EU health policy trends

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Executive Summary

EU Health Policy Overview

Although the Treaty Establishing the European Community enjoys limited authority regarding health policy, Community influence in the health sector is increasing. It was not until 1993 that the Treaty of Maastricht expanded Community interest in contributing 'towards a high level of human health protection by encouraging cooperation between Member States'. In 1999, the Treaty of Amsterdam amended and renumbered the public health section. The current Article 152 defines the role of the EU as complementing national policies, setting out procedures by which the EU institutions may act in the health field, but excluded the authority to harmonize national legislation. Member States retain the responsibility for the organization and delivery of health services and medication (Art. 152(5)).

Chapter 1 – EU Institutions

The Council is the primary decision maker, representing the governments of the Member States. It adopts Community legislation in the form of regulations and directives. The European Parliament represents the citizens of the Union and expresses the democratic will of the people in discussions with other EU institutions. The Parliament's powers have increased to the role of co-legislator through the expansion of the co-decision procedures, defined in Treaty Article 251. The European Court of Justice (ECJ) is responsible for interpreting and applying EU legislation and to rule on proceedings against Member States and Community Institutions. Throughout the history of the Community the Court's decisions have lead the path towards integration faster than the political institutions expected, or were prepared to accept.

The European Commission is the EU institution most active in the health sector. Known as the 'Guardian of the Treaty', the Commission's authority is a unique combination of administrative, executive, legislative, and judicial responsibilities and activities. In 1995, the Commission proposed that "the Community institutions and the Member States should embark together on a process of common

reflection on the future measures which should be taken to make social protection systems more employment friendly and more efficient.[1] The Health and Consumer Protection Directorate-General (DG-SANCO) was established in 1999 and employs 'soft law' approaches to health policy. Several other DGs also have influence in the health sector, such as enterprise, environment, internal market, and agriculture. Assisting DG-SANCO are a number of health organizations including regulatory agencies and non-governmental organizations (NGOs). Agencies have been created to monitor problems associated with illicit drugs, to authorize medical products for human use, to promote health and safety at work, to monitor food safety, and to identify and assess health threats from communicable diseases, to name a few. NGOs also play an active and significant role in EU policy development and implementation.

Chapter 2 - EU Legal Basis and Soft Law Processes

There are several Treaty articles that directly or indirectly impact Member State health systems. Article 152 dictates that:

> Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obtaining sources of danger to human health. Such action shall cover the fight against major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education.

Therefore the bulk of the Community's authority with regard to the health sector is in the area of public health. Since the Community was established initially as an economic union, provisions regarding the integration of the Single European Market (SEM) are more detailed and may required harmonization of national laws. The four fundamental freedoms ensure that health services can be sought by patients across the EU, that health professionals can establish their professional practices, and that organizations may invest in health facilities and services across the EU. EC competition law will be of increasing importance as health systems incorporate market-based reforms. Competition rules were established to ensure that participants in the SEM compete on a level playing field, free from

[1] European Commission, Communication on the Framework for Action in the field of Public Health, COM (93) 559.

unfair advantages stemming from government grants (Article 87), or undertakings abuse of market dominance (Article 82), or engaging in anticompetitive cartels (Article 81). Most legislation issued by the Community has been based on Article 95 to establish the internal market.

Secondary Legislation are laws based on Treaty authority. Regulations are directly applicable to all Member States, while directives are more narrowly tailored and require transposition into national law by each Member State. In this section several of the significant directives that influence health policy are presented. The directive defining public procurement procedures[2] requires public contracts to be awarded following public and transparent procedures without discrimination. The General Food Law was enacted as a consumer safety measure in the wake of the BSE crisis.[3] The Working Time Directive[4] defines minimum periods of daily and weekly rest, annual leave, and maximum weekly working time, which may create staffing problems for small 24-hour care facilities. There have been numerous directives relating to specific aspects of Health and Safety at Work. The Third Non-Life Insurance Directive covers all forms of private health insurance.[5] Chapter 2 also provides analysis of the as yet un-enacted Lisbon Treaty and the recently proposed patients' rights directive.

Since the Community's legislative authority in the health sector is limited, the Commission has also pursued 'soft law' law strategies to build consensus for voluntary health policies. The last category of legal authority for health policy are international agreements. Depending on the sphere of competence, international agreements are either concluded by the Community or jointly by the Community and Member States. The Framework Convention on Tobacco Control (FCTC) and the International Health Regulations are two examples of international health treaties.

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[2] Directive 2004/17/EC, for Procurement in the Utilities Sector, OJ [2004] L 134/1; Directive 2004/18/EC, the 'General' Procurement Directive, OJ [2004] L 134/114Directive 89/665/EEC of the Council of 21 December 1989 on the coordination of the laws, regulations and administrative provisions relating to the application of review procedures to the award of public supply and public works contracts, OJ [1989] L 395/33.

[3] Commission Decision 97/579/EC established several scientific committees composed of independent experts to provide technical advice on food, plant and animal safety. Regulation 178/2002/EC, known as the General Food Law, created the EFSA and brought the committees under the Agency's management.

[4] Directive 2003/88/EC OJ 2003 L 299/9-19

[5] Council Directive 92/49/EEC of June 1992 on the coordination of laws, regulations and administrative provisions relating to direct insurance other than life assurance (Third non-life insurance directive), OJ L 228(11.8.1992); 1-23

Chapter 3 – Health Programmes and Initiatives

Since 2003 the Commission has defined two five year Public Health Framework Programmes. The first Framework (2003-2008) focused on three strands of action: to improve information for the development of public health, to react rapidly to threats to health, and to tackle health determinants through health promotion and disease prevention. The second Framework (2008-2013) defined three new priority areas: health security, health promotion, and health knowledge. To implement these health strategies the Commission has funded a variety of activities and initiatives. To better monitor and assess the successes and deficiencies of health systems, the Commission has drafted an eHealth Action Plan and the European Public Health Report Series. To address threats to health security, the EU joined the Global Health Security Initiative, established the European Centre for Disease Control and adopted a green paper on bio-preparedness. The Community has enacted a series of directives to ensure the safety and quality of blood, blood products, and human tissues used for medicinal purposes. The Commission has also initiated an open consultation procedure to take similar action to regulate organ donation and transplantation. In 2005 the commission proposed a strategy for combating HIV/AIDs within the EU and neighbouring countries for 2006-2009.[6]

Recently there has been growing interest in addressing health determinants to prevent disease and encourage healthy lifestyles. In May 2007 the commission published "A Strategy for Europe on Nutrition, Overweight and Obesity related Health Issues.[7] There is also EU legislation regulating products harmful to health such as tobacco, alcohol, and drugs. The Tobacco Advertising and Products Directives establish strict labelling requirements and limits on advertising.[8] In 2007 the European Alcohol and Health Forum was established to facilitate the implementation of the

[6] Commission Communication, "On Combating HIV/AIDS within the EU and in the neighbouring countries, 2006-2009, COM (2005) 654, 15.12.2005.
[7] White Paper COM (2007) 279
[8] CEU (Council of the European Union) (2001). Directive concerning the manufacture, presentation and sale of tobacco products. Directive 2001/37/EC 2002 IP/02/1383 CEU, Brussels; and CEU (Council of the European Union) (2001). Directive concerning the manufacture, presentation and sale of tobacco products. Directive 2001/37/EC 2002 IP/02/1383 CEU, Brussels; and CEU (Council of the European Union) (2003). Directive relating to the advertising and sponsorship of tobacco products. Directive 2003/33/EC 2003 IP/02/1788 CEU, Brussels

Communication on alcohol related harm.[9] Due to the local nature of illicit drug use and related crime there is wide variation in national legislation, policies, and expenditures. The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) compiles and reports data regarding drug problems, but has no regulatory authority. In 2008 Mental Health issues finally received significant European level attention at a health conference entitled, "Together for mental health and well-being".

Health system support and research

Although Member States have primary responsibility for health systems there are several areas where the EU has sought to provide support through soft law mechanisms such as the Patient Safety Working Group; and through structural funds invested to improve health infrastructure and capacity. Research into the diagnosis and treatment of rare diseases has also been funded.

Pharmaceuticals and Medical Devices

Given the important of pharmaceutical and medical devices in restoring health, EU regulation of these related industries has attempted to balance economic and health objectives. At the Community level regulations address safety and quality issues through centralized pharmaceutical market authorization and medical device classification mechanisms. Member States have considerable discretion to set prices, and to define national monitoring and enforcement procedures, so long as the policies do not conflict with the broader internal market principles.

[9] EC (European Commission) (2007) Commission Press Release: "European Commission, businesses and NGO's create Forum to battle alcohol-related harm," June 7, 2007, http://europa.eu/rapid/pressReleasesAction.do?reference=IP/07/774&format=HTML&aged=0&language=EN&guiLanguage=en

Chapter 1

EU Institutions and Health Policy Actors

Introduction

The European Union (EU) is a supranational organization created by a series of treaties. The twenty-seven Member States pool their sovereignty to make joint decisions through shared institutions such as the European Parliament, which is elected by the EU citizens, and the Council, which represents national governments. Representing the interests of the EU as a whole, the European Commission makes proposals for legislation and enforces the laws that have been adopted by the Council and Parliament. The European Court of Justice ensures that EU law is complied with, and that the Treaties are correctly interpreted and applied. The European Community began as the European Coal and Steel Community in 1952 to achieve the political goal of peace, and the economic goal of a common market. During these early years, the Community had only limited concern for occupational health, and did not have legal authority to engage in public health issues. [10] Successive treaties have further unified the Member States and expanded the competences to include a wide range of policy areas, including health policy.

The EC Treaty is known as primary legislation. The treaties are negotiated and ratified by Member States' governments according to national procedures. Secondary legislation is comprised of instruments adopted by EU institutions including: binding legal instruments (regulations, directives, and decisions), non-binding documents (resolutions and opinions), and a variety of other internal documents used for the administration and implementation of Community programmes. The EU has also employed 'new governance' or 'soft law' techniques to encourage collaborative consensus building and sharing of best practices in areas, such as social policy, where prescriptive 'hard law' legislation would be unacceptable or inappropriate. The EU and Member States have also joined various international agreements that impact European and national health policy such as the Framework Convention on Tobacco Control and the updated International Health Regulation.

