COMMUNITY PHARMACIES AND
THE NEEDS OF MOBILE EU CITIZENS –
A STUDY ON FINNS LIVING IN SPAIN

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Doctoral dissertation

To be presented by permission of the Faculty of Pharmacy of the University of Helsinki for public examination in Auditorium XIII, Main building, Unioninkatu 34, University of Helsinki, on Friday 6th June 2008, at 12 noon.

Helsinki 2008
ABSTRACT

Migration within the European Union (EU) has increased since the Union was established. Community pharmacies provide open access to health care services and can be the first, most frequently used or even the only contact with a nation’s health care system among mobile community residents. In some of the mass-migration areas in Southern Europe, most of the customers may represent mobile citizens of foreign background. This has not always been taken into consideration in the development of community pharmacy services. Mobile patients have been on the EU’s health policy agenda, but they have seldom been mentioned in the context of community pharmacies. In most of the EU member states, governments control the specific legislation concerning community pharmacies and there is no harmonised pharmaceutical policy or consistent minimal standards for community pharmacy services in the EU.

The aim of this study was to understand medication use, the role of community pharmacies and the symptom mitigation process of mobile community residents. Finns living in Spain were used as an example to examine how community pharmacies in a EU member state meet the needs of mobile community residents. The data were collected by a survey in 2002 (response rate 53%, n= 533) and by five focus group discussions in 2006 (n=30).

A large number (70%) of the respondents had moved to Spain for health reasons and suffered from chronic morbidity. Community pharmacies had an important role in the healthcare of mobile community residents and the respondents were mostly satisfied with these services. However, several medication safety risks related to community pharmacy practices were identified: 1) Availability of prescription medicines without prescription (e.g., antibiotics, sleeping pills, Viagra®, asthma medications, cardiovascular medicines, psoriasis medicines and analgesics); 2) Irrational use of medicines (e.g., 41% of antibiotic users had bought their antibiotics without a prescription, and the most common reasons for antibiotic self-medication were symptomatic common colds and sore throats); 3) Language barriers between patients and pharmacy professionals; 4) Lack of medication counselling; 5) Unqualified pharmacy personnel providing pharmacotherapy. A fifth of the respondents reported experiencing problems during pharmacy visits in Spain, and the lack of a common language was the source of most of these problems.

The findings of this study indicate that regulations and their enforcement can play a crucial role in actually assuring the rational and safe use of medicines. These results can be used in the development of pharmaceutical and healthcare policies in the EU. It is important to define consistent minimum standards for community pharmacy services in the EU. Then, the increasing number of mobile community residents could access safe and high quality health care services, including community pharmacy services, in every member state within the EU.
ACKNOWLEDGEMENTS

This study was carried out at the Division of Social Pharmacy, Faculty of Pharmacy, University of Helsinki during 2002–2008. The financial support provided by Helsinki University Pharmacy, the Research Foundation of the University of Helsinki, the Association of Finnish Pharmacies and the Finnish Pharmaceutical Society is gratefully acknowledged.

I wish to express my sincere and deepest gratitude to my main supervisor, Professor Marja Airaksinen, Ph.D. (Pharm.). Without her continuous support, enthusiastic attitude and extensive knowledge, this study would not have been possible. I am also most grateful to my supervisor, Professor Alan Lyles, Sc.D., M.P.H., for sharing his knowledge, support and excellent advice. I am grateful to Kirsi Pietilä, Ph.D. (Pharm.), for supervising me in the beginning of this process, welcoming me to the Division and introducing me to the field of Social Pharmacy.

I want to express my gratitude to my kind reviewers, Associate Professor Janine Morgall Traulsen, Ph.D. (Sociology), and Professor Hannes Wahlroos, Ph.D. (Pharm.), for their valuable and expert comments, which lead to improvements in the thesis.

I have warm memories of Hannu Turakka, Dr. (h.c.), who encouraged me to start my Ph.D. studies and advised me in the design of the survey. I am grateful to Professor Riitta Ahonen, Ph.D. (Pharm.), for her advice in the design phase of the survey. I also want to thank Professor Antti Karisto, Ph.D. (Political Science), for sharing his knowledge of Finns in Spain and helping me with the survey design.

I want to thank all those people who have helped me with this study. I am grateful to all those Finns living in Spain who helped me in collecting the data. Without your cooperation, it would not have been possible to carry out this study. Especially I want to thank Nina Väänänen for her kind assistance. I also want to thank all those people who participated in this study.

I want to thank the previous and current staff of the Division of Social Pharmacy, University of Helsinki. My special thanks go to my colleague and dear friend, Marika Pohjanoksa-Mäntylä, M.Sc. (Pharm.), for her continuous support during these years.

I also want to thank my current colleagues at Ferring Lääkkeet Oy for being so supportive and understanding during the final phase of this process.
I am grateful to all my friends and relatives for their support during these years. I especially want to thank my mother-in-law, Pirjo Zaitri, for the continuous support with childcare matters. I also want to thank my cousin Katri Nokso-Koivisto for helping me with the language of this work.

I am deeply grateful to my mother, Aino Väänänen, M.Sc. (Pharm.), and my father Kaapo Väänänen for their love and support for all these years. Special thanks to my mother for taking part in the implementation of the study and sharing her experience with me in the field of community pharmacies. I am grateful to my father for those times we spent together in Spain. Thank you for being my roommate, chauffer and most important support during that period.

I owe my deepest gratitude and love to the two men of my life, my husband, Yacine, and my son, Maxi. Thank you for just being there.

Espoo, May 2008

*Minna Väänänen*
DEFINITIONS OF THE KEY CONCEPTS

Community pharmacy system
Each EU nation has a unique community pharmacy system reflecting the culture and history of the country. It is built to comply with the local laws and regulations. There are similarities in regulations between the member states, but the specific legislation on these services contains differences between pharmacy systems in member states. The differences between the member states occur in e.g. the pharmacies’ role as a distributor of medicine, the number of outlets per 1,000 inhabitants and the rules governing establishment, ownership and staff (Vogler et al. 2006). In this thesis, the terms "pharmacy system" or "community pharmacy system" are used in this context.

European Union
The European Union (EU) was established by six states in 1958, and now EU comprises 27 countries and 490 million people (Europa 2006a). The basic principles of the Union are to facilitate the free movement of goods, services, capital and citizens (Treaty establishing the European Community 2002).

European Union legislation
Community legislation is based on treaties, which act as the primary legislation. The secondary legislation is based on the treaties and is incorporated into regulations, directives, decisions, recommendations and resolutions. From these, regulations are binding as specifically described, directives are binding in their respective context and decisions are binding for the addressed parties. Recommendations and resolutions are legally non-binding (http://europa.eu.int/eur-lex).

Health immigrant
A person who indicates that health factors play a moderate or significant role in the migration process is categorised as a health immigrant.

Mobile patient
Community law provides EU citizens with the right to seek healthcare in other member states. When mobile community residents use health services in other member states, they can be called "mobile patients" (European Commission 2004).
Mobile community resident; Mobile citizen; Migrant
In this thesis, the terms listed above are used to describe people who move from one country to another. Some of these people reside permanently in the foreign country, but most of these people, especially those who move within the European Union, spend one part of the year in the foreign country and another part in their country of origin.

National drug policy
A national drug policy defines and sets forth medium and long-term goals for the pharmaceutical sector and sets up the strategies to reach the goals (WHO 2001).

Pharmaceutical policy
Pharmaceutical policy sets up the principles that guide pharmaceutical policymaking. It is a plan or a course of actions that influence, guide or determine present and future decisions in the pharmaceutical sector.

Self-medication
The term "self-medication" is used to describe the practice of consumers using medicines without consulting a physician. Self-medication may take place with either prescription or non-prescription medicines (undesirable self-medication).

Symptom mitigation path
Symptom mitigation path describes the possible actions that may be taken prior to the person with the symptoms receiving instructions on how to manage the condition. In this particular study, symptom mitigation path describes the sequence of alternative events, which may occur when a symptomatic mobile community resident uses community pharmacy services.
ABBREVIATIONS

ADD = Automated Dose Dispensing
AFP = The Association of Finnish Pharmacies
DRP = Drug related problem
E-form = A form (e.g., E111, E128) which enabled people to obtain health services in a foreign EU-country. E-forms are replaced by EHIC card (European Commission 2003a).
ECJ = European Court of Justice
EHIC = European Health Insurance Card
EMEA = European Medicines Agency
EU = European Union
FIP = International Pharmaceutical Federation
GP = General practitioner
HAI = Health Action International
IT = Information technology
NAM = National Agency for Medicines
OECD = Organisation for Economic Cooperation and Development
OTC = Over-the-counter medicine
PCNE = Pharmaceutical Care Network Europe
PGEU = Pharmaceutical Group of the European Union. A European association that represents community pharmacies.
Rx = Prescription medicine
SIDA = Swedish International Development Cooperation Agency
TIPPA Project = A four-year national project to implement national professional strategy in Finnish community pharmacies with a special emphasis on patient counselling.
WB = World Bank
WHO = World Health Organization
LIST OF ORIGINAL PUBLICATIONS

This thesis is based mainly on the data presented in the following original papers, referred to in the text by Roman numerals I-IV.


IV  Väänänen MH, Lyles A, Airaksinen M. The Symptom Mitigation Path Of Mobile Community Residents: Community Pharmacy’s Role (Accepted for publication in Health Policy).
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1 INTRODUCTION

The European Union (EU) was created by six states in 1958 in order to establish a common European market. In the beginning of 2007, the EU enlarged by two member states, thereafter comprising 27 member states and a population of up to half a billion (Europa 2006a). The basic principles of the Union are to facilitate the free movement of goods, services, capital and citizens (Treaty establishing the European Community 2002).

Migration within the EU has increased since the Union was established, and to date, thousands of people from different backgrounds have taken advantage of the possibilities for free movement. Many of these people work abroad, but another increasing trend is retirement migration (King et al. 1998). People from Northern European countries in particular are becoming permanent or part-time residents of Southern European countries where living costs are lower and the climate more moderate (Rosenmöller and Lluch 2006). Meeting the health service needs of this heterogeneous migrant population poses a challenge to the authorities in countries with high immigration rates – particularly if the people are not assimilated into that society. This situation will intensify as the number of EU member states and mobile community residents continue to increase (Europa 2006a).

In the EU, the responsibility for organising and delivering healthcare services, including community pharmacy services, is the responsibility of individual member states (Treaty of Amsterdam 1997, Article 152, Directive 2005/36/EC). On the other hand, the EC Treaty states that there should not be any barriers to the free establishment of services (Article 43) and that services should be allowed to be provided freely across the borders (Articles 49 and 50). Member states wish to maintain their responsibilities in the field of health services, and in many cases, conflicts relating to this have been settled in the European Court of Justice (ECJ) (Neroth 2005). ECJ rulings have shown that healthcare services are not merely a matter for member states, and that the balance between the competencies of member states and the EU is not always clear (Hämäläinen et al. 2004). The EU deals with two distinct objectives when it comes to healthcare policies, including pharmaceutical policy: it has to ensure public health and to promote a single market (Wahlroos 2003). There have often been intentions in the EU of promoting better provisions in the internal market, and in 2004 the first version of the Services Directive was announced in order to ensure that companies offering services might operate freely in all member states (European Commission 2005b). In the first phase, healthcare services were included in the proposal.
(European Commission 2005b). The inclusion of healthcare services in this directive would have increased competition in the field of health services, but it would have also affected member states' ability to plan their service provision (Neroth 2005). The proposal aroused criticism as being contradictory with the EU Treaty and as being open to interpretation (Kärkkäinen 2005). As a consequence, healthcare services were excluded from the final directive (Directive 2006/123/EC). However, the legislation concerning internal markets and EJC rulings have had a great influence on the healthcare services (Hämäläinen et al. 2004).

Community pharmacies provide open access to health care services and can be the first, most frequently used or even the only contact an immigrant has with a nation’s health care system. As pharmacy services play an essential role in primary health care, it is important that these services meet the different needs of their customers. In some of the mass-tourism and migration areas of Southern Europe, most of the customers are mobile citizens, that is, foreign nationals. This, however, has not always been taken into consideration in the development of pharmacy services. Even though mobile patients have been on the EU’s health policy agenda (European Union 2006), they have seldom been mentioned in the context of community pharmacy services. However, pharmacy systems should be able to offer high quality as well as safe and effective services to all of their customers. At the moment, there is no harmonised pharmaceutical policy in the EU concerning community pharmacy practices. These practices differ between member states and the regulations and control over rational use of medicines and self-medication are not similarly interpreted in different countries (Vogler et al. 2006). It has been argued that the different practices between member states restrict cross-border healthcare (Mäkinen 2008). Pharmaceutical policy is not greatly studied from a community-pharmacy and health-services perspective. National and EU policymaking is focused on pharmaceuticals and on the costs they cause to the society.

As groundwork for this thesis, I have conducted a systematic search and reading of documents and scientific papers that are linked with pharmaceutical policy in Europe and in the EU. In the data gathering, I have used the electronic databases PubMed (including Medline), International Pharmaceutical Abstracts (IPA) and Medic as well as the online search engine Google. In addition, I have searched documents from the web pages of international organisations, such as the EU and WHO. In the first part of the literature review of this thesis, the key pharmaceutical policy documents are reviewed and, based on them, pharmaceutical policy is described: what it is, how it is developed and what influence it has on different stakeholders within the EU framework. The influence of pharmaceutical policy on
the role of community pharmacists is reviewed in more detail. Community pharmacy practices and patient self-medication are an essential part of this study, and they are examined in the following chapters as both are influenced by pharmaceutical policymaking. In pharmaceutical policy papers, it is often the case that less attention is paid to community pharmacy services and patient self-medication, though both are connected with important parts of pharmaceutical policy as they involve access to medicines, rational use of medicines, medication safety and drug expenditure.

The final part of the literature review provides the context for this study and introduces migrants and mobile patients. By using Finns living in Spain as an example, this study examines how mobile community residents experience the provision of pharmacy services in the EU. The aim of the study is to understand medication use and the role of community pharmacies in the symptom mitigation process from the perspective of how a pharmacy system and different state regulations affect medicine use, rational pharmacotherapy and medication safety. This is one of the first studies in the EU to focus on mobile community residents’ use of community pharmacy services in their new countries of residence. The results of this study will provide information for the implementation of the EU pharmaceutical policy for mobile community residents and mobile patients.
2 PHARMACEUTICAL POLICY

2.1 What is pharmaceutical policy?

According to Almarsdottir and Traulsen (2006): “Pharmaceutical policy deals with the principles guiding decision-making in the field of pharmaceuticals. The goal of pharmaceutical policy is (similar to other social policy) to contribute to the overall health, welfare and well being of society. It includes any policy that attempts to improve or regulate registration, reimbursement, and distribution of pharmaceuticals”.

Mossialos et al. (2004) list the intended effects of pharmaceutical policy as follows:

- Improved access to cost-effective medicines
- Minimisation of health risks
- Reduced drug over-utilisation
- Containment of expenditure growth

According to WHO (2001): "A national drug policy is a commitment to a goal and a guide for action. It expresses and prioritises the medium- to long-term goals set by the government for the pharmaceutical sector, and identifies the main strategies for attaining them" (WHO 2001).

National pharmaceutical policy is a formal document that directs co-operators to make decisions (WHO 2001). A national pharmaceutical policy lists the aims, decisions and commitments that the involved parties aspire to and commit to implement in the future (WHO 2001). National pharmaceutical policies might have different objectives, but generally pharmaceutical policies aim to ensure access, quality and rational use of medicines (WHO 2001). As most countries are experiencing rising drug expenditures, controlling these expenditures has become one of the major objectives of pharmaceutical policies (Jacobzone 2000).
2.2 Key pharmaceutical policy documents and research

As the power of the drug industry and the use of industrially manufactured medicines has increased, the interest in pharmaceutical policies has increased worldwide. As a consequence, pharmaceutical policy is found on the agendas of international organisations such as the EU, WHO, OECD and World Bank (WB). This section describes the key pharmaceutical policy documents. Most of the pharmaceutical policy documents concentrate on drug expenditures and on the role of pharmaceutical policies in reducing these expenditures. They seldom address policies concerning community pharmacies and their role in reducing medicine costs, promoting rational use of medicines and medication safety.

2.2.1 Pharmaceutical policy in the European Union

European Pharmaceutical policymaking has always had a dual objective: to ensure public health and to promote the competitiveness of the industry (European Commission 2007a). In the European Community, the pharmaceutical policy work was started as early as 1965 with the first European Community directive on pharmaceuticals (Council Directive 65/65/EEC). At that time, the focus of the policymaking was on public health perspectives as the thalidomide catastrophe was influencing the preparation of the directive, and the main objective of the directive was to ensure that medicinal products for human use would help maintain the high level of protection of public health and prevent the reoccurrence of such a disaster (European Commission 2000a). However, already in the 1960s pharmaceutical policymakers had their sights on the free movement of pharmaceuticals within the Community, and the European Pharmacopoeia was founded to improve the trade by harmonising the manufacturing and quality control standards in the Community area (Stainier 1975, European Commission 2000b). In 1970s the preparation of more centralised marketing authorisation procedures was started and the Committee for Proprietary Medicinal Products (CPMP) was established by Council Directive 75/319/EEC and Council Decision 75/320/EEC. At the same time, requirements were introduced concerning the content of marketing authorisation application dossiers (Lisman and Lekkerkerker 2005). By these directives, the important steps towards creating a single market for pharmaceuticals were taken, and since 1985, many community directives have been adopted with the aim of promoting a single market of pharmaceuticals (European Commission 2000a). In 1987, the first European marketing authorisation procedure was introduced (Council Directive 87/21/EEC). In the beginning of 1990, the rational use of medicines was an important pharmaceutical issue and the “rational use of medicines” package of directives was introduced (European Commission 2000b).
One remarkable development in the process towards more harmonious pharmaceutical policy in EU was the creation of the European Medicines Evaluation Agency in 1995. The establishment of the EMEA introduced new marketing authorisation procedure - the Centralised Procedure – which enabled patients to have faster access to innovative pharmaceutical products within the Community (Lisman and Lekkerkerker 2005). EMEA evaluates the safety, efficacy and quality of the medicinal products, and since its establishment, EMEA has offered scientific advice, harmonised drug information practices (SPCs, PILs and labelling) and improved transparency and pharmacovigilance practices (Garattini and Bertele 2001, Li Bassi et al. 2003, Garattini and Bertele 2004).

At the moment, the EU’s pharmaceutical policy mainly follows the recommendations of the High Level Group on Innovation and Provision of Medicines – G10 Medicines. This group was set up in 2000 with the aim of determining how pharmaceutical, health care and business policies could achieve two distinct goals: to improve competitiveness and to encourage health protection (European Commission 2002a). The final report included 14 recommendations and most of which concentrated on developing the competitiveness of the pharmaceutical industry (European Commission 2003b). Public health issues were also addressed in a recommendation to enhance medicine information and to improve the pharmacovigilance system (European Commission 2003b). In 2005, the Commission created the Pharmaceutical Forum in order to continue the process around three key themes: information to patients on pharmaceuticals, pricing policy and the relative effectiveness of medicines (Pharmaceutical Forum 2007).

The future challenges for the pharmaceutical policymaking concern the globalisation of the pharmaceutical sector, functioning internal markets and the advantages provided by science and technology (European Commission 2007a). Globalisation brings more actors into the pharmaceutical sector, leading to an increase in competition, both in the field of pharmaceutical innovations and in business. Removing the barriers to a better functioning internal market has been seen as important to increasing the competitiveness of European actors. Although there are harmonised procedures in the field of marketing authorisations, the different national pricing and reimbursement systems pose challenges for pharmaceutical policymakers. Improving the safety of the medicines in the EU while not affecting patient access to medicines is also seen as challenging (European Commission 2007b). Counterfeit medicines may be mentioned as one of the safety threats that makes the policymaking challenging.
2.2.2 Pharmaceutical policy and international organisations

The WHO has published several publications concerning pharmaceutical policy (WHO 2001, 2004a). In 1988, WHO published “Guidelines for Developing National Drug Policies”, which has been updated and replaced by the publication “How to develop and implement a national drug policy” (WHO 2001). This work has been extended with “Medicines strategy in 2004” (WHO 2004a).

Similarly, the OECD has studied pharmaceutical policy and has found the tasks involved challenging because of its dualistic nature to be in the middle of industrial and health policy goals (Jacobzone 2000). It is challenging for policymakers and governments to find a balance between rising pharmaceutical expenditures and the benefits resulting from the use of pharmaceuticals. A new discipline, pharmacoeconomics, studies ways of finding this kind of balance (Bootman et al. 2006). Even though the OECD has studied pharmaceutical policies in OECD countries, more research in areas that concern community pharmacy services is still required (Jacobzone 2000).

In recent years, the WB became one of the most important actors in the field of pharmaceuticals and international health care in low- and middle-income countries (Falkenberg and Tomson 2000). After the publication of the WB development report in 1993, there were subsequent studies that examined World Bank loans and questioned their commitment to their stated pharmaceutical policy (Falkenberg and Tomson 2000, Homedes et al. 2005, Rodriguez-Monguio and Rovira 2005). The World Bank is the largest source of loans in the field of health care and pharmaceuticals in low and middle-income countries, but the study of Falkenberg and Tomson (2000) argues that only a small percentage of its loans have been directed to drug policy or to promote the rational use of medicines. Therefore, they argue that pharmaceuticals should have larger role in World Bank projects and that more research in the field of pharmaceutical policy is required.

2.2.3 European co-operation in pharmaceutical policy work

European Observatory on Health Systems and Policies is an international project that aims to improve healthcare systems in Europe. The partners of this project include the WHO Regional Office in Europe; the Governments of Belgium, Finland, Greece, Norway, Spain and Sweden; the European Investment Bank; the Open Society Institute; the World Bank; the London School of Economics and Political Science; and the London School of Hygiene & Tropical Medicine. As a part of this project, Mossialos et al. (2004) published the pharmaceutical policy
work "Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality". This book describes different approaches that governments and regulators have used to manage pharmaceutical policy and spending in different European countries. It describes how pharmaceuticals, prices and reimbursements are regulated and managed in the EU and what is the role of European Medicines Agency (EMEA). The book also contains information about prescription practices, patients and their medicines as well as it describes European drug distribution systems and community pharmacies (Mossialos et al. 2004). The main objective of the book, however, is to consider different approaches to manage pharmaceutical expenditures.

2.2.4 Pharmaceutical policy in Finland

In Finland, Ministry of Social Affairs and Health launched the first pharmaceutical policy paper in the history of the country (Ministry of Social Affairs and Health 2003). The aim of the paper was to define the most important objectives for national pharmaceutical policy until 2010. The main objective was to maintain the high level of medication safety in Finland and to secure access to medicines throughout the country. In this context it was stated that the sale of medicines (including OTC medicines) would continue to take place in pharmacies in the future. The paper promoted rational prescribing and use of medicines. The importance of professionally skilled staff, medication counselling and drug information was emphasised as well. The increase in drug expenditures was noted, and it was suggested that costs could be reduced by cutting down the pharmacies’ gross-margin of sales and by reforming the drug reimbursement system. It was also suggested that Finland should take a more active role in EU cooperation on this issue and that the development of new medical products and pharmacotherapies should be promoted. In 2008, Mossialos and Srivastava prepared at the request of the Health Department, Ministry of Social Affairs and Health, a policy review of the regulatory system of Pharmaceutical policies in Finland (Mossialos and Srivastava 2008).

