 §). Thus, the AIP price of the medicinal product and value added tax determine the consumer price (*apotekets utsalgpris* AUP) together. In Norway, the general value added tax, which is 25 percent, is applied to medicinal products²¹⁶.

The Agency reviews the maximum profit margin every four years. From 1 January 2014 onwards, the maximum profit for the sale of an individual medicinal product package has been as follows. The fixed amount for each package is NOK 25.00. The portion of profit determined as a percentage of the wholesale price has been divided in two parts and stands at seven percent for the first 200.00 Norwegian krone and three percent

²¹⁵ *Legemiddelverket*, Retningslinjer for prisfastsettelse p. 1–4. NOU 1997:6 Rammvilkår for omsetning av legemidler p. 56.

²¹⁶ Stortingensvedtak om merverdiavgift for budsjettåret 2015 (kap. 5521 post 70), § 2.

for the remaining part of the AIP. For prescription drugs in classified in groups A and B²¹⁷ the fixed portion of profit is NOK 10.00.²¹⁸

During the early 1990s drug expenses were growing at a significant pace. The Strøm Committee saw this as a result of a general increase in the price level and increased drug consumption and especially as a result of a transition to new, costlier pharmaceuticals. There had been calls for a greater level of regression in the maximum profit margin and this had been implemented in 1992. Additionally, the profit margin was amended in 1995 to cover fixed costs more effectively while reducing the percentage portion in the calculation. The profit margins were also cut in 1996 and 1997.²¹⁹

The Norwegian Medicines Act forbids rebates which are not granted at the time of purchase (NMA 6.1 §). However, rebates as are not forbidden as they can work towards lower retail prices. The state has ensured that rebates which pharmacies receive on wholesale prices are directed to the benefit of the consumer under a profit allocation system (*gevinstdelingssystemet*)²²⁰. In case pharmacy manages to negotiate a rebate on the maximum wholesale price, a minimum of 50 percent of the difference between the maximum wholesale price and the negotiated price should be allocated as a rebate on the consumer price (NMR 12:3.2 §). The pharmacy can keep the remaining portion of the rebate which increases the pharmacy's profit margin. This incentivizes the pharmacies to negotiate rebates from wholesale companies and ensures that rebates from wholesale companies are visible in retail prices.²²¹ For example rebates based on purchase volume at the end of the year are not allowed as the benefit from the rebate is provided to the pharmacy as a price refund. When rebates are defined beforehand, they impact the profit margin of the pharmacy and the retail price for the consumer directly. Furthermore, this increases transparency in pricing and facilitates pharmacies' price comparison and competitive bidding between

²¹⁷ These groups include medicinal products with addictive properties as described in section 5.3.6 Classification of Medicinal Products.

²¹⁸ *Legemiddelverket, Om apotekavanse 2014.*

²¹⁹ NOU 1997:6 Rammvilkår for omsetning av legemidler p. 8–11, p. 66.

²²⁰ *ECON Analyse, Evaluering av apoteklovet og indeksprissystemet s. 70.*

²²¹ *ECON Analyse, Evaluering av apoteklovet og indeksprissystemet s. 70.*

suppliers.²²² The profit allocation system is not applied to prescription drugs subject to internal reference pricing.²²³

7.2.4.3. *Reimbursement under the National Health Insurance System*

In Norway, citizens' medicine expenses have been kept at a reasonable level through reimbursements for prescription drugs from the national insurance scheme since 1953.²²⁴ For this purpose prescription drugs have been divided into products subject to standard reimbursement which in Norway are called drugs under blue prescription (*legemidler på blå resept*) and to other prescription drugs (*hvit resept*). Drugs under blue prescription are covered in the Regulation on Assistance for Covering Expenses for Important Medicines (Forskrift om stønad til dekning av utgifter til viktige legemidler mv. (*blåreseptforskriften*) (28. juni 2007 nr. 814), Blue Prescription Regulation, BPR).

The Norwegian reimbursement system includes similar requirements for prescription status as the Finnish one. The Norwegian Medicines Agency maintains a reimbursement list which includes all drugs under blue prescription that is medicinal products which have been preapproved for reimbursement. All patients, whose symptoms match with the purpose of use for the preapproved prescription drug and whose use of the product is long-term, that is three or more months per year, are entitled to partial or complete reimbursement for their medicine expenses (BPR 2 §). Preapproved reimbursement has also been enabled for certain contagious diseases. In addition to medicinal products, certain nutrition supplements and accessories which are used in connection with medical treatment or are necessary as a result of illness are also covered. Examples include catheters, syringes and insulin pens (BPR 5–6 §).²²⁵

Sometimes a patient is not entitled to preapproved reimbursement for a necessary prescription drug due to the nature of her symptoms or because the necessary medicinal product is not on the reimbursement list. For such cases, the doctor prescribing the drug can apply for special reimbursement under blue prescription on behalf of the patient (BPR 3 §).

²²² Ot.prp. nr. 16 (2002–2003) chapter 4.1 and 4.2.

²²³ *ECON Analyse*, Evaluering av apoteklovet og indeksprissystemet s. 71. See section 7.2.4.5 on Internal Reference Pricing in Norway.

