TURUN YLIOPISTON JULKAISUJA
ANNALES UNIVERSITATIS TURKUENSIS

SARJA - SER. D OSA - TOM. 790

MEDICA - ODONTOLOGICA

DELIVERY OF EUROPEAN CROSS-BORDER HEALTHCARE AND THE RELEVANCE AND EFFECTS OF EU REGULATIONS AND JUDICIAL PROCESSES

with reference to delivery of drugs and blood donor information material

by

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TURUN YLIOPISTO
Turku 2007

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ISBN 978-951-29-3468-3 (PRINT)
ISBN 978-951-29-3469-0 (PDF)
ISSN 0355-9483
Painosalama Oy – Turku, Finland 2007

To my Triplette

ABSTRACT

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Delivery of European Cross-Border Healthcare and the Relevance and Effects of EU Regulations and Judicial Processes with reference to delivery of drugs and blood donor information material
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Cross-border healthcare services are of great interest in the European Union. Optimal resource utilization and centralisation of knowledge is needed now when healthcare costs are steadily increasing. In addition, the European internal market freedoms of movement apply to healthcare-related services. However, the European Community has no mandate to regulate national healthcare systems. Instead, measures may be taken mainly in the promotion and protection of public health, also within other European Community policies.

The objective of the study was to analyse the impact of the European Union regulations on the healthcare sector, especially their influence on the delivery of healthcare services cross-border. Specific study areas were the delivery of non-national prescriptions from another European Union Member State; import of prescription-only drugs for personal use; use of electronic prescriptions nationally and possibilities for cross-border usage; online pharmacies' suitability for European internal markets; and the need for European Union level unification of blood donor information materials. Materials for the substudies were collected in 1999-2003 when the European Union had 15 Member States.

Non–national prescriptions issued from another Member State were in principle dispensed from pharmacies. Import of prescription-only drugs was restricted in all the countries, and there were limitations in the amounts and modes of import, in addition reimbursement of drug costs could be difficult. Electronic prescriptions were in everyday use only in two countries, but several were planning pilot projects. The chosen systems and standards varied between the countries. Established online pharmacies were found in Europe, with moderate scales of operation. Blood donor information materials did not meet the requirements of the Blood Directive in any of the participating countries.

The results showed varying national practices in restricting cross-border healthcare services. Even when the European Community's target is not to harmonise healthcare systems, some reconsideration of the division of tasks between the European Community and the national Member States seems to be necessary. National healthcare systems are not in isolation from European internal market but significantly influenced by it.

Keywords: European Union, the European internal market, pharmaceuticals, prescriptions, e-health, blood donor information

TIIVISTELMÄ

Mia Mäkinen
Valtion rajat ylittävät terveyspalvelut Euroopan unionissa sekä Euroopan unionin säädösten merkitys ja vaikutus erityisesti lääkejakeluun ja verenluovuttajille jaettavaan tiedotusaineistoon
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Valtion rajat ylittävä terveydenhuolto on suuren kiinnostuksen kohteena Euroopan unionissa. Resurssien hyödyntäminen parhaalla mahdollisella tavalla ja tiedon keskittäminen ovat tarpeen terveydenhuollon kustannusten alati noustessa. Terveydenhuoltopalvelut kuuluvat Euroopan sisämarkkinoiden vapaan liikkuvuuden piiriin. Euroopan unionilla ei ole kuitenkaan toimivaltaa säädellä terveydenhuoltojärjestelmiä, vaan sen mahdollisuudet ovat enimmäkseen kansanterveyden edistämisessä ja suojelussa, myös muilla toimialueilla kuin terveydenhuollossa.

Tutkimuksen tavoitteena oli tutkia Euroopan unionin säädösten vaikutusta terveydenhuoltosektoriin, erityisesti valtion rajat ylittäviin terveydenhuoltopalveluihin. Erityiskohteena olivat lääkemääräyksen toimittaminen toisen Euroopan unionin jäsenmaan apteekista, resepti-lääkkeiden maahantuonti omaan henkilökohtaiseen käyttöön, sähköisen lääkemääräyksen käyttö kansallisesti ja mahdollisuudet sen käyttöön eri jäsenmaiden välillä, online-apteekkien soveltuvuus Euroopan unionin sisämarkkinoille sekä verenluovuttajille jaettavan tiedotusaineiston yhtenäistämistarve Euroopan unionin alueella. Tutkimuksen osa-alueiden aineisto koottiin vuosina 1999–2003, jolloin Euroopan unioniin kuului 15 jäsenmaata.

Apteekit toimittivat useimmiten myös ei-kansalliset, toisessa Euroopan unionin jäsenmaassa annetut lääkemääräykset. Kaikki jäsenmaat rajoittivat lääkemääräyksen vaativien lääkkeiden maahantuontia. Rajoituksia oli maahantuontimäärissä ja -tavoissa. Lisäksi sairasvakuutuskorvausten saaminen ulkomailla lunastetuista reseptilääkkeistä oli hankalaa. Sähköiset lääkemääräykset olivat käytössä vain kahdessa maassa, mutta useissa maissa suunniteltiin niiden kokeilua. Standardit ja käyttöjärjestelmät olivat erilaisia eri maissa. Euroopan unionin alueelle on perustettu online-apteekkeja, joiden toiminta on kuitenkin vaatimatonta. Verenluovuttajille annettava tiedotusaineisto ei missään maassa täyttänyt veridirektiivin vaatimuksia.

Tutkimuksen tulokset osoittivat kansallisten käytäntöjen eroavaisuuksien rajoittavan valtion rajat ylittäviä terveydenhuoltopalveluita. Vaikka Euroopan unionin tavoitteena ei ole yhtenäistää terveydenhuoltojärjestelmiä, on tarpeen arvioida uudelleen unionin ja jäsenmaiden välistä työnjakoa. Kansalliset terveydenhuoltojärjestelmät eivät ole erillään Euroopan sisämarkkinoista, jotka merkittävästi vaikuttavat terveydenhuoltoon.

Avainsanat: Euroopan unioni, Euroopan sisämarkkinat, lääkkeet, lääkereseptit, e-health, verenluovuttajille jaettava tiedotusaineisto

CONTENTS

ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
CHMP	Committee for Medicinal Products for Human Use (is part of EMEA)
COM	Commission
DG	Directorate-General
EBA	European Blood Alliance
EC	European Community
ECJ	European Court of Justice
eCommerce	Electronic commerce
EEA	European Economic Area
EEC	European Economic Community
EFTA	European Free Trade Area
EMEA	European Medicine Agency
ENV	Prestandard of the European Committee for Standardization
ePrescription	Electronic prescription
ECSC	European Coal and Steal Community
EU	European Union
EudraVigilance	Pharmacovigilance network
FDA	Food and Drug Administration
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
HL7	Health Level 7 – organisations which develop and maintain health care standards; Standards developed by these organisations
HON	Health on the Net
ISO	International Organisation for Standardisation
ID	Identity
IT	Information technology
MedPre	Medical prescription message
NHS	National Health Service (of the United Kingdom)

OJ	Official Journal of the European Communities
OTC	Over the counter drug
POM	Prescription-only medicine
UK	United Kingdom
UN/EDIFACT	United Nations/Electronic Data Interchange For Administration, Commerce, and Transport. A standard developed under the United Nations, adopted to an ISO standard.
US/USA	United States of America
VIPPS	Verified Internet Pharmacy Practise Sites
XML	Extensible Markup Language
WHO	World Health Organisation

LIST OF ORIGINAL PUBLICATIONS

I Mäkinen M, Forsström J, Rautava P. Delivery of non-national prescriptions within the EU: How flexible is the common market for pharmaceuticals? Eurohealth 2001; 7(1):23-5.

II Mäkinen M, Rautava P, Forsström J. Restrictions on import of drugs for personal use within the European single market. Eur J Public Health. 2002 Dec;12(4):244-8.

III Mäkinen M, Rautava P, Forsström J. Do online pharmacies fit European internal markets? Health Policy 2005:72 (2): 245-252.

IV Mäkinen M, Forsström J, Äärimaa M, Rautava P. A European survey on the possibilities and obstacles of electronic prescriptions in cross-border healthcare. Telemed J E Health. 2006 Aug;12(4):484-9.

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1. INTRODUCTION

European integration started after the Second World War (Fontaine 2006). International organisations were set up to advance international co-operation. The European Community (EC) was the successor of the European Coal and Steal Community (ECSC), the latter consisting of six national countries of Belgium, France, Germany, Italy, Luxembourg and the Netherlands. The aim of co-operation was to rebuild the war-ruined Europe (Fontaine 2006). The first measures were mainly economic, targeting at increasing material welfare and at avoiding war between former enemies (Fontaine 2006). Co-operation spread gradually to other sectors of society and resulted in the establishment of the European internal market with free movement of goods, services, people and capital. Several countries joined the six founder countries of the ECSC, which grew into the European Community. Today, in 2007, the European Community has 27 Member States. Further co-operation required harmonisation and integration of national legislations and establishment of shared standards. It required a shift of part of the national decision-making power to the international organ.

Community legislation is based on treaties as its primary legislation, on which secondary legislation, regulations, directives, decisions and recommendations are based. Of these entities, regulations are binding as such, directives as to their contents (while the measures taken to meet them are decided by the national governments); decisions are binding to those whom they are addressed to; recommendations are legally non-binding. Community legislation is superior to national legislations (description available from the official site of the European Community, http://europa.eu.int/eur-lex/lex/en/droit_communautaire/droit_communautaire.htm). In some cases, the legislation allows national Member States to depart from Community legislation, like in the case of the profounding Treaty Articles, or to establish stricter measures than directives as secondary legislation. One example is a situation when a national Member State considers Community legislation to endanger public health (Article 30 and Article 46 of the consolidated version of the Treaty establishing the European Community, Appendix 1).

The healthcare sector was not included in the targets when European integration started. Exceptions were measures taken in the protection of health and safety at work in the 1960s (DG Employment and Social Affairs, 2006) and in the co-ordination of provisions for social security a decade later, in the 1970s, including healthcare. The latter was meant to safeguard the already obtained benefits of citizens who moved cross borders within the Community area (Regulation (EEC) No 1408/71).

However, healthcare and public health are not separate from economic activities. For years, Community policies have increasingly affected healthcare and public health, directly and indirectly (Piha 2000, Duncan 2002, Hämäläinen et al 2003). The European internal market has probably had the greatest impact on the healthcare sector. The internal market is concerned with such public health and healthcare influencing sectors as pharmaceuticals, medical devices, mobility of medical professions, and also necessities of life. Decisions made in common agricultural policy and energy policy, just to mention a few, also affect people's health (Piha 2000, Duncan 2002, Hämäläinen et al 2003).

The Community gained a mandate in healthcare only in 1992, when the Treaty of Maastricht established the Community's Public Health Article, Article 129 (Treaty of European Union 1992). The Article was renewed in 1997 in the Treaty of Amsterdam to include some new areas like blood safety, under the Community mandate (Treaty establishing the European Community 2002). The principle tasks of the Community are: advancement of co-operation and co-ordination of national health policies; protection and promotion of public health; and supervision of public health aspects in other Community policies.

There is an increasing interest in cross-border healthcare/health services at the Community level, thanks to the internal market. The internal market has offered free movement to pharmaceuticals and medical devices, due to strict harmonisation of their production and quality and authorisation requirements. Healthcare personnel can easily be established and practise in other Member States, as their qualifications are mutually recognised. Cross-border healthcare services have followed the other healthcare related sectors in movement but in minor steps. The national Member States are responsible for organising their healthcare services, but citizens have been able to obtain services from another Member State at the cost of their national competent authority or been justly reimbursed according to certain rules. Indeed, the past ten years have opened possibilities for concrete cross-border healthcare services. The European Court of Justice (ECJ) has perhaps acted as the main promoter when it has interpreted internal market legislation in individual cases where national citizens have obtained healthcare services from another Member State and required reimbursement from their national sickness funds. These preliminary rulings of single cases are significant to the whole Community as they are legally applicable and binding interpretation of the Community legislation not only to the counterparts but also to other Member States on similar occasions (European Court of Justice 2005). In addition to traditional healthcare services, development of telecommunications in the healthcare sector has made services independent of location, facilitating cross-border activities. Several interest parties, including national governments, patient and professional organisations and industries, are monitoring the development of cross-border healthcare. Thus, it is no wonder that their lobbies are established in Brussels, the centre of the European Community organisations.

This study analysed some healthcare aspects in the European internal market, with a special focus on cross-border activities, delivery of health services cross-border with attention to patient and consumer safety protection. Especially, the following issues were studied: recognition of prescriptions in another Member State; import of drugs for personal use from another Member State; online pharmacies in the virtual European internal market; electronic prescriptions and possibilities for their cross-border use; and, the need for Community level legislation to ensure minimum blood donor information contents. The latter refers to cross-border health services, when the patient receives blood products in another EU member country or when blood components or products are imported from another EU member state. The materials for the sub-studies were collected in 1999-2003. The review of literature of this thesis reflects, however, beyond this time, highlighting some important policy changes, until April 2007.

2. REVIEW OF THE LITERATURE

2.1. EU and its competence in the healthcare field

2.1.1. The Public Health Article

The European Community did not have much competence to act in the healthcare field before the establishment of the Maastricht Treaty in 1992 (Treaty of the European Union 1992). The Maastricht Treaty founded the European Union (EU), with new sectors for Community level actions, including public health. Earlier, the Community's emphasis in healthcare field was restricted on health and safety at work, as the mobility of labour force required some harmonisation in this field (Mossialos et al 1997). The first public health article, Article 129 of the Maastricht Treaty (Appendix 2) offered the Community protective measures that were to be carried out by encouraging and supporting cooperation between the Member States. Preventive measures were to be targeted at major health scourges, including drug dependence. Co-operation was also to be encouraged in the public health field with international public health organisations and with third countries, meaning countries outside the European Community**.** The Article stated that health protection requirements were a constituent part of other Community policies. Harmonisation of Member States' legislations was excluded (Article 129 of the Treaty of the European Union 1992).

The successor of Article 129 was Article 152 (Appendix 3) of the Amsterdam Treaty, established in 1997 (Treaty establishing the European Community, 2002). It included new issues for the Community's mandate. The Community's supervisory role of public health interests in other Community policies became more highlighted. Article 152 also empowered the Community to act in some new fields. These included assurance of high quality and safety of materials of human origin, organs, blood and its derivatives; and measures in the veterinary and phytosanitary fields with the aim of protecting public health. The Article emphasized Member States' decision-making power in organisation of their healthcare services. This means that the Member States decide which healthcare services they should offer to their citizens and how these services should be organised.

The initiative role for public health matters first lay with the European Commission Directorate-General (DG) DG Employment, Industrial Relations and Social Affairs (known as DG V). In 1999, after the reorganisation of the Commission DGs, health issues have been taken care by a specific DG, DG SANCO (Public Health). It is part of the DG Consumer protection and Public Health (Duncan 2002).

To carry out the task set up by the Public Health Article, the Commission has launched multi-annual public health programmes. The first concentrated on disease-specific sectors, like cancer, AIDS and other communicable diseases, drug dependence, pollution-related diseases, rare diseases, accidents and injuries and also to health

monitoring and health promotion (DG Employment, Industrial Relations and Social Affairs 1997, Piha 2000). Some of these programmes have been running until recently. Today, the multi-annual action programme has broader targets, with three main themes of improving health information and knowledge, rapid responses to health threats, and addressing health determinants (Decision No 1786/2002/EC). Health-related Commission financed programmes are also executed under other programmes than those governed by DG SANCO, including programmes under the auspices of DG Research, DG Environment, DG Information Society.

The action programmes finance projects which are carried out in co-operation between one or more Member States or with third countries. Co-operation is also carried out with other international organisations, e.g. in the blood safety sector, the Council of Europe and pharmaceutical sector, where co-operation is carried out with organisations such as the Council of Europe and the International Committee of Standardisation (European Commission 2000a).

Public health protection is ensured in several ways, some of which are presented below. An inter-service group on health, chaired by the DG SANCO's policy unit, convenes all European Commission DGs whose policies influence public health (Piha 2002). The group discusses future and on-going policy initiatives with influence on health before these initiatives are considered for approval. Participants in this group may come from the DG Information Society, when telemedical issues are addressed to, from DG Enterprise and Industry for pharmaceutical issues and from DG Internal Market to address to mutual recognition of foreign diplomas of healthcare professionals. Assistance is also provided by DG Sanco's guide for other Commission DGs in evaluating the health impacts of their policies (DG Health and Consumer Protection 2001). In addition, before a new policy proposal is presented to the other Community institutions, it passes a consultation phase via all other DGs, and must be approved by them before further processing. Altogether, since 1995, DG SANCO (up till 1999 the DG V) has prepared a regular report on supervision of public health protection in other Community policies (DG Employment, Industrial Relations and Social Affairs 1997).

A new Commission health strategy will improve health protection through other policies where this issue has a central position. The Commission decided to have the strategy introduced by mid 2007 (DG Health and Consumer Protection 2006).

2.1.2. Health in other policies

Earlier, the Community's impact on the healthcare sector tended to be underestimated (Hämäläinen et al 2003). Today, it is evident that most if not all the Community policies have an impact on the healthcare field. The European internal market based on economic interests is a good example, with a great deal of influence on healthcare (Legemaate 2002, Hämäläinen et al 2003). Free movement of people, goods, services and capital has required harmonisation of national legislations and creation and adoption of European standards. Harmonisation guarantees some level of quality and

safety standards in every part of the internal market area. Some important parts of legislation that the internal market has offered to healthcare field are those that harmonise pharmaceutical markets and establish mutual recognition and standardisation of education and qualification requirements for medical professions.

Agricultural, environmental as well as industrial policies also influence the healthcare sector. Tapani Piha, MD, who worked for several years as a councellor of EU-related health issues in Finland's Permanent Representation to the EU and later on as head of a Unit of the DG SANCO of the European Commission, defined "the EU health sector" as the Community's internal market policies regarding pharmaceuticals, medical devices, tobacco and recognition of medical professions. In addition, he used the term "health in other policies" for policies that have a less direct effect on health. These may be agricultural and environmental policies (Piha 2000). Mr. Ben Duncan, former European liaison officer of the British Medical Association and a spokesman in the European Centre for Disease Prevention and Control, presented EU health policy-making as direct and indirect health policy-making and unintentional policy-making (Duncan 2002). The first category includes those policies falling into the mandate of Article 152 as well as tobacco control. The second category covers such policy areas as pharmaceuticals and the third category includes common agricultural policy and the preliminary rulings of European Court of Justice applying to the healthcare sector (Duncan 2002).

2.1.3. Community policy-making and stakeholder relations

To understand how the Community's health-related policies are formulated, one must understand policy-making, a complex issue, with several parties influencing. Policy-making progresses as follows: The European Commission holds the initiative role, the European Parliament together with the Council make decisions on policy and legislation proposals. In general, Commission officials represent the European Community, aiming to develop policies within the legislative limits of the Treaties for the benefit of the Community. The European Parliament with its Members of Parliament represents European and national citizens and political parties in the interests of these two. In the Council, national member states advocate national interests.

During the various steps of the policy formulation process, a variety of stakeholders such as national governments, industrial, professional and social associations or representatives of patient organisations at the European level communicate with Community institutions. An illustrative example of stakeholder communication with the European Commission for health service related matters is Commission Consultation regarding Community action in health services in 2006, aiming to gather stakeholders' views on matters for future actions (DG Sanco 2006). A Commission report on responses to this consultation was based on 276 responses from stakeholders, which were, in this case, national governments, regional authorities, international and national umbrella organisations, social security institutions, universities, industries and even individual citizens (DG Sanco 2006). Stakeholders often have representatives in

Brussels who follow and influence on-going policy proposals. In addition, two Community institutions, the Economical and Social Committee and the Committee of Regions, which both represent some of the stakeholders, are formally consulted during the policy-making process.