2.2.5 Research on pharmaceutical policy in Europe

Little research has focused on pharmaceutical policy in Europe. Traulsen and Almarsdottir have published an article series on pharmaceutical policy (Almarsdottir and Traulsen 2005a-b, 2006; Traulsen and Almarsdottir 2005a-c). In contrast to the policy work of most of the international organisations, they have studied pharmaceutical policy from a community-pharmacy perspective (Almarsdottir and Traulsen 2005a-b, 2006; Traulsen and Almarsdottir 2005a-c).
This reflects the fact that, in Scandinavian countries, deregulation of pharmacy systems has been a hot topic since the mid-1990’s, especially in Denmark, Iceland and Norway (Morgall and Almarsdottir 1999, Anell 2005, Noerreslet et al. 2005, Larsen et al. 2006, Vogler et al. 2006). The market deregulation of OTC drugs has been studied in Germany also (Stargardt et al. 2007). In Finland, Wahlroos (2003) conducted an extensive document analysis on how decision-making in the EU seeks a balance between internal market goals and public health, and how these decisions influence pharmaceutical legislation and patient information. Generally, the research in pharmaceutical policy within the EU has mainly followed themes similar to those emphasised by the G10 group in their report. Based on their review of the literature the focal point of recent European studies has been on pharmaceutical cost and reimbursement systems, access to pharmaceuticals, and pharmaceutical regulation (Mossialos et al. 2004, Cohen et al. 2006, Permanand et al. 2006, Cohen et al. 2007, Garattini et al. 2007, Mossialos and Srivastava 2008).

The pharmaceutical policies of international organisations examine pharmaceuticals from the perspective of the industry (product safety, quality) and of governments (access to medicines and drug expenditures). Although WHO promotes the rational use of medicines, retail sales of medicines and their use in health care have received less attention in its pharmaceutical policy papers. Retail sales outlets and community pharmacies are often seen as third parties when it comes to the development of health care and pharmaceutical policies (Kuusi et al. 2006). Active debate within the pharmaceutical community has resulted in very few attempts to influence actual policymaking. The pharmaceutical community is not accustomed to being a partner and to influencing society-wide matters on health care or medication. This can also be seen within the political decision-making process. For example, in the Finnish Ministry of Social Affairs and Health there is no professional expertise in the pharmaceutical sector involved in preparing pharmaceutical policies or in evaluating the influences of these policies.
2.3 Key areas included in pharmaceutical policy documents

The key objectives of pharmaceutical policy are to ensure access and quality of medicines, to promote rational use and to control the rising drug expenditures. Table 1 lists the components of pharmaceutical policy and their relation to the key policy objectives according to the WHO (2001). Each component of the pharmaceutical policy affects one or more objectives.

Table 1. Components of a national pharmaceutical policy, linked to key policy objectives (Created based on WHO’s table, WHO 2001)

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<thead>
<tr>
<th>COMPONENTS</th>
<th>OBJECTIVES</th>
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<td>Access</td>
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<td>Selection of essential drugs</td>
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<td>Affordability</td>
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<td>Drug financing</td>
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<td>Supply systems</td>
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<td>Regulation and quality assurance</td>
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<td>Rational use</td>
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<td>Research</td>
<td>x</td>
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<td>Human resources</td>
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<td>Monitoring and evaluating</td>
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X =direct link; (x) = indirect link

2.3.1 Access to essential medicines and cost-effective medicines

According to WHO (2001): essential medicines are those that satisfy the priority health care needs of the population. Availability and affordability of essential medicines are important issues in national pharmaceutical policy. Most developed country governments have lists of essential medicines that are carefully selected and based on clinical guidelines (WHO 2005). The absence of such lists and the lack of access to essential medicines are greater problems in developing countries than in developed ones and should be carefully taken into account when planning national pharmaceutical policies in such countries. The price of the medicines is a factor affecting the access. The WHO and HAI (Health Action International) have studied the access to medicines in developing countries and found that the affordability of medicines is poor in many countries as the prices of the medicines are so high that it takes several days earnings to buy one single
packet of medicines (Ewen and Dey 2005, Gelders et al. 2006). The prices of medicines vary also between EU countries (Vogler et al. 2006). Therefore, there is a possibility that some medicines are bought abroad because of the lower price level. Government funding on medicines for the poor and disadvantaged in addition to the development of drug-reimbursement systems as well as supply and distribution systems lead to a better and more equitable access to medicines not only in developing countries but also in the EU.

In developed countries the problems are different. There is a wide range of alternatives in each therapeutic group and out of each active ingredient many different products have been manufactured. After the brand name product launch, generic products, “me too” drugs and different products formulations enter the market (Huskamp 2006). New, more expensive classes of medicines also enter the market regularly, although the advantages of these more expensive medicines compared to the less expensive older ones are not always unquestionable (Huskamp 2006). An American study examined the frequency with which brand name vs. generic medicines were prescribed. For 20 commonly used medicines, the median brand-name prescription use was 98%. The researcher argued that physicians may find brand names easier to pronounce and remember, and therefore they are often used in prescriptions (Steinman et al. 2007). The problem of brand name use is, however, that they are more expensive than the generic drugs and increase the health care costs (Haas et al. 2005). This problem also concerns consumers; the increasing promotion may encourage consumers to persist in demanding certain prescriptions from their doctor, and advertising may also affect patients’ OTC-medication decision-making (Deshpande et al. 2004, Huskamp 2006).

2.3.2 Quality of medicines and minimisation of health risks

Building up a national or institutional list of essential medicines that are selected for safety and cost-efficiency will indirectly affect the quality of medicines (WHO 2001). However, regulation and quality assurance authorities play a major role in ensuring the high quality of the medicines. Counterfeit products constitute a quality problem for developing countries, but developed countries are not immune from this problem, either (e.g., it is a problem in US) (Zarocostas 2006, FDA 2007). It has been estimated that 5-7% of all the products sold around the world are counterfeits (Ten Ham 2003, Deisingh 2005, WHO 2006). Counterfeits can be found both in brand name and generic products, and they may include products that 1) contain no active ingredient 2) contain the wrong quantity of active ingredient 3) do not contain the correct active ingredient or 4) are in incorrect or misleading packaging (Ten Ham 2003, FDA 2007). The regulatory authorities
play a major role in the battle against counterfeits. The increasing sales of pharmaceuticals on the Internet may increase this problem in the future.

2.3.3 Rational use of medicines

Rational use of medicines can be defined in several different ways. The World Health Organisation defines rational use as follows: “The rational use of medicines requires that patient receive medications appropriate to their clinical needs, in doses that meet their own requirements, for an adequate period of time and at the lowest cost to them and their community” (WHO 2001). There are several factors connected to the rational use of medicines. The essential list of pharmaceuticals may lead to the use of certain medicines. The regulatory authorities can target the issue of rational use by means of laws and regulations applied to different sectors connected to pharmaceuticals and their production- and distribution-chains (WHO 2002). The authorities’ decisions on whether medicines are to be sold over-the-counter or by prescription only also affect the use of medicines. Health care professionals (for example, physicians and pharmacists) have an important role in promoting the rational use of medicines. In addition, rational use of medicines is also dependent on whether people actually understand how and when their medicines should be used (WHO 2001).

2.3.4 Drug expenditure

The growth of pharmaceutical expenditures along with health care expenditures over the last 20 years is a major concern in many developed countries, especially in the US, but also in the European countries (Jacobzone 2000, Ess et al. 2003). Drug expenditures are influenced by various components of pharmaceutical policy (Table 1). Therefore, the impact on drug expenditures should always be considered by policymakers when making decisions on the different components of a policy. Recently, several pharmaceutical policy decisions were made in Europe in order to control drug expenditures (Ess et al. 2003). These decisions include generic systems, reimbursement policies and pricing policies. The latter includes product price control, reference pricing and profit controls (Jacobzone 2000, Mrazek 2002, Ess et al. 2003, Rocchi et al. 2004, Vogel 2004, Simoens et al. 2005, Yfantopoulos 2008). There have also been policies aimed at influencing physicians' prescribing practices (Ess et al. 2003).
2.3.5 Research, human resources, monitoring and evaluating

Research, human resources, monitoring and evaluating are linked to all the key objectives of a pharmaceutical policy. Research may facilitate the implementation of different aspects of pharmaceutical policy, and pharmaceutical policy should be based on evidence that can be obtained as an outcome of research (Almarsdottir and Traulsen 2006). Social pharmacy is one of the important disciplines providing evidence for pharmaceutical policymakers. Although there have been many studies inside the pharmaceutical sector focusing on practices within community and hospital pharmacies and the pharmaceutical industry, there is a lack of studies on the role of pharmaceuticals in health care and in the society (Figure 1). There should be more studies on pharmacoeconomics and policymaking. Healthcare processes, including patient and medication safety, could be studied from a systems approach. This type of study could be conducted in order to facilitate the work of policymakers.

Figure 1. Illustration of the function of social pharmacy research in providing evidence to pharmaceutical and health care policymakers and facilitating discourse about the role of pharmacy in health care and the society.
2.4 Pharmaceutical policy – A combination of different policy inputs

Pharmaceutical policy is mainly influenced by public-health, healthcare and industrial policies (Traulsen and Almarsdottir 2005c). It has also been argued that there are not significant differences between health care and pharmaceutical policies, but Traulsen and Almarsdottir (2005a) argue that different knowledge is required of those making pharmaceutical policy than those who make general healthcare policy, because of the essential differences between these sectors. There are differences in the actors involved, in the power relations among professionals and between professionals and management, as well as in the business and political nature of the actors involved (Traulsen and Almarsdottir 2005a). Also, the focus of the pharmaceutical profession’s work is different from the focus of the professionals providing the components of health care, because pharmacists sell not only services but also products (Hepler and Strand 1990, Traulsen and Almarsdottir 2005a). Although pharmaceutical policy may be considered separate from health care policies, pharmaceuticals are functionally a part of health care. Therefore, health care and health policies should be taken into account when designing pharmaceutical policy. Pharmaceutical policy should be designed to fit within the surrounding health care system, and the goals of the policy should support the broader objectives created to improve health care (Mossialos et al. 2004).

Creating pharmaceutical policy is not always simple since serving three different policy inputs is likely to cause conflicts between the different interest groups (Traulsen and Almarsdottir 2005a). On the one hand, public health policy is interested in safe and high quality medicines, and on the other hand, industrial policies may be more interested in price development and sales promotion (Table 2, Permanand and Altenstetter 2004). This is a fairly accurate reflection of the situation within the EU. Within most individual EU countries, pharmaceutical policies are the responsibility of the domestic Ministry of Social Affairs and Health, but at higher levels the EU as a whole, the situation is more complex. A central EU objective has been the creation of an internal market, and since 1965, of a pharmaceutical sector (Wahlroos 2003). When the issue concerns pharmaceuticals, medication safety and the promotion of public health should be always taken into account by all interest groups. Therefore, EU pharmaceutical policy has had two distinct objectives: to promote public health and to meet the needs of an internal market (European Commission 2000b). In the EU, matters related to pharmaceuticals have been characterised as matters of public health, but the framing of these matters has been approached with an eye towards industry and internal markets. The study by Wahlroos (2003), however,
suggested that the EU is gradually putting more emphasis on the principles of safeguarding and promoting public health in its pharmaceutical policy.

This contradiction between competing interests might deepen as pharmaceutical expenditures rise in the EU. Different EU countries have made different pharmaceutical policy decisions in trying to control their drug expenditures (Jacobzone 2000, Ess et al. 2003, Duerden et al. 2004, Rocchi et al. 2004, OECD 2005, Espin and Rovira 2007). The different methods of cost-savings have affected the pharmaceutical industry, wholesalers, retailers, pharmacists as well as consumers and those who prescribe medicines (Ess et al. 2003). Almarsdottir and Traulsen (2005a) divide the cost-containment into four types: (1) price and profit controls in all stages of pharmaceutical distribution chains, (2) changes in the reimbursement system, (3) other fiscal measures and (4) quality measures. Italy’s pharmaceutical strategies have taken advantage of the price-related strategies in the battle against pharmaceutical expenditure, and in the UK, quality was the most influential background factor (Duerden 2004, Rocchi 2004). Mossialos et al. (2004) argue that the focus of the analysis should be on the drug consumption driven by patient need, by physicians’ prescribing choices, by dispensing practices and by price. Although there are many possibilities for trying to influence costs, the policies affecting pharmaceuticals costs should be evaluated while incorporating of other factors such as cost efficiency, quality of care and equity (Mossialos et al. 2004). For example, saving money on drugs might sometimes lead to more hospital visits, meaning that while saving in pharmaceutical expenditures, other health care expenditures might increase (Soumerai et al. 1991). Therefore it is highly imperative to consider healthcare expenditures as a whole with these inter-relationships rather than as individual sectors alone (Mossialos et al. 2004).
Table 2. Competing influences on pharmaceutical policies (Source: Mossialos et al. 2004)

<table>
<thead>
<tr>
<th>Health care policy</th>
<th>Industrial policy</th>
<th>Public health policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Cost containment and improving efficiency in health services and health care</td>
<td>• Promoting local research and development capacity</td>
<td>• Safe medications</td>
</tr>
<tr>
<td>• Cost effective medication</td>
<td>• Intellectual property rights protection</td>
<td>• High-quality preparations</td>
</tr>
<tr>
<td>• Regulating doctor and consumer behaviour vis-à-vis medicines</td>
<td>• Supporting local scientific community</td>
<td>• Efficacious treatments</td>
</tr>
<tr>
<td>• Generic promotion and/or substitution</td>
<td>• Generating and protecting employment</td>
<td>• Innovative cures</td>
</tr>
<tr>
<td>• Improving prescribing</td>
<td>• Promoting small and medium enterprise policies</td>
<td>• Patient access to medicines</td>
</tr>
<tr>
<td>• Ensuring access to medicines</td>
<td>• Contributing to positive trade balance</td>
<td></td>
</tr>
<tr>
<td>• Sustaining the university research base</td>
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</table>
2.5 The development of pharmaceutical policy

Traulsen and Almarsdottir (2005a) argue that, while there is no single pharmaceutical policy, policymakers are trying to avoid formulating poor policies during the process. As new pharmaceutical policies are developed, there is a need to create new policies or modify present ones (Figure 2). The policymaking is often influenced by other countries’ decisions to change their policies (for example, deregulation in Nordic countries). However, there are many factors, such as social, economic, medical, health care, the political climate, as well as historical and institutional frameworks that affect how policies are eventually developed and implemented. Since directly adopting a pharmaceutical policy from another country does not always work, policies should be modified when applied to the new national contexts (Mossialos et al. 2004). New pharmaceutical policies are often based on older ones; the strengths and weaknesses of the older policies are analysed and new policies are implemented to meet the current needs. In an ideal case, pharmaceutical policies are based on scientific evidence, but they can also be based on values, ideology or politics (SIDA 2001, Traulsen and Almarsdottir 2005a). The development of a policy should go through a systematic process, and all the parties involved, both private and public, should be consulted during the process (Figure 2). In Australia, this kind of process was instituted in order to improve the development of policies, and the quality of documents as well as to facilitate the implementation of the policies (NSW Health Department 1998).
Figure 2. Development process of pharmaceutical policy (Created based on the NSWs policy development guidelines, 1998)
2.5.1 Who is involved in pharmaceutical policymaking?

The most important actors in the decision-making process involving pharmaceuticals and pharmaceutical policy at the level of the European Union are the European Commission, the European Parliament, European Council and EMEA (Duncan 2002, Wahlroos 2003). The responsibility of EMEA is to protect and promote public health, and it does not have legislative power (Garattini and Bertele 2004). The European Parliament and Council primarily focus on legislative work, whereas the European Commission is the primary organisation responsible for legislative work as it has the sole and exclusive right to put forth policy proposals, in addition to responsibility for enforcing and overseeing the implementation of policies. The Commission is divided into Directorate-Generals (DG). Issues concerning pharmaceuticals are prepared in DG Enterprise (European Commission 2000b). DG Sanco is responsible for health care and consumer related matters (Europa 2007). Most of the health/pharmaceutical policy related preparation work is being done in G-Public Health, which is a section of DG Sanco (Wahlroos 2003). Lobbying is widely used and the Pharmaceutical Group of the European Union (PGEU) is an important lobbying organisation in the field of community pharmacies (Wahlroos 2003). National policies are mainly defined by the governments of the member states, the various national agencies of medicines, and by professional organisations.

The parties included in the pharmaceutical policymaking are the pharmaceutical industry, healthcare professionals (such as pharmacists, physicians, nurses and pharmacy technicians) as well as the public (Figure 3, SIDA 2001, WHO 2001). The public is involved through their national parliaments, patient organisations and networks, even though the operation of patient organisations has been criticised because of connections to the pharmaceutical industry (Maynard 2002/2003). Patient groups are often poorly funded, and therefore the industry uses its financial capacity to support the patient groups (Maynard 2002/2003). Industry has seen this as a powerful way to reinforce their influence on policy-making (HAI 2005). The involvement of the patient groups in the pharmaceutical policy process has been questioned as there is some uncertainty as to whether the groups represent more the interests of the public or the interests of the groups' financial sponsors (HAI 2005).
However, the majority of the public does not have advocates to represent them in the policy arena, even though the policies concerning pharmaceuticals – availability, access, pricing and safety – affect everyone’s life (Traulsen and Almarsdottir 2005b). The key issues of pharmaceutical policy from a public-interest standpoint are listed in Table 3.
Table 3. Key issues in pharmaceutical policy from the public interest perspective (Source: Coulter 2002/2003)

<table>
<thead>
<tr>
<th>Ensuring affordable, equitable and timely access to effective treatments</th>
<th>Access to evidence-based information to support informed treatment choices</th>
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<tr>
<td>- Pricing, co-payments and reimbursement</td>
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<tr>
<td>- Defining ‘added therapeutic value’</td>
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<tr>
<td>- Evaluating cost-effectiveness</td>
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<td>- Medicines for neglected diseases</td>
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<tr>
<td>- Quality standards for patient information leaflets</td>
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<td>- Quality of information on health websites</td>
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<tr>
<td>- Tools for shared decision-making</td>
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<td>- Regulating advertising</td>
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<tr>
<th>Clinical trials: improving recruitment, design and reporting by involving consumers</th>
<th>Patient safety: reducing risk and monitoring adverse events</th>
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<tr>
<td>- Public education about research methods</td>
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<tr>
<td>- Patient involvement in trial design, implementation and assessment</td>
<td></td>
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<tr>
<td>- Patient-assessed outcomes and quality-of-life</td>
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<tr>
<td>- Research ethics and data protection</td>
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<tr>
<td>- Publication of trials</td>
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<tr>
<td>- Licensing and regulation</td>
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<tr>
<td>- Drugs for children, pregnant women and older people</td>
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<tr>
<td>- Packaging and labelling</td>
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<tr>
<td>- Post-marketing surveillance</td>
<td></td>
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<tr>
<td>- Safe medication practices</td>
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2.6 Pharmaceutical policy defining the role of community pharmacies and pharmacist

As seen in Table 3 the decisions related to pharmaceutical policy have effects on the lay public, their medication usage and medication safety. In most cases, pharmaceuticals reach the public through community pharmacies; hence, pharmaceutical policy also defines the role of pharmacies in society. This comes back to the principal question of whether pharmaceuticals are to be regarded as a part of health care, or as non-regulated products in conformity to the market ideal of business freedom? And how do these fundamental political approaches influence the supply of medicines? Even though the goal of policymakers is to ensure the overall health and well being of society, policymakers have conflicting views of pharmacies and pharmacists (Traulsen and Almarsdottir 2005c). Traulsen and Almarsdottir (2005c) argue that pharmaceutical policy depends on how policymakers see pharmacists and pharmacy owners in the policymaking...
process. The community pharmacy sector can be seen as a business contributing to the economic good of the community and regulated similar to other commercial enterprises, suggesting that the best person to own a pharmacy would be determined by the possession of business skills (Traulsen and Almarsdottir 2005c). On the other hand, community pharmacies can be seen as local primary health care units – as often the first contact the public has with the healthcare system when experiencing symptoms, and as a unit that is functionally integrated with other local health services (Traulsen and Almarsdottir 2005c). Pharmacies could be regulated as are other health care services and professionals, and be thus obliged to follow similar professional standards and evidence-based therapeutic guidelines. The final outcome of the policymaking is determined by the interests of policymakers: for example, is the main interest in EU to create a European internal market or is it more important to enhance public health? It is not surprising that politicians find it difficult to form a clear view of the role of pharmacists and pharmaceuticals when pharmacists themselves do not agree about whether commercial or professional values should come first (Morgall and Almarsdottir 1999, Traulsen and Almarsdottir 2005c). Society is lacking scientific evidence on the value of pharmacists’ professional contributions to public health.

2.6.1 Deregulation of community pharmacy systems and the role of the pharmacy

Deregulation of community pharmacy systems has been the rule in recent EU member states (Vogler et al. 2006). The model that has been put forth is of a modern system that is competitive, based on free ownership and free access to commodities and services, including medicines and pharmacy services.

There has been debate on whether disagreements within the pharmacy profession have contributed to changes in professional practices and the regulation of the pharmacy system (Morgall and Almarsdottir 1999). In Iceland, the internal divergence in the profession partly contributed to the deregulation of the system and the break up of the monopoly in the mid-1990s (Morgall and Almarsdottir 1999). Other factors that contributed to these changes were the political desire to obtain the advantages of competition and of deregulated policy as well as a desire to reduce the health budget (Morgall and Almarsdottir 1999). In Iceland and Norway, the deregulation of pharmacy systems has dramatically changed the pharmacy profession. The increasing competition demands that pharmacists expand their knowledge of pharmaceuticals to include marketing and communications skills are among the most striking changes (Morgall and Almarsdottir 1999, Anell 2005). Similar deregulation, although less
comprehensive, occurred elsewhere, e.g., in Denmark (Noerreslet et al. 2005, Larsen et al. 2006), but Iceland and Norway represent the extreme end of recent liberalisation in Europe. Through the recent deregulations, OTC medicines can be sold outside pharmacies (Norway, Portugal), only the maximum prices of pharmaceuticals are controlled and discounts, as well as the free ownership of pharmacies are allowed. The purpose of these changes, from the view of governments, has been to decrease government’s financial burden for drug expenditures by increasing price competition and by allowing pharmaceutical companies to offer discounts (Morgall and Almarsdottir 1999, Anell 2005). However, the deregulation strategies have brought little improvement in this respect (Anell 2005). On the other hand, governments were surprised by the rapid changes in competitive behaviour and market structure as they had merely wanted to increase competition while keeping the community pharmacies and services otherwise unchanged. This combination of benefits was not achieved (Anell 2005).