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[10] Holland, Walter and Elias Mossialos. (1999) *Public Health Policies in the European Union* Aldershot, UK: Ashgate Publishing Company, p. 3.

Although the Community started sponsoring public health education campaigns earlier, the first major public health initiatives were the Europe Against Cancer Program[11] (EACP) established by the Council in July 1986. The main components of this program were cancer prevention, information and public awareness, and training.[12] Within this mandate EACP developed legislative proposals for tobacco control, funded the Bureau for Action on Smoking Prevention (BASP) and encouraged the coordination of national cancer groups. Similarly, the 1991 Europe Against AIDS program[13] had seven areas of activities, such as measures targeting children and young people, prevention programmes, data collection and combating discrimination against people diagnosed with HIV or AIDS[14].

It was not until 1993 that the Treaty of Maastricht expanded the authority of the Community to establish the EU and to include an explicit legal basis for provision of health. However, the legal authority was still limited to contributing 'towards a high level of human health protection by encouraging cooperation between Member States, and, if necessary, lending support to their action". (originally Article 129 EC) In November 1993, the Commission published the first framework for action in the field of public health, identifying several areas for action, including health promotion and monitoring, cancer, injury prevention, pollution-related diseases, rare diseases, injury prevention and AIDS.[15] Then in 1999, the Treaty of Amsterdam amended and renumbered the public health section. The current Article 152 defines the role of the EU as complementing national policies, setting out procedures by which the EU institutions may act in the health field, and delineating the types of measures that may be enacted, but is explicitly barred from harmonization. Member States retain the responsibility for the organization and delivery of health services and medical care.

Chapter one will review the primary actors involved in policy-making at the EU level. Chapter 2 will present the legal authority for the EU to participate in health policy definition, including both hard law and soft law mechanisms. Finally, Chapter three will detail the EU's health policies and programmes in the health sector.

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[11] OJ 1986 C 184/19; Decision 88/351/EC OJ 1988 160/52

[12] Hervey, Tamara, (2002) "The Legal Basis of European Community Public Health Policy" in *The Impact of EU Law on Health Care Systems.* (pp. 23-56) Belgium: P.I.E. Peter Lang Presses Interuniveritaires Europeennes.

[13] Decision 91/317/EEC of the council OJ 1991 L 175/26

[14] COM(1995) 521, 7.11.95

[15] Commission Communication on the Framework for Action in the Field of Public Health. COM (93) 559 final, 24 November 1993

Council

The Council is the primary decision maker, representing the governments of the Member States. It adopts Community legislation in the form of regulations and directives, either by their own authority after consulting with the European Parliament or jointly with approval of the European Parliament through the co-decision procedure. Under Article 249, the Council individually approves secondary legislation such as decisions, non-binding recommendations and resolutions. The Council ensures coordination of the economic policies of the Member States under Article 145 and makes political decisions on monetary policy. The Council has adopted a number of decisions and recommendations relating directly or indirectly to health policy. A separate institution, the European Council is the name given to summit conferences held by Heads of State or government of the Community Member States, It defines general political guidelines for the Community.

European Parliament

The European Parliament has been the representative body evolving along with the Community from the creation of the EEC, the ECSC and subsequent enlargements. The parliament represents the citizens of the Union and expresses the democratic will of the people in discussions with other EU institutions. It has final approval of the membership and the President of the Commission. The Parliament is comprised of a number of committees and delegations. Several committees are relevant to health policy including employment and social affairs, environment public health and food safety, and internal market and consumer protection. Parliament has sought the establishment of a coherent public health policy and the promotion of health policy through the publication of numerous opinions and reports, on topics ranging from tobacco and smoking to research in biotechnology and its medical implications. Since most of EU policy discussions have occurred in the context of soft law processes and not in the form of legislation, the parliament has had limited presence in health policy.

The Parliament's powers have increased to the role of co-legislator through the expansion of the co-decision procedure, defined in Article 251. The Commission submits proposed legislation jointly to the Council and Parliament, specifying the Treaty articles that provide the 'legal basis' for the proposal. The first reading requires the relevant parliamentary committee to consider the proposal and may either approve the draft or submit a draft legislative resolution with suggested amendments. During the Council's first reading it could adopt the legislation as is, or adopt a 'common position' and send it back to the Parliament. The Commission has the right to amend or withdraw its proposal after the Parliament has adopted an opinion. If the Council indicates that it accepts the Parliament's amendments, the Commission is unlikely to take action. During the second reading, the Parliament may approve, reject, or suggest further amendments to the Council's common position. The Council's second reading begins when the Council receives the amendments from the Parliament's second reading. The Council may approve the measure or offer amendments and convene the conciliation

committee. The conciliation committee consists of representatives from both the Council and the Parliament jointly drafts compromise language for legislation after the second reading. If no agreement is reached then the legislation is not adopted. (see diagram 1)

European Court of Justice

The main responsibilities of the European Court of Justice (ECJ) are to interpret and apply EU legislation (Article 220) and to rule on proceedings against Member States (Article 226, 227) and Community Institutions (Article 229-233). The ECJ has exclusive jurisdiction over cases brought by Member States or Community Institutions. The judges are assisted by advocates-general who make reasoned submissions in open court. Alongside the ECJ, is the Court of First Instance has jurisdiction to hear first instance actions by private parties against Community institutions. (Article 224, 225)
Throughout the history of the Community the Court's decisions have lead the path towards integration faster than the political institutions expected or were prepared to accept. ECJ decisions cause 'unplanned and unwelcome consequences for the health sector'.[16] Member States have been disturbed by the primacy of Community internal market and competition laws when applied to health services. Member States have resorted to political strategies in attempt to ameliorate the adverse outcomes and the resulting legal uncertainty. As will be discussed in later sections, the fact that EU laws have not had a larger impact on health systems reflects unrealized potential and a lack of political will, as much as the lack of explicit health policy competence. Consequently, ECJ rulings applying the fundamental principles of the internal market to the health sector served as the primary catalyst for raising the profile of health policy on the EU agenda.[17]

European Commission

Known as the 'guardian of the Treaty', the European Commission authority is a unique combination of administrative, executive, legislative, and judicial activities and responsibilities. The powers of the Commission, set out in Article 211 are to ensure that Member States comply with Treaty obligations, to initiate legislative procedures, to exercise powers conferred by the Council, and to enforce Treaty obligations such as competition law. Thus, the Commission also enjoys a management role over the operation of several Treaty areas including the Common Agricultural Policy and the

[16] Hervey, forthcoming
[17] Case C-120/95 *Decker* [1998] ECR I-1831; Case C-158/96; and *Kohll v Union des Caisses de Maladie* [1998] ECR I-1931

common Commercial Policy. Commissioners themselves are required to be completely independent from any government or other body in the performance of their duties under Article 213. The Commission's role in the budget procedure is to develop the preliminary draft budget, to implement and manage the structural funds and submit accounts.

The Commission is also responsible for initiating the 'Comitology' procedures used to develop rules and regulations necessary to implement EU legislation. In addition to primary and secondary legislation, there are detailed technical measures explain how to execute secondary legislation by EU institutions and Member States. To resolve the debate between the Council and the Commission regarding how these documents should be drafted, Member States crafted the comitology system of committees creating the opportunity for national officials to collaborate with the Commission.

The 1993 framework for public health action outlined an ambitious scope of Community action and objectives.[18] In addition to the areas of action, the framework identified mechanisms from consultation and cooperation to education, research and training of health professionals. The Report on Social Protection in Europe from 1995 expresses similar ambition but employed more aspirational language recognizing the primacy of internal market legislation. The Commission proposed that "the Community institutions and the Member States should embark together on a process of common reflection on the future measures which should be taken to make social protection systems more employment friendly and more efficient".[19] With limited resources and even less legal authority under the Treaty, the Commission was limited protecting the freedom of movement and to debate what Europe should do in the area of health policy.

The Health and Consumer Protection Directorate-General (DG SANCO), established in 1999, is primarily responsible for health policy within the Commission. DG SANCO employs 'soft law' coordinated approaches to address major health determinants, to reduce the burden of disease and to promote the health of the general population. However, other DGs also have indirect, and in circumstances direct influence on health policy. DG Agriculture and Rural Development manages the Common Agricultural Policy that subsidizes the production of products harmful to health such as tobacco and alcohol and the destruction of one million tones of fruit and vegetables each year. DG Environment's areas of action include indoor and outdoor air pollution, housing conditions, water

[18] European Commission, Communication on the Framework for Action in the field of Public Health, COM (93) 559.

[19] Commission Report on Social Protection in Europe 1995, COM (95) 457, 31.10.1995

policies and chemical exposures. DG Enterprise and Industry supervises regulation of the medical devices and pharmaceutical industries. Conflicts between these different priorities have lead to internal discord among the DGs, as competitors for resources, allies on complementary policies, and enemies on conflicting issues. For example, DGs SANCO and Enterprise have attempted to jointly supervise the pharmaceutical forum, but do not seem to coordinate well and host separate web pages for the forum and its working groups.[20] The internal discord between DGs on health policy issues is exhibited in the lack of unified leadership and the inability to publish a long promised framework or directive on health services and patients' rights.

In an attempt to coordinate the Member States and their health officials, DG SANCO organized a high level group on health services and medical care in July 2004. They discuss within working groups on seven priority issues: cross-border health care purchasing and provision, health professionals training and migration, centres of reference for specialized care, health technology assessment, information and e-health, health impact assessment and health systems, and patient safety. The most recent report of the group indicates that some areas, such as health technology assessment and information and e-health, had clear and uncontroversial mandates that have allowed for successful completion of their tasks, while other areas remain interminable.[21] Studies on the issues of health professionals are hampered by lack of data, and diversity of definitions for scope of practice for different categories of professionals. Cross-border healthcare and patient safety issues are similarly hampered by limited access to information and the significant financial risks involved with potential solutions. The group's work is ongoing, but also seems stunted, perhaps intentionally, by the Commission's lack of leadership and concrete proposals for action.