Here should also be mentioned the six-month-long Council Presidency, during which the presidential member state aims to propose a health policy with attention to its specific interests.

2.2. Healthcare cross-border services

2.2.1. Harmonisation of national provisions for social security and healthcare benefits

The citizens of one EU Member State have been able to receive medical care from another EU Member State while staying abroad and to be reimbursed by the national social security system under certain conditions. The same applies to citizens from the member countries of European Economic Area (EEA), i.e., Norway, Iceland and Liechtenstein, which are also members of European Free Trade Area, and Switzerland, which is also an EFTA member. The EEA Agreement has been made between the European Community and the EFTA member countries, expect for Switzerland, which ties itself with bilateral agreements with the European Community. The EEA countries participate in the internal market without all the responsibilities that the EU Member States have. The EEA countries can be consulted for formulation of Community legislation but they do not have decision-making power in the process (more information from http://ec.europa.eu/external_relations/eea/index.htm. The EEA agreement is available from the EFTA website http://secretariat.efta.int/Web/legaldocuments/).

The basis for receiving medical care from another Member State at the expense of a national sickness insurance institution or receiving reimbursement lies in Community legislation co-ordinating the national provisions of social security since the early 1970s. This legislation aims at ensuring that people who move within the internal market area do not loose their social security benefits gained in another Member State while staying in another Member State (Regulation (EEC) No 1408/71, Regulation (EC) No 883/2004). The two co-ordinating regulations are Regulation (EEC) No 1408/71 and it's implementing Regulation (EEC) No 574/72. Regulation (EEC) No 1408/71 has since been revised with Regulation (EC) No 883/2004, which simplified principles to better respond to current needs (Van der Mei 2003), including citizens from third countries living in the EU area and entitled to social security in one of the Member States. However, its implementing Regulation is still (April 2007) under the decision-making process, so the first two regulations are still valid.

The implementing regulation states how the actual costs are reimbursed between the competent institution and the service provider (Regulation (EEC) No 574/72). Some

Member States have made bilateral agreements about refunding or abandoning the services received (Sheaff 1997, Hämäläinen et al 2003).

In principle, the variety of available services and benefits has been related to the status of the person; for example an employee; posted employee; unemployed person seeking a job in another Member State; traveller; student; pensioner or a dependant(s) of one of these groups (Regulation (EEC) No 1408/71). Non-acute, necessary medical care is offered only to some special groups like pensioners, students and employees. Immediate necessary medical care is offered to all groups entitled to healthcare benefits in one Member State (Regulation (EEC) No 1408/71). The decision about what is included in immediate necessary care has been made by the medical staff (Sheaff 1997). Urgent care should always be given to anyone, regardless whether the ultimate payer is recognised in the beginning. As the Member States have decision-making power in healthcare services (Article 152 of the Amsterdam Treaty), the systems and benefits which they offer show differences. The principle of equal treatment requires that a citizen from another Member State should receives healthcare services with the same rights and restrictions as that country's own citizens, naturally within the limits of the regulations (Regulation (EEC) No 1408/71).

The regulations list the conditions entitling a person to seek medical care in another member state at the expense of the competent institution, with prior authorisation by this institution (Regulation (EC) No 883/2004): This situation may occur when a person is entitled to such benefits by his/her national sickness insurance institution and he/she cannot receive this treatment in the country where he/she is insured without any undue delay in respect to his/her medical condition and the natural course of the sickness (Article 22, Appendix 4).

The Community has provided the E-forms system to assist reception of social security benefits in another Member State. The healthcare related forms proved that a person was insured by the national sickness fund in one Member State and was then entitled to specified benefits (immediate necessary care, non-acute necessary medical care) in another Member State. The form also gave information about the competent institution (Sheaff 1997). The E-forms had the same contents in every country, with only the language differing. The E-forms were issued by the competent institution and administered treatment was charged to this institution. Entitlement to immediate necessary care was given with the E111-form for temporary stay abroad, e.g. to tourists (Sheaff 1997, Hermans 2000). The E128 form was also for non-urgent necessary medical care during longer stays abroad for students and posted employees. If the person did not have any E-form with him/her, he/she possibly had to pay the actual cost of the medical treatment and later apply for refund from the national insurer. E112 entitled a person to seek planned healthcare in another Member State at the expense of the competent institution when the person had applied for prior authorisation (Sheaff 1997; Hermans 2000) or entitled a pregnant or chronically ill person to healthcare benefits in the other country (Kansaneläkelaitos 1998).

The E-forms for healthcare services should gradually be replaced with a European health insurance card in all EU Member States, EEA countries and Switzerland

between 2004-2008 (European Commission 2003, Council Decision 2003/753/EC). The purpose of the card is to facilitate access to medical treatment in another Member State and speed up reimbursement from the competent institution (European Commission 2003). E111, E128 and E119 forms have acted as a foundation of the reform. The European health card is currently a plastic card containing standardised information, identity of the card holder and the competent institution. By mid-2005, 30 million EU citizens had obtained it (Watson 2006). The plastic card will be replaced with an electronic health insurance card (European Commission 2003). The Commission has proposed under eEurope 2002 that smart health cards could contain such functions as enabling access to the patient's electronic health record online rather than serving as storage for medical and administrative data (European Commission 2003).

2.2.2. Obtaining healthcare services in another Member State

European citizens have been entitled to travel to another Member State to receive medical care and be reimbursed (Regulation (EEC) No 1408/71). Some countries like Luxembourg and Italy, Belgium and the Netherlands (Hermans 2000), especially their border regions, have traditionally more easily given prior authorisation to their citizens with the possibility for medical treatment in another country. The reasons have been such as a lack of expertise or limited health care infrastructure like that in the small country of Luxembourg (Sakslin 1999, Hämäläinen et al 2003), which has issued the highest number of E112 forms (of the old 15 Member States)(Hämäläinen et al 2003); and cultural and language links between the countries (Hämäläinen et al 2003).

The European internal market has given a challenge to national healthcare services in the last ten years. Citizens receiving medical treatment without prior authorisation from another Member State have been entitled to reimbursement from their competent institution (Hermans 2000) under certain rules. This has been a result of the European Court of Justice (ECJ) preliminary rulings on national cases where the ECJ has interpreted Community law.

The internal market rights for free movement also apply to healthcare services. Free movement of people applies to patients and medical professionals. Community legislation has harmonised by means of sectoral directives, although very roughly, the education of certain medical professions, doctors (Directive 93/16/EEC), dentists (Directive 78/687/EEC), nurses (Directive 77/452/EEC and Directive 77/453/EEC), midwives (Directive 80/154/EEC and Directive 80/155/EEC)) and pharmacists (Directive 85/432/EEC and Directive 85/433/EEC) and their mutual recognition by the national competitive authority. They are considered to have similar qualifications regardless of the Member State where they have been educated. Today, sectoral directives have been replaced by one, Directive 2005/36/EC, which gathers these medical professions recognition under the same directive. The right to provide services in another Member State is established by the Community Treaty in Articles 49 and 50, (Appendix 5). Closely related is the Article 43 on the right of establishment (Appendix 5).

However, national healthcare services within the internal market remain a complex issue. First, it should be borne in mind that national healthcare services normally include three parties, the patient, the service provider and the service payer; the patient rarely pays fully for the services. Second, healthcare systems show differences. In principle, universal coverage and solidarity in financing is the aim (Hämäläinen et al 2003). Sickness insurance may be based on residence, like in the United Kingdom (UK) and Finland or associated with the person's status (employee, pensioner etc.) like in Luxembourg. The benefits they offer can be "benefit-in-kind", meaning (practically) free healthcare services or cost-reimbursement, referring to systems where the patient first pays for the service and is later reimbursed (Nickless 2001). Third, the benefits offered vary. Fourth, issues related with patients' rights and liabilities are variably organised. Healthcare is a special form of services and thus a difficult consideration for free movement. The revised proposal for a European Service Directive (2004) did not include public healthcare services, but only commercial healthcare services, despite several attempts by policy makers (European Commission 2004a). The actual Service Directive, Directive 2006/123/EC, did not include healthcare services at all. The national Member States and Members of the European Parliament were against it, both participating in European law-making.

Much of the practises for patient mobility, in other words, in seeking healthcare in another Member State, have been formulated by the European Court of Justice's (ECJ) preliminary rulings, which have applied to cases where patients have sought medical treatment abroad and applied for compensation from their national insurer. Preliminary rulings are official interpretations of Community law. National courts and tribunals of the Member States may refer a question to the ECJ on the interpretation of Community law when it is necessary to resolve a dispute in the national court. In addition, national courts and tribunals must refer a question to the ECJ when it doubts the validity of an instance of Community law. The ECJ issues its interpretation of Community law or its validity, and the national court then, on the basis of the interpretation, resolves the situation underlying the main proceedings. Preliminary rulings are legally binding to similar cases in every EU Member State (European Court of Justice 2005).

The starting point for European patient mobility occurred in the mid-1990s (Watson 2006). Below, some important and famous preliminary rulings are shortly presented in chronological order. They all apply to cases where the citizens have sought medical treatment, outpatient or hospital treatment in another Member State. These persons applied for prior authorisation and despite refusal went to receive medical care abroad and applied for reimbursement of treatment costs from their competent institution. The systems concerned were both benefit-in-kind and cost-reimbursement systems. In most cases, the applicable instances of Community legislation were Articles 49 and 50 on free movement of services (Appendix 5) and Regulation 1408/71, especially its Article 22(1)c on situations where a person goes to another Member State to obtain medical treatment (Appendix 4). Thus, legislation on European internal market freedoms has had a great influence on the healthcare services of the Member States (Hämäläinen et al 2003).

- Case C-120/95, Nicholas Decker v Caisse de Maladie des Employés Privés. A Luxembourgian Mr. Decker's sickness fund refused to reimburse Mr Decker for spectacles obtained from an optician established in Belgium. A Luxembourgian regulation required prior authorisation before obtaining medical products from abroad to avoid unplanned healthcare costs. The ECJ considered that the requirement of prior authorisation formed a barrier to free movement of goods when a person who did not obtain prior authorisation was refused of being reimbursed. This was considered to guide purchases to the national country. Financial reasons alone were not regarded as justifying such restrictions. Reimbursement of the costs of spectacles was not considered to have any significant effect on the Luxembourgian social security system.
- Case C-158/96, Raymond Kohll v Union des Caisses de Maladie. Mr Kohll, a Luxembourgian, wanted his daughter to have orthodontic treatment in Germany and applied for prior authorisation for reimbursement. The treatment was obtained before the authorisation decision, which was negative as the treatment was regarded as urgent and was also obtainable in Luxembourg. The ECJ was asked whether the regulation for prior authorisation as a condition for reimbursement of the costs of benefits obtained abroad were in accordance with the principle of free movement of services and whether the requirement was justified as ensuring balanced medical and hospital services in the country. The ECJ determined that the treatment constituted outpatient care and thus the Community legislation on the free movement of services was applicable. In this case when the insured applied for reimbursement according to the rates of the country of insurance, prior authorisation was not necessary to maintain balanced medical and hospital care, and the requirement was thus contrary to Community law.
- Case C-368/98, Abdon Vanbraekel et al v Alliance Nationale des Mutualités Chrétiennes. Ms Descamps, a Belgian had undergone orthophedic surgery in France, and her sickness fund refused to reimburse her for it. She had applied for prior authorisation but had been refused as she had not received a favourable statement for treatment abroad from a national specialist as required by Belgian law. Yet she was operated on in France. Afterwards, a national specialist gave a favourable statement about the operation. The ECJ was asked about the applicable rate of reimbursement: whether it should be according to the country of operation (where the amount was smaller) or the country of residence (more expensive). The ECJ determined that reimbursement should be according to the regulations of the country of operation, but the difference between the reimbursement rates should be paid to the patient when favourable.
- Case C-157/99, B.S.M. Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Groep Zorgverzekeringen. Mrs Geraets-Smith, a Dutch citizen, asked her sickness fund to reimburse her for a Parkinson disease treatment in a German clinic. The sickness fund refused stating that adequate and appropriate treatment was available in the Netherlands and the treatment in a German clinic was not regarded superior. In addition, the mode of treatment was considered unconventional and was thus not eligible for reimbursement, either.
  Another case was that of Mr. Peerbooms, a Dutchman, who had fallen into coma after a road-traffic accident. He was first treated in a Dutch hospital and was then remitted to an Austrian hospital to receive special treatment. This treatment was experimental in the Netherlands and offered only by a few clinics to patients less than 25 years of age. Mr. Peerbooms was older. He recovered from the coma. The Dutch sickness fund was afterwards asked to bear the costs occurred from the treatment in Austria. The claim was refused as the mode of treatment was not considered as a treatment in the Netherlands and thus not eligible for reimbursement.
  The ECJ was asked whether prior authorisation of treatment abroad as a condition of reimbursement was in compliance with the Community freedom of services; and how

treatments that are not considered ordinary by professionals in the country of residence should be regarded or whether international medical standards should apply.
The ECJ determined that the requirement of prior authorisation is in agreement with Community law when its purpose is to maintain sufficient resources for hospital care in the national country. Authorisation should, however, be granted if a treatment was considered as "normal in the professional circles" and could be denied only if the treatment was not necessary for the health status of the patient or similar, or equally effective treatment could be offered without an undue delay in the country of where the patient was insured.

- Case C-326/00, Idryma Koinonikon Asfaliseon (IKA) v Vasilios Ioannidis. Mr. Ioannidis, a Greek pensioner, suffering from coronary artery disease was staying in Germany and admitted to a German hospital for acute care of angina pectoris. He had obtained the E111 form that entitled him to acute medical care. The German sickness fund asked Mr Ioannidis's Greek social insurance institution IKA for an E112 form which would have entitled him to seek medical treatment abroad. IKA refused, considering that Mr Ioannidis had a chronic disease and had thus not fallen ill suddenly: For reimbursement of a pensioner's treatment costs abroad, Greek legislation required that the illness has manifested suddenly and that acute treatment was necessary. The ECJ noted that Community law to pensioners is different from that to employers. Pensioners are entitled to a wider scale of healthcare services abroad, also in case of a chronic disease when a change in the patient's medical condition requires acute medical treatment. The ECJ determined that the person's own sickness fund should reimburse the costs of treatment, when the person has wrongly been refused of having the benefits**.**
- Case C-56/01, Patricia Inizan v Caisse Primaire d'Assurance Maladie des Hauts-de-Seine. Ms. Inizan, a French citizen, suffering from chronic pain had asked her French sickness fund for prior authorisation of a multidisciplinary pain treatment in Germany. The authorisation was denied as a medical official considered treatment abroad was not necessary; the health status of the applicant did not require it and equivalent adequate treatment was available in France. However, Ms. Inizan claimed that the treatment in Germany was necessary as she had earlier received available treatments in France without any benefit. She also defended her claim with the fact that costs for the treatment were reimbursed in the German social security scheme. The ECJ was asked whether the requirement for prior authorisation in Article 22 of the EC Regulation 1408/71 was compatible with the freedom to provide services and whether the sickness fund could deny reimbursement of the costs of the treatment in Germany on the basis of an adverse opinion from a national medical officer**.** The Court stated that the requirement for prior authorisation was not against EC law. Prior authorisation should, however, be granted if the treatment was within the scope of the patient's insurance scheme and similar or equally effective treatment could not be provided to the patient without undue delay.
- Case C-8/02, Ludwig Leichtle v Bundesanstalt für Arbeit. Mr. Leichtle, a German citizen, applied for prior authorisation from his German insurer Bundesanstalt für Arbeit for reimbursement of costs of a spa treatment in Italy. Authorisation was denied on the grounds that the treatment was not considered more beneficial than that available in Germany. The German regulation stated that in order to receive reimbursement for the costs of a spa treatment abroad, the patient needed prior authorisation and the treatment obtained abroad should be considered more beneficial. The amount of reimbursement varied from a limited amount to of all costs included (accommodation, meals etc.); for full reimbursement, the spa must have been included in a special list of spas. Mr. Leichtle filed an appeal with Court and, meanwhile, travelled to an Italian spa. The German Court turned to the ECJ asking whether the national rules for full reimbursement were against EC law on the free movement of services, as German regulations required that the treatment was absolutely necessary

and more beneficial in the other country and that the spa was included in a special list; whether refusal of full reimbursement was against EC law when treatment was received before the authorisation procedure. The ECJ considered the requirement of prior authorisation justified as well as the requirement for the spa to be included in a special list. However, the requirement of better expected benefits was considered a barrier for the free movement of services and not justified in the present case. In addition, the ECJ determined that refusal of reimbursement for the costs of treatment already received authorisation is contrary to Community law: Because of their health status, most patients have to have their treatment before authorisation.

- Case C-145/03, Annette Keller v Instituto Nacional de la Seguridad Social and others. Annette Keller, a German citizen living in Spain received an E111 form from her Spanish social security institution before visiting Germany. The E111 form entitled her to immediate necessary medical care abroad. She was diagnosed in Germany with a malignant tumour. She received an E112 form from her Spanish social security institution entitling her to seek medical care in another EU Member State. In Germany, doctors considered that appropriate treatment would be available in a private Swiss clinic, to which Ms. Keller was afterwards referred. The Spanish social security institution was not consulted prior to Ms. Keller's referral to the Swiss clinic outside the EU area. The Spanish social security institution refused to refund the costs of the treatment as Ms. Keller had been aware of her health status before seeking medical treatment in Germany and had not applied for authorisation from the Spanish social security institution for treatment outside the EU. The ECJ was asked whether the (Spanish) institution issuing E111 and E112 should pay for the costs due to the diagnosis and treatment outside the EU (Switzerland) when prior authorisation has not been applied for. The ECJ was also asked whether the requirement for equal treatment of people insured in one country and staying in another obliged the competent country to bear the costs for treatment outside the EU when the treatment was among the benefits of its social scheme. The ECJ determined that physicians of the country where the patient is staying can decide about the necessary treatment. Thus E111 and E112 entitled Ms Keller to receive the same care as citizens of the country of stay (in this case Germany), and the insurer who had issued these forms (the Spanish Social Security) was to cover the costs.
- Case C-372/04, Yvonne Watts v 1) Bedford Primary Care Trust and 2) Secretary of State for Health. Ms Watts, a UK citizen, needed hip replacement surgery. She was put on the National Health Service's (NHS) waiting list. She applied for authorisation to receive the treatment abroad sooner, but her application was refused on the grounds that the treatment was available for her within the government's target waiting time**.** She appealed and was offered an earlier operation date. However, she decided to have the treatment even earlier and was operated on in France. The NHS refused to reimburse her. The case was taken to the ECJ, with questions about the position of hospital treatment free of charge provided by the national health services in respect to the free movement of services; justified refusals of prior authorisation of hospital treatments; and about reimbursement procedures for accepted hospital treatments abroad. The ECJ determined that irrespective of how the person's national healthcare system operates (in this case NHS universal and free-of-charge services), the principle of free movement of services applies. Refusals solely based on official waiting times were not considered justified; the accepted waiting time should be considered with respect to the patient's medical condition, not to administrative standards. A patient who had obtained prior authorisation or was refused authorisation unduly should be reimbursed just as he/she would be in the country where the treatment was provided. The ECJ also ruled about how the costs should be reimbursed. Ms. Watts's special case was to be decided by a local court, determining whether she had faced undue delay in the sense that the ECJ meant.