2.6.2 Self-medication and the role of community pharmacists

The community pharmacists’ role differs between wealthy, middle-income and low-income countries. In the low-income and middle-income counties, pharmacies have traditionally been the primary points of contact with the healthcare system when seeking medical help. The availability of prescription medicines without prescription has been one factor attracting patients to pharmacies (Van der Geest 1987, Hardon 1987, Greenhalgh 1987, Price 1989). The lack of health services might also force people to self-medicate. In addition, financial problems, lack of transportation, long waiting hours and social distance may also be factors that inhibit the use of health care services other than those provided by pharmacies (Van der Geest 1987). This is not only a problem in developing countries. In the US, for example, 47 million people lack health insurance and may experience financial barriers to accessing the health services and prescription medicines they need to treat their medical conditions (Department of Health and Human Services 2007, De Navas-Walt et al. 2007). Apart from its economic importance in all kinds of societies, self-medication has not been recognised as an important part of healthcare from a health-policy viewpoint. Policy changes in the direction of increasing the number of non-prescription medicines and extending the range of existing OTCs for new indications, such as cholesterol and birth control would change the role of community pharmacies in developed countries as well. The switch from Rx to OTC medicines increases the importance of the role and medication counselling of pharmacists, as they might be the only healthcare professionals seen by people with health concerns. Pharmacists could also play a larger role in triage, i.e., evaluating which customers need a physician’s
consultation. The changes may raise the question of whether pharmacists are ready and qualified for this expanded role.

General practitioners in particular have been worried about the increasing number of OTC medicines and the expanded role of pharmacists. The possibility that self-medication is masking serious conditions and delaying diagnosis has been discussed (Erwin et al. 1997, Sihvo 2000). Self-medication does not necessarily mean that there has been contact with a pharmacist. In many Western countries this seldom applies as sales clerks and cashiers are taking care of OTC customers in pharmacies that are more like grocery stores than primary health care units. It seems, however, that general practitioners’ attitudes have been changing through the years (Spencer and Edwards 1992, Erwin et al. 1996). As physicians have an important role in health care and they often co-operate with pharmacists, their attitudes have an impact on the development of health and pharmaceutical policies. Two comparable studies examining the views of general practitioners about the role of community pharmacists in dispensing over-the-counter medications in the UK in 1990 and 1994 showed an increased acceptance of community pharmacists taking part in the self-medication process (Spencer and Edwards 1992, Erwin et al. 1996). The Finnish study of Sihvo et al. (1999) showed that general practitioners still viewed themselves as the most suitable source of drug information in many cases. Differing opinions were detected between general and private practitioners. Those working in the public health centres more often thought that pharmacists would be the most suitable source of medicine information. General practitioners’ more positive attitudes about pharmacists might arise from the fact that increased self-medication decreases the workload of general practitioners (Sihvo et al. 1999). The study of Sihvo et al. (1999) reflects the situation from the 1990s and thus does not necessarily reflect the current state. The same applies to the two UK studies mentioned above.

2.6.3 The role of community pharmacists in different countries

In a Vietnamese study, consumers reported diverse views on the appropriate role of community pharmacists (Olsson et al. 2002). Pharmacists were seen as counsellors, or people to whom customers and general practitioners can turn in matters concerning medicines. On the other hand, pharmacists were also seen as the general practitioners’ assistants whose role was to follow the GP’s instructions. The third role identified with pharmacists was as businesspersons who sell medicines and whose main motivation is to sell as much medicine as possible. Even though pharmacies and circumstances in Vietnam are different compared to developed countries, these results reflect the same contradictory role
of pharmacies, i.e., between business and healthcare, which makes it difficult for the public and policymakers to define pharmacists' position in the society.

In Europe, the situation is different. Pharmacies are often seen by customers as the best place to seek treatment for minor ailments, and as an initial step to take before seeking the care of a GP (Hassell et al. 1997). There is evidence that community pharmacists can deal with most of the minor ailments and that pharmacists prescribing for minor ailments would benefit patients and reduce costs (Bojke et al. 2004). In the UK, the pharmacists' authority to write supplementary prescriptions was introduced in 2003, and in 2006 the pharmacists' role was expanded as they were given the right to prescribe independently (Tonna et al. 2007). This is the direction the Royal Pharmaceutical Society of Great Britain (RPSGP) would like to see the community pharmacy practice take in the UK, but it is not in common practice yet. Although prescriptions by pharmacists increased from 2,706 prescriptions in 2004 to 31,052 prescriptions in 2006, this represented only 0.004% of all prescriptions in the community and primary settings in the UK (Guillaume et al. 2008). This has also been the case globally. Professional pharmacy organisations have created ideal strategies about the role of the pharmacies, but these have failed in implementation.

In a Danish study, 12 interviews were conducted among pharmacy professionals and Ministry of Health representatives to define the role of pharmacist (Norgaard et al. 2001). Pharmacists were seen as technical advisers, drug experts, pharmacy leaders and providers of individual advice. As a technical adviser, the pharmacist is to dispense medicines and give brief instructions about the product, whereas a drug expert provides services and medication information to customers and other health care professionals. As a leader, the community pharmacist has responsibility for the pharmacy staff and its education. The provider of individualised advice has responsibility for the customer’s specific needs in order to determine the best medical treatment for the customers. In Denmark, pharmacies have been under political pressure and the role of pharmacists has changed in recent years (Norgaard et al. 2001). Therefore, the study by Norgaard et al. (2001) did not show any consistent future expectations about the role of community pharmacists. Pharmacists were also seen as possibly having no future role if their counselling becomes no longer necessary if they become simply become something like IT experts who offer information and sell medicines through the Internet, as authorities on disease management and as patient educators (Norgaard et al. 2001). In the US, both patients and physician assistants saw pharmacists primarily as a source for medications and medication information, but not as a contributor to comprehensive drug therapy management.
As mentioned before, the manner in which pharmacists are seen is a reflection of the development of pharmaceutical policy (Traulsen and Almarsdottir 2005c).

However, the line between medicines and other goods may not always be clear for customers, as in some countries (the UK and the US), OTC medicines have been displayed in pharmacies in the manner, that they could be compared to any other goods. In addition, the deregulation of OTC medicines in some European countries has changed the role of pharmacies into something comparable to that of retail stores. Pharmacists may also sometimes fail to take responsibility and do their best in assuring that patients get the best possible outcomes from their medicines. Quality-of-practice evidence on this is lacking from most countries, including in Europe. Even in Finland, the practice is still far from optimal in many pharmacies, although much effort has been put into systematic service development with strong support from the profession and the authorities (Puumalainen 2005, Kansanaho 2006).

2.6.4 Pharmaceutical care and the role of community pharmacists

From a long-term perspective, the pharmacists’ role has shifted from compounding to dispensing medicines, and recently towards providing professional services, with this trend being driven by the concepts of pharmaceutical care and the clinical pharmacy (Van Mil and Schulz 2006). The term pharmaceutical care was published as early as 1975. Hepler and Strand (1990) reinvigorated the term with their 1990 definition, according to which, pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve the patient’s quality of life. Since then, the same term has been used for numerous different reintegrated functions (Van Mil et al. 2004a, Van Mil and Schulz 2006). Consequently, by the 1990s the key community pharmacy organisations in Europe started to look at pharmaceutical care as the strategic future of the profession (Van Mil and Schulz 2006). Figure 4 describes how pharmaceutical care has been evolved from definition to implementation. In Finland, the study conducted by NAM in 1988 defined the lay public view of pharmacy services (Airaksinen 1996). The profession has had a proactive role in building up new professional services to meet the needs of the consumers and medicine users. The strategy has been successful, and community pharmacies have had a normative and functional role in the Finnish health care system, which has been recognised in recent pharmaceutical policy documents of the Ministry of Social Affairs and Health (2003, 2007). This has been the case even though Finland's neighbouring countries have been deregulating their systems or are debating doing so (Reje et al. 2008).
Figure 4. Pharmaceutical care from definition to implementation from a European perspective
2.6.5 FIP defining the role of community pharmacists

The International Pharmacy Federation (FIP) is a worldwide federation of national pharmaceutical associations and it represents and serves pharmacy and pharmaceutical sciences around the world (FIP 2007a). FIP activities are designed to improve the long-term effectiveness of patient care. In 2000 WHO launched the “seven star pharmacist” concept, which introduced seven future roles for pharmacists, and in 2000 FIP included these roles in its policy paper “Good Pharmacy Education Practice” (FIP 2000). In 2006, WHO and FIP continued their joint project in order to further develop pharmacy practices, and they added one more role to the pharmacists (Wiedermayer et al. 2006). In the last version, pharmacists were described as 1) caregivers (provide caring services) 2) decision-makers (on the appropriate, efficient, safe and cost-effective use of resources) 3) communicators (linking prescribers and patients) 4) managers (managing resources) 5) life-long learners (keeping their knowledge and skills updated) 6) teachers (providing education and training to future generations) 7) leaders (able to make decisions, communicate and manage effectively in multidisciplinary caring situations) as well as 8) researchers (able to use evidence). In the performance of these roles, pharmacists should adhere to the FIP code of ethics (FIP 2004). In addition, FIP has issued the Standards for the Quality of Pharmacy Services (FIP 1997).
2.7 Medication and drug safety

Medication safety is an issue that has become a hot topic in the international medical literature (Institute of Medicine 1999, Council of Europe 2006, 2007). It should always be considered when pharmaceutical policy decisions are made. As long as the health care system includes sufficient mechanisms to prevent medication errors from occurring, the safety issue will remain invisible and politically dormant. But should the system begin to produce errors, the issue will become politically heated. Little evidence exists on whether deregulation of pharmacy systems and of the sales of pharmaceuticals will jeopardise patient and medication safety. It is, however, often given less attention in pharmaceutical policy papers.

Pharmacovigilance consists of actions taken to improve drug safety, i.e., the safety of the pharmaceutical products on the market (Medicines Act 395/1987, WHO 2004b, STAKES and ROHTO 2006, Council of Europe 2007). Medication safety is related to the safety of the drug use process, including prescribing, dispensing, compounding, administration and information practices (National Coordinating Council of Medication Errors and Prevention 1998). National governments and pharmaceutical policy play important roles in ensuring medication safety (WHO 2004b). Within the EU, there are harmonised procedures and regulations on the marketing authorisation required for medicinal products (Directive 2001/83/EC). The EMEA and national authorities are key actors, having responsibility for ensuring that only high quality and safe medicinal products are on the market. These regulations mainly impact the operations of researchers and the pharmaceutical industry. Drug safety is concentrated on the safety of actual products, their pharmacological features and effects, good manufacturing practices (GMP) and the availability of information on the products (Directive 2001/83/EC, STAKES and ROHTO 2006). Prevention and monitoring of adverse drug reactions is an important part of the procedure.

Patient safety is defined as the freedom from accidental injuries during the course of medical care and encompasses activities to avoid, prevent or mitigate adverse outcomes resulting from health care (Council of Europe 2005). There have been several international efforts at improving patient safety (Council of Europe 2006). In 1999 the report “To Err Is Human: Building a Safer Health System” raised concern about patient injuries and safety, and in 2002 the World Health Assembly of WHO urged greater attention on patient safety, leading to the WHO’s launch of the World Alliance for Patient Safety in 2004. In 2002, the Council of Europe’s Committee of Experts on Management of Safety and Quality in Health Care
started their work on preventing adverse events in health care (Council of Europe 2007). In 2005, the first EU conference on patient safety was held (European Commission 2005a). In 2005 the SIMPATIE project (Safety Improvement For Patients in Europe) began with the aim of creating a European-wide set of resources for the improvement of safety in health care. Although there have been several activities aiming to improve patient safety, less attention has been paid to safe medication practices (Council of Europe 2007). In many countries (e.g., Australia, Finland, USA), medication safety has been prioritised as the place to start in creating a systems approach to patient safety (Australian Council for Safety and Quality in Health Care 2002, Ministry of Social Affairs and Health 2006, Institute of Medicine 2006).

Medication safety is part of patient safety. It has been defined as freedom from accidental injury during the course of medication use, and includes a list of activities to avoid, prevent, or correct adverse drug events that may result from the use of medicines (Council of Europe 2005). Prevention of medication errors is the main idea in medication safety. All the actions that are taken or omitted by health care professionals (pharmacists, nurses, physicians) or by patients have an effect on medication safety. In 2006, the Expert Group on Safe Medication Practices finished their work with the publication of an international medication safety report with a special focus on Europe (Council of Europe 2007). The report mainly deals with medication errors and their prevention. There were several hurdles to cross in preparing the report as European countries differ in their regulations, clinical practices, medication use practices and organisational cultures. There is also a lack of information concerning medication errors in the member states (Council of Europe 2007).
3 HEALTHCARE AND COMMUNITY PHARMACIES IN THE EU TREATIES AND LEGISLATION

3.1 Healthcare in primary community legislation

At the beginning of European integration, the healthcare sector was not considered a part of the integration. However, the Treaty of Rome already contained some indirect health considerations, such as the free movement of workers (patients and health professionals), the right to establishment (health professions and services) and the free movement of health services (Treaty establishing the European Economic Community 1957). The health protection related to pharmaceuticals was also mentioned (Treaty establishing the European Economic Community 1957, Cucic 2000). The Treaty of European Atomic Energy Community (Euroatom 1957) also deals with the health protection of the public and of workers (Treaty establishing the European Atomic Energy Community 1957, Cucic 2000). In 1986, the Single European Act revises the Treaty of Rome and strengthens the role of the EEC in the field of health protection (Single European Act 1987, Cucic 2000).

The Maastricht Treaty established the European Union in 1992 (Treaty on European Union 1992). The Maastricht Treaty defined the Community’s competence to act in the healthcare field. Article 3 of the Treaty deals with the strengthening of consumer protection, but Article 129, concerning public health, had the greatest influence on the healthcare sector. The key messages in this article were to encourage cooperation between member states to ensure a high level of human health, to direct actions towards the prevention of diseases, especially the major threats (including drug dependence) and to promote research, information and education on these diseases. It was also stated that health protection should be an essential part of the community’s other policies. Article 129 was followed by Article 152 in the Treaty of Amsterdam (1997). Article 152 emphasises the Community’s role in the field of health protection, and it also enabled the Community to act in the new fields by assuring the quality and safety of organs and substances of human origin, blood and blood derivates and measures in the veterinary and phytosanitary fields (Treaty of Amsterdam 1997). Article 152 emphasises that the health care services in the community are the responsibility of member states.
Since the Treaty of Maastricht, the European Commission has started to work in the field of public health to prevent and control the communicable diseases in the Community (Decision 2119/98/EC). Since then, the public health programmes 2003-2008 and 2008-2013 replaced the initial programmes (Decision 1786/2002/EC and Decision 1350/2007/EC). The latest programme began in early January 2008, and it aims to improve citizens’ health security, promote health, reduce health inequalities, and generate and disseminate health information and knowledge (Decision 1350/2007/EC).

### 3.2 Community legislation relevant to pharmaceuticals

The first Community pharmaceutical directive was established in 1965 (Council Directive 65/65/EC). The purpose was to maintain the high level of public health protection by harmonising the regulations concerning marketing authorisations (European Commission 2000b, Wahlroos 2003). In 1975, the Committee for Proprietary Medicinal Products (CPMP, now Committee for Medicinal Products for Human Use, CMPH) and the Pharmaceutical Committee were established with the aim of improving access to innovative pharmaceuticals in the European Community (Council Directive 75/319/EEC and Council Decision 75/320/EEC). At the same time, the marketing authorisation procedure for mutual recognition was introduced. These directives were amended several times in the 1980s as the harmonisation in the field of marketing authorisations did not work out as planned. At the end of the 1980s the directive concerning pharmaceutical product pricing and reimbursement was introduced (Council Directive 89/105/EEC). The next significant step in the field of marketing authorisation harmonisation was the establishment of EMEA in the 1990s and the centralised marketing authorisation procedure (Council Regulation EEC 2309/93 replaced by regulation 726/2004, Wahlroos 2003). In 1992 the directive on the classification for the supply of medicinal products for human use was established (Council Directive 92/26/EEC). In the same year, the directives on the information given on medicinal products (regulations on PILs and labelling, Council Directive 92/27/EEC) and on the advertising of medicinal products (Council Directive 92/28/EEC) were established. Council regulation EEC/2309/93 together with the Council Directive 75/319/EEC requested that member states establish national pharmacovigilance systems (European Commission 2000b). Many of the pharmaceutical directives were gathered under one directive in 2001 (Directive 2001/83/EC, amended later with the Directives 2004/27/EC and 2004/24/EC), which included topics such as marketing authorisation procedures, labelling and PILs, advertising, pharmacovigilance, supervising and sanctions. Good manufacturing and clinical practices are regulated in Directive 2001/20/EC and Directive 2003/94/EC.
Although legislation concerning marketing authorisations is harmonised within the Community, the implementation of these regulations is the responsibility of individual member states. Even when a marketing authorisation is granted, this does not mean that the availability of the medicine is harmonised with other member states (Li Bassi et al. 2003, Ess et al. 2003). The prices and the reimbursement decisions are matters of the individual member states, and they are related to government policies, health resources and public health systems (Li Bassi et al. 2003).

3.3 Community legislation, pharmacists and community pharmacies

The directive on the recognition of professional qualifications (Directive 2005/36/EC) came into force in 2005. The purpose of the directive is to guarantee that the education of professionals follows certain criteria, to facilitate the free movement of qualified professionals within the European Union and to facilitate the free provision of services.

Pharmacy services are highly regulated by national agencies and other control bodies and member states have different legislation concerning the regulations. Article 152 in the EU Treaty states that a high level of human protection should be ensured and that the organisation of and delivery of health services to citizens are the responsibility of the individual member states (Treaty of Amsterdam 1997). Directive 2005/36/EC (amended version of Council Directive 85/432/EEC and Council Directive 85/433/EEC) also states that the provision of community pharmacy services at the national level (e.g. the geographical distribution of and monopoly on dispensing medicines) is the responsibility of the individual member states (Directive 2005/36/EC). In addition to these directives, the principle of subsidiarity is adhered to in the Community, meaning that the Community should only perform those tasks that cannot be performed effectively at a national level.

As the pharmaceutical policy in the EU is trying to strike a balance between two distinct goals – promoting public health and establishing an internal market (Wahlroos 2003) - there have been several cases where the European Commission has considered that the legislation concerning the provision of community pharmacy services in member states is not consistent with the EC Treaty, leading to proceedings against Italy, Austria and Spain (Europa 2006b). The Commission has taken Italy to the ECJ because of infringements concerning Articles 43 (Freedom of establishment) and 56 (Free movement of capital) of the EC Treaty (Case C-531/06, Europa 2006b). The reasoned opinion was sent to
Spain on account of Spain having territorial rules for the establishment of pharmacies and Spanish pharmacists being allowed to own only one pharmacy at a time. In the Austrian case, the reasoned opinion was sent because there are rules in Austria that restrict the free establishment of community pharmacies, e.g., discriminate on the basis of nationality with respect to obtaining a pharmacy licence and have rules limiting the number of pharmacies and the establishment of pharmacies to certain areas. Earlier, EJC made a decision that the Swedish state-owned pharmacy monopoly is in conflict with Community law (Case C-438/02). Questions concerning online pharmacies in the Community area have also been resolved in the EJC (Case C-22/01).

3.4 Community pharmacies and the internal market

The European Union has had initiatives for changing member states' community pharmacy systems to bring them in line with the principles of the internal market. The idea of the internal market is to create an area without internal borders where people, services, goods and money may move without restrictions. The aim is to make the EU the most competitive and dynamic knowledge-based economy in the world (European Commission 2005b). Based on the state of the Internal Market for Services report, there were still several barriers in the way, hampering service development in the Community in 2002 (European Commission 2002b).

The Commission announced the first draft proposal of the Services Directive in 2004 (European Commission 2005b). The aim of the proposal was to provide a legal framework that would remove the barriers to the free establishment of service providers and the free movement of services between the member states (European Commission 2005b). In this proposal, community pharmacy services were included. If the proposal had been approved as it was, it would have been in conflict with the present legislation of many member states and also with Article 152 of the EU Treaty. At the moment, pharmacy services in member states are strictly regulated: pharmacies are either licensed by the authorities or require some other registration in order to be established (Vogler et al. 2006). To put the directive into action, member states should have reviewed their legislation to eliminate any rulings that would have discriminated against foreign services providers (Neroth 2005). The directive would also have affected member states' ability to plan their health care services. Most concerns arose among the country of origin principle. It was argued that many safety problems would have occurred if services were provided in one country under the regulations of another country, and that service providers could have chosen countries with weakest legislation as their permanent base (Neroth 2005). The Pharmaceutical Group of European
Union, which represents community pharmacists in 29 European Countries, were convinced that healthcare services, including community pharmacy services, should have been excluded from the directive in order to guarantee sustainable, high quality and universally accessible health care services in Europe (PGEU 2004). The proposal was criticised for being in contradiction to the EU Treaty and that it was open to interpretation (Kärkkäinen 2005). In 2005, Commissioner McGreevy announced that health care services would be excluded from the directive, but that did not mean that they would be left outside the internal market (Kärkkäinen 2005, McGreevy 2005).

In 2006, the Services Directive (Directive 2006/123/EC) on services in the internal market was finally launched in order to facilitate freedom to establish distributors in other member states and the freedom to provide services between member states. Health care services were excluded from the directive.
4 COMMUNITY PHARMACIES IN THE EUROPEAN UNION

In the EU, community pharmacies are the main distributors of medicines to outpatients. Yet, there is no harmonised pharmaceutical policy covering community pharmacy services. There are about 400,000 community pharmacies in Europe (PGEU 2007). The distribution of medicines is controlled through both supranational and national regulations (Taylor et al. 2004). In most of the member states, the specific legislation governing community pharmacies is controlled by governments. Community pharmacies in the EU have traditionally been small privately owned enterprises operating under tight government controls (Anell 2005, Vogler et al. 2006). Although nowadays there are more similarities between the regulations of member states, specific national legislation on pharmacy services shows that large differences still remain between the pharmacy systems. The fundamental difference is associated with the degree of deregulation and ownership of the pharmacies, i.e. whether international pharmacy chains are allowed to incorporate into the local markets.

There are differences between nations in the requirements for becoming a pharmacy owner. The Swedish pharmacy system is unique: all pharmacies have been state owned since 1971, but the practice has been questioned in recent years (Westerlund and Björk 2006, Reje et al. 2008). In some other EU countries, pharmacy systems have undergone changes only recently. The Norwegian system has changed dramatically since the implementation of its new policy in March 2001. Until then, each pharmacy in Norway was owned by an individual pharmacist. The new policy allowed free ownership and the establishment of new pharmacies, although pharmacists are personally responsible for the services provided in each pharmacy (Anell 2005). In 2006, 81% of Norwegian pharmacies were owned by retail chains and 19% by individual pharmacists (Vogler et al. 2006). Sweden and Norway are the two extremes in terms of the ownership of community pharmacies in Europe, even though pharmacy chains similar to those in Norway also exist in other EU countries (e.g., in the Netherlands, the UK and Estonia). In most of the other EU countries, pharmacies are owned by individual pharmacists, although the ownership regulations also vary between these countries. In some EU countries, it is allowed to trade a pharmacy licence after owning the pharmacy for a predefined period of time (5 years in France, 3 years in Spain and 2 years in Portugal) (Taylor et al. 2004). The national agencies for medicines in Finland and Denmark select the best-qualified applicants to grant pharmacy licences to (Taylor et al. 2004, Vogler et al. 2006). The establishment of
new pharmacies also differs between countries. In Germany, pharmacists are free to establish a new pharmacy, but in most EU countries, the establishment of pharmacies is regulated by demographic and geographic regulations at the national level (Taylor et al. 2004).