²²⁴ NOU 1997:6 Rammevilkår for omsetning av legemidler p. 68.

²²⁵ NOU 1997:6 Rammevilkår for omsetning av legemidler p. 69.

Reimbursements for medicine expenses are covered at the time of purchase by the Norwegian Health Economics Administration (*Helseøkonomiforvaltningen HELFO*) which works under the Norwegian Directorate of Health (*Helsedirektoratet*). Each patient pays 38 percent of the retail price but only up to NOK 520.00 per prescription. Children under 16 years of age, war invalids and individuals living on minimum pension are exempt from payment and their medicine expenses are reimbursed in full. Medicine expenses are also covered in full under the national insurance scheme for certain illnesses and contagious diseases (BPR 7 §).

In case the necessary prescription drugs are not subject to blue prescription or special reimbursement the patient will pay the full price of the product. However, in case the medicine expenses exceed NOK 2185 during the year, the patient is entitled to a reimbursement of 90 percent on remaining expenses. Patients with high drug costs can also receive assistance for their expenses on social grounds (NNIA 5:22 §).²²⁶

7.2.4.4. *Generic Substitution*

From 1987 onwards doctors had an obligation to prescribe the medicinal product with the lowest price and from 1991 onwards the obligation was to prescribe the most inexpensive generic product. This increased the market share of generic products for certain drug groups. However, generic prescription did not ensure price competition effectively as doctors' knowledge of price developments was limited.²²⁷ In connection with the 2001 law reform, Norway adopted generic substitution. Pharmaceutical personnel can substitute the original medicinal product prescribed by a doctor to a parallel imported product or less costly generic product (NPA 6:6 §). They also have an obligation to inform the patient about lower price generic products (NPA 6:4 §). The Norwegian Medicines Agency maintains a list of substitutable products (*byttesten*) which is updated twice each month.²²⁸ Medicinal products which are substitutable with each other form a substitution group (*byttegruppen*). Similarly as in Finland, the chief aim for adopting generic substitution was to lower drug prices and

²²⁶ *Martikainen, Jaana & Rajaniemi, Sinikka*, EU-maiden, Islannin ja Norjan lääkekorvausjärjestelmät p. 74. *Rikstrygdeverket*, Rundskriv – § 5-22 - Bidrag til spesielle formål s. 1.

²²⁷ NOU 1997:6 Rammevilkår for omsetning av legemidler p. 8, p. 71.

²²⁸ *Legemiddelverket*, Om byttesten.

reimbursement costs for the state.²²⁹ Parallel import has been allowed in Norway since 1995 and parallel imported products are included in generic substitution²³⁰.

In Norway, doctors can indicate in the prescription that generic substitution is not allowed on medical grounds (NMR 12:16 §). This practice is similar to the medical grounds on which generic substitution can be restricted in Finland. The patient has a right to forbid generic substitution. However, in that case the product is only reimbursed up to the price of the least expensive product in the substitution group or in accordance with the reference price (BPR 8 §).

7.2.4.5. *Internal Reference Pricing*

In 1993 Norway introduced a reference price system for those medicinal products for which their patent had expired. Under this system, a maximum price was set for the reimbursement granted for certain substitution groups. This resulted in the prices within these drug groups falling to the level of the reference price. However, in connection with the 2001 law reform, the reference price system was discontinued on the grounds that its administrative costs were higher than the achieved savings.²³¹

In 2005 internal reference pricing was reintroduced to support price competition established through generic substitution. Since 2005, reference prices have been lowered several times. In connection with its proposal to reduce reference price levels and pharmacy profit margins in 2013, the Ministry of Health and Social Affairs found that the Norwegian reference price system and generic substitution had been successful in decelerating the increase of pharmaceutical prices.²³²

The Norwegian reference price model aims at ensuring effective pharmaceutical care and mitigating reimbursement costs for the state. The Norwegian Medicines Agency can decide to set a reference price for a particular substitution group and determines to which generic products the reference price is applied. As a prerequisite for setting a reference price, the products must be on the Agency's substitution list and at least one generic product must be competing steadily with the original product in the Norwegian

²²⁹ Ot.prp. nr. 29 (1998–1999), chapter 11.1.2.1.

²³⁰ Ot.prp. nr. 29 (1998–1999), chapter 11.1.2.1. and 11.1.2.2.

²³¹ NOU 1997:6 Rammvilkår for omsetning av legemidler p. 8. Ot.prp. nr. 58 (2007–2008) p. 1–2.

²³² *Helse- og omsorgsdepartementet, Høringsnotat: Forslag til endringer i prising av byttbare legemidler og apotekenes maksimalavanse ved salg av legemidler* p. 7.

market (NMR 12:14 §). The contrast to Finland is that in Norway the reference price is not necessarily applied immediately when a new generic product enters the market as steady competition must first be established.

HELFO reimburses drug costs up to the reimbursement based on the reference price. In case a more expensive product is chosen, the patient has to cover any amount above the reimbursement level at reference price. This amount is also not considered part of the patient's overall yearly drug expenses. (NMR 12:16.1 §, 12:16.3 §, NNIA 8.3 §) However, in case the doctor prescribing the original or other more expensive product has prohibited generic substitution, reimbursement is granted on the basis of the actual price paid for the medicinal product (NMR 12:16.2 §).