It is uncertain how the preliminary rulings apply to other types of healthcare systems than those of countries whose courts raised the issues. Thus the significance of preliminary rulings in cross-border healthcare is uncertain (Mossialos and McKee 2002). In general, the ECJ's preliminary rulings in cases where patients have sought medical treatment abroad have declared about medical services that:

- Free movement of services is applicable to ambulatory and hospital care; benefit-in-kind and reimbursement systems.
- For hospital care, the requirement for prior authorisation from the competent national institution is justified, but authorisation cannot be refused if the treatment is necessary; is included in the benefits of the insured person; is internationally regarded as normal; and similar or equally effective treatment cannot be given in the competent country without undue delay in respect of the patient's health status and the natural course of the disease.
- When prior authorisation is granted, the patient should be reimbursed by the institution of the country of stay (where patient receives the medical treatment) according to its rates. The competent authority compensates the service provider for the actual treatment costs. If the value of reimbursement is greater in the competent country, the competent institution should pay the difference to the patient.
- If prior authorisation has not been obtained, the person can still be reimbursed by the competent authority if the treatment is included in the system's benefits or is internationally regarded as normal. Reimbursement should then be provided as if the treatment were given in the country of residence.
- Member States can maintain lists of registered medical service providers.
- Purely economical arguments do not justify restrictions of the freedom of movement of medical devices or patient mobility/reimbursement for the costs of medical treatment if included in the benefits of the patient but obtained abroad. The Member States can apply restrictions to the free movement of services when necessary for balanced financing of their social security system and/or maintenance of medical competence.

Patient mobility has resulted in actions where different interest stakeholders, led by the European Commission, have been brought together. These stakeholders have been for example national governments, European level non-governmental organisations representing patients and doctors, social security and sickness insurance organisations. They were also represented in the High-Level Process of Reflection on Patient Mobility and Healthcare Developments in the EU, established in 2002. This Process of Reflection recognised a need for European level strategy for patient mobility which could assist in the challenges of the national healthcare systems. It came up with several recommendations (European Commission 2004b). The European Commission responded to these recommendations in its Communication in 2004 and established a High Level Group on Health Services and Medical Care. This group also involves different stakeholders. The High Level Group investigates areas which appeared in the Commission response. These include for example cross-border healthcare purchasing and provision, including financial impact and sustainability of cross-border care, liability issues and continuity of care; health professionals, their migration and continuing professional development; centres of reference for rare disease and other conditions requiring specialised care (European Commission 2004b).

Yet a further action was needed at the European level. The Commission proposal for a directive on services in the internal market included health services, but it (health services) was rejected. As a continuation in 2006 the Commission set up a consultation regarding

Community action on health services (European Commission 2006). The consultation invited stakeholders to communicate their views on how the Community should promote and support patient mobility in the future. A Commission proposal addressing issues derived from the consultation process could be expected later, by 2007. In addition, the Commission will address patient mobility in its policy proposal for health strategy (DG Consumer Protection and Health 2006), so that the issue will be included in several Community actions.

Multinational programmes have tested patient mobility, some of them with promising results (e.g. Boffin and Baeten 2005, Glinos et al 2005). Border areas of the Netherlands, Germany, Belgium and the UK have been involved in several studies. Typically, patients have been able to choose whether they wanted to receive treatment in their own country or the other country. Both ambulatory and hospital care have been involved. The studies have found that patients using the option to receive care in another country were often immigrants or cross-border employees and had had previous contact with the foreign healthcare system (Brouwer et al 2003). A minor driving force was found to be avoidance of the waiting list in the country where they normally obtained healthcare services (Brouwer et al 2003). One study evaluating English and Dutch patients who were voluntarily by their own choice operated on in Belgian public hospitals showed that patients receiving care in another country, in this case in Belgium, were satisfied. Studies have shown that the national resources of the countries were better used, although the cross-border experiment did not apply to any extensive population (Boffin and Baeten 2005, Glinos et al 2005). However, researchers recommend that patient mobility should be encouraged with caution to avoid any risks that can occur. These risks include effects on pricing and national waiting times and hospital capacities (Boffin and Baeten 2005, Glinos et al 2005). Currently, the significance of patient mobility is estimated to be minor. It is no surprise then that experiments carried out between the Netherlands and the neighbouring countries have shown that the majority of patients still prefer healthcare provided by the home country even with longer waiting times (Brouwer et al 2003).

2.3. Harmonisation of the European pharmaceutical market

2.3.1. Legislation

Harmonisation of European pharmaceutical market aims at guaranteeing safe, high-quality and efficient pharmaceuticals at reasonable prices to European citizens (European Commission 2000a). At the same time, the European pharmaceutical policy should guarantee sufficient profits to the European innovative medical industry and ensure the European industry's competitiveness in global markets (European Commission 2000a, Wahlroos 2003). However, Hämäläinen et al claimed that industrial policies have been more important than health aspects in the development the Community policy on pharmaceuticals (Hämäläinen et al 2003). After all, the pharmaceutical industry is a significant industrial sector in Europe. Wahlroos, however, claimed in his study of the development of summaries of product characteristics and patient information leaflets within the EU that public health aspects also has an important role in the pharmaceutical policy, even before the Community had a mandate in the public health field (Wahlroos 2003).

The Community's pharmaceutical policy is managed by two units of the DG Enterprise and Industry; one is responsible for regulative issues and the other for competitiveness (situation of the Units according to the official website of the European Commission, Directorate General Enterprise in April 2007).

Harmonisation of the European pharmaceutical market started in 1965 with the establishment of the first Community pharmaceutical directive. At that time, the main target was, from the public health point of view, prevention of undesirable phenomena like the thalidomide catastrophe[2] from occurring again (European Commission 2000a, European Commission 2000b, Waller et al 2005). Since then, the pharmaceutical sector has become strictly regulated at the Community level (European Commission 2000a).

The Council of Europe's[3] work in the pharmaceutical field has influenced greatly the Community's pharmaceutical legislation **(**European Commission 2000a**).** It publishes the European Pharmacopoea, which contains monographs of pharmaceuticals. A monograph defines the qualitative (i.e. identification) and quantitative (i.e. content of the active ingredient and limits for impurities) characteristics of a substance (more information available from the Council of Europe website for European Directorate for the Quality of Medicines and Healthcare: http://www.edqm.eu/site/page_628.ph). Community pharmaceutical legislation refers to these monographs. They were made compulsory in 1975 by the Community Directive 75/318/EEC (European Commission 2000a). Both the European Community representatives and the EU Member States participate to produce the European pharmacopoeia (Council of Europe: http://www.edqm.eu/site/page_628.php). Co-operation is also carried out with other international organisations such as the International Conference of Harmonisation, which convenes the European (EU), Japanese and American (the US) drug regulatory authorities and the pharmaceutical industry to discuss scientific and regulatory aspects of drug registration. One of the aims is protection of public health (European Commission 2000a).

The Community's regulations for pharmaceuticals cover their whole life cycles. Earlier, different topics were regulated by divergent directives, but today some of them have been gathered under one directive, Directive 2001/83/EC. This Directive includes such topics as classification, marketing authorisation procedures, wholesale and distribution, advertising, labelling and package inserts, and pharmacovigilance. In addition, the

[2] Thalidomide was used during the 1950s and early 1960s for sleeping disorders and for hyperemesis gravidans. It was found to cause developmental disorders in the human foetus when used during organogenesis, especially between 3-8 weeks of pregnancy, resulting in short extremities, blindness and deafness, defects in heart, kidneys, gastrointestinal tract and in gonads of the newborns. The drug also caused miscarriages and still births. The required amount for disadvantages was diminutive. Approximately 10 000 children in the world were injured by the drug. The reasons for the Thalidomide Catastrophe were inadequate testing before entrance to the market.

[3] The Council of Europe was founded in 1949. It is not part of the European Community. The Council has 46 member countries, including all current 27 EU Member States. It aims at developing European continent wide agreements to standardise social and legal practises. Its civil servants run the Council's everyday activities but the policies are formed in the expert groups of national representatives and decisions made in the plenary meetings by national governments. The Council does not have any legislative power but its member countries have agreed to follow shared agreements. More information available from: www.coe.int.

Community has established directives for the development of new drugs, clinical trials (Directive 2001/20/EC, Directive 2003/94/EC, Directive 2005/28/EC. Marketing authorisation procedures are also regulated by Regulation 726/2004. Still, harmonisation does not unify the national pharmaceutical markets: the Community provides the framework, and the Member States decide how they implement the legislation. Authorisation procedures and the Member States' mandate to decide on their healthcare systems and varying traditions of treatments increase all fragmentation.

Harmonisation of the European pharmaceutical market has not ended up with equal European-level prices. The Member States have different systems to set up and control the prices and dispensing of pharmaceuticals (Watson 1998, Ess et al 2003). In all (15 old) EU Member States except the UK and Germany, prices of drugs for which costs will be reimbursed are negotiated and approved by the national drug authorities (Martikainen and Rajaniemi 2002). This aim of such price control is to keep pharmaceutical costs tolerable for national healthcare systems (Ess et al 2003). Pharmaceutical prices are difficult to compare as there are several stages of pricing (wholesale, retail etc.) but also because the national markets are fragmented which confound comparisons (Folino-Gallo et al 2001).

Recently, the Community's pharmaceutical policy and legislation were reviewed. It was preceded by the Commission-organised three Roundtables in the late 1990s (Kanavos and Mossialos 1999) and by the G10 group, the High Level Group on Innovation and Provision of Medicines, in early 2000. Both convened the European pharmaceutical industry, the relevant Commission services and the EU Member States. Participants of G10 were more selected and few in number. They defined defects of harmonisation of the pharmaceutical market and discussed methods needed to complete the harmonisation process (European Commission 1998). Some defects had a more direct effect on public health, e.g. parallel trade due to price differences; in addition delays were found in the entry of pharmaceuticals to the national markets, the delays were especially due to national pricing negotiations (High Level Group on Innovation and Provision of Medicines 2002). The group came up with proposals for the improvement of national authorisation procedures, the pharmaceutical industry's competitiveness, stimulation of European innovative industries, advertising of over-the counter (OTC) drugs; all also influencing public health (High Level Group on Innovation and Provision of Medicines 2002).

2.3.2. Marketing authorisation

The two Community procedures for authorisation of pharmaceuticals, centralised procedure and mutual (decentralised) recognition procedure, aim at guaranteeing equal quality and safety to pharmaceuticals entering all parts of the European market. The centralised procedure has been operating since the mid-1990s when the European Medicine Evaluation Agency (EMEA), today known as the European Medicines Agency, was founded (Council Regulation (EEC) 2309/93, replaced by Regulation 726/2004**)** in London. The centralised procedure evaluates all biotechnological products; for them it is the only possible procedure. The manufacturer/licence holder

may also choose the centralised procedure for a new innovative drug or a drug with new indications. Its Committee for Medicinal Products for Human Use (CHMP) evaluates marketing applications. The CHMP has expert members from each EU Member State and from two EEA countries (Iceland and Norway); in addition, there are some co-opted experts of the field. Final (and formal) approval is granted by the European Commission (Regulation 726/2004)**.** Community authorisation is valid in every Member State where the manufacturer/licence holder decides to market the drug. Only price negotiations with national authorities may be needed before the drug can enter the market. Centralised authorisation ends up with a drug having the same classification (prescription-only medicine POM/OTC) and trade name in every country where it will be marketed (by the decision of marketing license holder).

One task of the EMEA is to provide manufacturers with scientific advice on research, development and authorisation applying to document-related matters, and to promote safety of medicines via the pharmacovigilance network, EudraVigilance. The EMEA's activities are partly financed by the European Commission but its main source of income is fees from the applicants, i.e. from the industry. EMEA has been criticized for its advisory and evaluation role, as the same officials have been considered to be disqualified to carry out both tasks. In addition, some weaknesses have been found in the evaluation procedure (Li Bassi et al 2003) (More information about EMEA available from the EMEA website: www.emea.eu.int.).

Mutual recognition has been in operation since the mid-1970s. The mutual recognition procedure authorises other than biotechnological products, such as conventional pharmaceuticals and generic products, except generic products from original pharmaceuticals authorised by the centralised procedure (European Commission 2000a, European Commission 2000b). A reference state chosen by the drug manufacturer/licence holder reviews the application for drug authorisation. After the drug has been authorised, the manufacturer/licence holder can apply for authorisation in another/other Member State/s and refer to procedures already executed in the reference State (European Commission 2000a). Applications filed in other Member States can be adjusted to local conditions regarding of the trade name and classification of the individual drug: classification of the drug is decided on by respective national authorities independently (European Commission, DG III Industry. IT project results. EudraMat, Market Transparency Database, available from http://dg3.eudra.org, accessed June 12, 1999).

After the drug marketing authorisation procedure, with either centralised or mutual recognition, the marketing license holder decides, where and which of the approved pharmaceutical products will be launched in the markets of a single Member State. Therefore, the available amounts of active ingredients, product forms, packet sizes of the same product can differ from one Member State to another.

In addition to the Community procedures, national recognition is possible and authorisation may be applied for the national market only; or the application is about additions to an earlier granted national authorisation; or authorisation is applied for the first time. A centralised procedure is then not obligatory.

2.4. Drugs in cross-border trade for personal use

Consumers may want to buy drugs in/from other EU member countries for several reasons. Cheaper prices may attract: the enlargement of the EU in 2004 when the Community received ten new Member States from eastern and central Europe also meant cheap drugs from these countries. Earlier some old Member States of Southern Europe had also offered drugs at attractive prices (Krosnar 2005). Another reason may be that people simply run out of their medication when staying in another Member State. Issues which come up when drugs are bought in/from another Member State are about acceptance of foreign prescriptions, availability of the required drug as selections can vary between countries, import of drugs cross-border and reimbursement from the sickness fund.

2.4.1. Recognition and delivery of non-national European prescriptions

The question about the delivery of non-national European prescriptions appeared several times in the EU institutions during the early 1990s. Members of the European Parliament posed three written questions[6] to the European Commission about the delivery of drugs with prescriptions issued in another EU Member State (Written questions no. 2491/92, no. 3594/93 and no. 2306/96). Two of these questions especially were about the problems of Belgium pharmacies which by the Belgium law could deliver only prescriptions issued by doctors registered in Belgium (written questions no. 2491/92 and no. 3594/93). The questions were answered by Commissioner Bangemann and later Commissioner Monti from the DG Enterprise and Industry and Commissioner Archirafi from the DG Internal Market. The three answers were based on existing Community legislation. First, the Community definition for a pharmaceutical prescription as stated by the Directive 92/26/EC concerning classification for the supply of medicines does not determine which nationality the prescribing doctor should represent. Second, the European level harmonisation of doctors' and pharmacists' educational requirements and the conditions to practise these professions (i.e. the Community's sectoral directives) can be considered to give the same guarantee regardless of the country. Third, pharmacists were regarded as entitled to make individual refusals about the delivery of suspicious prescriptions (answers given to the written questions by Commissioners Bangemann (Written question no. 2491/92), d'Archirafi (Written question no. 3594/93) and Monti (Written question no. 2306/96)).

[6] The Rule 110 of the Rules of Procedures of the European Parliament (from 1996) states that Members of the European Parliament can pose written questions to the European Commission and to the Council. When a written question is posed to the European Commission, to one of its services, all the Commission services must agree on the answer. The answering time is limited according to the type of question, varying between three to six weeks. Written questions and their answers are published in the Official Journal of the European Communities. Rules of procedures available from the website of the European Parliament: http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+RULES-EP+20070101+TOC+DOC+XML+V0//EN&language=EN

The Council has also put emphasis on the recognition of non-national European prescriptions in another EU Member State: The Council Resolution on mutual recognition of the validity of medical prescriptions was approved in 1995. The position and the arguments were similar to those presented by the Commissioners' answers to the written questions (Council Resolution 1995).

Since 1977, the Nordic countries have had an agreement where each Nordic country recognises a prescription issued in another Nordic country (Nordic Council of Ministers 1977). The agreement has been concluded in the Nordic Council, a co-operative institution of the Nordic countries. This agreement is implemented in the respective national legislations in Denmark, Finland, Iceland, Norway and Sweden. As for general rules, it applies to prescriptions which are ordered within one year and are not for narcotics or for alcohol-containing preparations. Cases where the trade name and packet size may be different are specified, for example, by Finnish law.

2.4.2. Import of drugs for personal use

Citizens' right to import or receive a reasonable amount of drugs from another Member State, obtained lawfully for personal use is noted in the introduction part of directive 2001/83/EC, which combined several earlier pharmaceutical directives. It is based on the fundamental right of free movement of goods included in the Treaties.

Already earlier, the ECJ has issued some preliminary rulings on the import of drugs for personal use from another EU Member State. Two of these cases were of German citizens and their attempts to import drugs to Germany. The first case, Heintz Schumacher v Hauptzollamt Frankfurt am Main-Ost (Case C-215/87) was about buying an OTC product to Germany from a pharmacy in another EU Member State, France, where the drug was also an OTC product. Mr. Schumacher placed a mail order to get this drug for his personal use. Meanwhile, German law forbids mail order of drugs for personal use, but allows personal import across the border in a reasonable quantity. The issue was taken to a German Court which in turn asked the ECJ for a preliminary ruling. The Government of the Federal Republic of Germany argued that Community legislation allowed a Member State to put restrictions on the free movement of goods when it posed a possible threat for the safety of public health (Article 36, today Article 30, Appendix 5). It argued that a mail order of drugs from abroad was a threat to public health as the ordering person could not receive a pharmacist's personal guidance and the product instructions were in foreign language. The ECJ did not accept these arguments. National provisions prohibiting a person to import pharmaceuticals purchased from a pharmacy established in another Member State to a Member State where the pharmaceutical was authorised and available without prescription (i.e., OTC product) were not justified for the protection public health and were thus contrary to the Community's legislation on free movement of goods (Case C-215/87).

The second preliminary ruling, the Commission of the European Communities v the Federal Republic of Germany (Case C-62/90) was also about German legislation,

restrictions on the import of POMs for personal use from another EU Member State. The restrictions were found to be contrary to Community law on free movement of goods (Article 30, Appendix 5). The German restrictions were based on the protection of public health. Germany argued that when a patient was in another country than the prescribing doctor and the drug dispensing pharmacy, this caused a potential health risk, in addition to confusion with packet leaflets in a foreign language and to possible misuse of prescriptions. The ECJ did not agree as it regarded that these risks were avoidable. The ECJ argued that when a drug was purchased from another Member State using a prescription issued by a doctor established in that Member State, it was contrary to the Community law of free movement of goods to prohibit import of drugs for personal use to a Member State where it was also obtainable only by prescription (Case C-62/90).

2.5. Information technology and eHealth in the EU

2.5.1. European framework for online acting society and eHealth

The European Community aims at making Europe the most competitive information-based society by the year 2010 (European Council 2000). This aim has required special legislation in order to create internal markets also in the electronic field, safeguarding the interests and rights of consumers. The telecom package was created between the late 1990s and the early 2000s, followed by eCommunication, an extensive and profound collection of special legislation. This legislation is applicable to:

"Services or networks that transmit communications electronically, whether it is wireless or fixed, carrying data or voice, Internet based or circuit switched, broadcasting or personal communication"

(European Commission, Europe's Information Society website, available from: http://europa.eu.int/information_society/policy/ecomm/index_en.htm)

The healthcare sector is one of the targets of the information society for several reasons. The EU member states are sharing challenges in healthcare. The Europeans are ageing and thus need more healthcare services; medical science offers increasingly specialised and advanced treatments, which are also more costly; people are more aware of scientific developments and demand them. These factors result in ever-increasing costs for the healthcare sector. Utilisation of information technology has been seen as one way of controlling healthcare costs while high-quality services are maintained.

What is then eHealth? Several definitions are available. One definition according to G. Eysenbach says that eHealth is

"an emerging field in the intersection of medical informatics, public health and business, referring to health services and information dispensed or enhanced through the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a state-of-mind, a way of thinking, an attitude,

and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology"

(Definition by Dr. Eysenbach, editor of the Journal of Medical Internet Research. Eysenbach 2000b).

Community legislation establishes the framework for electronic commerce and supporting activities. This legislation is put to practice by many procedures. The Commission DG Research runs multiannual Research and Technological Development Programmes, which finance research and piloting projects involving co-operation between several member states. These programmes have included eHealth-related research programmes (European Commission 2004c, Iakovidis 2000). DG Information Society has had the main responsibility for the eEurope Action Programme. The eEurope programme has set up significant targets in special fields to be realised in co-operation with the member states. The programme attempts to establish an IT framework for the European societies and bring electronic communications into everyday activities, including healthcare.