Differences between member states in the pharmacies’ role as a medicine distributor include; the number of pharmacies per 1,000 inhabitants; the rules governing establishment; ownership; and the staff. Table 4 shows a comparison between the pharmacy systems of 12 EU countries and Norway. In some of the countries, for instance Denmark, Norway, the Netherlands and the United Kingdom, OTC medicines can also be sold outside of pharmacies (Turakka and Paaskoski 2005). In these countries, the assortment of non-pharmacy OTC medicines authorised for sale is limited. In the Netherlands, there is a long tradition of drugstores (as distinct from pharmacies) being allowed to sell non-prescription medicines, but since January 2005, OTC agents may also be sold by gas stations and supermarkets (Van Mill 2005). The deregulation took place in Norway and Denmark in 2001.
Table 4. PHARMACY SYSTEMS IN 12 EU COUNTRIES AND NORWAY

<table>
<thead>
<tr>
<th>Country</th>
<th>Number of pharmacies</th>
<th>Inhabitants per pharmacy</th>
<th>Pharmacists per pharmacy</th>
<th>Medicines sales outside pharmacies</th>
<th>Establishment of pharmacies</th>
<th>Pharmacy ownership</th>
<th>Pharmacy chains allowed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norway</td>
<td>559</td>
<td>8,533</td>
<td>1.8</td>
<td>Yes</td>
<td>FREE</td>
<td>Legal entities*</td>
<td>Yes</td>
</tr>
<tr>
<td>Sweden</td>
<td>900</td>
<td>10,000</td>
<td>0.2</td>
<td>No**</td>
<td>N/A</td>
<td>State</td>
<td>Aboteket AB owns all pharmacies</td>
</tr>
<tr>
<td>Finland</td>
<td>802</td>
<td>6,580</td>
<td>1.7</td>
<td>No**</td>
<td>Licence</td>
<td>Pharmacist</td>
<td>No***</td>
</tr>
<tr>
<td>Germany</td>
<td>21,392</td>
<td>3,900</td>
<td>Not available</td>
<td>Yes</td>
<td>Free</td>
<td>Pharmacists</td>
<td>No***</td>
</tr>
<tr>
<td>Netherlands</td>
<td>1,825</td>
<td>8,300</td>
<td>1.6</td>
<td>No licence</td>
<td>Anyone</td>
<td>Yes</td>
<td>No***</td>
</tr>
<tr>
<td>Spain</td>
<td>20,741</td>
<td>2,156</td>
<td>2</td>
<td>No</td>
<td>Licence</td>
<td>Pharmacist</td>
<td>Yes</td>
</tr>
<tr>
<td>Ireland</td>
<td>1,394</td>
<td>3,038</td>
<td>1.4</td>
<td>Yes</td>
<td>Free</td>
<td>Anyone</td>
<td>Yes</td>
</tr>
<tr>
<td>Austria</td>
<td>1,200</td>
<td>6,729</td>
<td>4</td>
<td>NO</td>
<td>Licence</td>
<td>Pharmacist</td>
<td>No</td>
</tr>
<tr>
<td>Denmark</td>
<td>322</td>
<td>16,916</td>
<td>2.6</td>
<td>Yes</td>
<td>Licence</td>
<td>Pharmacist</td>
<td>Maximum 4 pharmacies</td>
</tr>
<tr>
<td>France</td>
<td>23,228</td>
<td>2,696</td>
<td>2.4</td>
<td>No</td>
<td>Licence</td>
<td>Pharmacists</td>
<td>No</td>
</tr>
<tr>
<td>Italy</td>
<td>18,000</td>
<td>3,220</td>
<td>2.77</td>
<td>Yes (only NPMs)</td>
<td>Licence</td>
<td>Pharmacists (wholesalers ****)</td>
<td>Yes, but only public pharmacies</td>
</tr>
<tr>
<td>Portugal</td>
<td>2,775</td>
<td>3,782</td>
<td>2.1</td>
<td>Yes (only NPMs)</td>
<td>Licence</td>
<td>Anyone, with some exceptions*</td>
<td>No, Maximum 4 pharmacies</td>
</tr>
<tr>
<td>UK</td>
<td>12,943</td>
<td>4,900</td>
<td>Not available</td>
<td>Yes</td>
<td>Dispensing contract</td>
<td>Anyone</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*Not pharmaceutical manufacturers or prescribers  ** In sparsely populated areas pharmacy representatives and outlets allowed. In Finland NRT products have been available in supermarkets and other retail outlets since 2006. *** 1 main pharmacy and max. 3 branch pharmacies /owner. **** Wholesalers can own public pharmacies. NPM = non-prescription medicine. Source: All data come from PGEU and were updated in 2006.
Pharmacists by law must have similar educational backgrounds irrespective of the member state in which they work, although the way the curriculum is designed in different pharmacy schools and member countries differs markedly. According to Directive 2005/36/EC, pharmacists must have a formal university degree. The competencies of other pharmacy workers and the work that they are allowed to do in the community pharmacy differ between the nations (Table 5, Vogler et al. 2006). Worldwide, pharmaceutical education has shifted towards including more clinical content, and pharmaceutical care, including patient interactions, have become part of the pharmacy curriculum and continuing education programmes of many countries.

Table 5. Pharmacy education in different EU countries and Norway

<table>
<thead>
<tr>
<th>Country</th>
<th>Education of those who are authorised to dispense medicines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Finland</td>
<td>Pharmacist: a 5-6 year university degree (M.Sc. in Pharm.)</td>
</tr>
<tr>
<td></td>
<td>Prescriptionist: a 3-year university degree (B.Sc. in Pharm.)</td>
</tr>
<tr>
<td>Spain</td>
<td>Pharmacist: a 5-year university degree</td>
</tr>
<tr>
<td>Norway</td>
<td>Pharmacist : a 5-year university degree</td>
</tr>
<tr>
<td></td>
<td>Prescriptionist: a 3-year university degree</td>
</tr>
<tr>
<td>Germany</td>
<td>Pharmacist: a 5-year university degree</td>
</tr>
<tr>
<td>The Netherlands</td>
<td>Pharmacist : a 6-year university degree</td>
</tr>
<tr>
<td></td>
<td>Pharmacy assistant: a 4-year secondary education</td>
</tr>
<tr>
<td>Sweden</td>
<td>Pharmacist: a 5-year university degree</td>
</tr>
<tr>
<td></td>
<td>Prescriptionist: a 3-year university degree</td>
</tr>
<tr>
<td>Ireland</td>
<td>Pharmacist: a 5-year university degree</td>
</tr>
<tr>
<td></td>
<td>Qualified assistant or assistant to pharm. Chemist: a 3-years vocational training</td>
</tr>
<tr>
<td>Austria</td>
<td>Pharmacist: a 5.5-year university education</td>
</tr>
<tr>
<td></td>
<td>Pharmacy assistant: a 2 or 3-years vocational training</td>
</tr>
</tbody>
</table>
4.1 Pharmacy services and pharmaceutical care in European community pharmacies

Community pharmacies in the EU offer a wide range of professional and commercial services to their customers. Since the philosophy of pharmaceutical care was internationally launched in 1990 (Hepler and Strand 1990), community pharmacists have been pushed by their professional organisations to take more responsibility for patient care (FIP 1997). As a consequence, some pharmacists have developed their services and taken a more comprehensive role as health care professionals (Farris et al. 2005, Van Mil and Schulz 2006). However, the change from traditional dispensing to cognitive services has been slow, and the pharmacies are dividing into two camps in this respect, even within the same country: those which are integrating health care services by providing a variety of professional services, and those that limit themselves to traditional dispensing (Kansanaho 2006). Countries where dispensing medicines is no longer pharmacies’ sole function have demonstrated how the role of pharmacists can be expanded. Within the EU, those countries particularly include the UK, the Netherlands, Sweden, Denmark and Finland, though most European countries have conducted at least some local service development projects. International professional organisations, such as FIP, WHO EuroPharm Forum, and Pharmaceutical Care Network of Europe (PCNE) have had a crucial role in providing platforms for sharing experiences of service development projects in different countries and extending knowledge about their implementation and evaluation.

Regarding professional community pharmacy services, the minimum that is required by law in most EU countries is that people can obtain health advice and assistance with pharmacotherapeutic issues for managing their diseases (Roughead et al. 2005, Farris et al. 2005, Puumalainen 2005, Van Mil 2005, Eickhoff and Schulz 2006, Kansanaho 2006, Westerlund and Björk 2006, Bell et al. 2007). There is also evidence of the development of more advanced medicine-related services, one of the most popular being different kinds of medication review services carried out in collaboration with physicians (Royal et al. 2006, Holland et al. 2008). The most recent discussion has revolved around pharmacist’s involvement in prescribing (Tonna et al. 2007, Guillaume et al. 2008).

One of the most studied areas in professional community pharmacy services is medication counselling practices, which has been under discussion since the 1980s (Airaksinen 1996, De Young 1996, Vainio 2004, Puumalainen 2005, Kansanaho 2006). This is also a service area prioritised by consumers
(Airaksinen 1996). Most of the research and development has focused on communications practices regarding prescription medicines, the lack of attention paid to the role of self-care and self-medication as the means by which many people manage their symptoms (Sihvo 2000, Turunen 2007). This trend can also be seen in health policy decision-making, which has not taken a full advantage of the fact that, as the number of OTCs and the variety of symptoms that can be managed by OTCs has increased, the importance of providing counselling on the proper use of OTCs has increased. On the contrary, many countries have made, or are in the process of making, political decisions for releasing OTC medicines to the open market. This trend has been particularly pushed by the lobbying organisations of the retail market. The drug industry has discrete opinions, part of the companies promote the free market and use consulting firms to assemble evidence in support of their agendas (Shifman and Sweeney 2007).

Although it is common for pharmacies to have a self-selection department, it is not so common for them to have OTC medicines available there (i.e., self-medication products that have a marketing authorisation as medicinal products). The OTC assortment available in the self-selection area may be limited, or contain only other health-related goods, such as health food products, hygiene and health supplies. A system with consumers’ free access to all OTC medicines is most typical in countries with an Anglo-Saxon business orientation. Regardless of the way of organising OTC sales in the pharmacy, it can be done so that pharmacists are available for counselling. In Finland, for example, medication counselling on OTC medicines is required by law, even though all the OTC medicines are available to the public in the self-selection department (Medicines Act 395/1987). The counselling service is provided free of charge. Thus, pharmacists are providing a potential professional primary-health-care resource in managing minor symptoms, although evidence is lacking on its health-economic value and it has not been included in health and pharmaceutical policy decisions.
4.1.1 Initiatives taken to improve professional community pharmacy practices

The trend is that initiatives taken to improve professional community services are mainly taken voluntarily within the profession and without incentives for providing the new services.

In Finland the patient counselling development project TIPPA (2000-2003) promoted long-term professional development in community pharmacies (Puulanlaiinen 2005, Kansanaho 2006). TIPPA was a systematic project implemented in Finnish pharmacies nationwide. TIPPA project was supported by the Ministry of Social Affairs and Health, the National Agency for Medicines and the Social Insurance Institution, and these authorities were also actively involved in planning the project and following up on its progress. An important part of the TIPPA project was a drug information database (Tietotippa) created to support pharmacies in their daily work. In addition, emphasis was put on determining how training and extension studies could be directed to support the development of the skills needed in professional community pharmacy services (e.g., management skills).

Another area of discourse based on the pharmaceutical care philosophy by Hepler and Strand (1990), is related to the recognition of drug-related problems (DRP) in pharmacies. For this purpose, a DRP classification model has been developed (Westerlund 2002, van Mil 2005, PCNE 2006). A huge effort has been made to create computer-based programs to identify DRPs, and in many countries, DRP identification, resolution and documentation have been at the core of pharmaceutical care (Van Mil et al. 2004b). In Sweden the DRP classification system was incorporated into the Swedish community pharmacy software in 2001 (Westerlund 2002). During the first year, nearly 300,000 prescription and OTC-related DRPs showed that adverse reactions were the most frequently documented type of drug-related problem (Westerlund and Björk 2006). In the Netherlands, the following DRPs are being monitored by all three competing pharmacy software products: daily dose, interactions, double medication, contraindications, allergies and adherence (Van Mil 2005). The pharmacists resolve the detected problems together with the patient and/or the physician.

Pharmacists are also urged to provide preventive care services to patients suffering from chronic disease (EuroPharm Forum 2008a). In Germany, an asthma programme was started to change the image of community pharmacists as being merely a dispenser of medicines to that of a highly qualified advisor. The asthma programme started initially as a controlled intervention trial, leading to an intervention study and later, in 2003, to nationwide implementation (Eickhoff and
Schulz 2006). This project demonstrated that community-pharmacy based interventions significantly improved clinical parameters, asthma-specific quality of life, self-efficacy, self-management and the self-knowledge of the patient (Eickhoff and Schulz 2006). Since the asthma program was introduced, similar methods have been offered for different diseases, such as chronic pulmonary disease, coronary heart disease/angina, diabetes and breast cancer.

In recent years, there have been multiple nation-wide projects in Finnish pharmacies in order to prevent, or to enhance the treatment of, national diseases. These programmes have been part of the national health programmes, and the majority of Finnish pharmacies have participated in the programmes. The primary purpose of the professional programmes has been to ensure the success of the treatment of patients in an optimal way. A substantial part of the work towards reaching the target involves co-operation between the different healthcare professionals and pharmacies. The first programme, the Asthma Programme, started in pharmacies in 1997 following the Diabetes Programme in 2001 and Heart Disease Programme in 2005 (The Association of Finnish Pharmacies 2005). The Association of Finnish pharmacies (AFP) evaluates the implementation of these programmes and organises training that supports the pharmacies involved in the programmes. AFP is also regularly in contact with the national programme-coordinators.

4.1.2 Services provided by community pharmacies in Europe

Blood pressure and glucose and cholesterol level measurements are everyday pharmacy practise in many countries, although the motives of pharmacy owners for providing these services are discrete. They can be planned as follow-up activities to assure optimum outcomes of drug therapies when they support health strategies and health policy goals. On the other hand, they can be provided as sales promotion activities of the pharmacy without an evidence-base and without integration with other local health services. When properly planned and integrated into the healthcare system, these services can help people to maintain health and keep them aware of the effects of their medicines (Gastelurrutia et al. 2005, Westerlund and Björk 2006). There is also evidence that people are willing to use these services if provided by pharmacists (Nuffield Foundation 1986, Airaksinen 1996, Närhi 2001).
Information is accumulating on the wide range of other services provided by community pharmacies in various European countries either on the routine or experimental basis. These include many kinds of health promotion services, and in the case of illnesses, the promotion of rational prescribing and the appropriate use of medicines (Eickhoff and Schulz 2006). In Sweden, pharmacists offer fitness check services, providing advice on weight loss, diet and health, as well as lectures on fitness, health and group exercises (Westerlund and Björk 2006). Smoking cessation services are offered by pharmacists in many countries, including Finland (Gastelurrutia et al. 2005, Westerlund and Björk 2006, Eickhoff and Schulz 2006, The Association of Finnish Pharmacies 2006a, Herborg et al. 2007). In many countries (e.g., the UK, Spain, Portugal) community pharmacists are involved in providing methadone-supply services to opiate-addicted patients (Gastelurrutia et al. 2005, Costa et al. 2006, Noyce 2007). Moreover, a needle exchange programme is used in many EU countries (Gastelurrutia et al. 2005, EMCDDA 2005).

Although community pharmacists in the EU are involved in offering a wide range of services within primary health care, there is no harmonised policy on the services that pharmacists should or must offer. Many of the pharmacy services are offered free of charge, but the trend seems to be that additional services are becoming chargeable. In many countries, new services have become reimbursable, so that health systems and insurance companies are paying for these services. For example, in Germany a pharmacy-based intervention service for asthma patients was proven effective and therefore the health insurance fund made a contract with the representatives of community pharmacists in order to take part in this programme (Eickhoff and Schulz 2006). In Portugal, community pharmacists have obtained reimbursement for diabetes disease management (Anderson 2005, Farris et al. 2005). This service is a combination between disease state management principles and a pharmaceutical care approach. The certified pharmacists analyse patient complaints, measure blood glucose against target values and review drug therapy between physician visits (Anderson 2005). In many countries, pharmacies offer medication review services (Westerlund and Björk 2006, Herborg et al. 2007, Noyce 2007). In Finland, automated dose dispensing for the elderly, including medication review, is the first service mentioned in the Health Insurance Act that is reimbursed by the public insurance, which covers the whole population (Health Insurance Act 1224/2004).
4.2 A comparison of Spanish and Finnish community pharmacy systems and practices

In both Spain and Finland, medicines can be legally sold only in pharmacies. Spain differs from Finland in that there is more competition among pharmacies since there are more pharmacies per inhabitant (1:2000 in Spain vs. 1:6500 in Finland) (WHO 2000, Gastelurrutia et al. 2005, The Association of Finnish Pharmacies 2007a). However, in Spain there are on average fewer pharmacists or academic prescriptionists (who are allowed to dispense medications) per pharmacy outlet – two in Spain compared to 6.3 in Finland (Vogler et al. 2006, The Association of Finnish Pharmacies 2007b). The size of pharmacies in terms of number of personnel and operations performed is also smaller in Spain than in Finland on average. In Spain there are on average 3.3 persons and in Finland more than 10 persons who work in the pharmacy (Vogler et al. 2006, The Association of Finnish Pharmacies 2006a). In both countries, pharmacies are equipped with premises for preparing medicines extemporaneously, and the main operations are mostly computerised (Finland 100% vs. Spain 96%). In Finland, e-prescribing has been under development since the end of the 1980s (Hyyppönen 2005). Electronic prescribing has been piloted nationwide since 2002, and the law on e-prescribing was enacted in 2007 (Hyyppönen 2005, Law on Electronic Prescription 61/2007). It has been predicted that by 2010 half of all prescriptions in Finland will be e-prescribed (Vogler et al. 2006, Ministry of Social Affairs and Health 2008).

Pharmacies in both Spain and Finland are privately owned, and only pharmacists are allowed to own a community pharmacy, with two exceptions. In Finland there are two University pharmacies, one owned by Helsinki University and another by Kuopio University, both having a special duty by law to support pharmacy education and research (Medicines Act 395/1987). In Finland pharmacists are able to operate a maximum of four outlets: one main pharmacy and, with approval, up to three branch pharmacies. In Spain one pharmacist can own only one pharmacy, but multiple pharmacists can also own one pharmacy. However, pharmacy chains are not allowed forms of ownership in either country, though private community pharmacies have formed coalitions for coordinating marketing services and staff training in Finland. In Spain a new pharmacy can be established or a licence for an existing pharmacy can be bought if the current licence has operated the pharmacy for at least 3 years. The rules for establishing a new pharmacy are based on the population per pharmacy and the proposed distance to the closest neighbouring pharmacies (Gastelurrutia et al. 2005). The minimum population required to open a new pharmacy ranges from 700–2,500 in different provinces and the minimum distance between pharmacies ranges from
150 to 250 meters. In Finland, a licence from the National Agency for Medicines is needed to operate a retail pharmacy in a specific municipality or part of it. If there are several applicants for a pharmacy licence, it shall be granted to the applicant whom the NAM considers best qualified to operate the pharmacy (National Agency for Medicines 2007). Applicants’ qualifications are assessed by considering their demonstrated competence, by their aptitude for business as shown in their earlier work in pharmacies, and by other work relating to pharmaceutical services (Vogler et al. 2006, National Agency for Medicines 2007). Recently, more emphasis has been put on the managerial skills of the applicants.

In both countries, only academically trained pharmacy workers are allowed to dispense medicines and counsel patients. In Finland there are two university degrees for pharmacy: Master of Science (Pharm.) and Bachelor of Science (Pharm.). The Master of Science degree takes five to six years to complete, including six months of practical training in a community or a hospital pharmacy. The Master of Science degree is granted by either Helsinki or Kuopio University. The Bachelor of Science degree takes 3 years to complete, including a similar practical training of six months. The Bachelor's degree can be obtained from Helsinki or Kuopio University or from Åbo Academi. Only those having a Master of Science (Pharm.) degree can be granted a pharmacy licence, which expires when they reach 68 years of age (Medicines Act 395/1987). In Spain, there are 14 pharmacy faculties where individuals can study for a higher university degree in pharmacy (FIP 2007b, Mason 1999, Vogler et al. 2006). The program takes five years to complete and is followed by six months of supervised work in a community or hospital pharmacy. After qualifying, the pharmacist can work anywhere in Spain. Hospital pharmacists, however, undergo several more years training before they can be in charge of a pharmacy. In both countries, continuing education is mandated by law and strongly supported by the professional associations, in Finland by the Association of Finnish Pharmacies and the Medicines Act 395/1987) and in Spain by the general Spanish Council of Pharmacists (Vogler et al. 2006) and the law on health professions (44/2003).

In both countries there is a regulated monopoly that emphasises professional practice and service obligations without price competition (Gastelurrutia et al. 2005, Bell et al. 2007). In both countries the government fixes the pharmacy profit margins, and the availability of generic substitution is obligatory by law. In Spain a reference price system is in use (Montoro 2000). In Spain there are more pharmaceuticals registered on the market than in Finland (11,783 in Spain vs. 6,078 in Finland in 2005, including different pharmaceutical forms and strengths), but the number has been steadily increasing in Finland since generic substitution was implemented in 2003 (Vogler et al. 2006). In Spain there is also a wide range
of non-pharmaceutical products available in pharmacies (Vogler et al. 2006). In Finland, 95% of pharmacy sales are drugs vs. 85% in Spain (Gastelurrutia et al. 2005, The Association of Finnish Pharmacies 2007b). Furthermore, there are more self-care alternatives in Spanish than in Finnish pharmacies, because some prescription medicines, such as antibiotics, may be purchased directly from the pharmacy without a prescription (Mason 1999, Figueiras et al. 2000, Caamaño Isorna et al. 2004, Ras Vidal and Moya Ortiz 2005, Barbero-Gonzalez et al. 2006). However, recently authorities have begun to enforce the regulations governing prescription-only medications (Jubete Vazquez 2004, Scrip 2005).

In Spain, medicine prices are lower than in Finland, but when adjusting for purchasing power, the difference is not remarkable (Vogler et al. 2006). In both countries, the price of prescription medicines has dropped in recent years (Vogler et al. 2006). However, when examining the reimbursement systems of the two countries, the medicine expenses paid by the consumers differ greatly, especially for pensioners. In Spain, the reimbursement system provides medicines to pensioners for free; working age people pay 40% and those suffering from chronic illnesses 10% of the cost of their medicines. In Finland, the reimbursement rate is determined by the disease, being classified into three categories according to the severity of the disease. Drugs for the treatment of life threatening and severe conditions, such as cancer and diabetes, are 100% reimbursed with a €3 deductible per medicament. Drugs for chronic conditions such as hypertension, asthma, dyslipidemia and cardiac insufficiency are included in the category with 72% reimbursement. Any other drugs that have an approval from the government-based Pharmaceutical Pricing Board to be reimbursed because of having a reasonable wholesale price are reimbursed in the Basic Refund Category, which is 42% of the retail price (The Social Insurance Institution 2006, Health Insurance Act 1224/2004). In Spain approximately 25% and in Finland 16% of total healthcare expenditures are for drugs (Gastelurrutia et al. 2005, The Association of Finnish Pharmacies 2007b).