The reference price is calculated by making two to three percentage cuts to the price of the original medicinal product. The maximum wholesale price of the original product is usually used as the starting point. The reference price is relatively lower for substitution groups where the total value of sales within the group was NOK 100 million or more during a 12-month period within two years before generic competition was established. For these substitution groups the first cut is made as a 35 percent reduction from the original price and it takes effect at the moment generic competition begins. The second cut amounts to an 81 percent reduction from the original price and it is made six months after competition has been established. For other substitution groups the first cut is 35 percent and the second cut is 59 percent. A third cut can be made 12 months after the second cut based on the sales volume of the substitution group. (NMA 6.2 §, NMR 12:15.1–12:15.4 §)²³³

8. Legal Principles in Preparatory Materials of Pharmacy Legislation

This section highlights the legal principles and fundamental rights which the Finnish and Norwegian legislator have taken into account in their choices regarding their respective pharmacy systems. The findings are based on an examination of the preparatory materials for Finnish and Norwegian pharmacy legislation in relation to the main features of the system as described in sections 6 and 7.

²³³ Depending on the sales volume of the substitution group, the cut is 69 percent if total sales exceed NOK 15 million, 86 percent if total sales exceed NOK 30 million or 90 percent if total sales exceed NOK 100 million. (NMR 12:15.8 §)

The following central principles play central a role in the argumentation provided in preparatory works: the right to health and the patient's right to self-determination. The following chapters will outline their role in the pharmacy sector.

However, other fundamental rights have also been referenced in the *travaux préparatoires*. For example, the Finnish legislator has reviewed entrepreneurial freedom under Section 18 of the Finnish Constitution in the context of the pharmacy sector. In its evaluation of the impacts of legislative measures such as subjecting certain activities to a permit process, the legislator has referred to opinions of the Committee for Constitutional Law. Permit processes are justified for example in order to ensure health or safety. In regard to generic substitution, the legislator on the other hand evaluated whether changes in the reimbursement system restricted entrepreneurial freedom of pharmacies and pharmaceutical companies. The legislator concluded that generic substitution did not prevent the sale of specific products and that the economic impact of the amendment on pharmacies and industry actors was not so significant as to constitute a limitation of their fundamental rights.²³⁴

8.1. Right to Health

The substance of the right to health is multi-faceted and has a wide scope. Many different legal principles and policy aims can work towards the fulfilment of the right to health. For example, Section 7.1 of the Finnish constitution has been interpreted to support measures promoting public health in connection with Section 19 of the Constitution²³⁵. Considerations relating to the right to health within the pharmacy sector can be grouped under the following themes: equal access to healthcare, allocation of resources and drug safety.

These themes and the more specific principles described in connection with them have not been derived from the right to health. I see the right to health to be on a deeper level of sedimentation within the legal system than perhaps the legal principle of equal access to healthcare. The right to health through its standing in international conventions and its impact on other areas of law, for example criminal law, provides institutional support to the principle of equal access to healthcare. Furthermore, in

²³⁴ HE 94/2010 p. 19. HE 21/2009 p. 12. HE 165/2002 p. 21–22.

²³⁵ *Saraviita*, Suomalainen perusoikeusjärjestelmä p. 339–340.

working closer to the surface of the legal system, the principle of equal access to healthcare is useful for determining the substance of the right to health. The themes of drug safety and allocation of resources, on the other hand, are reflections of the right to health in the factual context of the pharmacy sector and the principles are legal principles which are related or overlap with the right to health.

8.1.1. Equal Access to Healthcare

As described in section 4.4.2, equal access to healthcare is provided for in several international treaties regarding social human rights. Both the Finnish and the Norwegian legislator places pharmaceutical care within the field of healthcare by acknowledging its role within medical care and its potential as an alternative to medical care²³⁶. The impact of the principle of equal access is evident in many ways in the preparatory works of pharmacy law in Finland and Norway.

The state needs to take many practical matters into consideration in order to ensure equal access to healthcare. Equal access to healthcare is multi-faceted in its substance. Therefore, different mechanisms for ensuring equal access within the pharmacy sector are discussed separately under the following topics: affordable medicine, pharmacy service network and customer service. These practical factors also reflect different aspects of the principle of equal access.

8.1.1.1. Affordable Medicine

The principle of equal access to healthcare requires the state to apply a standard of equality within the health sector. According to the Finnish and Norwegian legislator one central factor for ensuring equal access in practice is the price of medicinal products. The state has an obligation to ensure that the pharmacy system works towards lower consumer prices and restrains the trend of increasing prices for pharmaceuticals. Price control of prescription drugs is a practical way of ensuring a reasonable price level.

In its call for efficiency within the pharmacy sector in connection with the 2001 law reform, the Norwegian legislator did not only consider drug reimbursement costs and pharmacy assistance costs of the state. The legislator argued that reduced costs within the pharmacy sector and increased competition would also lead to lower prices for

²³⁶ NOU 1997:6 Rammevilkår for omsetning av legemidler p. 9–13, p. 99–100.

consumers. Also, by introducing generic substitution and reference pricing, the Finnish and the Norwegian legislator both adopted measures which had successfully reduced prices in other countries. These measures were not justified based on a political aim to improve the position of the manufacturers of generic products. Such a goal existed but only in order to serve the aim of lower prices on medicinal products and thus improved access to pharmaceutical care.