The eHealth/eEurope Programme puts emphasis on ordinary citizens' possibilities to use electronic communications to obtain health services. One of its achievements has been the establishment of quality criteria for health-related websites (European Commission 2002), which is particularly important as people increasingly seek online health information. For example, a study from the USA estimated that 80% of the American Internet users seek health information from the Internet. A similar number is probable in Europe. As the targets of the eHealth programme are based on volunteer co-operation, nation-specific solutions and practices exist.

2.5.2. Electronic prescriptions

The eEurope/eHealth programme aims at introducing electronic prescriptions (ePrescriptions) in the member states by 2008 (European Commission 2004c). e-Prescriptions are "messages for electronic information exchange of prescription sets sent by a prescriber to a dispensing healthcare party (dispensing agent) and to healthcare persons/organisations or official authorities as permitted by national regulation" and "electronic information exchange of prescription sets sent by the prescriber to a relaying agent and from a relaying agent to a dispensing agent" (the prestandard of the European Committee for Standardisation 2000**,** today this prestandard has been approved by the European Committee for Standardisation). Thus, an electronically processed prescription dispensed in paper print from a doctor to a patient is no electronic prescription according to this definition, it is only a computer-assisted prescription.

Generally, ePrescriptions have been regarded as tools that should decrease medication errors and save costs, as they are easier to read and process than traditional handwritten prescriptions. They avoid misunderstandings resulting from unclear handwriting and thus save time for both the doctor and the pharmacist (Papshev and Peterson 2001). A

Finnish study analysing problems related with both traditional handwritten and computer-assisted prescriptions, found faults in 2.6% of the studied prescriptions. Major problems with handwritten prescriptions included administrative issues such as the difficulty of reading the signature and name clarification of the doctor, issues essential for reimbursement of a prescription in Finland. Patient safety related problems occurred in 0.6% of the prescriptions, absent or erroneous strength of the product and problems associated with dosages (Ihantola-Vormisto 2001). These problems were also found with computer-assisted prescriptions, which avoid handwriting-related problems (Ihantola-Vormisto 2001).

Further benefits can be obtained when ePrescription programmes are linked to decision-making programmes that take into consideration the patients' other medications, drug allergies and medical histories (Armstrong and Chrischilles 2000, Ochs 2002, Higgins et al 2002, Tamblyn et al 2003). For example, they have been shown to reduce inappropriate prescriptions for the elderly (Tamblyn et al 2003). In addition, information technology can offer other assistance such as lists of available drugs, including generic products, prices and reimbursement information (Armstrong and Chrischilles 2000).

Studies of ePrescriptions have, however, proposed caution about e-prescribing and emphasised the need for further studies (Bell et al 2004, Miller et al 2005). One problem is the lack of common interests among commercial software vendors, software buyers and users, which has led to a lack of standards, and, consequently, divergent software systems that are incompatible and use divergent coding of health-related data (Papshev and Peterson 2001, Hammond 2004, Miller et al 2005). As a result, the data of drug databases may be limited or out-of-date. Therefore, commercial vendors should not work separately but in co-operation with involved other parties. Software usability and accuracy is not self-evident, either. Decision-assisting programmes been criticized for alerting too readily in clinically irrelevant situations (Reichley et al 2005).

2.5.3. Online drug trade for personal use

Online selling pharmacies have been called online-, internet- and e-pharmacies. One definition by Bessel et al states that online pharmacies, (or e-pharmacies, as Bessell et al called them) are web sites selling POMs and other products including non-prescription and complementary medicines to consumers via the Internet (Bessel et al 2002). Another definition by the Royal Pharmacy Society of Great Britain separates between registered internet pharmacies and other commercial suppliers and states that an internet pharmacy is "a registered pharmacy which offers to sell or supply medicines (or other pharmaceutical products) and/or provides other professional services over the internet, or makes arrangements for the supply of such products or provision of such services over internet (Royal Pharmaceutical Society of Great Britain 2006). Online pharmacies sell drugs online while traditional pharmacies' websites only advertise pharmacy services and inform consumers about healthcare and medications.

Online pharmacies have been classified into subgroups in several ways. Peterson groups online pharmacies into chain pharmacy extensions, independent pharmacy extensions, mail order pharmacies extended into the net and online pharmacies existing solely in the net (Peterson 2001). Crawford divides online pharmacies into traditional chain pharmacies with web presence, independent community pharmacies with web presence, stand-alone, exclusive pharmacy sites and rogue pharmacy sites. These definitions include pharmacies that also/only practise outside the internet. Illegal and suspect, exclusively online-practising pharmacies have been called rogue sites (Crawford 2003). They sell practically anything that consumers want, from legal drugs to questionable, self-made products that are not manufactured by authorised drug manufacturers. Drugs are sold with no regard to legislation or consumer-related issues. The so-called lifestyle pharmacies sell lifestyle-related drugs like sildenafil, used for male sexual impotence, orlistat, used to decrease appetite as well as finasteride and minoxidil, used for male-type hair loss. Maintainers of illegal sites have been called "fly-by-night" operators to describe their tendency to change websites, change names or disappear altogether to hide from the authorities (Clark 1999). In addition, there are online pharmacies that seem to operate abiding by law.

It is estimated that the birth of online pharmacies dates back to 1999 in the USA (Crawford 2003) and in Europe. Some figures about Internet prescription sales have been given: in 1999 the figure was $160 million for of total $101 billion in the USA market (Levin-Epstein 2000). The National Association of Boards of Pharmacy (USA) estimated in 2000 that POM sales amounted to $100 million and would increase up to $1 billion by 2003 (Lorman 2000). Another source from the US estimated that total online sales would be $ 20 billion by 2004 (Crawford 2003).

Online buying of drugs is attractive for many reasons. Online pharmacies are reachable by anyone with Internet access, from anywhere and at anytime (Landis 1999, Crawford 2003). This can be desirable for people such as elderly, disabled people and people living in remote areas (Henney et al 1999). As one advantage has been regarded the privacy they offer, which a traditional pharmacy cannot offer (Crawford 2003). The prices can be lower, as they skip some costs like maintenance (Levin-Epstein 2000, Lorman 2000, Crawford 2003), but price differences between different countries may also result in savings with international orders (Ashurst Morris Crisp and Executive Perspective S.A. 1998). Online pharmacies can provide products which are not yet available in the national markets. For example, Viagra (sildenafil), used for male impotence, was available online for Europeans well before it was authorised and available within the EU. These pharmacies are easy to find with internet search machines. Some even send email advertisements without a previous contact.

Consumers may not always be aware of the problems associated with the safety and quality of online drugs, not to mention their legality. In a Swiss study, 17 pharmaceuticals were ordered from nine online pharmacies. The orders contained inadequate amounts of the active ingredient and unidentifiable impurities. In some cases, the drug descriptions were misleading, package information leaflets were missing or packaging was inadequate. The drugs could also have suffered damages during transit (Scrip 2000). Online pharmacies can skip all safety measures developed

nationally to protect people's health. In these transactivities, data protection, of both personal and financial data, may be inadequate (Crawford 2003). The total costs could also be higher than those for drugs bought from traditional pharmacies, especially when online consultation is included (Scrip 2000). Even online consultation alone may be more expensive than traditional consultation (Bloom and Iannacone 1999). Online purchasing of drugs may be illegal. Finland, for example has forbidden online purchases of pharmaceuticals (Finnish Government Statute 1088/2002). People are not sufficiently aware about the illegality of online drug purchases as shown by telephone interviews executed by the Association of Finnish Pharmacies among Finnish citizens in 2006. The Association surveyed 1000 Finnish consumers, of whom 35% considered online purchasing legal and 30% were uncertain (Kostiainen 2006). Regardless of applicable law, some people will buy pharmaceuticals online anyway.

2.6. EU and blood safety

2.6.1. Towards common European-level blood legislation

It is essential to ensure that at least minimum safety standards for blood products are ensured within the EU internal market. The blood sector is not a nationally limited issue but applies to patients and citizens from other member states as well. First, the internal market has resulted in increasing movements of citizens, including patients travelling for private reasons and to receive cross-border care. Consequently, it is likely that citizens and patients increasingly face situations where they need blood donated in another country. Second, countries are not self-sufficient in blood products or need to import blood components or products for other reasons. Thus, everything possible should be done to ensure minimum quality and safety standards of blood products.

The blood sector was not legislated at the Community level until 2002, except for industrially-prepared medicinal products derived from the blood and plasma**,** regulated by the Community's pharmaceutical legislation (Farrell 2006). Instead, the EU and the Member States acknowledged and participated in other international organisations, the Council of Europe and the World Health Organisation WHO, with activities in the blood transfusion sector. Especially for Europe, the Council of Europe has done significant and profound work in the blood field by defining blood products, their production and quality requirements in its annually updated guidebook "Guide to the preparation, use and quality assurance of blood components" (Council of Europe 2003). This guidebook has been referred to in national legislations and has been used as an official standard for the preparation of blood and blood products. The Council itself does not have any legislative power.

A push to Community legislation in the blood sector was given by scandals in several European countries (Farrell 2006) during the late 1970s and early 1980s. These scandals hit mainly France (Dorozynski 1995 and 1998b), but also other countries like the UK (Farrell 2006), the Netherlands (Sheldon 1995) and Germany (Abbott 1993).

They concerned human immunodeficiency virus (HIV) and in minor extent, hepatitis C virus (HCV) contaminated blood products, which were used in several EU Member States. The reasons were such as transfusion of insufficiently processed clotting factors of US origin; in France collection of blood from areas and donors with high HIV risk (Dorozynski 1998a, Farrell 2006); delayed onset of introduction of HIV testing (Durand de Bousingen 1999) and of infectious-agent eliminating processes. High-level health authorities were involved and even accused in national courts (Bowen 1995-6, Casassus 2003). Often, the most vulnerable patient group was the haemophiliacs who regularly need plasma-derived clotting factors. In the lawsuit against US manufacturers, it was estimated that by 1992 alone of European haemophilics 5000 had caught HIV infection; 2000 had developed AIDS and 1250 had died of the disease (ABC Newsletter 2003).

The Community gained a mandate in the blood sector in 1997 when the new Public Health Article of the Treaty of Amsterdam came into force ((Treaty establishing the European Community 1997). The new Article allowed the Community to take measures ensuring high quality of blood and blood derivatives (Article 152, Appendix 3). A legally non-binding Council recommendation for the suitability of blood and plasma donors and screening of donated blood was introduced in 1998 (Council Recommendation 98/463/EC). It established the information topics that should be administered to blood donors (Appendix 6). Some years later, in 2002, the first legally binding directive ensuring blood safety was adopted. This Directive 2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood was complemented by a supplement directive, Directive 2004/33/EC. The first blood directive uses the Council of Europe's Guide in defining measures for safety and quality standards. It also sets up a framework for blood establishment organisations and their responsibilities, including testing, labelling and traceability of donated blood and blood products. The requirements of traceability of a single blood/blood component unit and blood products also apply to blood imported to the Community area from third countries (Directive 2002/98/EC). Thus, today, the blood products in any of the Community Member States and even from third countries should guarantee some level of safety and quality. However, quality and safety differences may occur even for such reasons as volunteer non-remunerated donations as a basis of safe donations are only an aim of the Community by the Directive, not a norm.

The last item of blood sector legislation was implemented in 2005. Commission Directive 2005/62/EC accomplished the earlier established Blood Directives by setting up a quality system to cover all activities of blood establishments. The requirements also apply to blood and blood components imported from third countries (Directive 2005/62/EC).

2.6.2. Blood safety and blood donor information

Blood donation and transfusion processes aim at providing high-quality and safe, infectious agent-free blood for recipients without harming donors' health. Both recipients and donors are best safeguarded partly with similar measures. Safe, high-

quality donated blood is associated with volunteer non-remunerated donations (e.g. Fiedler 1992, Korcok 1998). The WHO's statistics even show that the prevalence of HIV is lower among volunteer non-remunerated blood donors than among the general population (WHO 2001-2002).

Donor selection procedures include an interview and often a self-administered questionnaire on the subject's lifestyle and health status. The questionnaire may be combined with a personal interview on the basis of the questionnaire, reassuring its suitability (Kleinman et Williams 1998). The success of these methods depends on several factors such as the interview method and privacy during the interview (Kleinman et Williams 1998). The interview is followed by a general physical examination. The donated blood is examined for infectious agents and other essential markers (WHO GDBS report 2001-2002, Van der Poel and Janssen 2006). The processing of blood to products includes procedures aimed at eliminating infectious agents.

All risk factors for infectious agents like HIV, hepatitis virus B (HBV) and C (HCV) are not found in the donor interview. The coverage of blood tests for HIV, HBV and HCV infections is not 100%: these infections are undetectable during the seronegative window period, the early phase of the infection. For HIV, this period is at least a few weeks. Although several measures have reduced the risks of these infections from blood donations, the seronegative window-period can pose a greater risk in the near future. Globalisation seems to narrow national borders for people and goods. The lack of self-sufficiency in blood also requires import of blood and blood products in Europe (Farrell 2006). Donor education can complement other measures ensuring the safe and high quality of donated blood. Blood establishments offer printed information materials, and the Internet, organised public campaigns and educated personnel answer donor questions.

What is then sufficient blood donor information? For the EU Member States, the Commission Recommendation from 1998 (Appendix 6) defined the information that should be offered to blood donors. The volunteer Recommendation was followed by the Community's Blood Directives, of which Directive 2004/33/EC lists 11 topics for information (Appendix 7). The topics are similar to those given in the Recommendation. The required information includes the following: information on blood and blood products and the donation procedure (requirement no 1); reasons for donor physical examination, interview, testing of blood and understanding of informed consent and reasons for self-referral, temporary and permanent deferral (no 2); information of donor data protection (no 3); reasons for abstaining from donation when it is harmful to donor's own health (no 4); specific information on donation procedure and possible risks (no 5); the possibility of changing one's mind about the donation and withdrawal at any time (no 6); reasons why it is important that a donor should inform the blood establishment about reasons why a prior donation is unsuitable (no 7); the blood establishment's responsibility to inform the donor of significant abnormal test results (no 8); information of why unused autologous blood donations are not used for other patients (no 9); information that detection of certain microbiological agents from the donated blood leads to destruction of the blood and deferral of the donor (no 10); and the donor's possibility to ask questions at any time of the donation (no 11) (Directive 2004/33/EC).

3. AIMS OF THE STUDY

The study examined the cross-border delivery of European health care and the relevance and effects of EU regulations and judicial processes on it, with attention to patient and citizen safety. Special reference was given to cross-border and electronic delivery of drugs and harmonisation of the contents of printed blood donor information materials.

The study attempted to answer the following questions:

I Are non-national European prescriptions deliverable in another EU Member State?

II Does national legislation allow mutual recognition of non-national European prescriptions and import of drugs from another EU Member State for personal use?

III What type of online pharmacies exists and how would they fit into the European internal market?

IV Is e-prescribing possible in cross-border healthcare?

V Is EU-level regulation needed to improve the contents of printed blood donor information materials?

4. METHODS

The materials for the five sub-studies were collected during 1999-2003 when the EU had 15 Member States: Austria, Belgium, Denmark, Germany, Greece, Finland, France, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden and the UK. Today, the EU has 27 Member States. These new Member States consisting of eastern and central European countries differ from the old 15 Member States in cultural traditions and in their financial situation. This study does not address these countries.

Some of the substudies included Norway, which is an EEA and EFTA country, and Switzerland, which is an EFTA country and also has bilateral agreements with the EU on issues relevant to the European internal market.

EU legislation and EU policies on public health and other healthcare matters affecting fields such as policies on the internal market, enterprises/industries, social policies and information society were the framework of this study. Data sources were obtained from the official website of the European Union, www.europa.eu.int. Various studies were also reviewed. Some of them had been conducted by the Commission. Research and political articles were retrieved from medical reference databases.

4.1 An empirical study of mutual recognition of non-national European prescriptions

Finnish and Luxembourgian prescriptions were used to test the mutual recognition of prescriptions in pharmacies established in another EU Member State. Finnish prescriptions were issued by a Finnish doctor licensed to practise in Finland. Luxembourgian prescriptions were issued by a Finnish doctor licensed to practise both in Finland and in Luxembourg. The prescriptions were issued for phenoxymethylpenicillin. The trade name of the drug was selected among penicillins available in Finland when the prescription was Finnish and among those available in Luxembourg when the prescription was Luxembourgian. To avoid any confusion due to differencies in trade names, the generic name of the drug was also used. The prescriptions were formulated according to the respective national regulations in national prescription forms. Both Finnish and Luxembourgian prescriptions included instructions for the intake of the drug and the indication of the treatment, which was an imaginary acute tonsillitis. The valid treatment for acute tonsillitis in Finland is phenoxymethyl penicillin, unless there are contraindications, like drug allergy. The Finnish prescription was issued in the Finnish language and the Luxembourgian one in French, which is one of the local official languages. Both prescriptions were signed and stamped according to the respective national rules by the issuing doctor, including

the medical code[7] given by the competent Finnish authority or, respectively, by Luxembourgian authority. For the Luxembourgian prescription the issuing doctor used naturally only Luxembourgian medical code.

Attempts were made to avoid refusals for delivery of the drug due to misunderstanding. The prescriptions were typewritten for clarity. Both trade and generic names were used in the Finnish prescription, as the trade names can vary between the countries as well as selections of pharmaceuticals sold. The Luxembourgian prescription gave the generic name of the drug. Phenoxymethyl penicillin was chosen as it is a relatively harmless drug, unless the patient has penicillin allergy. It is also a common and well-known antibiotic.

Healthy individuals tried to purchase the prescribed drug while travelling in the EU area in 1999. They did not need or use the pharmaceuticals they bought. Thus, there was no ethical problem associated with a possible lack of treatment if the prescription was not dispensed or with misuse of the drug when dispensed.

The aim was to test at least one Finnish and one Luxembourgian prescription per an EU Member State; and one prescription per a pharmacy. However, this did not occur in every case, but depended on those who visited or lived in the country. In Finland only a Luxembourgian prescription was tested; respectively, in Luxembourg only a Finnish prescription was used. The persons testing the prescriptions could freely choose the pharmacies where to try to purchase the penicillin prescriptions. There was not any requirement for the pharmacy type, only the same pharmacy or a chain of pharmacies were not tested twice. There existed neither requirements for testing areas, like bigger cities, suburbs or rural areas. The prescriptions were tested in all EU Member States except Ireland.

The outcome measures were: a foreign prescription dispensed or not dispensed. In case of a dispensed prescription, the type of antibiotic dispensed was reviewed.

4.2. National legislation on mutual recognition of non-national European prescriptions and on import of drugs for personal use

After the empirical study, a case-report study was conducted. It concerned the Member States' national legislations on the delivery of non-national European prescriptions from pharmacies and import of POMs for personal use from another Member State. A questionnaire with open questions was prepared in English (Appendix 8).

[7] In Finland each licensed doctor receives a numerical code, "SV-tunnus" ("Sickness insurance number") issued by the Social Insurance Institution of Finland. The code must appear in all prescriptions. It proves that the doctor is licensed to practise in Finland and allows reimbursement to the insured. In addition, the Social Insurance Institution of Finland can check any restrictions for the doctor to practise his profession and issue prescriptions.

The questionnaire was tested by an official of the Finnish National Agency for Medicines before sending it out to the national medicines authorities of the remaining 14 Member States. The National Agency for Medicines in Finland assisted in providing contact persons in 10 national medicines authorities in 10 Member States. The remaining four officers in four Member States were selected from the websites of the medicines authorities of these Member States. The questionnaire was mailed, emailed or faxed. A reminder was sent twice at one month's interval when necessary. If no reply was received, the physicians' professional association with the largest coverage, trade union or equivalent of the respective country was contacted. The associations were chosen from a book containing national medical associations of the Member States of the European Region of WHO (Vigen and Rowl 2000) to represent the medical association with the largest coverage of the respective country.