Spanish and Finnish pharmacies offer a wide range of services to their customers. Medication counselling is the most important service pharmacies routinely offer. In both countries, the development of professional services has been strongly influenced by the WHO Euro Pharm Forum, in which they have been actively involved since the establishment of the Forum in 1992 (EuroPharm Forum 2008b). Both countries were among the first countries to carry out the “Ask About Your Medicines” campaign starting in 1993 (Airaksinen 1996, Airaksinen et al. 1998). Since then, medication counselling has had a special emphasis in the development of community pharmacy services in Finland, as can be seen in, e.g., the strategies of the AFP (The Association of Finnish Pharmacies 1997, 1998,
To follow-up the development of medication counselling practices in Finnish community pharmacies, AFP conducted a pseudo customer study in 1998, among one of the first countries using the method in community pharmacy context. The study revealed a need for further development, and led to the launch of the four-year TIPPA project in 2000 to improve the medication counselling of community pharmacies (Puumalainen 2005, Kansanaho 2006). In connection with this project, medication counselling has been widely studied, also from an organisational perspective, and improvements in practices have been documented (Puumalainen 2005, Kansanaho 2006).

In both countries, pharmacists are increasingly involved in health promotion and in the follow-up of patients with chronic conditions. In Spain, in contrast to Finland, measurement and laboratory tests, such as weight, height, blood pressure measurements and biochemical blood tests (glucose and cholesterol levels) are taken by pharmacists (Gastelurrutia et al. 2005). Finnish authorities allow pharmacists to be involved in screening only to a limited extent to ensure that practices remain evidence-based and that services remain integrated with local health services (Vogler et al. 2006).

In Finland, pharmacy programmes are designed to be integrated with national health promotion programmes. Over the years, pharmacists have been involved in asthma, diabetes, heart and hypertension, and obesity and smoking cessation campaigns (Mason 2000, Haahtela et al. 2006, Bell et al. 2007). The national Asthma Programme started in Finnish pharmacies in 1997, and now almost all of the Finnish pharmacies have taken part in this program (Haahtela et al. 2006). The aim of this project is to improve asthma care in co-operation with the local healthcare centres. In each pharmacy, one pharmacist is nominated to specialise in asthma and its treatment and to become a contact person. Similar programmes have been launched in diabetes and in heart diseases. The operative of the diabetes programme has been in the prevention of type 2 diabetes and in treatment effectiveness. Four-fifths of the Finnish pharmacy outlets have contact persons in diabetes programs and 66% of the pharmacy outlets have a heart programme contact person (The Association of Finnish pharmacies 2007b). In Spain, professional campaigns have been implemented in AIDS, hypertension, menopause and anorexia nervosa (Mason 1999). Since nicotine products became available in supermarkets and other retail outlets in Finland in 2006, pharmacies have launched a new type of cessation programme for smokers. The price of this service includes an independent pharmacist’s counselling to guide the patient in their project. The pharmacists and patient meet 4-5 times during a span of 3-6 months (The Association of Finnish Pharmacies
2006b). In Spain as well, smoking cessation activities are offered (Gastelurrutia et al. 2005).

In Spain, some pharmacies offer and are paid for methadone administration services to patients on opiate withdrawal programmes (Gastelurrutia et al. 2005). In Finland, the Pharmacy Agreement Model is in use with patients who have an addiction to medicines or drugs. It may be also used to prevent addiction or to assist patients whose medicine supply should be limited for some other reasons (Holopainen et al. 2005). In this model, physician and patient sign an agreement that patient may only receives a certain amount of medicines from the pharmacy at a time. The patient is obligated to always use the same pharmacy and to fetch the medicines by himself/herself. Pharmacies have an important role in this co-operation (Holopainen et al. 2005).

In Finland automatic dose dispensing (ADD) has been launched in community pharmacies. In ADD, patients’ medicines are packed in single dose packages for two weeks by the automatic tablet-packing machine. The aim of this service is to increase medication safety, decrease drug costs and reduce the workload of pharmacists or other health care professionals work involved in manual dosage dispensing (Saikkonen 2003). By the end of 2005, 10% of Finnish pharmacies were equipped to offer automated dose-dispensing, and in the beginning of 2008, more than half of the pharmacy outlets were offering this service (The Association of Finnish pharmacies 2006a, 2008). The Finnish Social Insurance Institution was involved in this process, so that these services are reimbursed for patients over 75-years who are on multiple medications. Patient medicines should be reviewed before this service is implemented (Health Insurance Act 1224/2004, The Social Insurance Institution 2006).
5 SELF-MEDICATION IN THE EUROPEAN UNION

Council Directive 92/26 Article 3: “Medicinal products shall be subjected to medical prescription where they are likely to present danger either directly or indirectly, even when used correctly if utilised without medical supervision. They are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to human health, or contain substances or preparations thereof the activity and/or side effects of which require further investigation, or are normally prescribed by a doctor to be administered parenterally”.

EU has directives on which medicines should be available over-the-counter and which by prescription (Council Directive 92/26/EEC and Directive 2001/83/EC), but the final decision as to whether a medicinal product is subject to medical prescription or not is taken in EU countries by national authorities connected to the ministries of health. Even though EU countries have approved the same directive, there are still differences in the classification of certain OTC products (Table 6). There are also differences between countries in the places where non-prescription medicines may be sold (see Table 5).

Table 6. Legal classification status of selected ingredients in the EU

<table>
<thead>
<tr>
<th>Active ingredients</th>
<th>EU-NATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Austria</td>
</tr>
<tr>
<td>Glucosamine</td>
<td>OTC</td>
</tr>
<tr>
<td>Omeprazole</td>
<td>Rx</td>
</tr>
<tr>
<td>Simvastatin</td>
<td>Rx</td>
</tr>
<tr>
<td>Levonorgestrel</td>
<td>Rx</td>
</tr>
<tr>
<td>Tetracycline</td>
<td>Rx</td>
</tr>
</tbody>
</table>

Rx, prescription only, OTC, over the counter, -, non-authorized or non-marketed. OTC use may be restricted to some specific dosages or routes to administration. Source: AESGP 2007.

*Year when the product became available over the counter.
In recent years several prescription products have become available without prescription. Some of these RX-to-OTC switches have divided opinions and created quite a lot of discussion regarding safety matters (such as adverse reactions, misdiagnosis, misuse, delays in primary diagnosis and drug-to-drug interactions), costs, advertising, availability and access (Bradley and Bond 1995, Bradley and Blenkinsopp 1996, Byrns 1998, Soller 1998, Lipsky and Waters 1999, Aronson 2004, Fenichel 2004, Shiffman and Sweeney 2008, Table 7).

Table 7. Positive and negative aspects of Rx-to-OTC switches

<table>
<thead>
<tr>
<th>+ Positive aspects</th>
<th>- Negative aspects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Easy access</td>
<td>Possibility of ADR’s will increase</td>
</tr>
<tr>
<td>Rapid access</td>
<td>Possible interactions with other OTC- or RX-medicines</td>
</tr>
<tr>
<td>Independency</td>
<td>Use might mask symptoms of serious illnesses</td>
</tr>
<tr>
<td>Decrease in utilisation of Rx-medicines</td>
<td>Possibility of choosing wrong medicines/making wrong diagnoses</td>
</tr>
<tr>
<td>Costs shifted from health care system to patients</td>
<td>Incorrect use</td>
</tr>
<tr>
<td>Reduces amount of contacts with GPs</td>
<td>Misuse/abuse</td>
</tr>
<tr>
<td></td>
<td>Change in the status of medicines</td>
</tr>
<tr>
<td></td>
<td>Increases indirect healthcare costs if health problems first mistreated by OTC medicines</td>
</tr>
</tbody>
</table>

Levonorgestrel, an emergency hormonal contraception, has been one of the medical treatments raising discussion. In many EU-countries (e.g., Belgium, Finland, France, Sweden and UK) these emergency contraceptive pills have been switched from Rx to OTC products (AESPG 2007). Several possible risks were recognised, but the change was supported because it was predicted to reduce unintended pregnancies and abortions as well as healthcare costs (Camp et al. 2003). Reducing third party healthcare costs has been behind many of these switches. An American study suggested that Rx-to-OTC switches may decrease the utilisation and cost of all prescription drugs and combinations in the group studied (Sullivan et al. 2005). There has been some debate whether these switches are made with intentions to switch costs from insurance companies to patients: in many countries national or private insurance companies do not cover OTC medicines (Bradley and Blenkinsopp 1996). However, shifting costs is not the only factor driving these switches. Nowadays, people are more educated and more interested in self-care. The responsibility for health care is shifted to consumers, and an extensive information network could make people more
informed and perhaps more willing to make their own decisions (Byrns 1998, Juhl 1998). OTC status would enable easier and more rapid access to these medicines, as well as more independence in choosing medicines for patients who can afford them.

On the other hand, problems might occur due to self-medication. Non-prescription medications have the potential for misuse. Previous studies revealed that the misuse of particular medicines (for example painkillers, cough mixtures, sleep aids, laxatives and antihistamines) is widespread, and well known to pharmacists (Hughes et al. 1999, Wazaify et al. 2005, Steinman 2006). An Irish study concluded that one-third of the public had personally encountered misuse or abuse of OTC medicines (Wazaify et al. 2005). In an American study more than one-third of patients indicated that they exceed the recommended dose of their OTC medicine to get the desired effect from the product (Schulke 1998). One study in Iceland suggested that liberalising the drug distribution system could be one factor leading to the increase in misuse of non-prescription analgesics containing codeine (Almarsdottir and Grimsson 2000). As the status of medicines has been changed from Rx –to OTC, the responsibility for screening misuse has shifted from general practitioners to pharmacists. A Swedish study demonstrated the need for more professional attention and intervention by pharmacy staff to prevent drug-related problems in non-prescription customers (Westerlund et al. 2001). Pharmacists have a major role in assuring that patients know how to use their medicines and that they understand the possible side-effects. A Welsh study reported that, on average, only one out of five users of ibuprofen could name one of its side effects, even though ibuprofen is one of the most common products to cause serious side-effects (Hughes et al. 2002).

The issue remains unresolved of who will take care of the medication-related problems of the public if more and more medicines are released outside the control of either physicians or pharmacists.
5.1 Undesirable self-medication

Some EU countries have faced problems where prescription medicines have been sold and used as non-prescription medicines. As antibiotic resistance is a rapidly increasing global problem, antibiotic use as a self-medication has been studied in different countries. A broad, European antibiotic-usage study examined self-medication with antibiotics in 19 European countries (Grigoryan et al. 2006). Clear differences were found between countries: self-medication rates were high both in Eastern and Southern European countries and low in Northern and Western Europe. Younger age, higher education and the presence of a chronic disease were associated with greater use. A Spanish study suggested that 50% of Spanish families used antibiotics as self-medication (Ras Vidal and Moya Ortiz 2005). A Swedish study suggested that 4% of Swedish respondents had antibiotics at home, but they were in almost all cases obtained with a prescription (Svensson et al. 2004). A Danish study suggested that 97% of antibiotics had been obtained after a medical consultation (Muscat et al. 2006). In a Maltese study 19% of the respondents admitted taking antibiotics without a prescription, and in Poland 13% of antibiotic therapies were taken without medical supervision (Borg and Scicluna 2002).

A Spanish study suggested that the prevalence of any kind of undesirable self-medication in Spain was 2.5%. Prescription medicine use without prescription was most common among students, persons older than 40 years and those who lived alone (Figueiras et al. 2000). A more recent Spanish study examined pharmacists’ opinions about selling prescription medicines without a prescription. Altogether, 83.5% of these pharmacists reported dispensing prescription nonsteroidal anti-inflammatories, 65.9% antibiotics, 46.3% ACE inhibitors and 13.4% benzodiazepines without a prescription (Caamano Isorna et al. 2004). This low prescription requirement was associated with pharmacy ownership and size (pharmacists per pharmacy) and with the high economic level of the population. In addition, the pharmacists’ workload and pharmacists' overestimations of their own qualifications to prescribe were associated with this practice (Caamano Isorna et al. 2004, Caamano et al. 2005). In another study prescription medicines were requested without prescription in 11.1% of the cases and dispensed in 10.8% of the cases (Barbero-Gonzalez et al. 2006). As undesirable self-medication has become a challenge in Spain, the authorities have begun to enforce the regulations strictly (Jubete Vazquez 2004, Scrip 2005).
5.2 Factors influencing the decision to self-medicate

There are several factors affecting self-medication behaviour. Symptom severity, earlier experiences with medicines and diseases and personal characteristics and attitudes affect decision-making on whether to contact health care professionals or to self-medicate (Sihvo 2000). This decision also relies on availability and access to health services and on the time which people have available. The social environment, family and friends as well as their earlier experiences and beliefs may affect the decision (Sihvo 2000). In addition, external information sources, such as advertising, the media, the Internet as well as contacts with pharmacists and other health care professionals may affect the decision (Sihvo 2000). Cultural aspects as well as policy decisions on the medicines available for curing minor symptoms may also affect the decisions.
6 MIGRANTS WITHIN THE EUROPEAN UNION

Migration within the European Union is not new. For decades, people have moved from the Northern European countries to Southern European countries such as Spain, Italy and Greece. In Spain, the number of foreign residents has increased significantly in the last quarter century (Table 8, Ortega Pérez 2003). Even though the number of immigrants from developing countries has increased rapidly, residents from European countries are the second largest group of foreign residents in Spain (Table 8).

Table 8. The number of official foreign residents/immigrants in Spain in 2000 and 2006 (Ministerio de Trabajo y Asuntos Sociales 2000,2006)

<table>
<thead>
<tr>
<th>CONTINENT OF ORIGIN</th>
<th>YEAR 2000</th>
<th>YEAR 2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Europe EU countries</td>
<td>360,007</td>
<td>1,028,678</td>
</tr>
<tr>
<td>Latin America</td>
<td>311,219</td>
<td>661,004</td>
</tr>
<tr>
<td>Africa</td>
<td>184,944</td>
<td>1,064,916</td>
</tr>
<tr>
<td>Asia</td>
<td>261,383</td>
<td>709,174</td>
</tr>
<tr>
<td>Oceania</td>
<td>72,447</td>
<td>197,965</td>
</tr>
<tr>
<td>North America</td>
<td>902</td>
<td>1,819</td>
</tr>
<tr>
<td>Not available</td>
<td>15,020</td>
<td>18,109</td>
</tr>
<tr>
<td>TOTAL</td>
<td>895,720</td>
<td>3,021,808</td>
</tr>
</tbody>
</table>

Previously, the largest resident groups in Spain from EU countries were British, German and Italian, but the situation has changed during the last few years: the number of people from new EU member states (e.g., Romania, Bulgaria, Poland) has increased, and in 2006 the number of Romanian people surpassed the number of people from Britain, Germany or Italy. Figure 5 shows the largest resident groups from EU countries and Norway in 2006. These numbers, however, should be viewed with caution as they only represent the people who are officially registered. Estimates of the actual number of migrants living in Spain vary for numerous reasons, for example, because of seasonal migration, difficulties with the bureaucracy, lack of clarity about reporting requirements and tax issues (Hardill et al. 2004).
Figure 5. Largest official resident groups in Spain from EU countries and Norway in 2006 (Ministerio de Trabajo y Asuntos Sociales 2006). Romania and Bulgaria, which joined the EU in the beginning of 2007, are also included in the figure.

*Instituto Nacional de Estadistica* statistics show that 40% of the British, 29% of German and 24% of French nationals living in Spain are more than 50 years old. However, these statistics include only the registered population and, for example, those who are employed in Spain are more likely to be registered than are pensioners. The British study suggested that two-thirds of British migrants settled in their destination area are between ages 50 and 64 (Casado-Diaz et al. 2004). In this study, four southern areas were examined and those who settled in the Costa del Sol region of Spain tended to be slightly older than migrants to other areas. Nearly 80% of migrants to the Costa del Sol region settled there after they had turned 50 years old (Casado-Diaz et al. 2004). The studies, which concentrated only on retired migrants, showed that the respondents were relatively young seniors, the overall average age being 66 years. More than 42% of these migrants were aged 65-74 and only 19 per cent were older. Two studies made in the Costa del Sol region suggested that men were a slight majority, at 51% and 52% of the respondents (Casado-Diaz et al. 2004). The two studies also
recorded the highest educational level of the respondents, one suggesting that 19% and the other that 41% of the respondents had a university-level education (Casado-Diaz et al. 2004).

The migrants are not a clearly identifiable group, since individuals are moving back and forth all the time; some migrate temporarily and others take up more permanent residence (Warne et al. 1999, O’Reilly 2000, Huber and O’Reilly 2004, Warnes et al. 2004). The migrants overall can be categorised into the following groups: short term-visitors; employees/working residents; retired residents/pensioners; and the “floating population”. Floating population or “false tourists” are residents who stay in Spain for more than three months of the year, but without registering with the authorities (Rosenmöller and Lluch 2006). Retirement migration has increased since its emergence in 1960 (King et al. 1998). Retirees are moving to regions where they believe their quality of life will improve during their older age (King et al. 1998). Many of these retired migrants have lived in Costa del Sol for more than 30 years, while others have just recently settled. The number and characteristics of retired migrants is difficult to assess as this group comprises both registered migrants and the floating population, which is unrecorded in official statistics (Williams et al. 1997, King et al. 1998). This floating population travel back and forth between Spain and their home countries, and because of the informality of their status, their numbers are difficult to estimate or even approximate. For example, in Valencia, 73,000 residents held official residence cards, and 158,000 had registered in the municipalities, but a significant proportion was not registered at all (Rosenmöller and Lluch 2006). In addition, the official number of Swedes residing in Spain is about 10,000, but it has been estimated that the actual number is somewhere near 40,000; and although the official number of British people in Spain is less than 200,000, almost a million own Spanish property where they live at least part of the year (Blakemore 1999, Hardill et al. 2004).

Migrants in mass tourist areas have little or no need to learn the local language, as many of the commerce and personal services are offered in their native language (this does not include all health services) (Casado-Diaz et al. 2004). However, many hospitals have realised the language problem and have included language skills as a criterion when hiring new staff (Rosenmöller and Lluch 2006). The two studies made in Costa del Sol suggested that 4% and 28% of migrants were fluent in Spanish, while 11% and 71% knew only a few words or had no language skills at all (Casado-Diaz et al. 2004). It is also known that many Swedes living in the region speak relatively little Spanish because they live among expatriates and have only limited contacts with Spanish residents (Gustafson 2001).
6.1 Reasons for migration

Most commonly migration is directed to Southern European countries in or close to mass tourists zones where the migrants may have stayed during previous tourist visits. The location of the second home may also influence decisions on where to settle (Bell and Ward 2000, Rodriguez 2001, Casado Diaz et al. 2004). Climate and other environmental factors are the most commonly cited reasons for making the move (Casado-Diaz et al. 2004). The Mediterranean winter climate, which enables outside activities, attracts many migrants. These activities are also connected to health, for example, a Swedish couple reasoned that they would surely have a longer life living in Spain than if they were spending the winters indoors in Sweden (Gustafson 2001). Financial advantages are the second most prevalent of the reasons expressed, even though the cost-of-living differential between Southern and Northern European countries has declined in recent years. Even though prices have risen, they are still found to be affordable. The prices of housing, in particular, are lower than in big cities in the Northern countries. In addition, the harmonisation of democratic, civic and legal frameworks has made property purchases more secure and attractive (Warnes et al. 2004). As the number of migrants has increased, many services are being offered in the migrants’ native language or in English, which makes daily life easier for those who have no or only modest language skills. Many people are also attracted to the Mediterranean way of life, and it is reported anecdotally that the social life and leisure activities have affected the migration. The improved access to the Mediterranean by frequent flights and budget airlines has enabled hundreds of thousands of people to visit and experience the region. The technological changes in telecommunications, cable television and information networks have also increased the movement (Warnes et al. 2004).

6.2 Mobile patients

6.2.1 Mobile patients in the European Union

Patient mobility has recently arisen on the Health Policy agenda in the EU (European Commission 2003c, 2003d, 2004). In 2002 the Commission brought together health ministers from across the EU with representatives of patients, of professionals, of providers and purchasers of health care and of the European Parliament in a high-level reflection process (European Commission 2003c, 2003d, 2004). This process issued a report that included 19 recommendations in five main areas: 1) European cooperation, 2) information 3) access and quality 4) reconciling national objectives with European obligations and 5) the Union’s
cohesion and structural funds (European Commission 2003c, 2003d, 2004, European Union 2006, Rosenmöller et al. 2006). The Commission responded to these recommendations and defined the areas of work. The Commission also recommended the creation of a High Level Group on Health Services and Medical Care, which would develop working groups on different issues such as cross-border health care, information, e-health and patient safety (European Commission 2003d, 2004).

Since the Treaty of Amsterdam in 1997, health systems have been the matter of national governments. In recent years, however, the increasing need for internal markets and international co-operation in health services have been discussed. Health services were excluded from the European Union Services Directive (2006/123/EC) in 2006.

Community law provides citizens with the right to seek healthcare in other member states and be reimbursed (European Commission 2004). The European Court of Justice has clarified the conditions under which a patient may be reimbursed in another member state (Palm et al. 2000, European Commission 2004). Community law also provides citizens with rights to health care in other member states when they move. However, citizens may not always know their rights and obligations (European Commission 2004). At the moment, citizens of the EU member states have a right to move and reside freely among the member states. The freedom of movement requires that people travelling within the EU be allowed to obtain all necessary health services during their visits. This has been resolved by European Council Regulation (EEC) No 1408/71 with its implementing regulation (Council regulation (EEC) 574/72 and with Regulation (EC) No 883/2004. Regulation (EEC) No 1408/71 established the E111 system, followed by the European Health Insurance Card (EHIC) (Decision 2003/753/EC, Rosenmöller and Lluch 2006). EHIC cards provides reduced-cost or free access (depending on state regulations) to any treatment that becomes necessary during visits to other EU/EEA countries or to Switzerland. In practice, this means that patients are treated so that they do not have to return prematurely to their country of origin to receive treatment.

The E112 system was established to enhance the benefits of collaboration across borders. The E112 form is used as pre-authorisation for the citizen of an EEA/EU country or Switzerland who will have planned treatments abroad (European Commission 2007b). The treatments may include hospital or other kinds of medical treatment. In the case of hospital treatment, pre-authorisation is needed in order to receive reimbursement. Other types of treatments may be reimbursed retroactively. In such cases the treatment will be provided in conditions similar to
those applying to residents. There are also other agreements between individual countries, although the agreements do not provide a clear framework, and in some cases unresolved issues have proceeded to the European Court of Justice (Palm et al. 2000).