In social law and health law, the principle of need plays a central role in defining the substance of equal access. This principle is evident in considerations regarding reimbursement of drug costs in Finland and Norway. Firstly, the principle of need is central to the very existence of the reimbursement system. Illness is something which can affect any citizen regardless of their actions. Individual citizens should not be faced with unreasonable financial implications due to the price of the medicinal products required to treat an eventual illness. In case of a long-term disease or serious illness, the individual has a particular need for medicinal products. Therefore, the state should provide financial assistance for covering drug costs in the form of reimbursements under a social or health insurance scheme.

Secondly, the principle of need is employed in the criteria and decision-making for granting reimbursement status for medicinal products. The legislator refers here to ensuring rational pharmaceutical care. Since the funds available for reimbursement are limited, the scope of reimbursement needs to be limited with use of the principle of need. Therefore, there are certain criteria in place for granting reimbursement status for medicinal products and for limiting the purpose of use for which reimbursement is possible. For example, products which are used short term pharmaceutical care or for mild symptoms are excluded from reimbursement. Special reimbursement in case of serious illness or expensive necessary treatment also reflects the principle of need.

8.1.1.2. Pharmacy Service Network

The availability of pharmacy services and medicinal products is a significant practical requirement for the equal access to pharmaceutical care. Due to the geography and demographic features of Finland and Norway, this question has been a particular challenge for the legislator in both countries. The means with which the reach of the pharmacy network has been ensured in sparsely populated areas is different in the

two countries. A comparatist would say that the institutions chosen to resolve the question of equal access to medicine are different.

The Finnish system relies on its pharmacy license and pharmacy fee systems. The former provides the state with means to determine the location of pharmacy services. Pharmacy fees on the other hand work as an income distribution model for pharmacies. The progressive structure of the fee ensures that larger pharmacies cannot drive prices down to a level where small pharmacies in scarcely populated areas no longer are profitable. In maintaining the pharmacy fee, the Finnish legislator has made a valuation regarding the substance of equal access to healthcare: the aspect of availability to services has been highlighted at the expense of the aspect of affordable medicine.

In Norway, the pharmacy fee was abolished in the 2001 reform and ownership was made available to others than individuals with a master's degree in pharmacy. However, this does not mean that the aim of a comprehensive pharmacy network as abandoned. The reform was introduced in order to increase the number of pharmacies in all of Norway. The state used special measures, for example direct agreements with pharmacy owners, to ensure the availability pharmacy services in sparsely populated areas.

The Norwegian legislator also aimed at improved availability in releasing certain over-the-counter drugs to sale outside of pharmacies, as did the Finnish legislator in relation to nicotine replacement products.

8.1.1.3. Customer Service

The state is successful in ensuring rights only if the relevant right is fulfilled in practice²³⁷. Access to healthcare is only the first step as the actual care must also correspond with the patient's needs²³⁸. In the context of pharmaceutical care this means firstly that the patient is provided with the appropriate medicinal product in relation to their specific need. Secondly, pharmaceutical care is only successful if the patient then uses the medicinal product correctly. Thirdly, equal access to healthcare also spans preventive care. The fulfilment of all three factors is dependent on

²³⁷ *Tuori, Kaarlo*, Lagstiftningsstrategierna inom social- och hälsovården p. 13.

²³⁸ *Pahlman, Irma*, Potilaan itsemääräämisoikeus p. 100.

customer service. Therefore, it plays a concrete role in ensuring equal access to pharmaceutical care.

The patient is more likely to purchase the necessary medicinal product if the purchasing process is easy and pleasant. The Finnish and Norwegian legislator has taken this into account in its regulation regarding pharmacy facilities and opening hours. Furthermore, the aim of improved customer service is a central reason why pharmacies are run as private businesses in both countries instead of as publicly owned healthcare units.

In connection with generic substitution, Finland expanded the requirement of providing information and guidance to cover over-the-counter drugs as well as the prices of medicinal products. Also the legislator in Norway took into account the role of pharmacies as information and service providers. Guidance on prices not only accelerates price competition but also decreases the asymmetry of information between the patient and pharmacy. Proper guidance on medicinal products, prices, correct use and possible adverse effects works towards improving the patient's confidence in the product and motivation to use the product correctly. This in turn works towards rational pharmaceutical care, makes treatment and preventive care more effective and thus frees state resources. In practice, customer service contributes to the fulfilment of the right to health as well as improves the state's capability to advance equal access to medicine.

8.1.2. Allocation of Resources

It is useful to discuss the idea allocation of resources separately from equal access to healthcare. This is a central question in health law but it works closer to the surface level of the legal system than equal access. The principle of equal access to healthcare deals with the manner in which institutions treat individuals. Scarcity of resources restricts the scope and defines the substance of equal access in a factual context. Resource allocation in turn deals with the manner in which scarce means are distributed in practice. The idea of resource allocation can be used to define the substance of equal access to healthcare as well as the substance of the right to health. Simultaneously, the requirements of equal access and the right to health, working on a

deeper level of sedimentation, are defining factors for the practical outcome of resource allocation.