European Health Organizations

There are several different types of organizations active in the health field. In this section we will focus on EU regulatory agencies and non-governmental organizations (NGOs). EU regulatory agencies provide expert opinions and advice, collect and disseminate information, and generally support Community institutions. It is worth emphasizing that EU regulatory agencies do not have traditional regulatory authority to monitor and sanction failure to comply with legal obligations, similar to most domestic counterparts. The EU does not grant these agencies any authority to obligate Member States

[20] http://ec.europa.eu/enterprise/phabiocom/comp_pf_en.htm, http://ec.europa.eu/health/ph_overview/other_policies/pharmaceutical/forum_en.htm

[21] http://ec.europa.eu/health/ph_overview/co_operation/mobility/high_level_hsmc_en.htm

to take corrective actions or to modify domestic policies. Executive agencies are distinguished as being established for the express purpose of completing defined tasks or programmes. For example, the Public Health Executive Agency implements the Public Health Programme and will be discussed in chapter three along with other EU health activities. From the perspective of the Member States, both types of agencies are an opportunity for more collective actions involving national counterparts without expanding Commission powers.[22] Here, we focus on those agencies and NGOs that are most directly related to health determinants, products, services, and professionals.

European Monitoring Centre for Drugs and Drug Addiction (EMCCDA)[23] is the hub of drug-related information in the European Union. Founded in 1993, the EMCCDA exists to provide the EU and Member States with a factual overview of European drug problems and a common information framework to support the drugs debate.[24] The Center coordinates and relies on a network of some 30 national monitoring centers (Reitox network) to gather and analyze country data according to common data-collection standards and tools. The results of this national monitoring process are fed to the Lisbon center for analysis and are ultimately released in annual reports on the state of the drugs problem in Europe.

European Medicines Agency (EMEA)[25] opened in 1995 to address the need to speed up market authorization for medical products by specifying new centralized and decentralized procedures.[26] Under the centralized approval process, applications are submitted directly to the EMEA for assessment by the appropriate committee. The decentralized process allows companies to present new products to the 'Reference Member State' where the product will be launched, and the EMEA facilitates recognition of

[22] Permanand and Vos, forthcoming
[23] http://www.emcdda.europa.eu/
[24] Council Directive 92/109/EEC on the manufacture and the placing on the market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances 14.12.1992; and Council Regulation (EEC) No 302/93 of 8 February 1993 on the establishment of a European Monitoring Centre for Drugs and Drug Addiction OJ L 036 , 12,02.1993
[25] http://www.emea.europa.eu/
[26] Council Directive 93/39/EEC of 14 June 1993 amending 65/65/EEC, 75/318/EEC and 75/319/EEC. Official Journal of the European Communities L214, 24.08.93: 22.

marketing authorization by other 'Concerned Member States".[27] Agency funding comes primarily from applications fees. EMEA also offers scientific advice and incentives to encourage the development of new medicines, and promotes best practices for medicines evaluation and supervision in Europe. The complexity of the scientific research necessary for the approval process makes detailed independent review of accuracy difficult. Thus, the agency enjoys a reputation of high credibility despite the fact that there is little transparency, and companies may anonymously withdraw applications if an unfavourable outcome seems likely.[28]

In 2005, EU legislation expanded the number of drugs covered by the centralized procedure, improved public access to data on pharmacovigilence information and required additional seats on the management board for two patients and one physician representative.[29] The review period for both the centralized and the decentralized processes was reduced to 150 days for applicant drugs of particular interest for public health or therapeutic innovation.[30] Another recent initiative is the Regulation of medicinal products for pediatric use[31], which establishes an EMEA pediatric board, and requires additional data and pediatric clinical trials. Despite these reforms, the lack of authority to compare the clinical efficacy of similar drugs, and inadequate reporting requirements for adverse reactions remains. The inability of the reforms to address ongoing criticism is underscored by the limited capacity of the agency, which apparently suffers from insufficient personnel and expertise.[32]

European Agency for Safety and Health at Work (EU-OSHA)[33] promotes a culture of risk prevention to make workplaces safer, healthier, and more productive. Since 1996, the agency has worked with governments, employers, and workers' representatives to collect health and safety

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[27] Permanand, G., E. Mossialos, and M. McKee, "Regulating medicines in Europe; the European Medicines Agency, marketing authoritzation, transparency and pharmacovigilence", *Clinical Medicine*, 6:1, Jan/Feb 2006 p. 87-90.

[28] Permanand and Vos, forthcoming

[29] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, *Official Journal of the European Communities* 30 April 2004: L136/01-33.

[30] Permanand, 2006

[31] EU Regulation on medicinal products for Pedeatric use by EU Parliament and Council, 27th December, 2006: http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/1_378/1_37820061227en00010019.pdf

[32] Permanand, 2006

[33] http://osha.europa.eu/en

information and statistics and to publish new scientific research and best practices. In June 2008, EU-OSHA launched a new campaign on risk assessment engaging with a wide range of businesses and organizations to focus on assessing high-risk sectors such as construction, agriculture, and healthcare. Once identified, employers and workers can develop more effective and better research of risk avoidance and accident prevention. Authority for the agency falls under Council Directive 89/391 on the introduction of measures to encourage improvements in the safety and health of workers at work.[34]

European Food Safety Authority (EFSA)[35] provides independent scientific advice, publishes information about existing and emerging food risks, and conducts risk assessment regarding food and feed safety in collaboration with national authorities and stakeholders.[36] The Scientific Committee on Food has informing Community food policy since the mid-1970s. The Bovine Spongiform Encephalopathy (BSE) crisis exposed serious gaps in both EU food safety regulation and the political processes intended to address such problems. In 2002, the General Principles of Food Law created the EFSA established under the management of DG SANCO. Despite the explicit public health goals, the Commission still views the EFSA as a vehicle of the internal market, ensuring the free movement of products.[37] EFSA coordinates national authorities, but does not regulate or monitor food additives, labelling, or promote harmonization of domestic legislation. In May 2003 all of the scientific committees were transferred to the EFSA. The Commission provides all of EFSA's funding and sets its political agenda. EFSA risk assessment opinions are sent to the Commission. After getting approval from the Member States' Standing Committee on the Food Chain and Animal Health, the Commission will adopt the decision.

European Centre for Disease Control (ECDC)[38] was established in 2004 to identify, assess and communicate current and emerging health threats from communicable diseases. [39] The ECDC

[34] COUNCIL DIRECTIVE 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work OJ L 183, 29.06.1989.
[35] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_home.htm
[36] Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31/1, 2.1.2002
[37] Permanand and Vos forthcoming
[38] http://ecdc.europa.eu/

complements existing national centres for disease control and European networks. As part of its responsibility for epidemiological surveillance, the ECDC and trains epidemiologists, provides scientific advice and technical assistance, and publishes Eurosurveillance, an epidemiological bulletin. Although it is a new agency, the ECDC has been actively pursuing its mission on many fronts. Several organizations and networks have been integrated into the ECDC activities, for example the European Influenza Surveillance Scheme (EISS), the Early Warning and Response System (EWRS), and EuroHIV. In February 2007, the ECDC hosted a coordinating meeting with 21 European scientific societies with a wide range of disciplines related to public health. The purpose for the meeting was to establish a consultation group and facilitate networking and collaborations among the organizations. In June 2007, the ECDC presented the first comprehensive report on the multiple threats posed by Communicable Disease in the EU. In April 2008, the ECDC signed a memorandum of understanding with the EFSA to intensify cooperation and exchange of information, and publish an annual report on zoonoses, diseases that infect both animals and humans.

The first external evaluation of the agency, published summer of 2008, identified additional programs and responsibilities.[40] The ECDC could develop benchmarks for national communicable disease surveillance systems. A recent study analyzing seven European surveillance systems found that while defining a gold standard would be difficult, establishing benchmarks would be an effective tool for comparison of systems and identifying priority areas for improvement.[41] When the national plans for pandemic influenza were analyzed for 21 EU countries, researchers identified the need for improved cooperation, sharing of best practices, and consistency in operability for specific programmes, all roles for the ECDC.[42] The real challenge for the ECDC is the lack of authority to coordinate or direct Member State disease preparedness plans and responses in the case of a serious disease outbreak.

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[39] Regulation (EC) No 851/2004 21.4.2004 establishing a European centre for disease prevention and control OJ C 32

[40] http://ecdc.europa.eu/en/files/pdf/About_us/External%20Evaluation%20ECDC%20Final%20Report.pdf

[41] Reintjes, Ralf, and M. Thelen, R. Reiche, and A. Csohan, 'Benchmarking national surveillance systems: a new tool for the comparison of communicable disease surveillance and control in Europe', The European Journal of Public Health 17 (2007) 375-380.

[42] Mounier-Jack, Sandra and R. Coker, 'How prepared is Europe for pandemic influenza? Analysis of national plans', Lancet, 367 (2006), 1405-11.

Non-Governmental Organizations, play an active and significant role in EU health policy development and implementation. Examples of some of the NGOs involved in public health include: European Public Health Alliance, European Network for Smoking Prevention, European Alliance on Drug Policy and Practice, and Eurocare European Alliance for Alcohol Policy. There are also a number of groups targeting specific diseases, health professional associations and industry lobbying organizations at the EU level. (see table 1)

From: "How EU Works" http://ec.europa.eu/publications/booklets/eu_glance/53/index_en.htm