According to Rosenmöller et al. (2006), mobile patients can be divided into five categories:

1) Those who are on holiday and need to use health care services in the country they are visiting
2) Those who retire in a different country and wish to use the health services
3) People sharing close cultural or linguistic links with the region where care is provided
4) Patients who cross a border to receive health care or buy health goods, i.e., “medical tourism”
5) Patients who are sent abroad by their own health system to overcome its capacity restrictions

Most migrants in Southern European countries, such as Spain, are included in the first two groups. Those who are using EHIC are provided the necessary health care. The health care is provided only within the Spanish State Health Service. Those who spend more than 90 days in Spain are required to register in person at the Foreigners’ Office. Official residents are entitled to the same healthcare as Spanish citizens, and they will be registered in the population registry. However, those official residents who are transferring their rights to the Spanish system retain their rights to also use health services in their country of origin. If they need health services while visiting their country of origin, they may use the EHIC or apply the pre-authorisation (E112) from Spain to use planned health services in their country of origin. Spanish health care guarantees access to medical attention and assistance in hospitals, but post-hospital assistance and home-care is scarce in Spain. This is problematic for those who do not have relatives living nearby (Rosenmöller and Lluch 2006). Consequently, many seasonal migrants rely on the EHIC system as they are afraid of losing their rights at home. Some migrants also have private health insurance, so that they would not have to transfer their rights in order to secure long-term health care (Hardill et al. 2005).

As many retirees are living with a foot in either country, they may feel that they are falling through the cracks. They are no longer the responsibility of their home country, yet the new country may also be unable to provide them with all of the services they need (Hardill et al. 2005). Some evidence suggests that cross-border health care is not consistently of high quality and may not always meet the needs of patients, especially when the patient does not have language skills or
does not understand the local health system (Rosenmoller et al. 2006). Previous studies have suggested, that many migrants did not transfer their rights, but used the E111 form to access health care when needed. Even hip replacements have been made under E111 (Rosenmöller and Lluch 2006). This floating population, however, complicates the improvement of health services in migrant areas. Without knowing the actual profiles of residents living in the area, the allocation of resources would become difficult (Hardill et al. 2004). Under-registration can thus lead to under-funding of health care services in the migrant areas, leading to a lack of resources in the hospitals and in healthcare overall. On the other hand, the existing registers are incomplete. They lack basic information on, e.g., the type of care provided and its costs. The latter leads to a large cost burden on Spain’s public finances (Rosenmöller and Lluch 2006). There has also been a widespread view in Spain that retired people from other EU countries are all very well-off, and it would not be right to improve the care of this group at the expense of Spanish citizens (Hardill et al. 2004). The survey made by Rodriguez et al. (1998) suggested that Scandinavian retirees in Spain are mostly upper middle-class, but other studies have found that there are retirees from different socio-economic backgrounds as well (Casado-Diaz et al. 2004).

Under-registration complicates the study of migrants and of their use of health services. Many studies have concentrated on young people and workers, but they do not offer information about the needs of older populations. The older population has greater needs for health services, and they have a growing influence on health and social welfare policies and legislation (Warnes et al. 2004). Even though many retired migrants have not registered with the system, they still have health care needs beyond primary care, such as care for chronic conditions, screening, health promotion and disease prevention (Rosenmöller and Lluch 2006). In some areas of Spain, private health care providers count on tourists´ willingness to pay, and tourists are often advised to use private clinics, where the EHIC does not cover the charges (Rosenmöller and Lluch 2006). Tourists and migrants are often poorly informed and confused about their rights.

Most of the studies on retirement migration have concentrated on estimating the size of the migration population, the reasons for migration and the impact of the migration in the receiving areas (Williams et al. 1997, Rodriguez et al. 1998, Williams et al. 2000, Gustafson 2001). In addition, most of the studies concern migrants who are in good health, but there is a lack of information concerning migrants’ health status, use of, and quality of used, health services and the problems involved. Some studies suggest that migrants have more health complaints than non-immigrants; that they seek care for common symptoms more often and expect a medical intervention from their general practitioner more often
than do the non-immigrants. However, these studies have not concentrated on
migrants within the EU (Bradley et al. 2004, Weilandt et al. 2006). Dutch studies
suggest that migrants do, on average, have a lower health status than does the
non-immigrant population and that they visit general practitioners more often
(Stronks et al. 2001, Uiters et al. 2006). Specialised healthcare use is lower
among immigrant groups, and there has been a debate over whether limited
access to these services may be an explanatory factor, since it is known that
specialised services may be more expensive and that ethnic minorities more often
represent a lower income group than that of non-immigrant populations (Smaje
The results of a British study, however, suggest that the health status reflects the
use of health services rather than the ethnic group.

Some studies also suggest that immigrants are healthier than the non-immigrant
population. This phenomenon is known as the healthy immigration effect, and it
has been observed in the U.S., Canada, Australia and in Western Europe
(Fennelly 2005). Studies conducted in the U.S. show that first-generation
immigrants are often healthier than people of the same ethnic origin who were
born in the U.S. (Singh and Siahpush 2001). The study of Muening and Fahs
(2002) suggests that foreign-born residents are healthier, have longer life
expectancy and have lower healthcare costs for the society than the non-
immigrant population. These health advantages seem to diminish over time, and
in the U.S., this has been explained by environmental factors such as poverty,
poor housing and barriers to access healthcare; as well as by behavioural factors
(unhealthy diet, tobacco, alcohol and drugs) (Fennelly 2005).

Migrants from other EU countries may have different needs for health services
than the non-immigrant population. The health care systems as well as the
pharmacy systems differ between European countries (Vogler et al. 2006). For
example, when people age in Northern European countries, there is a relatively
high provision of social services (Hardill et al. 2004). People are accustomed to
receiving home care and nursing home care, but similar arrangements do not
exist in Spain. In Spain, there are a growing number of migrants who are unable
to support themselves as a result of either health problems or lack of finances
(Hardill et al. 2005). The lack of language skills does not help the situation, and
the lack of systematic research evidence has created false expectations about the
daily life of the migrants (Hardill et al. 2005).
7 CONCLUSIONS OF THE LITERATURE REVIEW

The role of community pharmacies as providers of primary health care services is not well understood. In Europe, people often use pharmacies to find relief for minor illnesses and as a possible prelude to seeing a general practitioner, but in some countries, pharmacies are also used as a substitute for general practitioners or for other health services. Overall, pharmacies are often the first place of contact in the symptom mitigation process. However, community pharmacy services vary within the EU. In the EU, there is no harmonised pharmaceutical policy concerning community pharmacy practices (Figure 6), nor are there any minimum standards for community pharmacy services, although WHO, FIP, and national pharmacy associations have made recommendations and offered their views on the role of pharmacists and pharmacy services.

As migration, and especially retirement migration, has increased in recent years, the number of elderly and chronically ill mobile community residents is also increasing. As these people may suffer from multiple health problems, they will make demands on the local health care services. Even though hospitals and private clinics have started to offer services for mobile community residents, the actions of community pharmacies have been negligible. It would be important to understand migrants’ characteristics, their health seeking and medication behaviour, and the role of the pharmacy in their health seeking process in order to develop the pharmacy services of migrant areas, as well as all over the EU, to meet the needs of mobile community residents.

There is no harmonised policy in community pharmacy issues in EU and the community pharmacy practices vary between member states. As the amount of mobile community residents is increasing, there is a need to study how community pharmacies in EU are capable in providing adequate services to mobile community residents (Figure 6).
NEED TO STUDY HOW COMMUNITY PHARMACIES IN EU ARE CAPABLE IN PROVIDING ADEQUATE SERVICES TO MOBILE COMMUNITY RESIDENTS

Figure 6. Summary of the literature review
8 AIM OF THE STUDY

The aim of the study was to understand use of medicines, symptom mitigation and the role of community pharmacies in this process from the perspective of mobile community residents within EU. In this study, Finns living in Spain were used as an example. The specific study objectives were:

1. To describe the Finnish immigrant population in the Spanish Costa del Sol region and to study the extent of health immigration (I)
2. To study medication usage habits of the Finnish immigrant population in Spain (I,II)
3. To survey the opinions of the Finnish residents about community pharmacy services and possible risks related to access and use of medicines in Spain (III)
4. To describe the role of community pharmacies in the symptom mitigation path of mobile community residents (IV)

Figure 7. Study flow
9 MATERIALS AND METHODS

In this study, both quantitative and qualitative methods were applied (Figure 7), a process known as triangulation (Mays and Pope 1995, Eskola and Suoranta 1998). The term triangulation is used when different types of approaches, methods or data are used in the same research (Eskola and Suoranta 1998, Smith 2002). Qualitative and quantitative methods can be used in combination in several ways (Hirsjärvi et al. 1997):

- Qualitative study can be used as a pilot study for quantitative study
- Qualitative methods can be used in parallel with quantitative methods
- Quantitative study can come before qualitative study.

The aim of quantitative methods is to gather a sample of sufficient size according to a valid procedure leading to reproducible findings that can be generalised to the wider population. The methods include both descriptive and inferential statistics (Smith 2002). In social pharmacy research, survey methods are common quantitative methods, the data being collected by interviews or by survey questionnaires (Smith 2002). In this study, a survey questionnaire was used to gather descriptive information about the Finnish population in the Costa del Sol region of Spain, to characterise the population, to describe their medication use habits and to describe their views and attitudes about community pharmacy services.

The outcomes of qualitative research differ from those of quantitative methods. The idea in qualitative research is to develop a deeper understanding of the rationales (the why's), processes (the how's) and context (the when's) of the phenomena under investigation (Lehoux et al. 2006). The main idea is not to generalise the findings, but to describe the phenomena in a particular context and time. In this study, the qualitative research supplemented the quantitative study. The idea of focus group discussions was to provide a deeper understanding of the issues that emerged from the survey and to create a more comprehensive picture of the study objectives as a whole. By using focus group discussions it is possible to gain access to views that would be elusive in the survey design. The group dynamics of focus groups are important for revealing potential controversies, and in this case, belonging to a group of mobile patients provided participants with the opportunity to explore arguments and clarify their own views on this new and complex issue. As all methods have their limitations, combining these two methods yielded a more complete view on the study subject and enhanced the validity of the data (Pope and Mays 1995, Smith 2002).
9.1 Quantitative study (I-III)

9.1.1 Study design

The target population of the study were Finnish immigrants who reside at least part of the year in Spain, in the Costa del Sol region. Finns were chosen as a example population, because it was known that thousands of Finns reside in Costa del Sol and represent a typical group of Northern Europeans that move into Southern European countries such as Spain. The differences between community pharmacy practices in Spain and Finland were another reason why Finns were chosen as an example. The Finnish pharmacy system is strictly regulated, and it emphasises professional practices (Medicines Act 395/1987). Finns as customers are used to practices where pharmacists may dispense either prescription medicines by a prescription or non-prescription medicines for minor symptoms. Dispensing should be accompanied by medication counselling to assure proper and safe use of the medicine. There are other situations where the pharmacists` main professional assistance to patients is not a product but a service, e.g., advice to patients on managing their symptoms without medicines or a recommendation to seek care from a physician. In Spain the system is different. Previous studies have suggested that customers there may have more influence in the management of their conditions because in some cases customers have an option to buy prescription medicines directly from the pharmacy (Figueiras et al. 2000).

The exact number of Finns in Spain is unknown, as many of them are not registered in the official registries. Because of the lack of a precise sampling frame, it was decided to take a convenience sample of the population. Based on the previous knowledge, several years experience and three months observations in the region, it was known that Finnish immigrants actively use services (restaurants, churches, associations) that are offered in their native language. It was also known, that Finnish newspapers were sent to hundreds of Finnish people living in Costa del Sol. The sample method was determined on the basis of previous knowledge and reports from previous studies of EU migrants (Casado Diaz et al. 2004, Karisto 2005). These surveys also were faced with the unavailability of a precise sample frame. The sample size was determined on the basis of information from a previous study performed among Finns living in Spain, and statistical calculations were based on an estimated population of 15,000 (Karisto 2005).
One thousand (1,000) copies of a questionnaire were distributed in two ways: half (500) of the questionnaires were distributed by mail with Finnish newspapers and the other half through Finnish associations and outlets (e.g., churches, cafes, restaurants, communities) in Southern Spain. The researcher visited each of these associations and outlets and explained the idea of the study. These visits continued each week during the data collection, so that questions about the questionnaire could be raised and resolved. The telephone number of the researcher was also available in the questionnaires so that the researcher could be contacted in case of questions. The 16 associations and outlets were asked to distribute the questionnaires (with return envelopes) to individuals using their services. The questionnaire could be brought back either to return boxes of the associations or by mail to the researcher. The researcher advertised the study twice in local Finnish newspapers and once on Finnish Radio in order to raise publicity. The quantitative data (studies I-III) were collected in spring (February 15th—April 15th) 2002. Of the 1,000 questionnaires delivered, 533 were completed and returned (response rate 53%).

9.1.2 Questionnaire

A 12-paged semi-structured questionnaire was used (Appendix 1). Based on the literature review, there is no previous study focused on immigrants and pharmacy services. Therefore, most of the questions in the survey instrument were developed for this study. However, some of the questions were adapted from previously used questionnaires (e.g., those concerning background variables such as gender, age, marital status, and those measuring state of health and occurrence of symptoms) – in particular, the Finnish National Public Health Institute’s questionnaires on Health Behaviour and Health Among The Finnish Adult Population and Health Behaviour Among the Finnish Elderly (Sulander et al. 2001, Helakorpi et al. 2002). Most pharmacy-practice researchers have developed their own survey instruments, but it is also common to use or modify questions or question series from previous questionnaires (Smith 2002). To enhance validity and reliability, the questionnaire was first piloted with ten Finns living in Spain (Fowler 1995, Smith 2002). Based on the results of this pilot study, some questions were clarified and rewritten.

The questionnaire included questions about the following subjects: 1) background variables, 2) health status, 3) experience with community pharmacy services, 4) use of medicines in general, 5) use of antibiotics, 6) use of analgesics, 7) arthritis, 8) coronary heart diseases, and 9) asthma. The use of antibiotics was included as it was known that antibiotic resistance is increasing and that non-prescription use of antibiotics had occurred in Southern European countries such as Spain (Mason
1999, Figueiras et al. 2000). Pain is a very common symptom worldwide and analgesics use is common among Finns (Turunen 2007). Therefore, analgesics use was selected for the study. The specific disease categories were selected because they are generally known to be Finnish public-health diseases, and previous studies had also suggested that climate may have effect on the symptoms of these diseases (Guedj and Weinberger 1990, Rostand 1997, Helakorpi et al. 2002, Verlato et al. 2002). All respondents answered questions in the first four sections. In the latter sections, respondents were instructed to skip questions if they had no experience of the subject.

The background variables included gender, age, duration of time living in Spain, marital status, educational background, working situation, state of residency and the use of health services. Health status was determined based on questions about chronic morbidity and symptoms that had occurred during the previous weeks. The use of medicines in general was studied by asking questions about medicines used, symptoms related to medicine use and medicine use habits and perceptions.

9.1.3 STUDY 1. Health immigrants and analgesic use

The aim of this study was to describe immigration within the EU; determine the proportion of Finnish people who have moved to Spain for health reasons (health immigrants) and determine whether their health care and analgesic usage patterns differed from those of non-health immigrants. Respondents who indicated that health factors played a significant or moderate role in the migration process were categorised as health immigrants. If health-status factors did not affect the migration, the person was categorised as a non-health immigrant. The survey respondents were also categorised into analgesics users and non-users. Analgesic use was defined by asking whether respondents had used analgesics during the previous two weeks (i.e., 14 days). Those who indicated use of analgesics in the previous two weeks were defined as users and were asked specific questions about their analgesic use. Non-users were instructed to continue with questions from other sections. The purpose of this categorisation was to minimise the incidence of recall bias in questions about analgesic use. Information about the use of different Rx and OTC analgesics was gathered with a structured question: “Which of the following analgesics have you used during the previous two weeks?” After the ingredient names, some of the most common brand names were given to facilitate answering. The last alternative was “any other”, which the respondents were instructed to specify (Appendix 1). The list of analgesics was created based on the Finnish Medicine Statistics 2000 in order to incorporate the most commonly used analgesics in Finland. Factors associated
with analgesic use were examined by asking questions to determine background variables (listed earlier). In the analysis, the pensioners and part-time pensioners were grouped together. Language skills as well as the use of public health services were assessed. Three types of questions were asked to determine the respondents’ current health status, and these concerned: 1) health status, 2) chronic morbidity, and 3) the symptoms during the previous two weeks. Respondents were asked to categorise their health status as good, moderate or poor. They were also asked whether they had suffered from chronic morbidity and to list the symptoms they had suffered in the previous two weeks. Statistical analyses were conducted using the statistical software SPSS 11.5 (Statistical Package for Social Sciences). Cross-tabulation was used to compare different groups. Statistical comparison was done by chi-square testing, with p-value <0.05 considered significant.

9.1.4 STUDY 2. Antibiotic use via self-medication

The aim of this study was to determine the frequency of self-medication with antibiotics among the Finnish adult population living in Southern Spain. The population was divided into antibiotic users and non-users by asking “Have you used antibiotics during the previous six months?” Those who answered “yes” to this question were defined as users and continued answering the more specific questions about their antibiotic use. Non-users did not answer the antibiotic questions. The purpose of this categorization was to ascertain the validity and minimise the incidence of memory bias in questions about antibiotic use. Antibiotic users were asked whether they had bought antibiotics pursuant to a physician’s prescription (Prescription-antibiotics) or without prescription (OTC). Those who had used both prescription and OTC antibiotics were categorised as non-prescription antibiotic users. Respondents reported the number of antibiotic prescription courses taken and the name of their used products (when remembered). The purpose of the antibiotic use was asked by giving a list of the possible indications. The last alternative was “any other purpose” with respondents instructed to specify them. To gather some information about the effectiveness of antibiotics, the users were asked whether the first antibiotic course relieved their symptoms. They were also asked how many courses they had to take before healing. The occurrence of adverse reactions was determined by giving a list of the possible adverse reactions to antimicrobial therapies that the respondents may have experienced. The list included adverse reactions known as typical for antibiotics and the last category of response was open, i.e., the respondent could specify any other adverse reactions. Asking questions about background variables and health state identified the factors associated with antibiotic use: sex, age, marital status, working situation, smoking, health state
and chronic morbidity. The data were analysed with SPSS version 11.5 (Statistical Package for Social Sciences). In the analysis, the working situation was reclassified so that the pensioners and partial pensioners were grouped together. Cross-tabulation was used to compare differences between subgroups. To examine the factors related to antibiotic use, statistical comparison was implemented using logistic regression analysis. The adjusted prevalence ratios and their 95% confidence intervals were analysed. The variables which were included in the analysis were age, gender, marital status, working situation, self-reported health, chronic morbidity and smoking.

9.1.5 STUDY 3. Pharmacy services

The aim of this study was to assess Finns opinions of Spanish pharmacy services and their perceptions of risks related to access and use of medicines. The questionnaire included both structured and open-ended questions concerning their experiences with community pharmacy services in Spain. Based on their own experiences, the participants were asked to rate their satisfaction with the following areas of pharmacy services: customer service, counselling on prescription and non-prescription medicines, knowledge and language skills of the pharmacy personnel (in general), and the assortment of medicines available in the pharmacy’s inventory. Responses were scored on a 5-point Likert-type scale (1 = highly dissatisfied, 5 = highly satisfied, including the neutral intermediate choice = 3). In the open-ended questions, respondents were asked: a) which aspects of Spanish pharmacy services they preferred compared to Finnish pharmacy services (and vice versa); b) whether they had encountered problems during visits to pharmacies in Spain and, if so, what kind(s) of problems; and c) how important was it that pharmacy services in Spain be offered in their native language. These study questions were created based on the results of the previous pharmacy services study conducted in Finland (Airaksinen 1996). The data were analysed with Statistical Package for Social Sciences version 11.5 (SPSS). Descriptive statistics of the sample characteristics, background variables and questionnaire items were computed. The open-ended questions were analysed using content analysis. An experienced Finnish pharmacist, who was knowledgeable about the Spanish pharmacy system, independently reviewed the open-ended responses and derived similar themes to those identified by the primary researcher.
9.2 Qualitative study (IV)

The fourth study was conducted by using focus group discussions (FGDs). Focus groups are an effective and interactive way to interview people (Eskola and Suoranta 1998). It was decided to use focus groups because of their ability to capture people’s experiences, attitudes and opinions about the study subject. FGDs are also useful for gathering information about subjects in cases where little is known previously. The group setting helps people to explore their own thoughts and experiences in order to produce more complete responses (Eskola and Suoranta 1998). Also shy group members might be stimulated enough by other people’s opinions to volunteer their own (Eskola and Suoranta 1998). Focus groups have previously been used to analyse the experiences of other health care users, and therefore this method was chosen to collect data about pharmacy services (Lehoux et al. 2006).

9.2.1 STUDY 4. The role of the pharmacy in the symptom mitigation

The survey provided information about the characteristics of the Finns living in Spain, their medication use habits and experiences with pharmacy services. By conducting focus group discussions, it was possible to deepen the information that emerged from the survey in order to create a more comprehensive picture of the role of the pharmacy in the symptom mitigation process of mobile community residents. The interview guide included questions about Spain’s pharmacy system, the pharmacy’s role in the healthcare system and the health seeking behaviour of mobile community residents (Appendix 2).

The data were collected by conducting five FGDs among Finnish people living in Costa del Sol. Five FGDs were conducted in different locations in Southern Spain. The participants were well informed about the study procedures and they had a right to refuse their participation. Five contact persons chose the participants so that the inter-group dynamics were consistent in order to create natural surroundings. However, the groups themselves were different, representing different socio-economic strata from different locations in Costa del Sol (these included: a higher socio-economic group, i.e. "the golfer group"; a lower socio-economic group, i.e., "the pub group"; a church activist group; a suburban community-activist group; and a group of who were caregivers to their close relatives. The group size varied from 5-8 participants. Altogether there were 30 participants, and their age varied from 57-83 years (mean 68 years). Their duration of residency in Spain varied from 1-19 years (mean 8 years). A majority (83%) of the participants suffered from chronic morbidity, and the same proportion of people used Spanish health care services. Half of the participants bought their
medicines from both countries (Finland and Spain), 33% mainly from Spain and 13% mainly from Finland. One-fourth of the participants had some Spanish language skills, while 43% described only having Finnish language skills.

Two researchers were present during the five focus group interviews: one served as a moderator and the other as an observer and a note-keeper. Each session lasted around one hour, and they were tape-recorded and transcribed verbatim. The data was processed confidentially and the results are expressed so that no individuals can be identified. The analyses were done by the researcher (MV), but they were continuously discussed with the note-keeper during the process. This was done to validate the emerging themes and findings. Both inductive and deductive analysis was used (IV: Figure 1.). Deductive analysis was used to determine themes related to the pharmacy’s role in health care and in order to study the themes that emerged from the data: inductive analysis related to the mobile patients’ attitudes, opinions and experiences with pharmacy services.
<table>
<thead>
<tr>
<th>Study</th>
<th>Aim of the study</th>
<th>Method</th>
<th>Analysis</th>
</tr>
</thead>
</table>
| I     | • To describe the Finnish immigrant population living in Costa del Sol region, Spain  
      • To study the proportion of immigrants who moved to Spain for health reasons (health immigrants)  
      • To study analgesic use among Finnish immigrants  
      • To study whether health immigration influenced analgesic use | Survey (n=533) | Quantitative analysis  
      SPSS 11.5 program  
      • Chi-square test  
      • Descriptive statistics on the sample characteristics, background variables, means, standard deviations and frequency distributions |
| II    | • To study antibiotic use among Finnish immigrants in Spain  
      • To determine the frequency of self-medication with antibiotics and examine the factors related to the self-medication | Survey (n=533) | Quantitative analysis  
      SPSS 11.5 program  
      • Chi-square test  
      • Descriptive statistics on the sample characteristics, background variables, means, standard deviations and frequency distributions  
      • Logistic regression analysis |
| III   | • To survey Finnish immigrants’ opinions about pharmacy services and possible risks related to access and use of medicines | Survey (n=533)  
      3 open-ended questions | Quantitative analysis  
      SPSS 11.5 program  
      • Chi-square test  
      • Descriptive statistics on the sample characteristics, background variables, means, standard deviations and frequency distributions  
      • Qualitative analysis  
      • Open ended questions were analysed by content analysis |
| IV    | • To describe the role of pharmacy in the symptom mitigation path of mobile community residents | 5 Focus group discussions (n=30) | Qualitative analysis  
      • Inductive and deductive analysis |
10 RESULTS

10.1 Health immigration and analgesic use (I)

Seventy percent of the respondents (n=365) were categorised as health immigrants as they identified health reasons as having affected their decision to move to Spain (Table 10). Health immigrants differed in their personal characteristics compared to other immigrants; they more often reported suffering from chronic morbidity and they perceived their health status to be worse than did the non-health immigrants. Health immigrants also reported using more public health services and more often receiving reimbursement for their medicines than did the non-health immigrants (Table 10).