4.3. Online pharmacies

Online pharmacies were studied to evaluate whether they fit in the European internal markets. Online pharmacies operate in a virtual world without any national borders. Relevant Community legislation was first retrieved to evaluate the framework for electronic pharmacy operations from the official website of the European Community; especially, data from the relevant DG websites and EUR-Lex containing all Community legislation were looked for. Then pharmacies operating exclusively online were studied to find out issues in favour and against for cross-border operations. Online pharmacies were found with Internet search machines using the term "online pharmacy".

Only online pharmacies operating in English were chosen for language reasons. On the other hand, the use of English can be assumed to reach a wider clientele than many other languages. Another criterion was that online pharmacies were US- or European-based, as the marketing environment was considered to present some similarities: national Member States of the European Community and the federation of the United States of America.

Seventeen online pharmacies were included in the study to describe some characteristics of the three different types of online pharmacy categories. They were selected so that there was an approximately equal number of each category: authorised online pharmacies, online pharmacies selling lifestyle drugs and rogue sites. Some famous online pharmacies were identified from articles on online pharmacies. Most pharmacies, however, were chosen randomly from the Internet by using the Google search machine with the key word "online pharmacy". The survey resulted into thousands of links, to online pharmacies, but also to for example to articles and information on online pharmacies, of websites of national authorities, health related associations et cetera. The selection of online pharmacies was very rough, except for earlier mentioned criteria.

The online pharmacies were searched for on the basis of two major issues. First, the pharmaceutical selection sold and the extent of selection was reviewed. The selection could consist of POM, OTC drugs and other health and well-being-related products. Second, the dispensing policy of the pharmacy was studied, relating to all possible methods that a pharmacy may use to control the suitability of the ordered drug to the client, preparing for customs when the order is cross-border and issues related to shipping of the order.

4.4. Electronic prescriptions in cross-border healthcare

A case-report study method was used to evaluate the present state of the use of ePrescriptions in Europe and possibilities of using them in cross-border healthcare. A twelve-point multi-choice questionnaire was prepared (Appendix 9). The questions were about the use of ePrescriptions within the national healthcare systems (questions no 1,2); the chosen technology for ePrescriptions and use of international standards (questions 3,4); use of the same technology and ePrescription form for the whole country (question 5); the patient's possibility to choose the pharmacy (question 6); methods for verifying the identity of the doctor and the patient (question 5); integrity of the ePrescription (questions 7,8); acceptance of foreign ePrescriptions (question 9); problems associated with national and foreign ePrescriptions (question 10); and linkage of systems with other computer systems (question 11). In addition, attitudes towards the development of a common European ePrescription were evaluated by the last question of the study (question 12**)**. In addition to multi-choice answers, the contact persons were encouraged to give additional information with every answer. The questionnaire was not piloted before it was emailed to the contact persons.

The respondents were identified among the national representatives of consultative committee of the European Commission, the Working Party for Health and Persons with Special Needs. This working party was run by the European Commission's eHealth Unit in the DG Information Society. The members of the working party came from all other EU Member States except Luxembourg, from two EEA/EFTA countries (Iceland and Norway) and from some non-EU/EEA countries. Only those from the EU and the EEA/EFTA countries were contacted. There were one or more representatives per a country; all of them were contacted. If no reply was received, a reminder was emailed three times at monthly intervals.

4.5. Blood donor information materials

The aim of the study was to find out whether European-level regulation was necessary to improve the contents of blood donor information materials, and thus, to act as a method safeguarding health. The information materials given to blood donors before

the introduction of the Blood Directive were compared with the requirements of Directive 2004/33/EC (Appendix 7).

The materials were considered to meet the Directive's requirement when at least one of the topics listed in the requirements appeared in the text. When the information could meet two separate requirements, it was marked accordingly. The quality and the extent of the information were not considered in the study. One reason for this was linguistic. Two persons, a doctor and a nurse evaluated the materials twice. They knew best Finnish, Swedish, English, German, Luxembourgian and French.

The application of all requirements of Blood Directive 2004/33/EC except requirement 9 was evaluated. Requirement 9 is about autologous blood donation, which is still a rare event in most European countries (Van der Poel and Janssen 2005).

The study was conducted at the Finnish Red Cross Blood Service. Cooperation was done with the European Blood Alliance (EBA) to contact and collect blood donor information materials from the national blood establishments. The EBA itself is an umbrella organisation for European blood establishments, promoting cooperation between its members and lobbying issues of common interest to the European institutes. Its member associations are blood establishments operating within the EU, responsible for countrywide co-ordination, collection and preparation of blood.

Information was collected from both EBA members and associate members and some other blood establishments. The materials received from them were in principle distributed for the needs of the blood establishments of the respective country. The contacted blood establishments were from 12 EU Member States, i.e. Austria, Belgium (both Belgian Flanders and Belgian Wallons were contacted as they run their separate blood services), Denmark, England, Northern Ireland, Scotland and Wales (all contacted separately as these UK regions run their separate blood services), Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands and Portugal. In Germany, the blood establishment contacted did not represent the whole country, as there are different blood establishments governed by different organisations and producing their own materials (oral information by Ms Eila Sandborg, the then secretary of the EBA). In addition, blood establishments from Norway, an EEA country, and Switzerland, an EFTA country, were included in the study. The Italian blood establishment first contacted was later changed to another as the contact person of the first establishment had to resign for personal reasons.

The participating blood establishments were asked to send blood donor information materials given to blood donors before the end of the year 2002. The materials were asked to be organised into three subgroups according to the recipients of the materials, i.e. (1) first time donors, (2)all donors and (3) freely available to anyone interested.

5. RESULTS

5.1. An empirical study of the recognition of non-national European prescriptions

Altogether, 29 prescriptions were tested, consisting of 15 Finnish and 14 Luxembourgian prescriptions in 14 Member States. Only Ireland was missing from a full presentation of the 15 EU Member States. Most prescriptions, i.e. 21 of the 29 were dispensed by the tested pharmacies in the EU Member States. Only a few countries made the exception. In Sweden, only the Finnish prescription was recognised. In the UK, the tested pharmacies did not deliver Finnish or Luxembourgian prescriptions. One British pharmacy verified whether the prescribing doctor also had a valid license to practise in the UK, in which case they would have dispensed the drug. In Northern Ireland, the pharmacist consulted medicines authorities for advice about the Finnish prescription; one authority allowed the dispensing, another requested that it had to be translated before dispensing. In Denmark, Greece and Spain both prescriptions were dispensed.

Germany and Luxembourg dispensed the tested Finnish prescriptions. Austria, France and the Netherlands dispensed the tested Luxembourgian prescriptions.

The Luxembourgian prescription was recognised in Finland. The prescribing doctor's licence to practise in Finland was verified before approval of the prescription. In Portugal, one pharmacy did not dispense a foreign, Luxembourgian prescription.

Most pharmacies dispensed phenoxymethyl penicillin. Pharmacies in Belgium and one pharmacy in Portugal offered amoxicillin instead. Cephalexin was offered in Italy, as they did not stock phenoxymethyl penicillin. In Belgium, one pharmacy was about to order penicillin. Table 1 is a summary of the results.

Table 1. Dispensing of non-national European prescriptions in another EU country.

Country/City	Tested Prescriptions: the amount and the origin (Fin/Lux)	Dispensing: pharmaceutical generic name of the drug/no dispensing
Austria/Gatz	1 Lux	penicillin
Belgium/Brussels	3 Fin	amoxicillin
Denmark/Copenhagen	1 Fin, 1 Lux	penicillin
Finland/Helsinki	1 Lux	penicillin
France/Nice	1 Lux	penicillin
Germany/Frankfurt	2 Fin	penicillin
Greece/Athens	1 Fin, 1 Lux	penicillin
Italy/Rome	1 Fin, 1 Lux	cephalexin

Country/City	Tested Prescriptions: the amount and the origin (Fin/Lux)	Dispensing: pharmaceutical generic name of the drug/no dispensing
Luxembourg/Luxembourg	1 Fin	penicillin
Netherlands/Utrecht	1 Lux	penicillin
Portugal/ Costa Marin	1 Lux	amoxicillin
	1 Lux	no dispensing
Villa Real de San Antonio	1 Fin	penicillin
Spain/Barcelona	1 Fin, 1 Lux	penicillin
Sweden/Stockholm	2 Lux	no dispensing
	1 Fin	penicillin
UK/London	2 Fin, 1 Lux	no delivery
Belfast	1 Fin, 1 Lux	no delivery

Fin=Finnish (prescription)
Lux=Luxembourgian (prescription)

5.2. National legislation on mutual recognition of non-national European prescriptions and on import of drugs for personal use

Replies were received from 11 officials of 11 Member States of the consulted 15. Responses were obtained from Austria, Belgium, Denmark, Finland, France, Germany, Greece, Netherlands, Spain, Sweden and the UK. The officials were from specific medicines agencies in the Nordic countries, Ministries in the Western and Southern Europe and pharmacists' associations in Belgium and in the UK (Table 2). The responses varied from extended to short ones.

Table 2. The EU Member State and the responding authority.

EU Member State	Responding authority
Austria	Federal Ministry of Social Security and Generations
Belgium	Association Pharmaceutique Belge
Denmark	Danish Medicines Agency
Finland	National Agency for Medicines
France	Ministry of Employment and Solidarity
Germany	Federal Ministry of Health
Greece	Ministry of Health and Welfare
Netherlands	Ministry of Health, Welfare and Sport
Spain	Ministry of Health and Consumer
Sweden	Medical Products Agency
The UK	Royal Pharmaceutical Society of Great Britain

5.2.1. Legislation on the dispensing of foreign European prescriptions

Dispensing of foreign European prescriptions was possible in the responding countries, except that Germany did not state its attitude in its response.

Respondents in Belgium and in the Nordic countries, Denmark, Finland and Sweden stated that they had special national legislation on the dispensing of prescriptions issued from another Member State. The legislations of the Nordic countries allowed dispensing of other Nordic prescriptions with certain limitations associated with the type of the prescribed drug (e.g. narcotics would not be dispensed), the authorisation status of the drug in the country where the prescription was issued and the place where the prescription was to be dispensed. In Belgium, the law allowed dispensing of prescriptions issued by doctors established in other EU Member States. There was no special legislation in the UK, but the respondent stated that foreign prescriptions were dispensed if the prescribing doctor had a license to practise in the UK.

The dispensing of foreign European prescriptions depended on prescription-related issues, such as authenticity of the prescription and type of prescribed pharmaceuticals. Narcotics or psychotropic drugs would not be dispensed; neither would unauthorised drugs or drugs for hospital use only. Prescriptions only on paper were accepted. Table 3 is a summary of the existing legislation on the dispensing of foreign prescriptions.

Table 3. Dispensing of foreign European prescriptions in detail.

Country	**Acceptance of foreign European prescriptions: Yes/No**	**Existence of legislations on dispensing of foreign prescriptions: Yes/No**	**Restrictions on dispensing of foreign prescriptions 1=type of pharmaceutical 2=prescription authenticity suspicious 3=type of prescription (paper, fax, etc.)**
Austria	Yes	No	1,2,3
Belgium	Yes	Yes	n.s.
Denmark	Yes*	Yes	1,2,3
Finland	Yes*	Yes	1,2,3
France	n.s.	No	1,2,3
Germany	n.s.	n.s.	n.s.
Greece	Yes	No	1,2,3
Netherlands	Yes	n.s.	1,2,3
Spain	Yes	No	1,2,3
Sweden	Yes*	Yes	1,2,3
UK	Yes**	No	1,2,3

* Nordic prescriptions only

n.s. Not stated

** Foreign prescriptions dispensed only if the prescribing doctor was licensed in that country.

In principle, the respondents did not consider that harmonisation of regulations for recognition of foreign European prescriptions at the EU level necessary, or their opinion was neutral. Difficulties were assumed to be associated with availability of drugs, different trade names and dosage forms, reimbursement for drugs obtained from another country, understanding of a foreign language in the prescription and verification of the authenticity of foreign prescriptions.

5.2.2. Import of POM from another EU Member State for personal use

Import of POMs for personal use was legal in all responding countries. Restrictions existed in the amounts of imported drugs. In Finland and Sweden, the amount corresponded to one year's use, in France three months' use. In addition, in Finland and Sweden the import of narcotics was restricted to correspond to a shorter period of use**.** The type of import was often limited. Personal importation was the only possibility in Austria, Germany, the Netherlands and Spain; in Finland, France and Sweden mail orders were also permitted.

Reimbursement for the costs of imported drugs differed from that of drugs obtained from pharmacies in the national country. In Greece and Austria, reimbursement depended on the individual's insurance scheme. In Finland, Denmark and Sweden, it was required that the pharmaceutical was also sold in the national country and even had an approved price (by the authorities) in the national country (Finland). Finland also had further requirements for the trade name and package size for the imported drug when reimbursement was desired (Table 4).

Table 4. Methods used to restrict the import of prescriptions-only medicines (POMs)-.

Country	Restrictions on import of maximum amount	POMs within the EU: type of import	Restrictions on reimbursement
Austria	n/a	Personal	Yes
Belgium	n/a*	n/a*	Yes
Denmark	n/a*	n/a	Yes**
Finland	One year use	Personal, mail	Yes**
France	Three months use	Personal, mail	n/a
Germany	n/a*	Personal	n/a
Greece	n/a	n/a	Yes
Netherlands	n/a	Personal	n/a
Spain	n/a*	n/a	n/a
Sweden	One year use	Personal, mail	Yes **
UK	n/a	n/a*	n/a

n/a No answer or restricted, *but without further specification

** The drug has to be priced in the national country (where reimbursement is applied for). In Finland, the same trade name and package size is required.

5.3. Online pharmacies

5.3.1. European Community legislation during the present study

European Community treaties establish the fundamental freedoms of movement of people, goods, services and capital. These can be restricted by a single member state for significant reasons such as a threat to public health. However, the justified measures must be proportional to the seriousness of the threat.

Community pharmaceutical legislation strictly regulates sales of pharmaceuticals within the Community area. Different authorisation procedures lead to divergent national pharmaceutical markets, but the markets should guarantee the same safety and quality standards. The qualifications of pharmacists and doctors are defined by Community directives for mutual recognition of these professions (Directive 1985/433/EEC and Directive 93/16/EC). In addition, pharmacists and doctors must be licensed in the country where they practise.

The European Community has established special legislation for online and distance trade. At the time of this study, this legislation was under what is known as the Telecom package. Today, reviewed legislation in the area goes under the title of eCommunications.

Legislation for online pharmacies is based on the following directives:

Directive 97/7/EEC on the protection of consumers in respect of distance contracts and Directive 2000/31/EC on electronic commerce (eCommerce) establish principles for the special kind of services to safeguard both the service provider and the consumer. The two directives provide the basic framework for the presentation of goods or services, terms of dispensing, presentation of the service provider, contracts and invoicing.

Directives also establish the principles for personal data protection. These are Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data and Directive 1997/66/EC about the processing of personal data and the protection of privacy in the telecommunications sector. They include regulations about the collection, transfer and procession of data. According to them, medical data should be processed solely by medical professionals or other authorised persons.

5.3.2. Online pharmacy practises

The three subgroups of online pharmacies, i.e. legally practising, lifestyle pharmacies and rogue sites were identified easily, although the categorisation was found overlapping. All sold POMs and often also other products, either/and OTCs or other non-pharmaceutical products such as cosmetics. Rogue sites also offered home treatment and home test kits and had their own production. Lifestyle pharmacies usually had a limited selection of pharmaceuticals, concentrating on lifestyle

pharmaceuticals such as sildenafil, orlistat and finasteride. Rogue sites could sell whatever the consumer wanted, including non-authorised products.

Operation of the studied online pharmacies could be summarized as follows: The consumer registers with contact and payment information, in some cases providing insurance and medical history information, e.g. about other medications, any allergies and diseases. Both authorised pharmacies and lifestyle pharmacies claimed that a pharmacist or another qualified person would check the required medical data for any contraindications for the ordered pharmaceuticals and even contact the client when necessary. Some sites also had additional services to compensate for the traditional client-pharmacist face-to-face contact, such as toll-free telephone numbers.

The customer often placed the order by using an index, including the amount, form and strength of the drug. Re-orders were possible; some pharmacies even offered refill reminder services. Attitudes towards the dispensing of POMs varied between the three categories. Authorised pharmacies demanded a valid prescription for an order of POM; the prescription could be dispensed by ordinary post or fax or the online pharmacy contacted the doctor or vice versa. To avoid any problems associated with nation-specific pharmaceutical legislation, some online pharmacies did not deliver orders abroad or required that the client should investigate the matter and take responsibility. Of the studied lifestyle pharmacies, some required a valid prescription and offered online consultations to clients without a prescription. These consultations were typically made by filling in a questionnaire which was afterwards allegedly reviewed by a doctor or a pharmacist. A consultations was payable if leading to a prescription. Some lifestyle pharmacies dispensed drugs without a prescription. Rogue sites did not require any prescriptions. Rogue sites and lifestyle pharmacies also dispensed pharmaceuticals regardless of their authorisation status in the country of order.

All possible legal consequences of the order could be made on the responsibility of the client. Payments were made online. The mode of shipment could be chosen; the quicker, the more expensive. Some pharmacies also offered dispensing via local pharmacies.

More legitimate online pharmacies followed some sort of code-of-conduct, like HON (Health On the Net Foundation, more information available from http://www.hon.ch) based on ethical standards of presentation of medical information; the TRUSTe seal (more information available from http://www.truste.org), which is a sign for certain privacy principles for personal data; or the VIPPS (Verified Internet Pharmacy Practise Sites) seal, a seal confirming that the pharmacy acts according to rules developed for online pharmacies by the US National Board of Pharmacy (Criteria available from http://www.nabp.net/vipps/consumer/criteria.asp).

5.3.3. State of online pharmacy operations within the EU

European online pharmacies were found to have been established in the UK and its free trade areas in Gibraltar and the Channel Islands, in Denmark and in the Netherlands.

The UK online pharmacy was of the authorised type, operating only within the national borders. The online pharmacies in the British Channel Islands were of the lifestyle type, also delivering to customers abroad. Online pharmacies in Denmark and in the Netherlands fell best into the category of the authorised type. The Dutch pharmacy also traded abroad. In Sweden, the pharmacy monopoly Apoteket Ab was considering setting up online service. Traditional pharmacies had also established their own websites about their services and available health products.

Online pharmacies were already found to face problems in the EU. First, national legislations act as a barrier to online pharmacies, by prohibiting online orders (at least in Finland) or by prohibiting imports of POMs. One legal case had appeared at the international level: The Dutch online pharmacy had been sued and condemned in Germany for mailing pharmaceuticals, including POMs and non-licensed pharmaceuticals cross-border. In Germany, it was not allowed to use ordinary mail to import drugs for personal use. One German court took the case to the European Court of Justice, for it to decide whether German law on personal import of pharmaceuticals was against Community internal market freedom, free movement of goods (Case C-322/01). Meanwhile, the Dutch online pharmacy started to use couriers for its German customers or the customers collected their orders from the Netherlands.

5.4. ePrescriptions

Responses were received from the representatives of 11 countries of the contacted 16 countries. These included five completed questionnaires. Two responses were from countries which were already using ePrescriptions, i.e. Sweden and Denmark, and three from countries which considered introduction or had piloting trials of ePrescriptions, i.e. Finland, Germany and the UK. In the following presentation of results, reference is made to these five countries and their experience from ePrescriptions.

There were four free-format replies, from Belgium, Greece, Italy and Portugal. In none of these countries were ePrescriptions used or considered for introduction. The respondents were, however, not totally certain about the current state of ePrescriptions in their country. Responses from France and Portugal referred us to further contact persons, none of them responded regardless of several reminders. The respondent from the Netherlands referred us to a publication which could not be located. Thus, the use of ePrescriptions in these countries remained to be definitely documented. Table 5 shows the institutions responding.