Figure 1

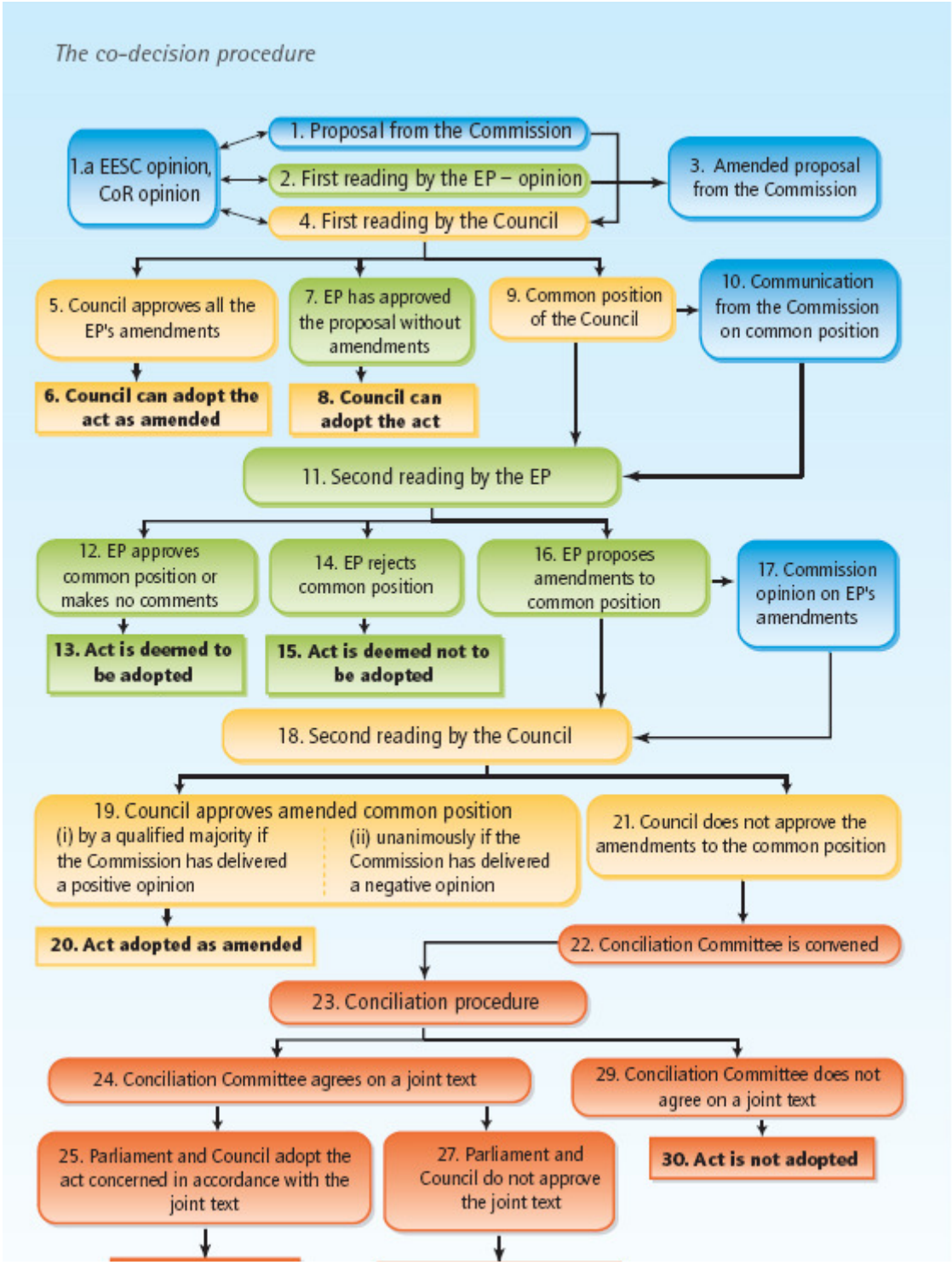

Table 1. Examples of Significant European Health NGOs	
European Public Health Alliance http://www.epha.org	EPHA is an international non-profit association composed of not-for-profit organizations working on all aspects of public health. EPHA's mission is to promote and protect the health of all people living in Europe and to advocate for greater participation of citizens in health-related policy making at the European level.
European Network for Smoking Prevention http://www.ensp.org/	ENSP's mission is to develop a strategy for coordinated action among organizations active in tobacco control in Europe by sharing information and experience and through coordinated activities and joint projects. ENSP aims to create greater coherence among smoking prevention activities and to promote comprehensive tobacco control policies at both national and European levels.
European Alliance on Drug Policy and Practice http://www.eadpp.eu/	The mission of the EADPP is to create a channel for dialogue between the European Institutions and key stakeholders involved in prevention, treatment, care and (community) empowerment in the drug field; to influence the development of policy on reducing drug related harm; to encourage bottom up ideas and models of good practice from local or national level to European level; and to communicate European drug strategies and action plans back to national and local level.
EUROCARE European Alliance for Alcohol Policy http://eurocare.org/	EUROCARE was formed in 1990 as an alliance of voluntary and non-governmental organizations representing a diversity of views and cultural attitudes and concerned with the impact of the European Union on alcohol policy in Member States. Member organizations are involved in the provision of information to the public; education and training of voluntary and professional community care workers; the provision of workplace and school based programs; counseling services, residential support and alcohol-free clubs for problem drinkers; and research and advocacy institutes.
Association Internationale de la Mutualite (AIM) http://www.aim-mutual.org/	AIM is an association of European mutual benefit funds in health insurance, providence, pensions and other sectors of social protection. AIM organizes the exchange of information between members, governments, and stakeholders in social and health services. AIM also represents members' interests and concerns to strengthen social protection systems and solidarity-based health care insurance.

European Federation of Nurses Associations (EFN)	EFN is an umbrella organization with members from national nurses associations with the mission to promote and protect nurses and the nursing profession in the EU. The EFN works to strengthen the status and practice of the profession of nursing by presenting a unified voice for nurses interests. http://www.efnweb.org/version1/en/index.html
European Federation of Pharma Industries & Associations (EFPIA)	EFPIA members include 32 national pharmaceutical industry associations and pharmaceutical companies with the mission of improving the competitiveness of the research-based pharmaceutical industry in Europe in a regulatory and political environment, which above all stimulates R&D and rewards innovation. EPFIA's priorities include strengthening the EU science base, speeding up patient access to innovative treatment, and improving the healthcare market environment in Europe. http://www.efpia.org/Content/Default.asp?
European Generic Medicines Association (EGA) http://www.egagenerics.com/	EGA represents the European generic and biosimilar pharmaceutical industry. EGA works with EU Members States and institutions to develop affordable solutions for pharmaceutical care and to increase Europe's competitiveness in the global market.
European Patient's Forum (EPF) http://www.eu-patient.eu/	EPF is the umbrella group of European patient groups representing a wide rage of disease-specific and grass-roots patient groups. EPF influences the EU health agenda by focusing on patient safety, information, education about disease prevention and treatment, patient mobility, and healthcare system sustainability. EPF also works closely with other public stakeholder groups such as the professional associations.
European Hospital and Health care Federation (HOPE) http://www.hope.be/	HOPE promotes a uniformly high standard of hospital care throughout the EU and to foster efficiency, effectiveness and humanity in the organization and operation of hospital services and the health system in which they function. HOPE advises EU institutions on hospital and health affairs, maintains information about panning and operation of hospital services, advises members, promotes best practice exchanges, and cooperates with international bodies including the WHO.
Pharmaceutical Group of the European Union (PGEU) http://www.pgeu.eu/	National pharmacy associations and pharmacist professional bodies are the members of PGEU representing the interests of community pharmacists. PGEU ensures that the public derives the maximum therapeutic benefit from prescribed medication

	dispensed in pharmacies with high quality advice. PGEU also cooperates with physicians to ensure effective management of medications and to protect public health.
Standing Committee of European Doctors CPME http://www.cpme.be/index.php	CPME represents all medical doctors in the EU by promoting the highest standards of medical training and medical practice to achieve the highest quality of health care for all citizens of Europe. CPME's priorities are exemplified by the four policy committees covering medical training, ethics and professional codes, organization of health care and health economics, public health prevention and the environment.

Treaty of the European Community

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 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 delivery 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.

Chapter 2

Legal Bases and Soft Law Processes

Treaty

In this section we will first introduce the public health article and then review other sections that have a direct or indirect impact on healthcare services. Due to the importance of European Court of Justice (ECJ) rulings in interpreting Treaty provisions and their application to the health sector, significant cases will also be mentioned.

Title XIII Public Health

Public Health Article 152

Public health first explicitly appeared in the Treaty of Maastricht in 1993. Article 129 (now amended and renumbered as Article 152) provided that "the Community shall contribute towards a high level of human health protection by encouraging co-operation between Member States, and, if necessary, lending support to their action". Under this section, the Community had no authority to harmonize national laws and were limited to co-ordinate policies or programmes. Member States were obliged to cooperate with Commission initiatives. This section was interpreted as either a limit to the expansion of Community level activity that had previously occurred without legal basis, or as an articulation of the status quo[43].

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[43] Hervey, Tamara, (2002), "The Legal Basis of European Community Public Health Policy," in *The Impact of EU law on health care systems,* ed. M. McKee, E. Mossialos, and R. Baeten, (Brussels: PIE Peter Lang)

In 1999, the Treaty of Amsterdam expanded the public health section into the current Article 152. The Community's authority was intensified from 'contribute to ensuring' to 'shall ensure' a high level of health protection in all policies and activities. The new subsection one also inserted the prevention of human illness and disease, in addition to improving public health. Subsection two defines the public health roles and powers for the Member States and EU institutions. Both subsection two and five explicitly enshrine the principle of subsidiarity to protect Member States' interests to preserve national competence over the organization and provision of health services. The types of actions available to the EU institutions are defined in subsection four. These include explicit responsibility to define standards of quality and safety for human tissues and blood, and measures to protect public health in the veterinary and phytosanitary fields. Incentive measures to protect and improve human health may also be adopted, but again harmonization is excluded. Thus, the significance of Article 152 can be found both in what it allows and in what it prohibits. The EU has no authority to enact direct health care legislation, but it does have power to establish public health programmes and incentives which may influence national health systems.