Half of the respondents (50%, n=263) reported using analgesics during the two weeks before the query. The most commonly taken analgesics were ibuprofen, aspirin and paracetamol, and the most reported symptoms being treated were articulation pain, headache and common cold/fever. Health immigrants were more often analgesic users and they more commonly used prescription analgesics (diclofenac, naproxen, tramadol and nimesulid) than did the other respondents. Health immigrants also reported using analgesics more regularly than did the others, with daily use occurring among 27% (n=49) of the health immigrants and 9% (n=6) of the others (p=0.02). The concomitant use of prescription and non-prescription analgesics was also more common among health immigrants than the non-health immigrants (p<0.001). Altogether, the concomitant use of prescription and non-prescription analgesics occurred among one-quarter of analgesics users. There was no statistically significant difference in the purchasing behaviours between the groups; most of the respondents (55%, n=144) indicated buying analgesics both from Spain and Finland, 27% (n=70) from Spain and 18%, (n=47) from Finland.

Among health immigrants, analgesic use was related to age, occurrence of pain symptoms and the length of residency in Spain. Analgesic use was decreased with age, but increased among those suffering from headache, joint ache or backache. Health immigrants who had lived in Spain 7-9 years had used analgesics more commonly than did residents of greater or less duration. Among the non-health immigrant group explanatory factors for analgesic use were age, occurrence of headache and joint ache, time of residency and employment.
Table 10. Characteristics of the respondents

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>All respondents</th>
<th>Health Immigrants</th>
<th>Non-health Immigrants</th>
<th>p-value between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>%</td>
<td>n</td>
<td>%</td>
<td>n</td>
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<tr>
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<td>187</td>
</tr>
<tr>
<td>Age</td>
<td></td>
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<td>55-64</td>
<td>35</td>
<td>183</td>
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<td>65-74</td>
<td>43</td>
<td>226</td>
<td>41</td>
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<td>75 or more</td>
<td>11</td>
<td>60</td>
<td>14</td>
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<td>Working situation</td>
<td></td>
<td></td>
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<td></td>
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<td>7</td>
<td>38</td>
<td>3</td>
<td>9</td>
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<tr>
<td>Retired</td>
<td>86</td>
<td>453</td>
<td>91</td>
<td>332</td>
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<tr>
<td>Other</td>
<td>7</td>
<td>35</td>
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<td>Chronic morbidity</td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>Yes</td>
<td>69</td>
<td>355</td>
<td>82</td>
<td>290</td>
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<td>No</td>
<td>31</td>
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<td>18</td>
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<td>Perceived state of health</td>
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<tr>
<td>Good</td>
<td>42</td>
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<td>Moderate</td>
<td>52</td>
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<td>217</td>
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<td>Poor</td>
<td>6</td>
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<td>Pain symptoms</td>
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<td>Headache</td>
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<td>Joint ache</td>
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<td>Years of living in Spain</td>
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</tr>
<tr>
<td>1-3</td>
<td>27</td>
<td>136</td>
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<td>7-9</td>
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<td>10-14</td>
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<td>15 or more</td>
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<td>Use of public health services in Spain</td>
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<td>175</td>
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<td>No use</td>
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<td>92</td>
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<tr>
<td>Reimbursement for analgesics</td>
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<td></td>
</tr>
<tr>
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<td>136</td>
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</tr>
<tr>
<td>Yes</td>
<td>49</td>
<td>129</td>
<td>54</td>
<td>105</td>
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</tbody>
</table>
10.2 Self-medication with antibiotics (II)

Of the respondents, 28% (n=145) had used antibiotics during the 6 month period before the query. Almost one-third (31%) of the antibiotic users had bought their antibiotics without a prescription, and 10% reported concomitant use of prescription and non-prescription antibiotics. Altogether 41% of the antibiotic users were using antibiotics as self-medication.

Most of the antibiotic users (64%, n=93) reported the use of one course during the previous six months, 30% reported using two or three courses, and six per cent four or more courses. Statistical differences in the number of courses or their effectiveness could not be found between prescription and non-prescription antibiotic users. The first course was perceived to be effective by 69% of the antibiotic users. Clearly, the most common reason for the antibiotic use was common cold (Figure 8). This applied to both use prescribed by the physician and self-medication with antibiotics.

![Figure 8. Reasons for antibiotic use and the proportions of self-medication](image-url)
Antibiotics caused adverse reactions in 17% of the users. The most common self-reported adverse reactions were stomachache/diarrhoea (5%) and dermatological problems (4%). Statistical differences in the prevalence of adverse reactions could not be found between prescription and non-prescription antibiotic users.

Of the background variables, only chronic morbidity affected antibiotic use (p<0.05, 32% vs. 16%). No statistical differences could be found between those who had used prescription or non-prescription antibiotics.

10.3 Finns’ experiences of community pharmacy services in Spain (III)

Of the services offered by Spanish pharmacies, respondents were most satisfied with customer service, followed secondly by the pharmacy personnel’s knowledge, and thirdly by the assortment of medicines available (Figure 9). The most dissatisfaction concerned the pharmacy personnel’s language skills.

Respondents were more satisfied with counselling on OTC medicines than the counselling on prescription medications (58% vs. 49%). Satisfaction with OTC medication counselling, the language skills of the pharmacy personnel and the assortment of medicines available were associated with the Finnish respondents’ Spanish language skills and time of residency in Spain (p<0.05). In addition, dissatisfaction with prescription medication counselling was reported more often among those who had lived in Spain for 3 years or less (chi-square p<0.05).

Altogether 60% of the respondents answered the three open-ended questions (n=318). Table 11 shows the positive and negative experiences with Spanish pharmacy services.
Figure 9. Satisfaction of the respondents with Spanish pharmacy services (% of those who had experiences with the service area)

Table 11. Positive and negative opinions about Spanish pharmacy services

<table>
<thead>
<tr>
<th>Positive</th>
<th>Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Easy access to all kinds of medication in the pharmacy, also prescription medications are sold without prescription</td>
<td></td>
</tr>
<tr>
<td>- Less bureaucratic, flexible and customer friendlier than pharmacies in Finland</td>
<td></td>
</tr>
<tr>
<td>- Cheaper prices (in 2002)</td>
<td>- Medicines are too easily available, there should be stricter control</td>
</tr>
<tr>
<td></td>
<td>- The professional skills and medication counselling of lower quality than in Finland</td>
</tr>
</tbody>
</table>
Almost a fifth of the survey respondents reported experiencing problems during visits to pharmacies in Southern Spain; the lack of a common language caused most of these problems (n=51). In eight cases respondents reported receiving a prescription that contained a medication error. Most of these cases concerned a wrong medication from the pharmacy. Other problems concerned service, pharmacy workers’ knowledge, medicine stock and differences between Spain and Finland in approved medicines. Those who had experienced problems were more often suffering from chronic morbidity than were those who had not experienced problems (88% vs. 66%). They also described a worse state of health. Sixty-eight percent of those having problems had no Spanish language skills. Altogether, 43% of the respondents reported having at least some Spanish language skills.

10.4 The role of the pharmacy in the symptom mitigation path of mobile community residents (IV)

Based on the results, a symptom mitigation path for mobile community residents was created (Figure 10). The path describes the sequence of alternative events that may occur when a symptomatic mobile community resident uses community pharmacy services.

The first step in the symptom mitigation path is to choose whom to contact when symptoms occur. Ambulatory patients in this study managed their symptoms by: contacting either pharmacies or general practitioners (or other health care professionals); managing the symptoms on their own; or soliciting help from friends and relatives. In many cases pharmacies were described as a more convenient and flexible way of obtaining information and medicines than were medical doctors or other health care professionals. They reported that pharmacies were easy to access and did not have long waiting hours, and that the services did not cost extra. Pharmacies were chosen especially in those cases when the focus group participant knew in advance what they wanted. They reported that this prior knowledge was based on their own previous experiences, relatives’ and friends’ advice or other health care professionals’ recommendations. In many cases, participants knew in advance whether it would be possible to buy prescription medicines without a prescription in the pharmacy that they used. Therefore, they found it pointless to contact a physician as they thought that would merely result in getting the same prescription medicine that they could have purchased directly from the pharmacy on their own.
If the participants chose to contact pharmacies, they were served either by a professional pharmacist or by sales clerks. The participants recounted that in Spanish pharmacies both pharmacists and sales clerks had sold medicines to them. It was not always clear to the participants whether the person serving them was a pharmacist or a clerk. However, those who had lived in Spain for a longer period had a better understanding. Although a sales clerk handled the general dispensing of medicines, participants realised that there was at least one pharmacist in every pharmacy and that the sales clerk could contact this person if questions or any problems arose. It was acknowledged that the salespeople were eager to serve, but the extent of their knowledge of medicines was questioned. Pharmacists, by contrast, were appreciated for their professional skills.

Pharmacists may dispense either prescription medicines by a prescription or non-prescription medicines for minor symptoms. There are other situations where the pharmacists` main professional assistance to patients is not a product but a service, e.g., advice on handling their symptoms without medicines or a recommendation to seek care from a physician. Among this study’s sample of mobile patients, it was commonly reported that in Spanish pharmacies there was an extra option of buying prescription medicines directly from the pharmacies without a prescription. Altogether 90% of the participants reported having used this option. Examples of products that participants reported purchasing without a prescription included antibiotics, sleeping pills, Viagra®, asthma medications, cardiovascular medicines, psoriasis medicines and analgesics. Such purchase-decisions were sometimes based on a physicians´ diagnosis, but other times based on input from the pharmacy employees or even self-diagnosis. Some people bought medicines for which the original physician's prescription had expired. Some just needed something for acute conditions. Some participants bought medicines in Spain to bring with them upon returning to their home country as the medicines were believed to be cheaper and stronger in Spain. Respondents appreciated the flexibility and convenience of buying prescription medicines directly from the pharmacy, although they noted that problems may occur if people do not know what to buy and if they do not receive instructions on how to use their medicines properly.
In conjunction with medication dispensing, pharmacists offered medication
counselling so that the respondents would know how to use their medicines.
Respondents received instructions such as how many units they should take per
day. But too often, the medication counselling did not include information about
possible adverse reactions or interactions with other medicines, food or alcohol.
Lack of information was mostly explained by the lack of a common language
between the customer and the pharmacy worker. Respondents who purchased
prescription medicines directly from the pharmacy without a prescription reported
that they often knew the active ingredient, but not the dosage or strength of the
medicine. One of the respondents’ themes is that they are expected to
understand the instructions by themselves. Package information leaflets (PILs)
were frequently used as the sole source of information. As many people did not
understand the language in which the leaflet was written, they were unable to
read them. Consequently, they consulted their friends and relatives. Responses
identified “the grapevine” as an important source of medicine information.
Figure 10. Symptom mitigation path for mobile community residents
11 SUMMARY OF KEY FINDINGS

<table>
<thead>
<tr>
<th>RETIRED MOBILE CITIZENS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Usually elderly</td>
</tr>
</tbody>
</table>

Need to use health services

Pharmacies have an important role in their symptom mitigation process

Pharmacies do not always meet the needs of mobile community residents

Lack of common language  
Lack of medication counselling  
Irrational use of medicines  
Medication safety risks

Figure 11. Conclusion based on the results
12 DISCUSSION

12.1 Immigrants or mobile patients?

In this study, I have concentrated on Finnish mobile community residents and mobile patients living in Spain. It should be noted, however, that the Finnish immigrants represent only a minority of the total group of migrants within the EU. The number of Finns living in Spain has been estimated to be from 15,000 to 25,000, whereas about one million British people are estimated to own properties in Spain (Hardill et al. 2004). Regardless of the size of these and other immigrant groups, there are many similarities among them: they all reside in Spain, use Spanish healthcare services and most do not have Spanish language skills or speak Spanish as their native language (Gustafson 2001, Casado-Diaz et al. 2004). Of Finnish immigrants, 43% described having at least some Spanish language skills. Even though the results of this study only describe the situation of Finns in Spain (and other migrant groups may have their own variances), the results may tell us something about the role of mobile community residents within the EU. In Spain there is also a remarkable number of immigrants from developing countries that may have their own lessons to teach.

Most of the Finnish immigrants in Spain were more than 55 years old (89%) and retired (86%). This kind of age trend also exists among studies conducted with other immigrant populations (Casado-Diaz et al. 2004). A large proportion of Finns (70%) described moving to Spain for health reasons, and 68% reported using public health services in Spain. As many of these people are in their “third age” (time period between the end of working period and old age) or are elderly and suffer from chronic conditions, it is not surprising that these immigrants have a greater need of health services than the normal/younger population. As the number of mobile patients may increase in the future, it would be necessary to know the number and background information on these people so that these facts could be taken into account when planning health services. At the moment, the problem is that most of the migrants within the EU are categorised as “floating population”, that is, they have not filled in official residence applications as they spend part of the year in their home country and another part in Spain. This population does have access to necessary public health care services by EHIC – the same as tourists – but they burden the local health care services with their unplanned needs. The improvement of these services becomes difficult if the number of this immigrant population is not known. Many of these immigrants might have fears about formally changing their residency to Spain as they also spend part of the year in their country of origin. These factors should be taken into
consideration in the EU. It would be valuable to evaluate whether it would be possible to create a system in which residents could reside part of the year in another member state and register there as "partial residents" who would have access to local health care services. This kind of system would benefit individual patients and would also be valuable in evaluating inter-member state healthcare costs.

Clearly the issue of responsibility for these patients should be resolved. Should the floating population, or partial residents, be the responsibility of their country of origin or should each EU member state be required also to offer health care to all of their immigrants? Could there be agreements between countries that would count the expenses of each country by the registers of their partial residents (their lengths of stay and usage of services)? At the moment, the system is incomplete. Those countries having large numbers of immigrants may be unwilling or financially incapable of offering extensive services to their immigrants since even their current expenses are inadequately covered (Rosenmöller and Lluch 2006).

12.2 The role of the pharmacy in the healthcare of mobile community residents

A large number of immigrants were using public health services, but private pharmacy services also seemed an important part of their healthcare. Among the Finnish immigrants, the pharmacy was used as the primary contact with the healthcare system. Participants described easy access and free services as a motivator for using the pharmacies. In some cases, respondents thought it to be waste of time to contact a medical practitioner, believing that they themselves knew best what was wrong with them and therefore knowing what to buy from the pharmacy. Similar to practices in developing countries, the possibility of buying prescription-only medicines without a prescription probably has increased the use of pharmacies at the expense of medical practitioners (Van der Geest 1987, Hardon 1987, Greenhalgh 1987, Price 1989).

Survey respondents found pharmacy services and the knowledge ability of the personnel satisfactory, even though it was not always clear whether they were in contact with a trained pharmacist or a clerk. In focus group discussions, some participants argued that pharmacy personnel could be the equivalent of ironmongers, that is, you get what you order at the hardware store, which is okay as long as you take responsibility for your choices.
Although the pharmacy was felt to be an important part of the immigrants’ healthcare experience, in many cases they found medication counselling dissatisfactory. In focus group discussions respondents described the process of medication counselling as “they give you the medicines and tell how many times a day you should take them”. But is this enough? In recent years, developed countries have developed advanced comprehensive pharmacy services and described pharmaceutical care as an important part of these pharmacy services (Farris et al. 2005). These kinds of services may be offered to Spanish customers in Spain (Gastelurrutia et al. 2005), but the services offered to the immigrants there seem less comprehensive. The minimum requirement should be that the pharmacist/salesclerk selling the medicines should ensure that the customer does not have any contraindications to the products and that the customer knows how to use the medicine safely. When considering immigrants, many of them are advanced in years, suffer from chronic morbidity, and use medicines regularly. These factors should be taken into account in pharmacies, otherwise the medication safety of these immigrants may be jeopardised. After all, it should be noted that pharmacists in the EU are expected to adhere to the internationally acknowledged professional standards of assuring high quality, safe and effective pharmacy services for all clients (FIP 1997, 2004).

This may sound simple, but it is not. In most of the cases, immigrants and pharmacy personnel do not share the same language. It cannot be expected that all Spanish pharmacists will speak foreign languages. Therefore those member states having immigrants in Spain or any other mass migration area (e.g., Southern France) should collaborate to find solutions to tackle the problems. A good example of such co-operation is EMEA’s data bank, which may in the future provide a patient information tool to overcome some of the language barriers (Wagner 2005). This multilingual data bank will include a summary of product characteristics and patient information. Both healthcare professionals and patients will have access to this databank. For example, the FGDs participants in this study described the problem of understanding the information in PILs, which were written in Spanish. The databank may solve this part of the problem. However, it will not solve all problems; the lack of individual medication counselling still exists and elderly immigrants and those with low educational skills may find this computer-based service difficult to use. It should also be noted, that a lack of information is not always the core of the problem. Nowadays people have access to masses of information by the Internet, but they may not know how to use this information properly (Peterson-Clark et al. 2004). There is always the possibility that, when the amount of readily available information increases, people will start making their own diagnoses and go directly to pharmacies to buy prescription medicines for their symptoms.
As it is predicted that the number of mobile community residents will increase in the future, there should be some EU-wide consideration of how to manage the health care of these people, especially in the mass-immigration areas. Perhaps it would be possible to provide EU-funded language courses to healthcare professionals so that there would be at least one English-speaking professional in each centre. To avoid this being construed as a compulsory practice, it could be presented as an opportunity to develop a competitive asset. There could alternatively be multilingual healthcare centres in tourist areas employing professionals from all the EU nations having immigrants in the area. In Spain, many private clinics are offering services in the customers’ native language, but similar services cannot be found in public clinics or pharmacies. However, pharmacies have an important role in the health care of immigrants, and unless the practice of selling prescription medicines without a prescription suddenly ceases, they could well become the only healthcare units to have contact with patients prior to pharmacotherapy. Therefore, pharmacy personnel should be well educated and able to answer the needs of their customers.

12.3 Medication use among immigrants – how safe and rational is it?

Most of the Finns in Spain were aware that they could buy a wide range of medicines directly from some pharmacies without a prescription, and some of them had done so. A large number (41%) of antibiotic users had bought their antibiotics without a prescription and also some prescription analgesics were bought without a prescription. In focus group discussions, participants reported that they had used antibiotics, sleeping pills, Viagra®, asthma medications, cardiovascular medicines, psoriasis medicines and painkillers without prescriptions. Many of these medicines were originally prescribed for them by their physicians, but some of the other diagnoses were made in pharmacies or by the customer. Does it constitute rational use of medicines when they are used based on a friend's or one's own diagnosis? Participants said that it was common for their friends, relatives or the grapevine to have an effect on their medication use habits.

In developed countries, pharmacies are normally seen as a stepping-stone to the general practitioner, and people tend to contact pharmacies to seek help for minor ailments (Hassell et al. 1997). In Spain, the role of pharmacy is much broader; by offering prescription medicines without a prescription, the pharmacist or sales clerk might become responsible for the overall healthcare of the patient. Patients are less likely to go to medical practitioners as they can gather everything they
need – both diagnosis and the medication – easily and directly from the pharmacies. But are pharmacy personnel capable of doing all this on their own? Pharmaceutical care in the areas of preventing drug-related problems and in follow-up treatment of chronically ill patients has been demonstrated to be effective in many studies (Chamba et al. 1999, Westerlund et al. 1999, Närhi et al. 2000, Tully et al. 2000, Närhi et al. 2001, Schulz et al. 2001, Leemans et al. 2003, Van Mil 2005, Fornos et al. 2006, Mangiapanne et al. 2005, Paulos et al. 2005). But in pharmaceutical care, most of the decisions are made in co-operation with different healthcare professionals, especially physicians.

This kind of action may not be defined as pharmaceutical care, but what then is it and why are pharmacies committing to it? Most of the participants in this study appreciated the freedom of being able to go directly to the pharmacy. Does this simply mean that the Spanish pharmacy system is good at customer service? Is selling medicines to the foreigners merely a business matter? Some of the participants of this study said that they bring medicines back to Finland as some of the medicines (for example, strong cough medicines) are difficult to obtain from Finnish pharmacies as they always need an original prescription. Good business or not, there should be clear control over what it means when a medicine has a prescription status. Within the EU, national authorities make decisions on Rx-to-OTC switches. In Spain, “by prescription only” is printed on prescription medicine packets, but despite the label, the medicines can be bought without prescription in some pharmacies. It is an illegal, but common practice (Figueiras et al. 2000, Caamano Isorna et al. 2004, Barbero-Gonzalez et al. 2006, II). The Spanish government has tried to enforce the regulations (Scrip 2005), but it continues to be a problem.

These findings indicate that regulations and their enforcement can play a crucial role in actually assuring the rational use of medicines. It is interesting to see that Finns, who are used to a strict policy with access and use of prescription medicines in their home country, totally change their medication use habits when they live in a less strictly regulated country. However, it may not be enough to enforce the regulations, because as long as customers are demanding prescription medicines without prescription and are ready to pay for them, at least some pharmacies may continue to sell them. Could the competition between pharmacies force some to sell as much medicine as possible, even though they may recognise the health risks? As mentioned in the focus group discussions, some pharmacists may think that they will never get caught if they sell prescription medicines to the foreigners. It could be that the health risks are widely recognised, but as long as this is not an actual problem among Spanish customers, are Spanish authorities supposed to take the whole responsibility or should the EU
It is important to persuade customers not to buy prescription medications without a prescription and raise awareness of the medication safety risks related to this action. They may not understand that these medicines are Rx medicines and that there are risks related to these medicines, perhaps seeing these medicines as less harmful, since they were available without prescription. They may also assume that the medicines pose fewer risks than strictly prescription-only medicines. In FGDs, some participants did recognise the safety risks, but many thought that they knew enough to make their own decisions. There are several risks related to this kind of action: a person with symptoms may go to the pharmacy, rely on the pharmacy workers’ knowledge (who might not be a pharmacist) and end up using a prescription medication without getting a proper diagnosis or any medication counselling or instructions on how to use the product.