Resource allocation is a difficult question for the legislator. As discussed in relation to health law, within medical care regulation is more open and elastic on the decisions of resource allocation by doctors than within pharmaceutical care. Within the pharmacy sector the most significant question of resource allocation is the reimbursement system for drug costs. The legislator in Finland and Norway was faced by the challenge of scarce resources and increasing costs. Therefore, in order to ensure the sustainability of the pharmacy system and the existing standard for pharmaceutical care, the legislator needed to bring down costs.

Considerations regarding rational pharmaceutical care and reimbursement status have been discussed in relation to the principle of need and equal access to healthcare, and they can be seen as exercises in the allocation of resources. The same applies for the legislator's decisions on the level of reimbursement. In deciding on recent savings in reimbursement costs, the Finnish legislator has taken into account considerations of need and equal access. The increases in drug costs have been allocated in a way that the impact is smaller for patients with long-term illnesses or expensive treatments. The greater part of the cost increase is allocated to citizens with low drug costs. Since this group of people is very large, the impact on an individual citizen is reasonable while the savings for the state are significant.

8.1.3. Drug Safety

The need for drug safety is clear to anyone already on practical and factual grounds as the results of poor drug safety could potentially be drastic. However, in understanding the role of drug safety in the legislator's choices, it should be discussed also from the perspective of the right to health. Due to its practical implications, drug safety is a significant factor for the fulfilment of the right to health.

In the pharmacy sector, drug safety in fact imposes a special obligation on all actors in the field. Pharmacovigilance is the task of pharmacies, pharmacists, doctors, wholesale companies, importers, manufacturers, researchers and public officials. Citizens need to trust that all relevant actors in the distribution chain have applied the necessary diligence in relation to drug safety. Otherwise, their right to health is jeopardized.

Pharmacovigilance also provides data on adverse effects. Access to this kind of information and its reliability is also central for the patient's right to self-determination. Therefore, in addition to the actors in the pharmacy sector, the legislator must ensure that these standards are applied in the pharmacy system. The legislator decides on amendments and reforms to legislation always in accordance with the requirement drug safety.

The release of certain OTC drugs to sale outside of pharmacies in Norway included an evaluation of the principle of equal access to pharmaceutical care was in relation to drug safety. This is for example the reason why not all OTC drugs were included in the scope of this amendment. In Finland on the other hand the legislator assessed the impact of such a measure differently and only permitted sale of nicotine replacement drugs as their impact on public health was thoroughly evidenced. These different assessments by the Norwegian and Finnish legislator demonstrate that it is not always clear, whether a specific measure is harmful to drug safety. In any case, within pharmacy law the requirement drug safety has significant weight. In cases where the evidence of a detrimental impact of a measure on drug safety is clear, the right to health will provide a strong argument against the adoption of such a measure.

8.2. Patient's Right to Self-Determination

The patient's right to self-determination is a central principle in health law²³⁹. Self-determination has been ensured in Section 1.2 of the Finnish Constitution and in Article 102.2 of the Norwegian Constitution. In the context of health law, self-determination is related to human integrity, the doctrine of informed consent, the right to participate in treatment and the right to information concerning one's health. The role which self-determination has in international treaties and the constitution in the countries is indicative of its profound weight in the legal system.

The Finnish legislator has cited the right to self-determination in its assessment of constitutional conformity of generic substitution in the government proposal

²³⁹ Within Finnish jurisprudence, Irma Pahlman has discussed the principle of the patient's right to self-determination in depth. Her work "Potilaan itsemääräämisoikeus" constructs a theory of a deliberation model for medical law (*lääkintäoikeudellinen punnintamalli*) and discusses the institutions of the advance healthcare directive, treatment of pain and euthanasia as application examples of the deliberation model.

165/2002. The legislator found that the patient's right to forbid substitution ensured self-determination²⁴⁰.

The pharmacy's obligation to provide information and guidance on medicinal products and their prices in Finland and Norway supports the patient's right to self-determination. The legislator in both countries has discussed the asymmetry of information concerning pharmaceuticals. In addition to considerations regarding price competition, asymmetry of information impairs the patient's capability²⁴¹ to participate in decisions regarding treatment and exercise the right to self-determination. By providing information and guidance, the pharmacy can empower patients to exercise their right to self-determination. Affordable prices are in practice a prerequisite for the patient's use of a medicinal product. Therefore, price control and policies promoting price competition also support the right to self-determination as patients can only exercise this right if they in practice have access to the product which they have chosen to use.

9. Conclusions

The research objective of this work is to understand why the pharmacy systems of the two countries have developed differently, and what kind of legal principles factor into their development. The following sections discuss the reasons why there are differences in the two systems, and the impact of principles and social development on legislation concerning the pharmacy sector. However, before dealing with those matters, the similarities between the systems should be discussed and the main differences should be summarized.

First of all, as discussed in relation to the different principles of health law, the main objectives of pharmacy policy in Finland and Norway are very similar. As Nordic welfare states, the two countries have gone through similar historical, economic and societal changes in the past. Even the pharmacy sector itself has been based on similar privileges and has faced the same disruptions and changes over the centuries. These

²⁴⁰ HE 165/2002 p. 21.