Table 5. The EU Member State and its responding institution

Country	Institution
Belgium	RIZIV
Denmark	Medcom
Finland	National Research and Development Centre for Welfare and Health
France	Ministry of Health
Germany	Verband der privaten Krankenversicherung
Greece	Institute for Language and Speech Processing
Italy	Ministry of Health
The Netherlands	Ministry of Economic Affairs, Welfare and Sport
Portugal	European Health Telematics Organisation
Sweden	Karolinska sjukhuset
UK	National Department for NHS IT

The technology used in everyday practice or in pilot trials or considered for future use varied from one country to another. Three countries of four had chosen a server; e-mail was used only in one country. All countries using or planning the use of ePrescriptions preferred a nation-wide system for the transfer of ePrescriptions. ePrescription forms usually followed an international standard, but these standards were different between the countries. In three countries, the system allowed the patient to choose the dispending pharmacy each time of purchasing drugs with the prescription. In Sweden and Denmark, which already had ePrescriptions in routine use, only one pharmacy could be chosen. Table 6 is a summary of the results.

In all five countries, the identity of the patient and the prescribing doctor was verified. The verification methods used varied. The doctor's identity was verified from a personal code in all countries; an identity card could be used in two countries. An electronic signature was possible in three countries. In addition, the doctor's licence and the integrity of the content of the ePrescription could be verified in three countries. The patient's identity was verified from an identity card or similar, a personal identity number was also used.

Most respondents did not consider that any of the problems stated in the questionnaire were associated with their national ePrescriptions. However, they noted several problems that were associated with foreign ePrescriptions such as the difficulty of identification of the patient. Four respondents considered that Community-level regulations should be developed for verification of foreign ePrescriptions. At the time of the study, foreign ePrescriptions were accepted only in two countries, Finland and the UK.

Table 6. Use of ePrescriptions in the EU/EEA countries studied and characteristics of the used systems.

Country	Current use	Planned use	Technology: diskette/ Smart card/ Server/ Email	International ePrescriptions standard	Common system: Yes/No	Selection of pharmacy: Once/ Continuously	Linkage of ePrescription system: Insurance company/Pharmacy/ Software vendor
Austria (1)							
Belgium (2)	No						
Denmark	Yes		Email	Yes (6)	Yes	Once	No
Finland		Yes	n/a	Yes (7)	Yes	Continuously	Software vendor
France (3)							
Germany		Yes	Smart card, server	Yes	Yes	Continuously	No
Greece (2)							
Iceland (1)							
Ireland (1)							
Italy (2)	No						
Netherlands (4)							
Norway (1)							
Portugal (2)	n/a	n/a					
Spain (1)							
Sweden	Yes	Yes	Server (5)	Yes (8)	Yes	Once	No
UK			Server	Yes (9)	Yes (10)	Continuously (11)	Software vendor (12)
Together (16)	Use (2)	Planned (3)	Email (1) smart card (1) server (3)	5	Common system (5)	Continuously (3) Once (2)	Software vendor (2)

1. No response received; 2. Respondent unaware of the current situation; 3. Questionnaire was referred to a person who did not respond;
n/a no answer; 4. Respondent referring to a publication which could not be located; 5. EDI X400 and SMTP; 6. MedPre (UN/EDIFACT); 7.Will follow the ISO standard, under development; 8. ENV 13.607; 9. Messages will comply with the HL7 standard which in turn will be wrapped in a standard XML format; 10. Three pilot projects using different ePrescription forms, but only one will be chosen for the whole country; 11. At the pilot stage, the patient can select a different pharmacy each time. At implementation stage, the situation may change; 12. A system being developed with interoperability.

5.5. Blood donor information materials

Blood donor information materials were received from 17 blood establishments in 13 countries of the contacted 18 blood establishments in 14 countries. Some of the information materials had not been divided into the three subgroups, i.e. information given to 1) first-time donors, 2) regular donors and 3) freely available to anyone interested. In these cases, the materials were considered to have been offered to all these three subgroups. Some of the requirements overlapped: For example, information about anemia met requirements 2 and 4 (the requirements are listed in Appendix 7). Requirement 2 is about reasons for temporary and permanent deferral and requirement 4 lists reasons that make it detrimental to health for individuals to donate.

Most information was given personally to first-time donors, comprehensive information materials were given to this group in Austria, Germany, the Netherlands, Switzerland and England (Table 7 and Table 10). Regular donors were given less information materials personally (Table 8 and 10). However, sometimes this could be compensated for with information materials which was freely available for anyone interested (Table 9 and 10). Freely available information materials were sometimes partly the same as those provided to the first-time donors but specific information could also be given on such issues as bone marrow/stem cell/organ donation, AIDS, hepatitis B and C, and malaria. Several blood establishments also published blood donor journals containing articles on donation and blood, interviews of blood donors and recipients etc.

The best requirement topics for all three donor groups were: blood and its components, the blood donation procedure and significance of blood donation to patients (in the Directive 2004/33/EC as a requirement no 1), reasons for taking the donor's health and medical history, testing of donated blood, temporary and permanent deferral (requirement 2), donor data protection (requirement 3) and specific information on the donation process itself and associated risks (requirement 5). The information materials did not always contain all topics listed in the respective requirement. The lack of information materials was associated with requirements related to donors' possibility to change their minds about or withdraw from donation (requirement 6), situations where donors should contact the blood establishment for re-evaluation of their suitability (requirement 7) and destruction of infectious blood and deferral of an infection-marker positive donor (requirement 10) (Table 10).

None of the materials given to any of the subgroups fulfilled all requirements of Blood Directive 2004/33/EC. In addition, the presentation of the issues varied from very simple to detailed. The most comprehensive information materials for all subgroups of donors were provided by the UK and Switzerland.

Table 7. Blood donor information materials provided for first-time donors before the year 2002. Information requirement topics and, in brackets, their respective number as stated in Directive 2004/33/EC and the countries of the consulted blood establishments.

Topic (no) Country	Information on blood and donation (1)	Medical examination and referral criteria (2)	Protection of personal data (3)	Conditions harmful to donor health (4)	Specific information on allogenic donation (5)	Possibility to change mind (6)	Donors responsibility to inform (7)	Establishments responsibility to inform (8)	Donor referral, destruction of blood (10)	Possibility to ask questions (11)	Total/ 10
Austria	x	x	x	x	x		x	x	x	x	9
Belgium-Flanders	*	x	x					x			4
Belgium-Wallons	*	*	*	*	*						4
Denmark	x	x									2
Finland	x	x			x						3
France	x	x	x		x			x			5
Germany	x	x	x	x	x		x	x		x	8
Italy	*	*		*	*						
Luxembourg	x	x			x			x			4
Netherlands	x	x	x	x	x			x	x	x	8
Norway	x	x			x						3
Portugal	x	x	x								3
Switzerland	*	*	*	*	*		*	*	*	*	9
UK-England	x	x	x	x			x	x	x	x	8
UK-Scotland	x	x	x	x	x			x		x	7
UK-North Ireland					x						1
UK-Wales	x	x	x	x	x		x	x			7
Total/17	15	16	11	9	13	0	4	10	4	6	

* Not stated to whom the information was given.

Table 8.. Blood donor information materials provided for regular donors before the year 2002. Information requirement topics and, in brackets, their respective number as stated in Directive 2004/33/EC and the countries of the consulted blood establishments.

Country	Information on blood and donation (1)	Medical examination and referral criteria (2)	Protection of personal data (3)	Conditions harmful to donor health (4)	Specific information on allogenic donation (5)	Possibility to change mind (6)	Donors responsibility to inform (7)	Establishments responsibility to inform (8)	Donor referral, destruction of blood (10)	Possibility to ask questions (11)	Total/10
Austria	x	x	x	x	x		x	x	x	x	9
Belgium-Flanders	*	x	*								3
Belgium-Wallons	*	*	*	*	*						5
Denmark		x									1
Finland											0
France	x	x	x		x			x			5
Germany		x		x	x						3
Italy	*	*		*	*						4
Luxembourg											0
Netherlands			x					x	x	x	4
Norway	x										1
Portugal	x	x	x								3
Switzerland	*	*	*	*	*		*	*	*	*	9
UK-England	x	x	x	x			x	x	x	x	8
UK-Scotland	x	x	x	x	x					x	6
UK-North Ireland		x	x		x			x		x	5
UK-Wales	x	x	x					x		x	5
Total/17	11	13	11	7	8	0	3	7	4	7	

Table 9. Blood donor information materials freely available to those interested before the year 2002. Information requirement topics and, in brackets, their respective number as stated in Directive 2004/33/EC and the countries of the consulted blood establishments.

Country	Information on blood and donation (1)	Medical examination and referral criteria (2)	Protection of personal data (3)	Conditions harmful to donor health (4)	Specific information on allogenic donation (5)	Possibility to change mind (6)	Donors responsibility to inform (7)	Establishments responsibility to inform (8)	Donor referral, destruction of blood (10)	Possibility to ask questions (11)	Total
Austria	x	x								x	3
Belgium-Flanders	*	x	x					x			4
Belgium-Wallons	*	*	*	*	*						5
Denmark	x			x	x			x			4
Finland	x	x			x			x		x	5
France	x		x		x		x	x			5
Germany	x										1
Italy	*	*		*	*						4
Luxembourg											
Netherlands			x					x	x	x	4
Norway	x				x						2
Portugal											0
Switzerland	*	*	*	*	*		*	*	*	*	9
UK-England	x	x	x	x			x	x	x	x	8
UK-Scotland			x		x			x			3
UK-North Ireland		x	x		x			x		x	5
UK-Wales		x	x		x		x	x		x	6
Total/17	11	9	9	5	10	0	4	10	3	7	

Table 10. Information requirement topic, in brackets their respective number in Blood Directive 2004/33/EC, and the number of the countries offering material on this topic for different target groups.

Topic (no) ---------- Target group	Information on blood and donation (1)	Medical examination and referral criteria (2)	Protection of personal data (3)	Conditions harmful to donor health (4)	Specific information on allogenic donation (5)	Possibility to change mind (6)	Donors responsibility to inform (7)	Establishments responsibility to inform (8)	Donor referral, destruction of blood (10)	Possibility to ask questions (11)	Total
First time donors	15	16	11	9	13	0	4	10	4	6	78
Regular donors	11	13	11	7	8	0	3	7	4	7	71
Freely available	11	9	9	5	10	0	4	10	3	7	68
Total/51	37	38	31	21	31	0	11	27	11	20	

6. DISCUSSION

6.1. Methods

The methods used in the five substudies are discussed separately in the following.

The first substudy, an empirical survey of the dispensing of foreign European prescriptions tested only a few prescriptions per a Member State, non-systemically. Thus statistical analysis was not possible; instead, qualitative analysis was conducted. The state of prescriptions had been made optimal, as everything possible had been done to avoid misunderstanding due to unclear hand-writing or differences in product names. Thus, the situation did not correspond real life. On the other hand, medical prescriptions are being computerized using electronic health records and associated software with computerized medical orders/prescriptions so that misunderstandings due to difficult handwritings can be assumed to decline.

The prescriptions were tested mainly in pharmacies in the larger cities or capital cities where pharmacies can be expected to be more experienced with foreign customers and demands for foreign medications or prescriptions. Thus, even in the absence of special legislation, pharmacies could have developed certain procedures for situations where the consumer asks for dispensing of a foreign prescription or foreign drugs that are not marketed in the country or have a different trade name. If the prescriptions had been tested in rural pharmacies or they would have been for special products like narcotics or other central nervous system affecting drugs, the outcome of the study could have been different.

In a case of testing an EMEA authorised drug, with a same trade name in every country where the drug is sold, similar results can be expected; with exception of special drugs, like narcotics or central nervous system affecting drugs (at least when an abuse could be suspected). The study was descriptive. Even though saturation of the data could be questioned, the results can, however, be considered suggestive, and were indeed supported by the following second substudy.

The second substudy analysed national regulations on mutual recognition of prescriptions and, consequently, possibilities of importing POMs from abroad for personal use. Due to linguistic reasons, the actual law texts were not analysed, instead, a questionnaire was used. Law texts would have offered the most comprehensive information; the value of a questionnaire greatly depends on its questions and respondents. The quality of the responses was variable, thus influencing the results. In principle, Northern European authorities gave the most extensive replies.

The third substudy aimed at describing different types of online pharmacies and their possibilities of operating across borders within the European internal market. The selection criteria for and the small number of the studied online pharmacies may have caused errors and thus missed some important phenomena such as certain essential

characteristics of their operations. Only European and US online pharmacies were studied. However, online pharmacies established in other countries are also accessible by the Internet. As the study explored possibilities for online pharmacy operations in Europe, the selection can be regarded as justified. Linguistic reasons also limited the study to English-language as English is the most important international language.

The fourth substudy was about the use of ePrescriptions in the EU Member States and possibilities for using them cross-border within the European internal market. The contact persons, representatives of the Member States for a special European Commission Working Party, appeared to represent a variety of institutions; some did not seem to be even (closely) involved with medical or healthcare-related fields. This can explain some of the brief, defective responses and lack of familiarity with the national situation of ePrescriptions. Some contact persons referred to another person for questions but these persons did not respond. The low rate of adequate responses was not expected when respondents were chosen for the study, as these persons worked with e-health issues as members of the Commission Working Group. This response problem could have been avoided if the respondents were chosen by a different method, i.e. via Finnish experts in the field.

The questionnaire about ePrescriptions was not tested before sending it out. Testing could have assist in avoiding some deficient responses.

The response rate of the fifth substudy of blood donor information materials was excellent and expected, thanks to the assistance received from the EBA. Blood donor information materials were received from almost all contacted blood establishments; only subgrouping was lacking in some. A possible error occurred at this point, resulting in excessively positive results. In addition, the difficulty of understanding materials in foreign languages other than English, French or Swedish, or basic Spanish, which was used to understand Italian and Portuguese texts could have affected the results. A native German speaker checked German-language materials. To minimize misunderstandings due to linguistic reasons, the leaflets were gone through twice carefully.

The information requirements of the Blood Directives contain multiple issues but the criteria used in the survey were less strict. Otherwise, only a few material items could have been regarded as fulfilling the topic requirements. The materials were examined by two medical professionals (according to their language skills) who perhaps understood the foreign-language information better than lay people did.

6.2. The results

6.2.1. Cross-border dispensing of foreign prescriptions

Any published previous study of mutual recognition of drug prescriptions was not found. The study showed that non-national European prescriptions were dispensed in

almost every EU Member State without special national legislation. Only a few pharmacies refused to dispense foreign prescriptions, following separate national legislation.

The problems with the tested foreign prescriptions appeared to be associated with the unavailability of the desired pharmaceutical. Differences in pharmaceutical assortments may in this case be due to local microbial resistance situations and differences in treatment protocols. Differences in pharmaceutical assortments have been shown by the EURO-MED-STAT Group, which compiled a comprehensive directory of all medicines available in the EU Member States. The group found only 7% of all active ingredients available in all studied 14 EU Member States in 1998 (Folino-Gallo et al 2001). In addition, the group studied lipid-lowering drugs in detail and found novel medicines more widely available (the EURO-MED-STAT Group 2003). The available packet sizes of the lipid-lowering drugs varied (the EURO-MED-STAT Group 2003). A similar finding may be obtained with other categories of medicines. Another reason for differences in the availability of pharmaceutical products is the generic drug markets. A study carried out by the Leuven Catholic University showed variations in generics markets which were due to different policies of reimbursement, cost-control of doctors and regulations on generic products (Simoens et De Coester 2006).

In the study, the pharmacist offered to switch the non-available drug to another with same or broader therapeutic field. Therapeutic substitution means exchange of the active ingredients, which may not be beneficial for the community, for example for resistance reasons when antimicrobial drugs are in question, not to mention the possible adverse effects that could occur in the patient. Generic substitution, on the other hand, means changing the drug to another with the same active ingredient but with different excipients, which is not without problem, either. The prescription-issuing doctor chooses the most suitable drug for the patient. If a drug is replaced with another without consulting the attending doctor familiar with the patient's medical history, there are risks such as drug allergies, interactions with the patient's other medications, unsuitability for other health-related reasons, such as the underlying disease, pregnancy and lactation. According to Kanavos & Mossialos, in 1999, change of a prescribed drug for any reason to another product, even to a generic product, required the prescribing doctor's permission in many countries (Kanavos et Mossialos 1999) or was even forbidden. Now, the situation may be different. At least in Finland, a pharmacist can and should change a drug generically to the cheapest available, unless the prescribing doctor has forbidden it or the patient refuses changement (Lääkelaki 10.4.1987/395, as amended, § 57b-57c, available from: www.finlex.fi).

Even when a drug containing the same active ingredient is dispensed, it might be confusing for a consumer with a different trade name, different appearance of the drug or possibly a new dosage or mode of administration. Communication problems related to a different language can also increase problems. The educational level of the pharmacy personnel is also likely to affect communication; their educational level shows variation among the EU Member States, with the highest level seen in Finland (Kärkkäinen 1995, Purasmaa 1999).

If a prescription is not dispensed, the treatment of the disease is delayed. This is not desirable, either. One solution could be that the patient makes a new appointment with a doctor abroad and receives a national prescription that can be dispensed. However, a new appointment causes new arrangements and costs, and is not even always possible.

Community legislation itself makes it possible and fairly safe to dispense foreign European prescriptions. Issues preventing or complicating such dispensing are mainly administrative and possible to overcome.

6.2.2. Import of drugs for personal use

The study showed that there are restrictions on the import of POMs for personal use that can be assumed to steer purchases to national pharmacies. The amounts of bought drugs can be limited as corresponding to personal need; if no limitations existed, it would be difficult to prove that huge amounts bought would be for personal use. The limitations can also be explained as protecting public health: continuous medication needs regular monitoring of health and adjustment of the drug therapy to the current health status. In addition, quantity limitations avoid problems with drugs deteriorated because of exceeded expiry dates and inadequate storage conditions. When imports are restricted to personal needs and purchases by persons crossing the border, this can also be health-protective, as dispensing itself can be damaging.

The study found that import of POMs by mail was possible in some countries. However, one study found, by contrast, that mail-ordering of POMs is not permitted within the EU or across borders (Kanavos 2000). The latter study did not state its source of information. It dates to the same time as this study, so changes in national regulations cannot explain this difference.

The study showed that reimbursement for the costs of imported drugs was a complicated matter, which may steer patients to purchase in national pharmacies (unless the price differences are wide). This is an obstacle for pharmaceutical internal markets for consumers. Indeed, Wahlroos claimed that until the Community has the competence and means to supervise national reimbursement systems in addition to pricing of drugs, internal pharmaceutical markets cannot be established (Wahlroos 2003). On the other hand, EU regulations harmonising social security provisions state that a person is entitled to healthcare benefits related to immediate necessary or necessary care during his/her stay in another Member State in the same way as residents of that country in respective conditions. One British study stated that EU citizens are entitled to pharmacy services on the same grounds as UK residents (Sheaff 1997), with a prescription from a doctor practising there. The present study, however, was limited to cases where the prescribing doctor was from another Member State, which makes the situation different. Private travellers' health insurances and private health insurances further complicate the issue.

But do national rules limiting reimbursement influence the free movement of pharmaceuticals and pharmacy services so that they can be regarded as being in

conflict with Community law? The ECJ has ruled about the reimbursement of health services obtained from another EU Member State, but the role of reimbursement of drugs purchased from another Member State remains to be determined. If the European Commission takes the chance to make clear rules about the reimbursement of cross-border health services, as proposed by some stakeholders (DG Health and Consumer Protection 2006), this could also result in procedures for reimbursement of pharmaceuticals obtained from another member state.

The introduction of the electronic European health card may change the situation in reimbursements and healthcare (European Commission 2003). Currently, different models and solutions are being tested in some Member States in the Netcards project, supported by the European Commission (Netcards website: http://www.netcards-project.com/index.php).