There is no harmonised policy on community pharmacy practises within the EU, as each national community pharmacy system is individual and has its own cultural and historical roots (Vogler et al. 2006). There is no one correct system to which all the other systems should transform. However, there are criteria that professional pharmacists should meet. The WHO emphasises the pharmacist’s role in the rational use of medicines, and the EU has guidelines on which medicines can be sold without a prescription (European Commission 2006). In addition, the FIP emphasises the professional responsibility that pharmacists have to provide sound, unbiased advice and to ensure that self-medication occurs only when it is safe and appropriate to do so (FIP 1996, 1997).

12.4 Theoretical considerations – advantages and limitations

The pharmaceutical policy perspective was chosen for this study in order to investigate how community pharmacies and mobile community residents are taken into account in EU’s pharmaceutical policymaking. The aim was for the study results to raise awareness of these issues, and to be used in the development of pharmaceutical policies at national and EU levels. Other theories and approaches could have been used to study this phenomenon (e.g., “professions theory” or “theory of risk society”), but pharmaceutical policy was chosen as it has the potential to contribute to policy change.
Policy changes are often based on the evaluation of older policies: in this case the policy approach in the literature review made it possible to evaluate the strengths and weaknesses of older policies, and the aim of the results was to provide evidence in which new policies or modifications of older policies could be based (NSW Health Department 1998). Using the pharmaceutical policy approach gave a clear structure for the analysis and interpretation of results that might provide ideas and suggestions that can directly be applied to policy development and change.

In the beginning of this study process, it was not clear that the pharmaceutical policy perspective would be chosen. In the first phase, the object of the study was examined using a more epidemiological approach, and the medication use of mobile community residents was the main focus of the study. This changed, however, as mobile patients became a more important part of the EU's health policies. Consequently, it became clear that the pharmaceutical policy perspective was lacking. The policy perspective and the desire for the research to contribute to policy change made the study both inspiring and challenging since, based on the literature, there are many different stakeholders that influence actual policymaking and determine if there is a need for policy change. This is the complex situation into which the present work was introduced, with a clear knowledge of the way that policymakers actually frame a situation will strongly influence the subsequent development of policies (Traulsen and Almarsdottir 2005c).

A variety of conceptual perspectives could have been used to study this phenomenon and they all would have had lessons to teach. For example, it could have been interesting to study the patients´ help-seeking process in more depth: especially how the symptom mitigation process of mobile community residents differs from non-mobile community residents. This approach could have contributed to a deeper understanding about differences between these two groups. With knowledge of these differences, the needs of the mobile community residents could have been identified and appropriate health care services could have been developed in the areas where mobile community residents reside. Although the pharmaceutical policy approach also provided valuable information about community pharmacy services, this approach excluded other health services from this study. One alternative approach would have been to study, in more depth, risks related to using health care services abroad. The present study identified several risks related to the use of community pharmacy services in Spain. A risk approach could be applied in the future, in order to understand risks related to the use of any health care services, and possibly leading to their improvement and to contributing to a higher level of public health within the EU.
Since the 1960s, there have been two main objectives in political decisions in the EU regarding pharmaceutical policies, i.e., ensuring public health, and ii. promoting industrial competitiveness. However, neither community pharmacies nor mobile community residents are mentioned in the context of pharmaceutical policies (European Commission 2000b). This made it more challenging to study this phenomenon, as there were no previous studies, which applied the pharmaceutical policy approach to the understanding of medication use, the role of community pharmacies and the symptom mitigation process of mobile community residents. On the one hand, due to the lack of the previous studies, the literature review was mainly based on the studies conducted on non-mobile community residents. On the other hand, the lack of previous studies made the research inspiring and exciting. Studying this subject was found to be important in raising the awareness about a phenomenon of which there was very little previous knowledge.

It was known that the number of mobile community residents within the EU has been increasing and that the developing Union with its new member states will face unique challenges to the development of pharmaceutical policies in the future. It was inspiring to follow the development of pharmaceutical and health care policies during these years. During the years the study was being conducted, mobile patients have become an important issue in the EU’s health policy agenda, and their rights to health care services (other than community pharmacies) have been broadly discussed in this context (European Commission 2003c, 2003d, 2004). However, the use of medicines or community pharmacy services has not been part of this discussion. This study provides additional information about the use of community pharmacies as a part of the total spectrum of health care services. Politicians do not always recognise community pharmacy services as a part of health care services, but the results of this study suggest that, the role of community pharmacies is important, at least in the symptom mitigation process of mobile community residents. One reason why community pharmacies are seldom mentioned in the EU’s pharmaceutical policies may be that health care services have been mainly the responsibility of the member states and have therefore received less consideration at the EU level (Treaty of Amsterdam 1997, Article 152, Directive 2005/36/EC). Studying this phenomenon from the pharmaceutical policy approach helped to clarify that pharmaceutical policies should consider the role of community pharmacies; that policy should not only be developed at the national level, and that general minimum standards for these services should be developed and evaluated.
12.5 Methodological considerations and limitations

None of the study methods are absolutely accurate or non-biased. In this study method-triangulation was used to strengthen the study methods employed. However, by using several methods, it should not be assumed that weaknesses in one method would necessarily be compensated by strengths in another. Triangulation should be seen more as a way of ensuring comprehensiveness (Mays and Pope 2000).

12.5.1 QUANTITATIVE STUDY I-III

In this study, a survey questionnaire was used. Surveys are widely used in pharmacy practice studies as a way to obtain data from a large group of people and to generalise the findings to the larger population (Smith 2002). It is also argued that survey research requires less time and is cost-saving compared to individual interviews (Smith 2002). However, the survey instrument should be well designed in order to measure what it was intended to measure. It should be suitable and effective in eliciting to potential responses (Smith 2002). The length of the questionnaire should also be reasonable. There is always a possibility that some questions will be misinterpreted or that people will not be able to provide the information (recall bias). Sampling procedures, sample size and response rates may affect the generalisability (Smith 2002). In this study, a convenience sample was used. A convenience sample is the selection of the most readily accessible or willing individuals, and it can be a useful way of collecting information on an otherwise difficult-to-access population (Smith 2002). However, convenience sampling diminishes generalisability and the value of the research, especially if other methods could be employed (Smith 2002). Overall, there are many issues that impact on the reliability and validity of the research.

Reliability

Reliability means the replicability and repeatability of the results. The higher the quality of the method, the lesser the amount of random "noise" in the results (Golafshani 2003, Taanila 2006). When measuring with a reliable method, the results of the study should be about the same regardless of when the study was conducted (test-retest reliability), or who was involved in the study (inter-rater reliability) (Roberts and Priest 2006). Factors that might decrease the validity include small sample size and errors during different study periods (for example, misunderstanding the questions, memory biases, motivations, and the situation and place in which the responses were given) (Taanila 2006).
Although questionnaires are generally an efficient method of gathering factual data, it should be assured that respondents are able to provide the data asked (Smith 2002). When people are asked to recall events (e.g., medicine use in the past), answers may be inaccurate (Smith 2002). In this study, we asked about analgesics use relating to the preceding two-week period. Klungel et al. (2000) argue that questions that ask about medications that were used during a preceding two-week period do tend to provide accurate information (Klungel et al. 2000, Smith 2002). On the other hand, it has been argued that events that are exceptional can be remembered for a longer period of time (Smith 2002). In this study participants were asked about their antibiotic use during the previous six months. Antibiotic use was classified as a more infrequent activity, and therefore, it was assumed that participants would remember it for a longer period. However, it is always possible that some inaccuracy in the answers may have occurred.

Validity

Validity describes the extent to which the study has measured the aspects it was supposed to measure. It can be divided into external and internal validity (Tuomi and Sarajärvi 2003, Roberts and Priest 2006). Internal validity could be increased by piloting the questions (content validity), comparing the questionnaire with other validated measurements of the subject (criterion validity) and by demonstrating the relationship between the concepts under study and the theory (construct validity). In this study, we piloted the questionnaire with 10 people who were similar to the intended study participants. To increase criterion and construct validity, and because we had no previous validated study methods or theories about the subject, the questionnaire was compared with several validated questionnaires that measured subjects under similar themes.

External validity is related to the generalisability of the results. If the sampling method is not valid, the findings cannot be generalised to the target population. An unrepresentative sample could be caused by errors in the sampling framework or by a low or differential response rate. Low response rates raise the issue that non-respondents may differ in some important or relevant way from the respondents; the results cannot be generalised to the whole population, but the respondents should be seen as a self-selected group. Non-respondents may include those who refused to participate, those who were unable to respond and those who were unable to provide the required information (Smith 2002). Low response rates cannot be compensated for solely by increasing the sample size. In this study, the response rate was 53, which is moderate for these kinds of studies (Heikkilä 2001, Smith 2002).
The sampling method of this study may have limited its external validity. The first challenge in designing the sampling method that emerged was the sampling frames. For a probability sampling frame, a list of the members of the population would have been preferable. However, there was no accurate information specifically about the Finns living in Spain, only estimates about their numbers as only a small percentage of this population is registered to the official registries. As a consequence of the absence of a sampling frame, it was not feasible to take random samples of the Finnish people living in Spain. The sampling method consisted of sending out the questionnaires with newspapers and by handing out the questionnaires to different associations in the Costa del Sol region. The questionnaire distribution centres were chosen based on their location and function within the community. They were located in different cities in Costa del Sol, and they gathered people from different backgrounds, ranging from the wealthy/active to the underprivileged. It is possible that this method resulted in a biased sample, but if only the registered population were studied, it would have been seriously biased. In addition, it would then not have been possible to study the same aspects examined in this study, since the registered population (if retired) may get all of their medicines for free (e.g., if they have a prescription from a general physician working in a public health centre). Therefore, it was assumed that among this population it would be uncommon to self-medicate and use the pharmacy as the only source of health information. In this study the main focus is on the role of the pharmacy and on self-medication with prescription medication. Therefore, by studying only those who had officially become residents, the study would have lost its meaning. This sampling method had been used in an earlier study made of Finnish immigrants in Spain (Karisto 2005). Indeed, a large number of the migrant studies have been conducted by using associations and snowballing in order to deliver questionnaires (Casado-Diaz et al. 2004). These surveys also were faced with the unavailability of a precise sample frame (Casado-Diaz et al. 2004).

12.5.2 QUALITATIVE DATA (IV)

Qualitative research have been criticised as lacking scientific rigour (Mays and Pope 1995), especially concerning limitations on the generalisability of its results. There are different opinions on whether qualitative study results could or even should be generalised (Smith 2002). Random samples are often not feasible and sample sizes may be too small to perform quantitative statistical analysis (Pope et al. 2000). More than gathering large amounts of data, the aim of the qualitative study is to gather deeper information about the phenomena in typical community settings (Pope and Mays 1995). Therefore, the number of focus groups interviews needed is not often determined at the beginning of the study, but decided based
on the rule of saturation (Eskola and Suoranta 1998). In qualitative research, generalisations are not made directly from the data, but from interpretations based on the data (Eskola and Suoranta 1998). Eskola and Suoranta suggest that the factors that influence the generalisation are the study subjects. It is preferable that they share a similar world of experiences and have some background information on, and interest in, the study subject. In this study, these factors were taken into consideration in the study design. The groups themselves were homogenous, but we created differences in the characteristics between groups. By bringing together individuals who share similar characteristics, it deepens and adds richness to the discussions (Lehoux et al. 2006). All of the participants had used pharmacies and were of a similar age, though groups were gathered from different socio-economic backgrounds in order to elicit broader perspectives from the subjects and to allow for comparisons. This also increases confidence in the reliability of the findings (Smith 2002). In this study, the issues that emerged in interviews were similar regardless of the group characteristics. Even though this does not strictly enable generalisation of the results, it does indicate that the beliefs and experiences do not represent only the views of a specific group. The interpretations should not be based on occasional pickings from the material, but to commonly reoccurring themes (Eskola and Suoranta 1998).

Reliability

The role of the researcher is one of the key issues affecting reliability. The reliability of qualitative research concerns the reproducibility of the findings, that is, the consistency between raters in the data collection (Smith 2002). The researcher should be aware of his subjective role, as an absolute objectivity is impossible to reach. Therefore, using more than one researcher may increase the reliability of the study if they are calibrated. It is also important to keep notes of the decisions that have been made throughout the process (Roberts and Priest 2006). In order to enable the reader to assess the reliability of the study, the study design and analysis methods must be described in detail (Mays and Pope 1995). All of the records and transcribing should be made accurately and include procedures designed to assure the accuracy. (Roberts and Priest 2006). In this study, two researchers conducted the discussions, one as a moderator and the other as an observer and note-keeper. The same two researchers performed the analysis, in order to avoid bias. However, this does not assure absolute objectivity of the results, as both of the researchers did have some previous knowledge of the study subject.
Validity

Validity is described as how well the research tool measures the study subject (Roberts and Priest 2006). Researcher bias may be one factor affecting the validity of the study. The influence of the personal characteristics of the researcher and their educational backgrounds should be taken into account (Mays and Pope 2000). It should be assured, that all the potential issues that are important to the participants are raised and that all identified participants are able to attend the discussion (Smith 2002). In this study, the sizes of focus groups were defined so that no one would be left out. However, the moderator has a major influence in guiding the conversations, and therefore it is important that the moderator maintain objectivity during the interviews. On the other hand, there is also a risk of researcher bias during the analysis. It has been discussed that it could be both advantageous and problematic if the researcher was familiar with the study subject (Roberts and Priest 2006). In this study, the researchers tried their best to be non-reactive and impartial during the study. On the other hand, previous knowledge about the subject enabled a deeper understanding of the outcomes of the interviews.
13 CONCLUSIONS

Based on the results of this study, the following conclusions can be drawn:

1. A large number of Finns in Spain are elderly and suffer from chronic morbidity. They are therefore assumed to have a greater need of healthcare services than the general population. Meeting immigrants’ health-service needs poses a challenge to the authorities in countries with high immigration rates – particularly if the immigrants are not assimilated into the society. This problem will grow as the number of immigrants continues to increase within EU countries.

2. Pharmacies provide open access and may be the first and most frequent continuing contact that an immigrant has with a nation’s healthcare system. Thus, community pharmacies play a role in a nation’s primary healthcare system, particularly regarding relief for minor symptoms, access to medicines and assurance of their safe use.

3. Community pharmacy services, however, did not meet all the needs of the immigrants, and there were several patient safety risks related to the actions of the pharmacies, including:
   
   a. Prescription medicine use without prescription
   b. Irrational use of medicines (e.g., needless use and use by self-diagnosis)
   c. Language barriers between mobile community residents and pharmacy practitioners (pharmacists and sales clerks)
   d. Lack of medication counselling
   e. Inadequately educated pharmacy personnel taking responsibility of the dispensing of patients’ medications
13.1 Policy implications

- All of the member states of the EU should take responsibility for promoting public health goals in their national policies regarding the rational use of medicines and medication safety. Programmes on these topics should also be offered to lay public.

- It would be important to define the role of the pharmacy in health care, and there should be European-wide minimum standards for pharmacy services as well as detailed strategies on how these could be implemented in each country.

- In every member state, there should be strict control over the regulations on which medicines can be obtained without prescription.

- Mobile patients should be added to the health and pharmaceutical policy agenda in the EU, and plans should be made so that, in the future, the mobile patients are able to rely on the safety and quality of health care services (including pharmacy services) in every member state.

- It is important to consider where the responsibility lies for these mobile patients and partial residents within the EU. The member state where migrants reside may not have resources to take all of the responsibility. The present system may not meet the needs of, e.g., immigrants who spend part of the year in Spain and another part in their country of origin.

- It would be important to more accurately estimate the number of the “floating population” so that they can be taken into account in planning local health services in the mass-immigration areas.

- The language barrier seems to be a cause of medication safety risks among mobile patients. The options to improve the language skills of both immigrants and health care professionals in Spain should be considered.

- The possibility of establishing EU funded multilingual healthcare centres and pharmacies in areas where millions of mobile community residents reside should also be considered.
13.2 Further research

This study demonstrates that there are developing issues regarding healthcare and community pharmacy services for mobile community residents within the EU. Additional study is recommended:

- to understand how the healthcare of mobile patients is managed in the EU
- to study mobile patients’ needs and their health service (including community pharmacy service) usage in the EU
- to examine the origins, occurrence and outcomes of the potential problems that mobile patients are facing
- to study the rationality of self-medication among mobile community residents
- to examine different approaches to creating drug reimbursement systems for mobile community residents.

These kinds of EU-wide studies could be implemented in co-operation with those member states that have large numbers of their citizens residing in another member state. The studies would be valuable for the implementation of EU-wide policies concerning the safety and status of mobile patients and immigrants within the EU.
14 REFERENCES


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APPENDICES

APPENDIX 1

QUESTIONNAIRE

This free translation of the questionnaire does not include all the questions. Only questions relevant to this study were translated.

BACKGROUND DETAILS

Gender
  1  Male
  2  Female

Year of Birth
  19__

How many winters have you stayed in Spain?
  __ Winters

Do you live in Spain?
  1  Around the year
  2  During winter time
  3  Few months per year
  4  Other, please define?

________________________________________________________________________

Are you
  1  Single
  2  Cohabitation without marriage
  3  Married
  4  Divorced
  5  Widowed

Are you living
  1  Alone
  2  Together with a spouse/partner
  3  Together with a member of your family
  4  Together with someone else

Are you
  1  Working
  2  Part-time pensioner
  3  Pensioner
  4  Other, please define?
What is your education?
1 Elementary school
2 Middle school
3 Graduate
4 Vocational school
5 University/College/Polytechnic
6 Other, please define?
______________________________________________________________

What is your current/former occupation?
______________________________________________________________

Did healthcare related matters play a role in your decision to move into Spain?
1 None
2 Moderate
3 Important role

Do you use Spanish public healthcare services?
1 Never
2 Sometimes
3 Often
4 Always

Are you able to communicate with some of the following languages (You can mark multiple languages)?
1 Spanish
2 English
3 French

STATE OF HEALTH

How would you describe your overall state of health currently?
1 Poor
2 Average
3 Good

Are you suffering from any long term disease?
1 No (Please move the question XX)
2 Yes, what? (please list all)
______________________________________________________________

Are you a smoker?
1 No
2 Yes
Have you been suffering from any of the following symptoms during the last two weeks?

1. Chest pain during physical stress
2. Joint ache
3. Headache
4. Back pain
5. Other aches
6. Shortness of breath
7. Anxiety/Irritation
8. Heartburns
9. Constipation
10. Other digestive tract problems
11. Eczema
12. Tiredness
13. Depression
14. Insomnia
15. Nausea
16. Other symptoms, please describe?

__________________________________________________________________________

**SATISFACTION ON PHARMACY SERVICES**

What is better or worse in Spanish pharmacies compared to Finnish Pharmacies?

__________________________________________________________________________

__________________________________________________________________________

Have you faced any problems when using Spanish Pharmacies?
1. Cannot say
2. None
3. Yes, what kind of?

__________________________________________________________________________

__________________________________________________________________________

How important do you think it would be to have pharmacy services in Finnish in Costa del Sol.
1. Not so important
2. Rather important
3. Very important
Should the Spanish Pharmacy system be developed in your opinion, so that it would serve better your needs?
1. No
2. Yes, please describe how?
___________________________________________________
___________________________________________________

How satisfied are you with the following items in Spanish Pharmacies / Services?
Please select the most appropriate choice in questions from a-f

Explanation of choices:
1. Very unsatisfied
2. Rather unsatisfied
3. Neutral
4. Rather satisfied
5. Very satisfied

a. The knowledge of the personnel
   1  2  3  4  5

b. Level of the service provided by the personnel
   1  2  3  4  5

c. Medication counseling while purchasing prescription medication
   1  2  3  4  5

d. Medication counseling while purchasing over the counter medication
   1  2  3  4  5

e. Selection of medications in pharmacies
   1  2  3  4  5

f. Language skills of personnel
   1  2  3  4  5

---------------------------------------------------

Where do you purchase your long-term medications?
1. From Spain
2. From Finland
3. From both countries
4. I do not use any long term medications
USE OF ANTIBIOTICS

Have you used antibiotics during the last 6 months in Spain?
1 Yes
2 No (Please move to question XX)
3 Cannot answer (please move to question XX)

For what purpose have you taken antibiotics during the last 6 months?
1 Common cold/flu
2 Sore throat
3 Some types of skin infections
4 “Tourist diarrhoea”
5 Wound infection or a post operation condition
6 Other, please describe?

Do you remember the name of the antibiotics you have taken during the past 6 months?
0 No
1 Yes, please write down the name

Where have you bought the antibiotics?
0 From the pharmacy without a prescription from a doctor
1 From the pharmacy with a prescription
2 Both
3 Cannot say

Have you had any of the following side effects during your antibiotics treatment?
0 No side effects
1 Diarrhoea
2 Stomach aches
3 Eczema/Rash
4 Shortness of breath
5 Other, please define?

How have the antibiotics affected your illness?
1 The first course have helped
2 I had to take two courses
3 I had to take more than 2 courses
4 They have had no effect
5 Cannot say
USE OF PAIN KILLERS

Have you used painkillers during the last two weeks?
  1 Yes
  2 No (please move to question XX)
  3 Cannot say

How often do you take painkillers?
  1 Daily
  2 Weekly
  3 Few times per month
  4 Less frequently
  5 Cannot say

Do you use any painkillers continuously?
  1 No
  2 Yes, how long and which painkillers have you been using?

Which pain killers have you used during the last two weeks?
  1 Ibuprofen (Neobrufen, Nurofen, Burana)
  2 Paracetamol (Panadol, Antidol, Dolostop)
  3 Acetylsalicylic Acid (Aspirin, AAS, Adiro)
  4 Ketoprofen (Ketorin, Orudis, Ketosolan)
  5 Nimesulid (Nimed, Antifloxil, Guacan)
  6 Tramadol (Tramal, Adolonta, Tralgiol)
  7 Naproxen (Naprosyn, Pronaxen)
  8 Diclofenac (Voltaren, Dolotren)
  9 Other, please define?

Are these painkillers you use:
  1 Medications prescribed by a doctor
  2 Medications bought without a prescription
  3 Both
  4 Cannot say

For which symptoms do you use painkillers?
  1 Headache
  2 Articular – or muscular pain
  3 Flu or fever
  4 Undefined pain
  5 Other, please describe?
Do you purchase your painkillers from?
1  Spain
2  Finland
3  Both countries
Comments:

Do you get reimbursement from your medications or do you pay them yourself?
1  I pay all of them by myself
2  I pay a 10% deductible
3  I pay a 40% deductible
4  I get all my medication free of charge
5  Cannot say/ don’t use
APPENDIX 2

INTERVIEW GUIDE

How do you describe Spanish community pharmacies (e.g., compared to Finnish pharmacies)?

- Number of pharmacies
- Size of pharmacies
- Facilities
- Pharmacy staff (service, education)
- Pharmacy services
- Selling lines: medicines and other goods
- Prescription medicines
- Over-the-counter medicines

Role of pharmacy

- Role of pharmacy in healthcare
- How to treat symptoms (doctor, pharmacy or some other option?)
- Availability of services
- Availability of medicines (Rx and OTC)
- Medication counselling
- Promotion of rational use of medicines
- Success of pharmacotherapy
- Chronic diseases and their medication treatments
- Compliance
- Medication safety
- Drug-to drug interactions
- Possible risks related to medication use
- Reliability
- Ethicality
- Competition between pharmacies (if any)