²⁴¹ Capability plays a central role in an individual's freedom and self-determination. In his pioneering work "The Idea of Justice" Amartya Sen discusses the role of freedom in justice and introduces his capability approach to freedom (*Sen, Amartya, The Idea of Justice*. p. 225–317). The knowledge interest of this research does not require an in-depth analysis of "freedom as capability". However, Sen's theory can be useful for legal scholars discussing justice and the importance of principles in the legal system.

days, both countries face the same challenges in the form of ageing population and increasing healthcare costs. Furthermore, the geographical features of the countries pose a particular challenge in terms of equal access to healthcare.

Most of the main features of the two countries' pharmacy systems are similar. Both countries apply some restrictions to the ownership and management of pharmacies. Finland and Norway both have a long history of pharmaceutical reimbursement. Recent developments include the introduction of generic substitution and an internal reference price system in each country. Professional standards of pharmacovigilance, pharmaceutical service, data protection, privacy, etc. are applied and regulated in a similar manner. Many of these features have been introduced in Finland and Norway in a similar timeframe.

From the perspective of function, particularly the question of equal access to pharmaceutical care has been resolved with use of slightly different institutions. This research finds that the most significant differences between the two systems are ownership and establishment under the pharmacy license system, the pharmacy fee, and sale of over the counter products outside of pharmacies. In practice, these factors have led to different structures in the market for medicinal products in the two countries. In Norway, as new international actors have entered the market and retail stores also engage in the sale of medicinal products, the interest groups as well as their aims within the sector have changed. This may lead to further differences in the development of Finnish and Norwegian pharmacy systems. The following chapter outlines why these different institutions were chosen in Finland and Norway to serve similar functions.

9.1. Interest Groups in the Legislative Process

In 2000, before the 2001 law reform was introduced, there were 397 pharmacies in Norway and 11,425 inhabitants per pharmacy²⁴². In the same year there were in total 794 pharmacies (591 pharmacies and 203 subsidiary pharmacies) in Finland and in 2002, when the number of pharmacies was 799, there were approximately 6,500

²⁴² *Apotekforeningen, Apotek og legemidler – Bransjestatistikk om apotekenes virksomhet og rammevilkår* p. 12. *ECON Analyse, Evaluering av apoteklovet og indeksprissystemet* p. 34.

inhabitants per pharmacy²⁴³. These figures highlight the difference between in the pharmacy networks of the two countries. At the end of the 1990s, the pharmacy sector in both countries faced increasing pressure to reduce costs and serve the public more efficiently.

In 1997 calls for the discontinuation of the pharmacy fee were not adopted as the policy of the Ministry of Social Affairs and Health. Instead, price control mechanisms were adjusted and a new working group was set up in 2000 to assess the need for reforms in the price control and reimbursement system. Finland clearly had a much more comprehensive pharmacy network than in Norway and thus the challenges of the system were less drastic and less immediate than in Norway.

Therefore, in the years preceding the 2001 law reform, the pressure for changing the pharmacy system was higher in Norway than in Finland. The Norwegian Pharmacy Association, together with the Norwegian Association of Pharmacists, opposed the 2001 reform. During the late 1980s and 1990s they argued actively against calls for opening the pharmacy system to free establishment. The Pharmacy Association did not succeed in maintaining the license framework and pharmacy fee and assistance system of the time. However, it should be noted that in light of some of the Strøm Committee members' proposals, the Pharmacy Association did not fully fail either – free establishment of pharmacies was not included in the final law proposal.

In its arguments regarding the ways in which the Norwegian pharmacy sector derogated from a perfectly competitive market, the Strøm Committee highlighted the positive impacts of competition. The view that competition would force the pharmacy sector to cut costs and develop was shared by the Ministry of Social Affairs and Health. Furthermore, in the government proposal regarding the 2001 law reform in Norway, the Ministry portrayed the pharmacy sector as a conservative profession averse to change.²⁴⁴

In its proposal the Ministry listed the following potential improvements which would follow from a more free establishment policy and license system for pharmacies: better customer service, lower prices, better access to pharmacies, leveling out of

²⁴³ *Suomen Apteekkariliitto*, Vuosikatsaus 2002p. 23.

²⁴⁴ Ot.prp. nr. 29 (1998–1999) chapter 9.4.2.3.

differences in profit between pharmacies, better use of pharmaceutical competence, new management competence from outside of the pharmacy profession, development and use of new technology and the use of business entity types which are more suitable for the pharmacy's activities than sole proprietorship.²⁴⁵

It is clear from the views of the Strøm Committee and the Ministry, that prior to the law reform, the Norwegian pharmacy sector had not demonstrated a will to reduce costs and improve efficiency. The Pharmacy Association's argumentation focused on drug safety and guidance towards the public. However, pharmacy owners did not adopt a strategy in which they would have renewed their business in market terms. The approach of arguing against reform resulted in the Ministry's mistrust toward the sector and its capability for renewal.