6.2.3. ePrescriptions

This study showed that although still to a limited extent, ePrescriptions are increasingly being used in the EU. A Swedish survey carried out in 2003 supports this finding, and found that the Netherlands and Belgium use or are going to use ePrescriptions (Tarre 2003). A Finnish preliminary survey on ePrescriptions from 2001 conducted by the Ministry of Social Affairs and Health reported that the Netherlands already uses ePrescriptions (Koponen-Piironen et al 2001). The present study received no response from the Dutch contact persons despite several reminders. The Finnish study supports other findings about the use or planned use of ePrescriptions as well as the chosen systems, except for Sweden, where matters are still at the planning stage (Koponen-Piironen and Kiiski 2001). Currently, ePrescriptions are legally valid according to recent legislation in the UK (Royal Pharmaceutical Society 2006) and in Finland (Regulation on electronic prescription 2007/61, available from www.finlex.fi).

Foreign ePrescriptions were associated with concerns about patients´ data-protection, data storage, and identification of the patient and the doctor. A Scottish study described similar concerns related to security issues, among patients, doctors and pharmacists (Porteous et al 2003), but these were due to national ePrescriptions. In addition, at the time of the Scottish study the NHS had a piloting project in progress about ePrescriptions in Scotland, but for true participants the situation was hypothetical (Porteous et al 2003).

The Commission consultation on health services from 2006 yielded results that show that several European stakeholders have approved cross-border pharmaceutical services and acknowledged the benefits of the use of ePrescriptions and the possibilities IT offers for the solution of problems in this field (DG Health and Consumer Protection 2006). The benefits of IT can include a database assisting in checking the validity of prescriptions and medicines sold in Europe. The consultation provided proposals for the development of a Europe-wide health professional card, including identity and professional identification numbers, and publicly assessable information about the registration status of doctors and pharmacies (European

Commission). Thus, all kinds of cross-border use of pharmaceutical services would be protected, whether taking place on the spot, by mail or online, with traditional prescriptions or ePrescriptions.

The study obtained two significant findings about ePrescriptions in the EU Member States. First, ePrescriptions were used mainly for administrative purposes only. Thus, the full potential of ePrescriptions was not used in the Member States. Secondly, although standardised ePrescription forms and systems were used or going to be used in all Member States, these standards and systems varied from one country to another. US experience has proved that standardisation, including health data standardisation, and interoperability between systems was necessary for wide use of ePrescriptions across institutional and other boundaries (Hammond 2005, Miller 2005). In Europe, differences in standards complicate cross-border e-prescribing and also movement of other information linked to ePrescriptions and patient mobility. The Commission has noted the problem of diversity when studying the European health card, and proposed to put more emphasis on interoperability (in that case on systems used for electronic health cards) (European Commission 2003). EU-level co-operation is still possible as long as e-prescribing has not been introduced into a wider circle of EU Member States. Technically, a European-wide ePrescription system will not be a problem. However, differences in reimbursement policies make it difficult to agree on common reimbursement policy for drugs. This will, in practice, make cross-border dispensing a challenge for pharmacies.

The EU aim of having ePrescriptions in use by 2008 does not seem to come true. Although the survey was carried out in 2001, the systems are slowly set up and require planning and piloting. Adoption rates are likely to differ owing to differences in healthcare systems, especially in systems where doctors work alone in their offices. Financing of the technical equipment of the doctor and the pharmacy will pose problems. In the USA, different jurisdictions at the federal, state or local government level, different practices of doctors and commercial vendors have resulted in varying ePrescription adoption rates (Miller et al 2005).

The European Community and its Member States should examine the benefits and disadvantages of the USA two level system, state and federal, for ePrescriptions, and analyse what kind of decisions and procedures have been carried out at the federal and state level. Europe's needs are certainly different, as its basic ideology for welfare is different, but it could learn from US experience.

6.2.4. Online pharmacies

The study found a few online pharmacies established within the EU area, in Denmark, the Netherlands and the UK, including Gibraltar and the Channel Islands. An Australian study from 2002, which examined 104 online pharmacies operating in the English language, found online pharmacies in Europe established in Italy, Spain, Switzerland and the UK (Bessell et al 2002). The reasons for differences between the studies could be that the latter was launched some years later: new online pharmacies

could have been set up after the present; on the other hand, online pharmacies, especially suspicious ones appear and quickly disappear all the time. In Finland, in 2007, there was an attempt to establish an online pharmacy, but it was found illegal (National Agency of Medicine News 23.3.2007, available from http://www.nam.fi/ajankohtaista/uutiset/valtahuijaus.html). Findings of this study about the ways online pharmacies operate are supported by other studies (e.g. Henkel 2000).

Some online pharmacies were operating only nationally, some also across borders. When online purchases operate across borders, differences in pharmaceutical markets, especially in pharmaceutical selections and authorisations, the difference between POM and OTC and patient safety related issues can cause problems (Ashurst Morris Crisp and Executive Perspective S.A. 1998). Regulations on the import of pharmaceuticals for personal use and rules for reimbursement for drugs further complicate the issue. Information technology could offer a means to resolve some of these problems, e.g. providing information on specific national systems and laws.

In Europe, pharmacies also have an advisory role, as defined by the Partial Agreement of the Council of Europe [1](Resolution ResAp (2001) 2). When the pharmacist dispenses a drug to a client it should be verified that there are not any contraindications for the use of a drug or interactions with other drugs. In addition it should be ensured that the client understands how the drug should be used. Online pharmacies skip the face-to-face contact, which is also one of the reasons why they are not favoured by the related professionals (Standing Committee of European Doctors and Pharmaceutical Group of the EU 1999, Standing Committee of European Doctors 2002). The pharmaceutical industry also has a cautious attitude (European Federation of Pharmaceutical Industries and Associations 1999). However, the American Medical Association has approved online prescribing and provided guidelines (Henkel 2000).

It is evident that online questionnaires do not replace normal medical examinations, nor do they guarantee that the person gives truthful answers of his or her medical condition. One well-known example mentioned in several US sources is a 52-year-old man from Illinois with symptoms of coronary heart disease. He ordered Viagra online and later died of a heart attack. Although his death was not associated with use of Viagra, his disease could have been detected if he had contacted a doctor to obtain the drug (Eysenbach 2001a, Henkel 2000). On the other hand, one controversial study of prescription of Viagra online and at a traditional doctor's appointment claimed the opposite, favouring access to data online (Jones 2001). Gynther Eysenbach, editor of the Journal of Medical Internet Research, called for further research on issues related to online prescribing, without prejudice (Eysenbach 2001a).

Protection of public health from illegally operating online pharmacies is difficult, as no comprehensive procedures are available to supervise online pharmacies, which reach their clientele globally. The illegal pharmacy, its employees, clientele and warehouse could all be situated in different countries or even different continents. The directive on

[1] Partial Agreement is binding to those countries that have signed it, although the Council of Europe itself has no legislative mandate.

eCommerce states that the applicable instance of legislation is of the country where the service provider is legally established (Directive 2000/31). In the USA, many states require that pharmacies dispensing their residents are licensed in that same state but also in the state where they are legally established (Appelquist 1999). Some states even have special legislation on online pharmacies. This legislation varies from one state to another (Landis 1999). So far, at least the US authorities and one German Court has taken action against illegal online pharmacies. The Food and Drug Administration FDA (of the USA) has investigated illegally operating online pharmacies and sued these pharmacies, sent official warning letters, and tried to involve website managers to voluntary remove illegal sites (FDA 1999). Individual states have also acted and sued illegal online-pharmacies (Charatan 1998, Carnall 1999). In cases where an online pharmacy is established in another country, the FDA has co-operated with the authorities of that country. However, such measures are not always possible: the Australian study found that 39% of the studied online pharmacies did not give any address information, and 65% did not give owner or other relevant information (Bessell 2002). In addition, one Austrian study found that 14% of the investigated 150 online pharmacies had disappeared within 2-3 months after initial contact (Austrian Health Institute 2000).

The German case of Dutch online pharmacy DocMorris was judged by the ECJ after the online pharmacy study had been carried out and published. This online pharmacy, whose popularity in Germany was based on low prices (Weber 2000), mailed an order to Germany. After being taken to the national German courts and the ECJ, it started to use couriers in an attempt to avoid violating the German regulation prohibiting mail sales of medicinal products meant to be sold only in pharmacies (Weber 2000, European Legal business 2001). The ECJ was asked about the German prohibition of sale of drugs by mail order, which the ECJ found justified in a case of a POM but not justified in a case of an OTC in the Member State concerned (OJ C 348 of 8.12.2001).

Consumer education is needed to guide people in internet purchases. For example, the FDA has provided a useful check-list for safer online shopping of pharmaceuticals (available from the FDA website; http://www.fda.gov/buyonline/) and other kinds of consumer education (Online pharmacies, frequently asked questions, available from http://www.fda.gov/oc/buyonline/prfaqs.html).

This study found that legally authorised online pharmacies use quality accreditation seals verifying their way of operation. A quality accreditation seal is a kind of code-of-conduct. The above mentioned Australian study found that only 12% of the studied 104 online pharmacies displayed quality accreditation seals (Bessell 2002), so that most online pharmacies advertising in the net seem suspicious. The Community directive on eCommerce called professional associations to set up Community level code-of-conducts to determine the types of information that can be used in eCommerce by the medical professions (Directive 2000/31/EC). At least one nationwide code-of-conduct has been established for online pharmacies in the UK, considering all aspects of online pharmacy services (British Pharmaceutical Society 2006). No European-wide code-of-conduct is yet available as online pharmacies have not reached support for true cross-

border operations. In the long term, the best way to control online pharmacies is supervision by the national authorities.

6.2.5. Blood donor information

The study found that there should be minimum standards for blood donor information content so that the central issues of blood donation and transfusion would be covered. The blood donor information materials showed remark variations among the countries, in respect to those basic information topics on blood and blood donation, as enumerated by the European Blood Directive. Even though the European Blood Directive had not been established at the time the information material was from, it was still slightly surprising as the Community Recommendation from the late 1990s, although legally non-binding, published a list of recommended requirements. This recommendation called the Member States to take necessary measures to disseminate it to interested parties, particularly the national blood establishments, but at least the studied material published before year 2002 did not follow this Recommendation.

Blood donation and processing are organised in different ways in different Member States. This can explain some of the trends seen in the blood donor information materials. When the system is centrally run, the materials are the same for the whole country. When this is not the case, separate blood establishments produce their own materials for the needs of small populations. The study found that the materials associated to these blood establishments or blood banks that operate alone or cover a small population were often modest in the amount of information topics.

The Directive does not make any difference between regular and first-time donors. The study showed that more information was normally given to first-time donors than to other donors. It was also shown that the information given to first-time donors was sometimes freely available to anyone interested. The information needs of first-time and other donors as well as those of occasionally donating persons compared to regular donors can be assumed to be different. This also reflects to the lifestyles blood donors. Norwegian study results show that blood donors in general seem to lead less risky lives than the general population (Stigum et al 2001). Regular donors seem to lead lives with less risk factors for blood safety than other donors: the WHO Global Database for Blood Safety from 2001-2002 showed that less infectious agents for HIV were found among regular donors than in the population as a whole. Thus it could be assumed that regular and first-time donors need at least slightly different information materials.

There is no guarantee that information materials are read or understood. A US survey in 1993 showed that 78% of blood donors reported that they had read the materials; only 32% of all (respondents) claimed that they had read them carefully (Rugege-Hagiza et al 2003). To solve the problem of essential information being lost, some European blood establishments require blood donors to sign a document to the effect that they have read and understood the provided materials.

Even high-quality information materials do not always make people withdraw from blood donation when they consider themselves unsuitable donors. For example, a Norwegian study circulating an anonymous questionnaire among those already accepted for donation found that there remained a small number of donor candidates who should have abstained (Stigum et al 2001). Another study found that anonymous contacts are favourable for evaluation of personal histories in donor selection (Zuck TF et al 2001). It can be assumed that once entering the donation procedure a person does not feel comfortable with dropping out even when he or she should withdraw.

In addition, it should be borne in mind that as long as no international regulations on blood safety and quality are enforced and blood and products are imported from countries such as the US which lack standards similar to those used by the EU, the advances achieved at the EU level are not fully implemented.

A survey of blood donor information is being carried out by the Finnish Red Cross Blood Service examining blood donor information materials before and after the establishment of the Blood Directive and possible differences in Finland, Belgium and Italy in blood donors' awareness of essential issues related to blood donation.

6.2.6. General

This study examined cross-border health services for the delivery and purchase of pharmaceuticals and the need for common minimum quality criteria for blood donor information materials. The latter will assist in increasing safety of blood products. The study found that EU regulations in these fields examined have had varying effects at the national level, with great problems in cross-border services. It is evident that European Community legislation functions similarly in other healthcare-related fields. The reasons are several:

- First, the principle of subsidiarity, on which the European Community operations are based, means that the Community acts only on matters which are better processed at the European Community level while all other issues are decided at the Member State level (European Parliament. Fact sheets 2006).
- Second, the European Community legislative order and legislation itself allow differences in implementation. In addition, the significance of the European Community case law as legally-binding interpretation of the European Community legislation to other situations than those in the preliminary rulings is unknown (Mossialos et McKee 2002). Case law is deficient law without the same universal views as the actual legislation can take. Case law also suggests that the legislation itself has not been adequate, but rather needs interpretation, at the national and individual level.
- Third, the actual mandate of the European Community on public health as stated in Article 152 Public Health is fairly narrative and not concise. The Article is about prevention, co-operation and supervision of public health benefits in other European Community policies, but the measures to be taken

on the basis of this instance of legislation have not been defined. Currently health and healthcare policies are supervised by several DGs in addition to DG SANCO whose task is to lead Community's public health policy. As a consequence, there is no integrated policy on health related policies within the context of a health policy, regardless of the inter-service group. One question is whether the full potential of the Article is being implemented or whether is it up-to-date at all.

- Fourth, the Public Health Article prevents the Community mandate from affecting national healthcare systems. But, clearly, Community action affects national systems, indirectly.

Since the introduction of the Public Health Article in 1992, health issues have gained more importance in the Community than expected. This is especially due to cross-border health services and eHealth, both of which have caused uncertainties about customs procedures in the internal market. The role of healthcare services cross-border compared to ordinary services has remained undetermined, despite the ECJ's preliminary rulings. However, current Commission attempts, including the Commission consultation on future Commission actions on health services (DG Sanco 2007), show that there will be more co-ordination in this field, to answer those questions which came up especially from the preliminary rulings and telemedicine innovations. This is necessary, not only because of the increasing use of cross-border health services but also because of the benefits that controlled development of this field could yield.

It is not surprising that there have been discussions about the validity of Article 152 for current needs. The Public Health Article shows that there is no proper or adequate mandate in healthcare sector related issues for the Community, and, thus, it cannot properly take health into account (Hämäläinen et al 2003). Belcher and Bergman have proposed that a wider Community dimension should be used for health matters, including health systems and public health considerations (Belcher et Bergman 2001) Measures aiming at supervising and improving public health needs at the Community level have been discussed, with open co-ordination being one possibility (Belcher et al 2002/2003, DG Sanco 2007), which is used in matters where the European Community has no competence but still has common objectives and difficult problems such as the European employment policy (Mossialos et McKee 2002). There are already several Community-led voluntary forums of the Member States and the Commission, where drug import topics and policy development for healthcare are discussed. Much emphasis has been put on patient mobility and the possibilities that centralised use of healthcare resources could offer at the Community level. Hämäläinen et al have proposed that the Member States need to be well informed about Community processes that have impacts on health and healthcare systems so that they could influence these processes and maintain national decision-making powers where desired (Hämäläinen et al 2003).

In addition to Community related matters, several other reasons complicate cross-border healthcare. These include differences in healthcare and social security systems due to cultural differences. The financial resources of a country also define what

services and treatments are provided for the citizens and which should be reimbursable and how. Treatment protocols can vary, as shown in some ECJ rulings (e.g. Case C-157/99) owing to differences in medical traditions and healthcare systems, local microbial resistance situations and financial resources.

The principles of liability insurance and measures to be taken when a suspected preventable medical error or adverse event has occurred must be thoroughly discussed when patient mobility is developed. Indeed several stakeholders consider patient safety one of the key issues for the next Commission action on health services (DG Sanco 2007). Patients also need to know what to do if they are not satisfied with the medical service received and want to file a complaint. Healthcare services have come under consumer protection (Legemaate 2002). Patients' rights have received much attention since the early 1990s when the WHO Regional Office for Europe issued the Declaration of the Promotion of Patients Rights. Afterwards, several EU countries have either established legislation on patients' rights or provided patient charters (Legemaate 2002). Like healthcare and social security systems, these legislations and medical care supervising systems vary. However, patients as well as national authorities must know which supervising authority the patient can first turn to, where investigations and possible legal action should be taken and what kind of disciplinary acts and compensations are possible when a medical service was given in another country. It should also be determined whether procedures should be different when a patient has applied for a service personally as opposed to a situation where the national healthcare provider has obtained care from abroad for the patient.

As long as procedures for cross-border healthcare are mainly developed on the basis of the European case-law, by preliminary rulings, European citizens remain in an unequal position. People are not always aware of "newly gained rights". Many people do not have the resources to exercise their rights for example by appealing to national courts, although they could be assumed to be entitled to healthcare or reimbursement. Insufficient personal financial resources can also exclude people from healthcare services that they could receive without a prior authorisation but with later reimbursement. Furthermore, the significance of the preliminary rulings is uncertain in other healthcare systems.

Different stakeholders may have different interests in cross-border health services. For example, Belcher et al claimed that the national Member States may not agree with the interests of the citizens' newly gained rights (Belcher et al 2002/2003). In other words, as Hämäläinen et al put it, "The interests of individual patients may conflict with broader public interests and the structures of social security systems" (Hämäläinen et al 2003).

7. SUMMARY AND CONCLUSIONS

- Non-national European prescriptions are dispensed by pharmacies in most of the old 15 Member States even without any special legislation, at least when the authenticity of the prescription is not questionable and the desired pharmaceutical is recognised and relatively harmless.
- Those Member States where pharmacies did not dispense non-national European prescriptions have special legislation forbidding the dispensing of foreign prescriptions. However, a legally non-binding Community recommendation supports mutual recognition of prescriptions.
- Import of drugs for personal use from another Member State is restricted by national law. As a consequence, it seems that pharmaceutical purchases are steered indirectly towards national pharmacies, even when these restrictions can be explained away as being protective.
- Online pharmacies vary from legally operating pharmacies to suspect operators. In the EU area, both legally authorised and lifestyle pharmacies were found.
- Online pharmacies could fit in the European internal market with special precautions. A legal framework already exists to regulate drugs, pharmacies, protection of personal data, distance trade and eCommerce as well as pharmacists and prescribing doctors.
- Currently, authorities do not seem to encourage e-prescribing cross-border. There are several reasons for this. E-prescribing is still rarely used, although is spreading to many countries. The systems and ePrescription forms vary between the countries, thus complicating cross-border utilisation.
- Contents of blood donor information materials varied among the EU Member States. EU-level regulation establishing minimum requirements on the contents of national blood donor information materials could improve the quality of information materials in this respect.
- Community legislation acknowledges unique, national factors. As a consequence, the European internal markets consist of national markets with special characteristics. Cross-border healthcare, including mutual recognition of prescriptions, cross-border prescribing and import of drugs should recognise the national characteristics, and cooperation should take place when true cross-border activities are desirable.
- The status of healthcare, especially that of health services, in respect to the European Community mandate needs to be reconsidered. Public Health Article 152 gives the Community only limited competence to act in the national healthcare field, but other Community policies and the European Court of Justice's preliminary rulings significantly influence national healthcare services. If new legislation is not to be drawn, the Community's existing mandate should be used more effectively and other measures such as open co-ordination could be developed or used as complementary. The latter might be of less value as Member States differ from each other in the organisation of social security and health care as well as in financial resources.