Title I & III – Free Movement of Goods, Persons, Services, and Capital

Between the dates that the Treaty of Amsterdam was signed and came into force, the ECJ published its rulings on the famous Kohll and Decker cases, indicating its intention to apply internal market policies to Member States' social policies. The Kohll and Decker decisions interpreted Treaty Articles 49 and 50 and EC Social Security Coordination Regulation 1408/71 to apply the free movement of persons and services to the healthcare sector.[44] Patients who receive medical care in different Member State should be refunded for the costs of treatment as if it had been delivered in the patient's home state. Alternatively, Member States providing

[44] Case C-120/95 Decker [1998] ECR I-1831; and Case C-158/96 Kohll [1998] ECR I-1931.

services free of charge could seek reimbursement for treatment from the patient's home Member State. Subsequent cases went further concluding that medical treatment qualifies as services under Article 50 without regard to method of payment or reimbursement, whether the treatment was provided in a hospital or on out-patient basis, or how the social security system is organized.[45]

The ECJ has also repeatedly discouraged obstacles to the freedom of movement for patients seeking medical treatment in host Member States, including prior authorization for care.[46] ECJ decisions have clarified that a distinction must be made between hospital care and non-hospital care. Member States could adopt a system of prior authorization for planned hospital medical services obtained abroad, so long as the system is not arbitrary or discriminatory, objectively justified as necessary and proportional, and timely. [47] The system would be permissible where the financial balance of the health and social security system would be undermined and there is "evidence of sufficient distortions of hospital health care provision due to cross-border hospital care".[48] However, non-hospital care does not require prior authorization, since the financial burden to the health system is minimal, citizens should be granted reimbursement for out-patient care under the same conditions and tariffs applicable at home.[49] Much has been written about the development of the patient mobility laws on the European health policy agenda.[50]

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[45] Case C-70/95 Sodemare ECR I-,3395 Case C-368/98 Vanbraekel [2001] ECR I-5363, and Case C-157/99 Geraets-Smits and Peerbooms [2001] ECR I-54.
[46] C-158/96 Kohll ECR I-1931, § 35; and later reaffirmed in: C-157/99 Smits-Peerbooms [2001] ECR I-5473 § 69, C-56/01 Inizan ECR I- § 54 ; C-372/04 Watts ECR I- § 98
[47] Case C-157/99 *Smits and Peerbooms* [2001] ECR I-54, and Case C-368/98 *Vanbraekel* [2001] ECR I-5363.
[48] Explanatory Memorandum, proposed directive
[49] Case C-385/99 *Muller-Faure and Van Riet* [2003] ECR I-4503
[50] See Hervey, T. and L. Trubek, (2007) 'The Current Legal Framework on the Right to Seek Healthcare Abroad', *Cambridge Yearbook of European Legal Studies* 2006-07, vol. 9 Cambridge:

In addition to ECJ court cases, the Commission has maintained the momentum to pursue patients' rights legislation. The Commission has pursued several approaches to provide clarity on the scope of patients' rights to cross-border health care through the 2002 "High level Process of Reflection", the 2004 "High Level Group on Health Services and Medical Care", and the 2004 proposal for a Directive on Services in the internal market. However, the Parliament voted in 2006 to exclude health services from the Service Directive in recognition of the special nature of health care. As promised, after delays caused by significant internal differences within the College of Commissioners[51], the Commission has finally offered its proposal for specific legislation addressing cross-border health services that will be discussed in detail below.

Health professionals also enjoy the freedom to establish businesses and provide services throughout the Community. Professionals seeking to establish permanently in a Member State must follow the same national licensure requirements applied to other resident professionals, under Treaty Article 47. If they seek to provide services temporarily, then Article 43 applies. The Court has ruled that the regulation of the establishment of services must be limited to what is necessary, proportional, and non-discriminatory. Directive 2005/36/EC on the recognition of professional qualifications has further clarified the concepts of mutual recognition and recognition of professional qualifications. The objective of the legislation is to avoid discouraging the free movement of professionals by imposing a double regulatory burden from more than one Member State. ECJ case law further clarifies how address issues of professional

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Hart Publishing; and *Patient Mobility in the European Union: Learning from experience*, M. Rosenmoller, M. McKee, and R. Baeten (eds.), World Health Organization Regional Office for Europe, The European Observatory on Health Systems and Policies, 2006.

[51] http://www.euractiv.com/en/health/confusion-surrounds-eu-health-services-directive/article-169882; see also Wallström raises objections to Kyprianou's directive, Europolitics, 17 December 2007.

experience, foreign earned diplomas, and specialist training.[52] However this regulation is a double edged sword for policy makers. It may provide flexibility in recruiting new health professionals, but it also limits health policy tools used to improve efficiency of the health system by regulating the supply of services. The Court recently held that German rules placing regional quotas on psychotherapists breached the right of free establishment.[53] There have been additional attempts to develop standards for quality of care and re-validation of certificates, but thus far no consensus has been reached.[54]

Title II Agriculture

The Common Agricultural Policy (CAP) (Articles 32 through 38), including fisheries, focuses on the economic aspects of the production and sale of agricultural goods and the protection of the social structure for those who are engaged in agriculture. There is no mention of ensuring the accessibility of affordable, high quality, and nutritional foods. In fact the CAP has been long criticised for subsidising unhealthy products such as tobacco and alcohol, while supervising the destruction of tonnes of fruit and vegetables each year. Recently, CAP reforms have shifted the focus towards encouraging sustainable economic development by rewarding the transition to healthy products and developing alternative sources of income and economic activity as the tobacco subsidies are being phased out by 2010.[55]

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[52] See Case C-319/92 *Haim* [1994] ECR I-425, Case C-238/98 *Hocsman* [2000] ECR I-06623I-06623, and Case C-110/01*Tennah-Durez* [2003] ECR I-06239

[53] Case C-456/05 Commission of the European Communities v Federal Republic of Germany [2007] ECR 0000

[54] *Report on the work of the High Level Group in 2006, HLG/2006/8 FINAL* (Brussels: European Commission DG Health and Consumer Protection, 2006).

[55] Commission Press Release, (2008) 'Commission proposes to continue financing Community Tobacco fund to pay for awareness raising on dangers of tobacco', http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/178&format=HTML&aged=0&language=EN

TITLE VI – Common rules on competition, taxation and approximation of laws

Competition Law Articles 81 through 86

Competition rules were established to ensure that participants in the Single European Market (SEM) compete on a level playing field. Article 81(1) prohibits *undertakings* from practices "which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market." If organizations involved in the health system are engaged in 'economic activities' the European Court of Justice (ECJ) or national courts could consider them to be 'undertakings' subject to competition law prohibitions. Community competition rules prevent the forming of cartels (Article 81) and the abuse of dominant position (Article 82) from negatively affecting the SEM. Cartels are formed by agreements between undertakings that collude to interfere with competition, by taking concerted action to fix prices, to limit sources of supply, or to require supplementary contract terms extraneous to the essential agreement. Abuse of dominant position occurs when an undertaking enjoys a dominant share of a particular market and distorts competition by exploiting their market power to discourage competitors from entering into the market, or by selective contracting, or predatory pricing, for example. EC competition law based on the principles of economic freedom endeavours to make markets open to all firms that should have the opportunity to attract business based on factors such as price and quality, rather than unfair market distortions. Although the ECJ has used the services of general economic interest (SGEI) exception in Articles 16 and 86(2) to avoid applying competition law to universal service obligations in the health sector, and should continue to do so, the scope of the exemption and when it applies remains uncertain, dependent on case-by-case analysis.

Undertakings

The first step in the court's analysis as to whether EC competition law applies is to determine whether the firm involved in the case is conducting economic activities as an undertaking. In this section we will compare undertakings with public service organizations (PSO), which perform primarily social activities organized on the basis of solidarity and frequently entrusted with certain rights and obligations from the state to facilitate social service provision. The concept of undertakings has been refined through several ECJ cases.

Undertakings are classified not by their structure, but by their actions, the context where they operate, and the purpose and affect of their activities.[56] Undertakings have the independence to enter into contracts based on negotiated terms. [57] While, firms engaged in social activities restricted by requirements of solidarity are not undertakings, as explained in the joined *Poucet and Pistre* cases and their progeny.[58] The Court's rulings have determined that social insurance schemes based on the principle of solidarity, with compulsory membership, statutorily defined benefit and contribution levels, perform exclusively social functions and are not undertakings.

In Germany, pharmaceutical companies complained that the sickness funds were colluding to fix reimbursement rates for prescription medications. In *AOK,* the ECJ ruled that the sickness funds were not undertakings since employees were obliged to be insured by the statutorily regulated funds, organized under the solidarity principle. On the other hand, when social insurance institutions compete with private insurers to provide supplementary or voluntary insurance benefits the Court applied competition rules to the economic activities of the undertaking. Even though the insurer exhibited some characteristics of solidarity, the fact that membership was voluntary and that the scheme was financed on the capitalization principle was insufficient to meet the criteria of a social activity.[59]

In a more controversial ruling, a business association alleged that hospitals in the Spanish national health service violated competition laws by abusing their dominant position when delaying to pay invoices for goods and services purchased in the market. The ECJ upheld the

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[56] Case C-159 & 160/91, Poucet and Pistre, joined cases, [1993] ECR I-637.
[57] Jost, T.S., D. Dawson, and A. den Exter, "The Role of Competition in Health Care: A Western European Perspective", *Jounal of Health Politics, Policy, and Law*, 31:3 June 2006 pp. 687- 703
[58] Ibid; Case C-218/00 INAIL [2002] ECR I-691; and Case C-264/01, 301/01, 354/01, & 355/01, *AOK Bundesverband v. Ichthyol-Gesellschaft Cordes.(AOK)* joined Cases, [2004] ECR I-2493.
[59] Case C-244/94, *FFSA, ECR,* 1995, I-4019, para. 17, Case C-67/96, *Albany, ECR,* 1999, I-5751, paras. 81 ff, Case C-115/97, *Brentjens, ECR,* 1999, I-6025, paras. 81 ff, Case C-219/97, *Bokken,* 1999, I-6121, paras. 71 ff, and Case C-180/98 to C-184/98, *Pavlov*, paras. 114 ff.

ruling of the Court of First Instance that found that the hospitals were not undertakings since they offered services for free, and were funded through social security contributions. Even though purchasing goods and services in the market is an economic activity, since they were used to provide health services and were not resold on the market, the activity was predominantly social.[60]

Article 81 anticompetitive cartels

Health care sector cases regarding anti-competitive cartels often involve pharmaceuticals, medical devices or related services. In 1999, the Italian Antitrust Authority ruled against two pharmaceutical companies for colluding to fix prices and coordinate market share.[61] Four pharmaceutical wholesalers in Germany engaged in a 'discount battle' after Andreae-Noris Zahn AG (Anzag) expanded discounts to increase its market share. After Anzag ended the price war, wholesalers exchanged information about customers and monthly transactions to re-establish the pre-existing market share. The German Competition Authority found that there was an anticompetitive agreement creating a quota cartel and fined all four companies and seven executives, personally.[62] The French Competition Council fined two companies for colluding to share the medical devices market during a public tender and reached a settlement with four pharmaceutical companies for anticompetitive agreements in the distribution of

[60] Case C-205/03, Federacion National de Empresas de Instrumentacion Cientifica Medica Tecnica y Dental (FENIN) v. Commission of the European Communities; [2006] ECR I-6295