In Finland however, the prospect of abolishing the pharmacy fee and the pressure to reduce costs motivated the pharmacy sector to renew itself. Pharmacy owners needed to improve their business in preparation of possible drastic changes in the license framework. Furthermore, they needed to demonstrate the significance of pharmacies in ensuring rational pharmaceutical care. Finnish pharmacy professionals participated in the process of introducing generic substitution in Finland. The Pharmacy Association worked towards improving guidance on OTC drugs through its 1997 strategy for professional pharmacies and through a joint project between professional pharmacy associations, education facilities and public officials²⁴⁶. Currently, the Ministry of Social Affairs and Health, Fimea and professional pharmacy organizations are cooperating in order to benefit more efficiently from the pharmaceutical expertise in pharmacies. The Ministry has proposed to develop the pharmacy sector in line with the upcoming changes in the overall social- and healthcare system, for example by improving services and developing new services which pharmacies could offer in the healthcare market²⁴⁷.

In my opinion, the main reasons why the two pharmacy systems, based on similar regulatory frameworks still in the 1990s, have developed differently are as follows. Firstly, despite the similarities in the legislative choices for the pharmacy systems, the

²⁴⁵ Ot.prp. nr. 29 (1998–1999) chapter 9.5.

²⁴⁶ *Finnish Medicines Agency Fimea*, "Itsehoitoasiakas tarvitsee neuvontaa" – Sic! Lääketietoa Fimeasta, 1/2012.

²⁴⁷ *Finnish Ministry of Social Affairs and Health*, *Apteekkitoiminnan ja muun lääkehuollon kehittäminen* p. 16–18.

license regime in Norway and Finland worked differently. By the end of the 20th century, the Finnish license system had been more successful in ensuring a comprehensive pharmacy network that covered also sparsely populated areas. The Norwegian license system on the other hand did not service the public sufficiently. Secondly, the Finnish pharmacy sector was ready to improve service on its own terms. Norwegian pharmacists however did not demonstrate a similar willingness to improve and renew their business. This in turn led to the Ministry's perception that in opposing the law reform, the Norwegian pharmacy sector was aiming at maintaining the privileges of pharmacy owners at the expense of public interest.

9.2. Principles in the Legislative Process

Much of the legislation concerning the pharmacy sector can be described as instrumental in nature and at times even interventionist. Many questions such as the reimbursement rate for medicinal products under the national social or health insurance scheme are seen primarily as budgetary or political questions. This view represents the pragmatic aspect of legislation²⁴⁸. In relation to this kind of regulation, discovering the legislator's aims, the *voluntas* of law, is a fairly straightforward process. However, this work has also discussed the principles which guide the legislator's choices.

One of the aims of comparison under this work is to understand *why* the pharmacy systems in the two countries are similar or different. An examination of *voluntas* and the arguments directly cited by the legislator provides answers on the vibrations on the surface of the legal system. The principles of health law work in the deeper structures of the legal system. Their role in the legislator's policies and choices has been discussed in section 8. Within health law, medical ethics and the principles of health law are central in ensuring the *ratio* of law.

Based on the review of the Finnish and Norwegian legislator's reasoning for legislative measures, the role of principles of health law within the respective pharmacy systems is significant. This research shows that many of the relevant fundamental rights and social human rights have in fact had an impact on the substance of pharmacy policy in each country. In some cases, the legislator has cited fundamental or social rights in its

²⁴⁸ Tuori, Kaarlo, Lagstiftningsstrategierna inom social- och hälsovården p. 9.

valuation of the best legislative strategy. Furthermore, in my opinion, the policies adopted by the legislator have been determined by principles of health law to a significant degree even when the legislator has not directly cited them in its argumentation.

Principles such as right to health and the patients' right to self-determination have been embedded in the sediments of legal culture both countries under comparison. They impose requirements on the services which the state provides to citizens. Principles of health law however also impact the substance of the policies and the horizontal rights of citizens in relation to each other. They determine the substantive manner in which resources are allocated in the pharmacy sector. Therefore, even in situations where legislative measures are introduced in response to scarcity of resources, these principles provide guidance on how the impact of public savings should be distributed among citizens.²⁴⁹

Health law includes an ethical dimension²⁵⁰. The value of human dignity, which is embedded in deeper levels of the legal system, is recognized as an undeniable professional standard in healthcare. Medical ethics is horizontally connected to the principles of health law and has an impact on the *prima facie* priority between principles. For example, in valuations regarding prioritization, whether it is in case of an individual medical procedure or in decisions of healthcare policy, significant weight is given to the right to life and the underlying value of human dignity²⁵¹.

9.3. Impact of Social Development on Pharmacy Legislation

The legal system changes as a response to social development. Changes in society and social ideology impact the development of the legal system through its institutions and sediments. The surrounding facts impact the substance of the legislator's choice. The practical challenges which the Norwegian legislator had to resolve and the different approach which it took in comparison to Finland works as an example. The relevant legal principles in the two legal systems were very similar; however the difference in factual circumstances warranted different responses.

²⁴⁹ Tuori, Kaarlo, Lagstiftningsstrategierna inom social- och hälsovården p. 14.

²⁵⁰ Tuori, Kaarlo, Lagstiftningsstrategierna inom social- och hälsovården p. 9.

²⁵¹ Pahlman, Irma, Potilaan itsemääräämisoikeus p. 118.