ACKNOWLEDGEMENTS

I would like to thank deeply my supervisors, docent Päivi Rautava, MD, and docent Jari Forrström, MD. Päivi Rautava has encouraged me continuously and extremely patiently during all these years, always with a positive attitude and sparing time to help me in finding solutions. Her long-term experience in the healthcare sector and healthcare administration was valuable for the thesis. Jari Forsström I thank especially for giving the financial chance to participate internship in the European Commission. I also appreciate his knowledge and experience in the field of telemedicine.

Professor Erkki Palva, MD and Professor Michael Rigby are gratefully acknowledged for their valuable criticism of this thesis. I am grateful to emeritus Professor Juhani Idänpää-Heikkilä, MD, for giving the honour to be my opponent for the thesis.

I would like to thank Professor Markku Koskenvuo, MD, and Professor Sakari Suominen, MD, for the opportunity to concentrate on my thesis during my post at the Public Health Department of the University of Turku.

I am also grateful to Markku Äärimaa, MD, former secretary general of the Finnish Medical Association FMA, for the interesting time I spent in my post as a secretary for international affairs in the FMA in 2001-2002, when Dr. Äärimaa had his presidency in the Standing Committee of European Doctors CPME. At that time I had the opportunity to participate in the Junior Doctors Permanent Working Group (PWG) as head of the secretariat, during the Finnish Presidency of Nina Tiainen, MD. This fascinating post gave me a real chance to see how cross-border co-operation of medical associations operates at the EU level and how lobbying is done with EU institutions.

I appreciate the time I spent as an intern in Commissioner Erkki Liikanen's cabinet in Brussels in 2000. Then, as an insider, I had the chance to see in the unique atmosphere of Brussels how the Commission operates, including association with lobbyists from the whole variety of the society. A similar experience I had in the DG Sanco, in Dr. Matti Rajala's Unit of Health Determinants in Luxembourg.

For a complete picture of my international associations, I should also mention Mr. Henri Scicluna and his team in the Health Department of the Council of Europe, where I spent a short internship. In the friendly atmosphere I learned about of the work of this international association, with respect to the EU. All this international experience has been valuable for an understanding of the functioning of the EU.

I am grateful to Dr. Tiina Mäki and Dr. Tom Krusius from the Finnish Red Cross Blood Service for the chance to study blood donor information materials. I also thank Mrs. Eila Sandborg, EBA secretary of that time, for her help in contacting the foreign blood establishments and sharing her long-term experience in the European blood sector. I would also like to thank Jeff, my supporter and beloved father of our children, for examining the German blood donor information materials.

There are several persons I would like to thank for their advice, help and contributions to this thesis. In the order of the substudies, I should first mention the persons who tried to buy those foreign prescriptions in the EU Member States. Without them, the coverage of the experiment would have been much smaller. Then, I would thank Hanna Koponen-Piironen, Senior Medical Officer, National Agency of Medicines, for her help in finding the contact persons for the second study of restrictions on the import of POMs, and Dr. Terhi Hermansson, Ministry of Social Affairs and Health, for her valuable comments on the manuscript of that study. I appreciate Mr. Olavi Luotonen, European Commission DG Information Society, for his help with contacting the representatives of the Working Party for Health and Persons with Special Needs. I am also greatful for Dr Tapani Piha, former Councellor of Finland's Permanent Representation to the European Union, today Head of Unit of Health Measures of the European Commission, for his guidance while I stayed in Brussels.

I thank warmly Ms. Helen Regan, Ms. Leila Roti, MA, who expertly edited the publications of the thesis and Mr. Simo Merne, MA, for editing my medical-English concepts.

I would also like to thank professor Esko Antola, who ran the course of European Studies at the University of Turku. I was then, in the mid-1990s, the only medical student attending. That course aroused my interest in the European Union and its influence on healthcare.

I am grateful to the officials in the Information Service of the European Commission Representation in Finland for their help in questions concerning the institution of the EU.

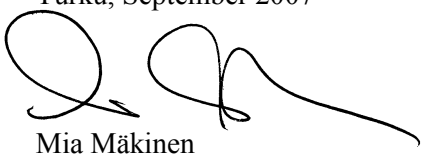
I thank Mrs Päivi Ovaskainen, PhD, for practical help with the final arrangements related to the thesis.

I am deeply grateful to my mother Ulla Mäkinen for her love and support and help with "my triplette". I thank my father Uolevi Mäkinen for support. I also thank Mrs Tuula Palonen, Mrs Riitta Ylirisku, Mrs Helena Vapaavuori and Ms Sanna Mantere for childcare help during the process. My twin-sister Tiia Mäkinen, my friends Cahterine Ebah-Moussa, Saila Loikas, Satu Roberg and Satu Laaksonen I thank for support.

I owe my deepest gratitude and love to my three lovely little children, the joys of my life, who have given me strength to complete this thesis.

This study was financially supported by grants and other financing from the Finnish Academy, Finnish Medical Society Duodecim, EVO-funding of the City of Turku, the Turku University Foundation and Postgraduate School of Health Science of University of Turku.

Turku, September 2007



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Appendix 1

CONSOLIDATED VERSION OF THE TREATY ESTABLISHING THE EUROPEAN COMMUNITY

FREE MOVEMENT OF GOODS/THE CUSTOMS UNION (Chapter 1)

Article 30

The provisions of Articles 28 and 29 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

FREE MOVEMENT OF PERSONS, SERVICES AND CAPITAL/RIGHT OF ESTABLISHMENT (Chapter 2)

Article 46

1. The provisions of this chapter and measures taken in pursuance thereof shall not prejudice the applicability of provisions laid down by law, regulation or administrative action providing for special treatment for foreign nationals on grounds of public policy, public security or public health.

2. The Council shall, acting in accordance with the procedure referred to in Article 251, issue directives for the coordination of the abovementioned provisions.

Source: Official Journal of the European Communities C325, 24.12.2002.

Appendix 2

TREATY ON EUROPEAN UNION

PUBLIC HEALTH

Article 129

1. The Community shall contribute towards ensuring a high level of human health protection by encouraging cooperation between the Member States and, if necessary, lending support to their action.

Community action shall be directed towards the prevention of diseases, in particular the major health scourges, including drug dependence, by promoting research into their causes and their transmission, as well as health information and education.

Health protection requirements shall form a constituent part of the Community's other policies.

2. Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination.

3. The Community and the Member States shall foster cooperation with third countries and the competent international organizations in the sphere of public health.

4. In order to contribute to the achievement of the objectives referred to in this Article, the Council:
- acting in accordance with the procedure referred to in Article 189b, after consulting the Economic and Social Committee and the Committee of the Regions, shall adopt incentive measures, excluding any harmonization of the laws and regulations of the Member States;
- acting by a qualified majority on a proposal from the Commission, shall adopt recommendations.

Source: Official Journal C 191, 29.7.1992

Appendix 3

TREATY OF AMSTERDAM

PUBLIC HEALTH

Article 152

1. A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities.

Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education. The Community shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.

2. The Community shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action.

Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination.

3. The Community and the Member States shall foster cooperation with third countries and the Member States, take any useful initiative to promote such coordination with competent international organisations in the sphere of public health.

4. The Council, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this article through adopting:

(a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;

(b) by way of derogation from Article 37, measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;

(c) incentive measures designed to protect and improve human health, excluding any harmonisation of the laws and regulations of the Member States.

The Council, acting by a qualified majority on a proposal from the Commission, may also adopt recommendations for the purposes set out in this article.

5. Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and dispensing of health services and medical care. In particular, measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.

Source: Treaty establishing the European Community (consolidated text), Official Journal C 325, 24.12.2002.

Appendix 4

Article 22

Stay outside the competent State — Return to or transfer of residence to another Member State during sickness or maternity— Need to go to another Member State in order to receive appropriate treatment

1. An employed or self-employed person who satisfies the conditions of the legislation of the competent State for entitlement to benefits, taking account where appropriate of the provisions of Article 18, and:

(a) whose condition requires benefits in kind which become necessary on medical grounds during a stay in the territory of another Member State, taking into account the nature of the benefits and the expected length of the stay;
(b) who, having become entitled to benefits chargeable to the competent institution, is authorized by that institution to return to the territory of the Member State where he resides, or to transfer his residence to the territory of another Member State; or
(c) who is authorized by the competent institution to go to the territory of another Member State to receive there the treatment appropriate to his condition, shall be entitled:

(i) to benefits in kind provided on behalf of the competent institution by the institution of the place of stay or residence in accordance with the provisions of the legislation which it administers, as though he were insured with it; the length of the period during which benefits are provided shall be governed, however, by the legislation of the competent State;
(ii) to cash benefits provided by the competent institution in accordance with the provisions of the legislation which it administers. However, by agreement between the competent institution and the institution of the place of stay or residence, such benefits may be provided by the latter institution on behalf of the former, in accordance with the provisions of the legislation of the competent State.

1a. The Administrative Commission shall establish a list of benefit in kind which, in order to be provided during a stay in another Member State, require, for practical reasons, a prior agreement between the person concerned and the institution providing the care;

2. The authorization required under paragraph 1 (b) may be refused only if it is established that movement of the person concerned would be prejudicial to his state of health or the receipt of medical treatment. The authorization required under paragraph 1 (c) may not be refused where the treatment in question is among the benefits provided for by the legislation of the Member State on whose territory the person concerned resided and where he cannot be given such treatment within the time normally necessary for obtaining the treatment in question in the Member State of

residence taking account of his current state of health and the probable course of the disease.

3. Paragraphs 1, 1a and 2 shall apply by analogy to members of the family of an employed or self-employed person. However, for the purpose of applying paragraph 1 (a) and (c) (i) to the members of the family referred to in Article 19 (2) who reside in the territory of a Member State other than the one in whose territory the employed or self-employed person resides:

(a) benefits in kind shall be provided on behalf of the institution of the Member State in whose territory the members of the family are residing by the institution of the place of stay in accordance with the provisions of the legislation which it administers as if the employed or self-employed person were insured there. The period during which benefits are provided shall, however, be that laid down under the legislation of the Member State in whose territory the members of the family are residing;
(b) the authorization required under paragraph 1 (c) shall be issued by the institution of the Member State in whose territory the members of the family are residing.

4. The fact that the provisions of paragraph 1 apply to an employed or self-employed person shall not affect the right to benefit of members of his family.

Source: Regulation 1408/71, available from http://eur-lex.europa.eu/fi/index.htm.

Appendix 5

FREE MOVEMENT OF GOODS

PROHIBITION OF QUANTITATIVE RESTRICTIONS BETWEEN MEMBER STATES (Chapter 2)

Article 28 (ex Article 30)

Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States.

Article 29 (ex Article 34)

Quantitative restrictions on exports, and all measures having equivalent effect, shall be prohibited between Member States.

Article 30 (ex Article 36)

The provisions of Articles 28 and 29 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

FREE MOVEMENT OF PEOPLE, SERVICES AND CAPITAL

RIGHT OF ESTABLISHMENT (Chapter 2)

Article 43 (ex article 52)

Within the framework of the provisions set out below, restrictions on the freedom of establishment of nationals of a Member State in the territory of another Member State shall be prohibited. Such prohibition shall also apply to restrictions on the setting-up of agencies, branches or subsidiaries by nationals of any Member State established in the territory of any Member State.

Freedom of establishment shall include the right to take up and pursue activities as self-employed persons and to set up and manage undertakings, in particular companies or firms within the meaning of the second paragraph of Article 48, under the conditions

laid down for its own nationals by the law of the country where such establishment is effected, subject to the provisions of the Chapter relating to capital.

SERVICES (Chapter 3)

Article 49 (ex article 59)

Within the framework of the provisions set out below, restrictions on freedom to provide services within the Community shall be prohibited in respect of nationals of Member States who are established in a State of the Community other than that of the person for whom the services are intended.

The Council may, acting by a qualified majority on a proposal from the Commission, extend the provisions of the Chapter to nationals of a third country who provide services and who are established within the Community.

Article 50 (ex article 60)

Services shall be considered to be "services" within the meaning of this Treaty where they are normally provided for remuneration, in so far as they are not governed by the provisions relating to freedom of movement for goods, capital and persons.

"Services" shall in particular include:
(a) activities of an industrial character;

(b) activities of a commercial character;

(c) activities of craftsmen;

(d) activities of the professions.

Without prejudice to the provisions of the chapter relating to the right of establishment, the person providing a service may, in order to do so, temporarily pursue his activity in the State where the service is provided, under the same conditions as are imposed by that State on its own nationals.

Source: Treaty establishing the European Community (consolidated text). Official Journal C 325, 24.12.2002.

Appendix 6

The issues the prospective blood donors should be made aware of according to the Council Recommandation on the suitability of blood and plasma donors and the screening of donated blood in the European Community (98/463/EC).

2. Provision of information to prospective donors. Member States should ensure that all prospective donors of blood or plasma are provided with:

2.1. For donor awareness

(a) accurate but generally understandable educational materials about the essential nature of blood, the products derived from it, and the important benefits to patients of blood and plasma donations;

(b) the reasons for requiring a medical history, physical examination, and the testing of donations;

information on the risk of infectious diseases that may be transmitted by blood and blood products; the signs and symptoms of HIV/AIDS and hepatitis, and the significance of "informed consent", self-deferral, and temporary and permanent deferral;

(c) the reasons why they should not donate which may be detrimental to their own health;

(d) the reasons why they should not donate which put recipients at risk, such as unsafe sexual behaviour, HIV/AIDS, hepatitis, drug addiction and the use and abuse of drugs;

(e) the option of changing their mind about donating prior to proceeding further without any undue enbarrassment or discomfort;

(f) information on the possibility of withdrawing or self-deferring at any time during the donation process;

(g) the opportunity to ask questions at any time;

(h) the assurance that if test results show evidence of any pathology, they will be informed and deferred from donation, as recommended in

Annex II B and C, for their own safety as well as

that of potential recipients; prospective donors who object to being so informed should be excluded from the donation process;

(i) specific information on the nature of the procedures involved in the donation process and associated risks for those willing to participate in whole blood donation or in apheresis programmes.

2.2. For confidentiality

(a) information on the measures taken to ensure the confidentiality of: any health-related information provided to the health personnel, the results of the tests on their donations, as well as any future traceability of their donation;

(b) the assurance that all interviews with prospective donors are carried out in confidence;

(c) the option of requesting through a confidential self-deferral procedure the blood and plasma collection establishment not to use their donation.

Source: Official Journal of the European Commuinities L 203, 21.7.1998, p. 16-17.

Appendix 7

Information requirements to be provided to the prospective donor as stated in the Commission Directive 2004/33/EC implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components.

INFORMATION REQUIREMENTS
(as referred to in Articles 2 and 3)
PART A
Information to be provided to prospective donors of blood or blood components

1. Accurate educational materials, which are understandable for members of the general public, about the essential nature of blood, the blood donation procedure, the components derived from whole blood and apheresis donations, and the important benefits to patients.

2. For both allogeneic and autologous donations, the reasons for requiring an examination, health and medical history, and the testing of donations and the significance of 'informed consent'.

For allogeneic donations, self-deferral, and temporary and permanent deferral, and the reasons why individuals are not to donate blood or blood components if there could be a risk for the recipient.

For autologous donations, the possibility of deferral and the reasons why the donation procedure would not take place in the presence of a health risk to the individual whether as donor or recipient of the autologous blood or blood components.

3. Information on the protection of personal data: no unauthorised disclosure of the identity of the donor, of information concerning the donor's health, and of the results of the tests performed.

4. The reasons why individuals are not to make donations which may be detrimental to their health.

5. Specific information on the nature of the procedures involved either in the allogeneic or autologous donation process and their respective associated risks. For autologous donations, the possibility that the autologous blood and blood components may not suffice for the intended transfusion requirements.

6. Information on the option for donors to change their mind about donating prior to proceeding further, or the possibility of withdrawing or self-deferring at any time during the donation process, without any undue embarrassment or discomfort.

7. The reasons why it is important that donors inform the blood establishment of any subsequent event that may render any prior donation unsuitable for transfusion.

8. Information on the responsibility of the blood establishment to inform the donor, through an appropriate mechanism, if test results show any abnormality of significance to the donor's health.

9. Information why unused autologous blood and blood components will be discarded and not transfused to other patients.

10. Information that test results detecting markers for viruses, such as HIV, HBV, HCV or other relevant blood transmissible microbiologic agents, will result in donor deferral and destruction of the collected unit.

11. Information on the opportunity for donors to ask questions at any time.

Source: Reproduced from the Commission Directive 2004/33/EC implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components. Official Journal of the European Community L 91, 30.3.2004, p. 25-39.

Appendix 8

Mutual recognition of foreign European prescriptions and restriction on import of pharmaceuticals for personal use. Questions asked from the national medicines authorities.

1. Is there any regulation concerning the dispensing of a prescription from another EU Member State from the pharmacy of your country? If yes, what is the number and the order of this regulation.

Are there any limitations on the type and amount of the pharmaceuticals that can be dispensed?
What type of foreign prescriptions is accepted (paper/call/fax/electronic)?

2. Does there exist statistics about dispensed foreign European prescriptions in your country? If yes, could you define the numbers in years 1995-1999 if available.

3. Is (and how) the import of prescription-only medicine for personal use regulated in your country?
How can the import happen/be done (personal visit to another country/mail/order/ fax/electronic order)?
Are there indirect restrictions for the import, for example in the form of restrictions on reimbursement?

4. Do you think that there should be harmonisation at the EU level on dispensing of a prescription from another Member State?
How should this be done?
Could information technology solutions be used in assisting the dispensing?
Are electronic precriptions used in your country?
Are online pharmacies allowed to practise in your country?

5. Other issues on the dispensing of prescriptions from another Member State you would like to address.

Appendix 9

Questionnaire concerning ePrescriptions.

1. Are ePrescriptions used in your country? Yes/No; Explanation.

2. If no, is your country considering the use of ePrescriptions? Explanation.

3. Technology of the ePrescription. What is the technique considered for communication? Stored on a diskette/stored on a smart card/sent by unsecure email to a pharmacy/sent by secure email to a pharmacy/sent to a server which can be assessed by pharmacies/other, what? Explanation.

4. Is/will the used ePrescription form (be) according to international standards? Explanation.

5. a) Is/will the same system (be) used in the whole country? If no, why?
   b) Do you have several ePrescription models which are used/will be used in your country? Explanation.

6. Can the patient select the pharmacy after the physician has described? Yes/No; Once/Continuously.

7. Is the authenticity of the prescription ensured in the pharmacy be checking

   A) the identity of
   a) the patient: with an identity card/with other means, which? Explanation.
   b) the physician: a number code/eSignature/with ID-card/with other means, which? Explanation.

   B) Is there an online possibility to check the licence of healthcare professionals to write ePrescriptions (online databases/help desk/other)? Explanation.

8. Is the authenticity of the ePrescription ensured in the pharmacy by checking the integrity of the contents? Explanation.

9. Is any form of foreign ePrescription accepted in your country? Yes/No. If no, do you think it should be made possible? Explanation.

10. Do you anticipate following problems with ePrescriptions if they are

    A) domestic: identification of the patient/identification of the physician/data protection related problems/integrity of the prescription/storage of prescriptions/ other, what? Explanation.

B) foreign: identification of the patient/identification of the physician/data protection related problems/integrity of the prescription/storage of prescriptions/ other, what? Explanation.

11. Is the ePrescription tool linked to a certain insurance company/a certain pharmacy or network of pharmacies/a certain software vendor? Explanation.

12. Among Scandinavian countries mutual recognition of prescriptions is based on common agreements. This means that a prescription is written in one Scandinavian country can be given out, with some exceptions, in a pharmacy in another country. Do you think that the European Union should develop a model where an ePrescription written in any Member State can be delivered in any other Member State? Explanation.

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