[61] Italian Antitrust Authority (IAA), Press Releases, July 22, 1999, (last accessed April 2008) http://www.agcm.it/eng/index.htm

[62] German Competition Authority (GCA), Press Releases, April 19, 2007: http://www.bundeskartellamt.de/wEnglisch/News/Archiv/ArchivNews2007/2007_04_19.php .

pharmaceuticals.[63] The Latvian Competition Council fined a medical gas monopolist for price discrimination ranging from 54 to 281%. [64] Similarly, four medical device companies in Italy refused to present tenders in the ostomy device market for two years in an effort to drive up prices in an unlawful cartel.[65] The Hungarian Competition Council (HCC) found three corporations violated competition laws to win contracts managing information systems for university hospitals. On appeal, the municipal court of Budapest concurred with the finding that the companies had entered into an anticompetitive agreement, but disagreed on the extent of the infringement upon competition and reduced the fines by 10 per cent.[66] More recently, the HCC fined a medical equipment distributor for establishing an exclusive distribution scheme. [67]

Health services agreements among providers or professional associations have been construed as anti-competitive cartels. As mentioned earlier, NCA and national courts in several Member States have found cases of unlawful price fixing agreements by professional associations. In 1994 German and French national courts each considered cases involving cartels of health professionals. The German Federal Supreme Court found that the Bremen Chemist Association membership rules included anti-competitive regulations. The chemists' professional

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[63] French Conseil de la Concurrence (FCC), Press Release, October 30, 2007: http://www.conseil-concurrence.fr/pdf/avis/07d22.pdf; January, 20, 2003. http://www.conseil-concurrence.fr/user/standard.php?id_rub=127&id_article=243. (last accessed Jan 24, 2008)

[64] Rubene, Andra 'The Latvian Compeition Council fines the medical gas monopolist for the application of an unfair and discriminating price', e-Competitions (2006) (last accessed April 2008) www.concurrences.com/article_bulletin_gratuit.php3?id_article=16460

[65] Italian Antitrust Authority (IAA), Press Releases, August 8, 2007: http://www.agcm.it/eng/index.htm.

[66] Hungarian Competition Council, Press Release, February 21, 2007: http://www.gvh.hu/gvh/alpha?do=2&st=2&pg=137&m166_act=3. (last accessed on Jan 24, 2008)

[67] Gabor Bathory, E-Competitions law bulletin, February 2008, www.concurrences.com/article_bulletin_gratuit.php3?id_article=15536. (last accessed on Feb. 14, 2008).

code of conduct restricted the advertising and sale of product samples. When a chemist was discovered selling the samples for a nominal fee, the association threatened to take legal action against him. The Court held that both professional code restriction on product sales and the threat of legal action violated German competition rules.[68] The French Constitutional Court was asked to strike down a law requiring suppliers of optical care appliances to be managed by licensed opticians. A distributor of contact lenses complained that the French law established a monopoly and the optician's trade association actions constituted either a cartel or an abuse of a dominant position. The French court rejected the argument and held that the sale of contact lenses may be restricted for the purpose of protecting public health. The court also explained that trade associations could encourage the observance of laws favourable to them.[69] These decisions show that national courts will permit some restrictions on competition necessary and proportional to protecting public health.

Article 82 abuse of dominant position

The Treaty prohibits an undertaking with dominant position from exploiting its market power to distort or restrict competition. The test for establishing an infringement of Article 82 requires a showing: that an undertaking is dominant in a given market; that it has abused its dominant position; that the abuse has an effect on trade between Member States; and the absence of any objective justification for the abuse. In the health care context there are several interesting opportunities for analysis.

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[68] European Commercial Cases 275 (1994) Re A Pharmacist's Sale of Stock (Case KVR 4/89) p.275-288.

[69] European Commercial Cases 457 (1994) Laboratoire de Prothese oculaires v. Union nationale de syndicated d'opticiens de France. P.457-461.

Once the organization involved is marked as an undertaking, the market is defined by its product, geographic area, and timeframe. The market could be defined utilizing the specifications for a medical device under an (anticompetitive) exclusive distribution agreement.[70] To define the market in the pharmaceuticals sector, several factors similar to those used in patent protection could distinguish between products, such as method of delivery, treatment pathway, or mode of action.[71] In health services cases defining the market should be intuitively simple. Patients should select providers based on their geographic proximity and the recommendation of their local GP. However, a number of objective and subjective factors frustrate this analysis. The market for health services is not as adaptable to changes in demand as other industries due to the high set-up and labour costs. A study of the Dutch partially-privatised hospital market found that both traditional and new economic approaches to defining markets failed to capture an accurate picture of demand within the health care system. Complexities, unique to contractual relationships between health insurers hospitals, and the subjectivity of patient preferences, influence hospital market definition.[72]

Second, the court will assess the dominance of the undertaking in the given market. If the market is narrow, it is easier to dominate. Thus, there is a strategic link between the first two steps in the analysis. Previously, the Commission allegedly blurred these issues by tailoring the definition of the market to guarantee a finding of dominance.[73] The Commission responded by

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[70] Gabor Bathory, E-Competitions law bulletin, February 2008, www.concurrences.com/article_bulletin_gratuit.php3?id_article=15536. (last accessed on Feb. 14, 2008).

[71] See the chapter by Hancher for a more detailed discussion of the pharmaceuticals market.

[72] Marco Varkevisser, et al "Defining hospital markets for antitrust enforcement: new approaches and their applicability to the Netherlands," Health Economics Policy and Law, (2008) 3:7-29.

[73] Gyselen, L. and N. Kyriazis, 'Article 86: the Monopoly Power Measurement Issue Revisited' (1986) 11 EL Rev. 134; S. Baker and L. Wu, 'Applying the Market Definition Guidelines of the EC Commission' [1998] DCLR 273.

adopting the Market Definition Notice approach based on accepted economic theory and formalized its methodology.[74] The Market Definition Notice approach analyzes whether there is sufficient demand and supply substitutability where no undertaking could influence market prices.[75] Where the undertaking is dominant in the market, the question then turns to analyzing the scope of the abuse. Monopolistic behaviours such as price fixing, selective contracting, reduction in quantity or quality, refusal to modernize production or service provision and refusal to deal, are classic examples of abuse of dominance.

The Dutch Competition Authority (DCA) examined a group of pharmacies that shared considerable market power due to participation in an electronic filing system that included patient information. The DCA found that the electronic system promoted efficiency for the health system and improved patient services. However, the exclusion of pharmacies from access to the system was an abuse of dominant position. The group voted to decide whether to admit a new pharmacy to the system, without employing any objective and transparent criteria or any procedure for appeal. This exclusion served as a barrier to entry into the market. Following the DCA's investigation and statement of objections, the contrite pharmacies voluntarily adapted their admission rules.[76] The DCA also reviewed a complaint filed by physiotherapists and GPs against Dutch health insurers. The therapists alleged that by refusing to negotiate a fee increase, the insurers were abusing their dominant position. The DCA ruled that there is no duty to negotiate contract terms when the procurement procedures were transparent, objective and non-

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[74] European Commission, 'Notice on the definition of relevant market for the purposes of Community Competition law', OJ 1997 C372/5.

[75] For a more in depth discussion of these legal issues see: GiorgioMonti, *EC Competition Law* (2007) Cambridge University Press: Cambridge, United Kingdom (Chapter 5).

[76] Dutch Competition Authority, June 6, 2003 http://www.nmanet.nl/engels/home/News_and_Publications/News_and_press_releases/2003/03_22.asp; (last accessed Jan 24, 2008)

discriminatory. These findings were further supported by the fact that there was an over-supply of physiotherapists.[77]

In the pharmaceutical sector, factors used in patent protection or in pricing policies are also distinguish markets. An English firm, Napp, used market segmentation and predatory pricing strategies to become super dominant in the supply of morphine tablets and capsules. Napp earned 90% of the hospital market by offering prices well below costs. As the access point for new patients, the hospital segment has significant strategic value even though it is only 10-14% of the total market. The UK Office of Fair Trade found that Napp had foreclosed the hospital market and the community market through predatory pricing.[78] Similarly, the OFT held Genzyme liable for abuse of dominant position for bundling the price for Cerezyme with the cost of providing home delivery, and awarded damages to an in-home-care provider, Healthcare at Home.[79]

Article 86 (2) services of general interest exception

The Article 86(2) SGEI exemption has received more extensive scrutiny than Article 16, but legal interpretations have still fallen short of clearly defining SGEI. The primary language provides:

Undertakings entrusted with the operation of services of general economic interest …shall be subject to the rules contained in this Treaty, in particular to the rules on competition, in so far as

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[77] Dutch Competition Authority, May 27, 2005: http://www.nmanet.nl/engels/home/News_and_publications/News_and_press_releases/2005/05_16.asp (last accessed Feb. 2008)

[78] Napp Pharmaceutical Holdings Ltd v. Director General of Fair Trading, (2002) Comp. AR 13 (CCAT).

[79] Genzyme Limited f. Office of Fair Trading, Case No 1016/1/03 (2004) CAT 4

the application of such rules does not obstruct the performance, in law or in fact, of the particular tasks assigned to them.

The first level of complexity can be found in the procedural process leading to Article 86(2). It may be easier to conceptualize the SGEI exception as a defence raised by Member States when market-correcting policies, resulting in the entrustment of public services, are challenged in court. It should be seen as the final phase of analysis once the court has found evidence of undertakings violating competition law. Thus the evaluation of SGEI is always subordinate to the analysis of market competition.

Once invoked, the courts will assess whether the public interest objective is proportional to the restriction placed on market competition.[80] The Member State must prove that the prohibition placed on economic activity was the least restrictive means, and the advantage of facilitating the public interest objective outweighs the harm to market competition. Since Member States have wide discretion to define the SGEI, limited only by manifest error[81], the Court focuses not on the nature of the public interest itself, but the anti-competitive mechanism employed to achieve that goal. For example, in Germany one of the Land granted an undertaking with the exclusive right to provide ambulance services in a rural area. The ECJ found that it would not be financially feasible to provide dependable emergency transport without monopoly rights that would allow for cross-subsidy from other parts of the business.[82] In contrast, the French Constitutional Court upheld a French law that required businesses selling optical care to be

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[80] Case C-320/91 *Corbeau* [1993] ECR I-2533 ;Case C-393/92 *Municipality of Almelo and Others v. NV Energiebedrift Ijsselmij* (Almelo) [1994] ECR I-1477; Case C-475/99 *Ambulanz Glockner v. Landreis Sudwetpflaz* (Glockner) (2001) ECR I-8089; Case C-309/99 *J.C.J. Wouters v. Algemene Raad van de Nederlandse Orde van Advocaten* (Wouters) [2002] ECR I:1577.