In a welfare state, justice is a central value in society and the state has an obligation to uphold and promote it in its policies. Within healthcare, justice is fulfilled by ensuring equal treatment and rational care, determined through fundamental rights, human rights, ethical standards and healthcare legislation. These standards of justice should also be applied to private service providers such as pharmacies. Furthermore, it can be argued that on the grounds of their engagement in activities relating to health, private actors are bound by these standards even in the absence of direct regulation by the state. Nevertheless, it is the task of the legislator to decide on resource allocation and to ensure that the healthcare system functions in a just manner in practice.²⁵²

Since the 1980s, the Nordic welfare state model has faced numerous challenges in terms of scarce resources. Social human rights are emphasized in welfare state thinking. However, recent developments in society and particularly in welfare state economy has highlighted neoliberal thinking. In this discussion, social human rights which are more collective in nature are pitted against individual human rights and freedoms²⁵³. This has led to calls for privatization of state functions and use of free market mechanisms to achieve greater efficiency. In my opinion, neoliberal ideology had an impact in the development of the Norwegian pharmacy system even as full liberalisation of pharmacy ownership was not introduced.

9.4. Final Remarks

In my opinion, public discussion regarding legislation in the health sector reflects an interventionist and instrumental approach to regulation. Positivist thinking plays a role in emphasizing the legislator's sovereign power and political aims. This research shows that legal principles play a role in the legislator's choices and in day-to-day healthcare. In times where the legislator is faced with significant pressure to cut costs, the substance and role of these principles should be brought to light more effectively in the legislative process.

In discussing the increased role the legislator's intention, Tuori introduces three legislative strategies. Under the instrumental method, decisions are based on the idea of applying means to achieve an aim. The substance of instrumental legislation is often

²⁵² *Pahlman, Irma*, Potilaan itsemääräämisoikeus p. 100–101.

²⁵³ *Pahlman, Irma*, Potilaan itsemääräämisoikeus p. 105, p. 114.

dictated by political or economic considerations. In the strategic method on the other hand, the legislator bases the outcome on a compromise of benefits and arrangements between interest groups. The third method is based on a consensus achieved through discourse. Under this discursive method, the legislative outcome receives its legitimacy from the public discussion surrounding the decision-making process. According to Tuori, the discursive legislative process is an ideal in which special interests and public interest are filtered through the democratic parliamentary process.²⁵⁴

In my opinion, the ideal of discursive legislation should be adopted as the goal for decision-making regarding healthcare regulation. This is particularly important due to the nature of health law. By highlighting the importance of legal principles in healthcare, public discussion can contribute to ensuring that regulation does not result in restrictions to fundamental rights. The nature of health law however poses a particular challenge in this respect. Medical expertise plays a significant role in determining the substance and weight of these principles in practical situations. For example, in order to achieve rational pharmaceutical care, the state must rely on pharmaceutical expertise to determine reimbursement criteria for medicinal products. The specialization required to make practical decisions regarding health is prone to exclude many actors from discussing the substance of health legislation.

On the other hand, if the views and valuations of healthcare professionals and experts are not brought to the legislator's attention, the risk of legislation based on budgetary considerations or compromises between interest groups rather than on principles of health law increases. This may even result in regulation which does not serve the purposes for which the legislator has intended it.

Furthermore, ethical decisions regarding health are relevant to everyone in society. Ethical decisions should reflect the morality of society and should not be reserved only to those with the professional expertise in that specific field. Therefore, there is a need for discussion and transparency between medical considerations, ethics and the regulatory aspect of the healthcare system. Sen discusses the importance of public reasoning and debate in ethics. Within his theory, public reasoning can ensure that the requirement of objectivity is fulfilled – if the group of people participating in decision-

²⁵⁴ Tuori, *Kaarlo*, Oikeus, valta ja demokratia p. 43, p. 188 – 189.

making is small or very similar, there is always a greater risk of misconceptions or personal opinions influencing the outcome²⁵⁵. Objectivity in turn improves the quality of the decision-making and brings it closer to the requirements of justice. Public discussion is also necessary for ensuring that the interest of vulnerable groups which are in need of protection but do not have the capability to fully voice their opinion is taken into consideration in the legislative process²⁵⁶.

I find that discourse regarding health law and legislation regarding healthcare has not reached its full potential. Healthcare professionals should be more active in voicing their concerns and views in the public²⁵⁷. There is a need for bridging the gap between considerations based on medical expertise and policymakers. The public should strive to educate itself in medicine and the special requirements of the healthcare sector and medical ethics. However, the main responsibility for disseminating information and engaging the public in questions of health lies on doctors, pharmacists and other healthcare professionals. The legal profession should pay close attention to this public discussion and participate in it actively. In particular, with their views on the principles of health law, lawyers can, *and should*, contribute to the substantive valuations made by healthcare professionals in practical cases as well as to policies and decisions of the legislator.

²⁵⁵ Sen, *Amartya*, *The Idea of Justice* p. 39–44, p. 88–89.

²⁵⁶ Tuori, *Kaarlo*, *Lagstiftningsstrategierna inom social- och hälsovården* p. 11.

²⁵⁷ In this I agree with Pahlman. Pahlman, Irma, *Potilaan itsemääräämisoikeus* p. 104.