[81] Case T-289/03, British United Provident Association Ltc. (BUPA) and Others v. Commission [2008] (unreported, 12.02.2008)

[82] Case C-475/99 *Ambulanz Glockner v. Landreis Sudwetpflaz* (Glockner) (2001) ECR I-8089

managed by qualified opticians was justified to protect public health. In this case the court disagreed with a distributor who alleged that the optician's trade association's activities to ensure the observance of the law violated both Articles 81 and 82 as anticompetitive concerted practices and an abuse of dominant position in the market.[83]

Decisions regarding the organization of health systems are well within the discretion of the Member State under Article 152. Who and how the social services will be provided depend on local preferences so long as the rules of transparency, equal treatment, mutual recognition and the protection of individual rights are met. However, in many health systems it is difficult to determine whether the organizations involved in the purchase or provision of health care are public, private or somewhere in between.[84] Mixed public and private cases have arisen in primary care trusts in the United Kingdom that both purchase and provide long-term care services to public and private patients[85], in public hospitals in Finland offering private health services at below market rates[86], and semi-privatised public hospitals in Germany and Austria[87]. There are also a number of public-private partnerships (PPP) that have developed in post-communist

[83] European Commercial Cases 457 (1994) Laboratoire de Prothese oculaires v. Union nationale de syndicated d'opticiens de France. P.457-461.
[84] SGEI progress SEC(2007) 1515 p. 4
[85] BetterCare Group Ltd v. Director General of Fair Trade [2002] 229 (CCAT)
[86] OECD, (2000) Annual Report On Competition Policy Developments In Finland, (last accessed July, 2008) http://www.oecd.org/dataoecd/52/63/39553988.pdf
[87] Schulten, T. (2006) 'Liberalization, privatization and regulation in the German Healthcare Sector/ Hospitals', Wirtschafts- und Sozialwissenschaftlisches Institut (WSI) PIQUE; and Fidler, A., R. Haslinger, M. Hofmarcher, M. Jesse, T. Palu. (2007) 'Incorporation of public hospitals: A "Silver Bullet" against overcapacity, managerial bottlenecks and resource constraints? Case studies from Austria and Estonia', Health Policy 81:328-338.

states.[88] Although the Commission conducted a consultation in 2005 "to clarify how EU rules should apply to the choice of private partners in 'institutionalised PPPs'",[89] the Commission has still failed to produce a document addressing these issues. If challenged, the court would still conduct the same undertaking analysis as in the cases discussed above. But this innovation unique to SGEI does not easily fit into the binary alternatives. Paradoxically, organizations providing the same services may be governed by completely different rules as a result of this determination.

Thus, under the Court's formulary for analysis, the term undertaking plays a controversial gate-keeping function, potentially resulting in an irrational paradox that the provision of the same services could be governed by different rules and obligations.[90] This binary division presents domestic health policy makers with a dilemma. They may either maintain a vertically integrated health system free from the interference of EU economic regulations, or incorporate market structures risking 'big bang' liberalization and the ensuing uncertainty.[91] The undertakings threshold does not allow for gradual experimentation of particular aspects of market reform without an opening of the competition law floodgates.

Aid Granted by States Article 87

Member States may not provide financial assistance from public funds to commercial-public or private- enterprises that distort conditions of competition. The article goes on to list types of aid that are or may be compatible with the common market. States must notify the Commission regarding the grant of aid, which has the authority to block grants or insist on repayment. The Commission determines whether the aid meets the criteria defined in Article 87. The Court formalized this analysis in the *Altmark* case, by holding that financial support may not

[88] Lear, forthcoming
[89] SGEI progress SEC(2007) 1515 p. 4
[90] Souter, 2008, p.168
[91] Ibid, and Ferrera, 2000, p.280

constitute a state aid when four conditions are met cumulatively[92]. The Altmark test requires: 1) clearly defined public service obligations; 2) compensation defined in advance in a transparent and objective manner; 3) compensation does not exceed costs; and 4) the efficient provider has been found through a competitive tendering procedure. The Commission's Decision on the de minimis rules limits the application of public procurement rules to contracts falling below a minimum threshold[93]. The Decision goes on explain the four principles of public procurement: non-discrimination, transparency, proportionality, and mutual recognition. The *Altmark* decision and Commission publications have clarified state aid rules to a point, but have fallen short of clearly delineating when hospitals or other health system providers are exempted as services of general interest (SGEI). In an effort to promote fairness, the Court defined and Commission clarified rules require burdensome analysis rather than identifying with precision which entities qualify as 'contracting authorities and which circumstances meet the *Altmark* requirements.

Approximation of Laws Article 95

The legal basis for Community authority to establish the internal market legislation is defined in Articles 95. Regulations based on Article 95 must facilitate new trading opportunities within the SEM and cannot be used as a basis for general regulation of economic life. In *Tobacco Advertising* [94], Germany argued that the initial directive banning tobacco advertising failed to improve the workings of the internal market by facilitating trade or by eliminating distortions of competition that existed because of differences in national legislation.

> [A] measure adopted on the basis of Article [95 EC] must genuinely have as its object the improvement of the conditions for the establishment and functioning of the internal market.

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[92] Case C-280/00 *Altmark* [2003] ECR I-7747
[93] Commission Decision 2005/842/EC, OJ [2005] L 312/67
[94] Case C-376/98 *Germany v. Parliament and Council* 'Tobacco Advertising' [200] ECR I-8419.

If a mere finding of disparities b/n national rules and the abstract risk of obstacles to the exercise of fundamental freedoms or of distortions of competition.[95]

Use of Article 95 requires that there is a need for legislation intended to improve the functioning of ingle market, due to differences in national legislation that are actively disturbing or threatening the functioning of the single market. The Court agreed with Germany that the legislation's true objectives were to protect public health and the ban on advertising would have obstructed trade. It should be emphasized that the majority of the Community's liberalization legislation is based on Article 95. The public health article does not provide any basis for harmonization of national laws. Thus most legislation impacting health policy (directly or indirectly) is based on Article 95, including the proposed directive on patients' rights to cross-border care.

Subsections 3 through 6 discuss the consideration of scientific evidence, especially in the case of emerging risks, relevant to promoting health under the proportionality principle. Restrictions on trade could be permitted if necessary and proportionate for the protection of health. Member States must seek Commission authorization for exemptions under subsections 4 or 5. For example, in 1973 the Commission refused to authorize an exemption from Directive 95/2/EC regulating food additives for a Danish law that banned specific nitrites and sulphates from foods since there was insufficient evidence to of a threat to public health.[96]

Title IX Common Commercial Policy

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[95] Ibid.
[96] Damian Chalmers, Christos Hadjiemmanuil, Giorgio Monti, and Adam Tomkins; European Union Law (2006) Cambridge University Press: Cambridge, United Kingdom. p. 488

Common Commercial Policy Article 133(6)

Generally the EC acts as a single entity in the area of trade. However, subparagraph six lists some subject areas that Member States retain shared competence including social and human health services.

Title XI Social Policy

Social Policy Article 137

Initially, EC social policy focused exclusively on promoting the social conditions for workers. Thus, the protection of workers' health and safety in the working environment is a crucial component to EC social protection policies. This article provides the basis for a variety of directives including the Working Time Directive, that are not specifically directed at the health sector but have significant (unintended) impacts on the provision of health services.

Title XIV Consumer Protection

Consumer Protection Article 153

Similarly, The Community shall contribute to protecting the health, safety and economic interests

of consumers, as well as to promoting their right to information.

Title XIX Environmental Policy

Environmental Protection Article 174

Naturally, the protection of human health is one of the primary goals of environmental protection, but is tempered by the need to respect the diversity of of situations in the various regions of the Community. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.

Secondary Legislation

Although the legal character of a measure does not depend upon its official designation, but on its content, the Community has taken on a standard vocabulary to identify different types of instruments. Regulations are generally and directly applicable to all Member States, binding in their entirety without national transposition. Directives may have a more narrowly defined scope and are binding upon those specified institutions or subject matters. The national legislators of the Member States involved must transpose the directive into binding national legislation within a time period defined by the directive. Decisions are binding upon those to whom they are addressed and also require an act of transposition on the part of the Member State concerned. Instruments that are not legally binding such as recommendations and opinions, suggest a line of possible action or provide guidance regarding the interpretation of Community law.

In this section we will introduce a range of legal instruments with primary objectives outside of the health sector but give the EU indirect influence on health policy. Chapter 3 will discuss specific health legislation and programmes by subject area in more detail.

Charter of Fundamental Rights in the EU

The legal weight of the Charter of Fundamental Rights remains the subject of debate. The Charter was enacted as a convention in October 2000, and thus is also known as the European Convention of Human Rights.[97] The Constitutional Courts of Spain[98] and Italy[99] recognize the Charter as an authoritative source of fundamental rights. The Constitutional Treaty treated the Charter as a statement of principles. Some authors view the document as a signpost

[97] Charter of Fundamental Rights of the European Union, OJ C 303 of 14 December 2007
[98] Decision 292/2000 of 30 November 2000.
[99] Decision 135/2002 of 11 April 2002, para 2.1

for new directions and aspirations for the EU institutions, while others are much more critical.[100] The Court has not yet ruled on the legal weight of the Charter, leaving the Charter's legal significance an open question.

The Charter includes three articles concerning health issues. Articles 31 and 32 address health and safety at work for adults and young people. Article 35 defines the right to Health care as:

> The Union recognises and respects access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities.

The difficulty in applying these rights in controversial issues where wide differences in religious and ethical perspectives across member states illustrates the difficulty of utilizing a fundamental human rights approach in developing health law and policy across the EU. For example, some Member States, such as the Republic of Ireland and Poland, give specific legal status to the embryo and/or a human foetus.

[100] Damian Chalmers, Christos Hadjiemmanuil, Giorgio Monti, and Adam Tomkins; European Union Law (2006) Cambridge University Press: Cambridge, United Kingdom. p.253.

Convention for the Protection of Human Rights and Dignity of the Human Being with respect to Biomedicine

The Convention on Biomedicine[101] address patients' rights issues such as informed consent (Article 5-9), the right to information (Articles 12), controls on genetics and prohibition of discrimination (Articles11-13), and research and removal of organs and tissue from living donors for transplantation purposes (articles 21-22). Subsequent protocols also address cloning and biomedical research.[102]

Public Procurement- Directive 2004/17/EC and 2004/18/EC and 89/665/EEC[103]

The rules on public procurement defined in Directives 2004/17/EC and 2004/18/EC, require that public contracts are awarded following stringent requirements of publicity, transparency, mutual recognition and non-discrimination. As mentioned above, the rules on state aids in Article 87 prohibit the use of public funds either indirectly through public contracts or directly through subsidies, unless the Commission approves the grant following a notification procedure. Whereas, the rules of public procurement apply to public contracting entities, state aid rules apply where state resources are transferred to undertakings. Therefore the rules apply alternatively, and not simultaneously.

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[101] Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to biology and Medicine

[102] Ibid.

[103] Directive 2004/17/EC, for Procurement in the Utilities Sector, OJ [2004] L 134/1; Directive 2004/18/EC, the 'General' Procurement Directive, OJ [2004] L 134/114Directive 89/665/EEC of the Council of 21 December 1989 on the coordination of the laws, regulations and administrative provisions relating to the application of review procedures to the award of public supply and public works contracts, OJ [1989] L 395/33.

These rules will impact health systems depending upon the choices Member States make regarding the financing and funding of health care. How the State defines the split in financing infrastructure versus costs associated directly with patient care could impact how contracts should be tendered. Lack of transparency in cost calculation by private providers frustrates systems of public tendering. How the *Altmark* decision impacts the funding of public hospitals entrusted with public service obligations raises a number of questions. What is the state's obligation to monitor the hospital to determine whether the organization fulfils its mission, allowing for some reasonable profit, and what must the state do if the hospital fails? If the organization qualifies as a contracting entity there are still some circumstances where competitive tenders are not required such as closed awards, where the state confers an exclusive or special right on an undertaking; or where there is no contractual relationship because the services are provided between two bodies belonging to the same public entity.

Health care systems in most Member State are evolving in response to rising costs, and within the context of political and legal uncertainty. The choice of regulatory technique may fall under the scrutiny of the Commission under soft law mechanisms or the Court applying economic legislation. In either case, Member States can no longer rely on the EU's inertia in the field of health policy. Once a Member State shifts their health services from a model based on primarily on solidarity to include market based principles, the ambiguity of EU law could result in unintended reforms broadening the markets influence on health services, despite the dampening effect of the services of general economic interest.

General Food Law

Prior to the BSE crisis, Community rules on food safety were primarily created through ECJ jurisprudence or on an ad hoc basis. Although Member States have long traditions of food laws,

the Community viewed many national provisions as trade barriers and were one of the first targets for harmonization. Commission Decision 97/579/EC established several scientific committees composed of independent experts to provide technical advice on food, plant and animal safety.[104] Regulation 178/2002/EC, known as the General Food Law, created the EFSA and brought the committees under the Agency's management.[105] The Food law employs an integrated farm to fork approach at both the national and EU level and defines consumers' rights to safe food and to accurate and honest information. It also continues the process of harmonizing national requirements to ensure the free movement of food and feed in the EU.

To address past criticisms, the Food law establishes principles of risk analysis and a framework for greater transparency with the aim of ensuring consumer confidence. EFSA manages structures and mechanisms for the scientific and technical evaluation of food safety. The regulation delineates a three over-lapping components of risk analysis including assessment, management, and communication. To improve public awareness and consumer information, the framework involves stakeholders in all stages of the development of food policy.

Working Time Directive

The Working Time Directive, consolidated in Directive 2003/88[106], lays down minimum periods of daily and weekly rest, annual leave, and maximum weekly working time, as well as regulating certain aspects of night work, shift work and working patterns. It is important to stress that Member States are free at any time to apply laws that go further than the Directive (Art. 15) to protect the health and safety of workers. The minimum requirements include a 48-hour maximum working week, including overtime (Art. 6), a minimum of 11-hours' continuous rest in every 24-hour period (Art. 3), a rest break after every six hours worked (Art. 4), a minimum

[104] OJ L 237, P. 0018-0023, 28.08.1997
[105] OJ L 31/1, 2.1.2002
[106] Directive 2003/88/EC OJ 2003 L 299/9-19

period of 24 hours' continuous rest in each seven day period (Art. 5), and a minimum of four weeks' paid annual leave (Art. 7).

The night workers should not work longer than eight hours in any 24-hour period or eight hours in any period if their work involves special hazards or heavy physical or mental strain (Art. 8). Night workers are entitled to a free health assessment, and should be transferred to day work, whenever possible, if they develop health problems related to night work (Art. 9). More generally, night and shift workers should have dedicated health and safety protection, including access to protection and prevention services or facilities, appropriate to the nature of their work (Art. 12). Article 16 lays down reference periods during which these requirements should be fulfilled. For example, for the 48 hour week, this is averaged over four months.

It applies to all workers in the health sector, including doctors in training. The immediate complication for the hospital sector was how to address on-call responsibilities, especially in small hospitals with limited numbers of specialists. The ECJ interpreted the definition of 'working time' in relation to on-call duties in the *SIMAP* and *Jaeger* cases. The Directive defines "working time" as the period a worker is working, at his employer's disposal and carrying out his activity or duties (Art. 2, 1). Many employers had assumed that time spent awaiting emergency calls but not actually working was excluded from working time. In the SIMAP case, the Court ruled that on-call duty by doctors, counts as working time where they are present at the facility but, where they are on-call from home, it only counts when they are actually working[107]. The Jaeger case, between the German municipal authorities and Dr. Jaeger, was brought before the Court to clarify whether on-call duty hours in the emergency department were to be considered working time[108]. The authorities argued that German law distinguishes between "readiness for work", "on-call service" and "stand-by", stating that only "readiness for work" constitutes actual

[107] Case C-303/98 Simap [2000] ECR I-07963
[108] Case C-151/02 *Jaeger* [2003] ECR I-8389

work which is eligible for payment, while the others are considered resting time as no professional tasks are performed. However, the Court ruled in favour of Dr. Jaeger stating that his on-call hours at Kiel municipal hospital were to be considered working time regardless of whether he actually treated patients or rested. Thus, this ruling further clarified that being present in the hospital but not carrying out activities must be seen as "working time", even when the doctor is resting.

In May 2005, the Directive was amended to include an emphasis on the reconciliation of work and family life as an essential element for achieving the objectives in the Lisbon strategy, particularly for increasing the rate of employment amongst women. The specification of 72 hours was replaced by a reasonable period, to be determined by national legislation or in collective agreement between the social partners. [109] In the second half of 2007, the Portuguese EU-presidency proposed that the opt-out would be seen as an *exception to the general rule* of a 48 hour working week in the EU; implementation of the opt-out must be laid down by collective agreement, agreement between the social partners or by national law; and a weekly limit of working hours would be set for workers who agree to the opt-out; among other stipulations.[110]

Agreement on the Working Time Directive and similar measures applying to temporary agency work[111] was postponed in December 2007, after the UK Prime Minister threatened to boycott

[109] CEC (2005) Amended proposal for a Directive of the European Parliament and of the Council amending Directive 2003/88/EC concerning certain aspects of the organisation of working time, COM (2005) 246 final of 31 May 2005

[110] CEC (2007). Press Release, 2837th Council meeting, Employment, Social Policy, Health and Consumer Affairs, 16139/07 (Presse 284) of (5-6 December 2007). Available at: http://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressData/en/lsa/97445.pdf (accessed 8 May 2008)

[111] The Council sought to reach political agreement on two draft directives: amending Directive 2003/88/EC and establishing working conditions for temporary agency workers. Due to

the Treaty signing ceremony in Lisbon. He argued that giving enhanced rights to temporary workers would damage the flexible employment market in the UK[112] and linked the issue to the EU Treaty. Nevertheless, a majority of Member States are in favour of action to help agency workers. Both issues are expected to be discussed in late 2008 likely under the French EU-presidency, which is clearly in favour of these proposals.[113] In the mean time, there have been complaints, upheld by the European Ombudsman, that the Commission is not dealing with infringement complaints on the Working Time Directive in a timely manner.[114]

Health & Safety at Work Directive

The Community has been promoting the health and safety of workers since research programs of the mining and steel industries under the European Coal and Steel Community starting in 1978. As the EU economy became more knowledge-based through information technology the Community had to adapt to the changing work environment. The 1996-2000 Community Programme was based on the following principles:

better health and safety improves competitiveness;

existing legislation must be better enforced;

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difficulties in finding separate solutions for these drafts, the Portuguese EU-presidency decided that there would be added value in working on a simultaneous and integrated solution.

[112] The UK government was concerned that if agency workers were treated equally to permanent workers, flexible employment would become less useful.

[113] European Citizen Action Service, 'EU ministers bow to Brown over working time, temp work', http://www.euractiv.com, (7 December 2007)

[114] European Citizen Action Service. 'Ombudsman urges Commission: 'Get going on working time'', http://www.euractiv.com, (19 September 2007)

New risks and hazards may require new legislation, requiring additional investigation and evaluation; and

Social dialogue with social partners remains central to the development of policy.

For example, Council Directive 1997/42/EC addressed the protection of workers from the risks related to exposure to carcinogens at work. The wide breadth of health and safety legislation is listed in the chart below. The 2002-2006 strategy on health and safety at work encouraged Member States to re-launch prevention policies and national action programmes focused on reducing the rate of workplace accidents.

The 2007-2012 Community Strategy maintains the objective of reduction accidents at work and occupational illnesses through implementation of Community legislation especially in the new Member States and by addressing modern issues such as electromagnetic fields and optical radiation. The Commission further encourages Member States to monitor the implementation of national strategies and the promotion of rehabilitation and reintegration of workers after long periods of absence. To deal with social and demographic changes the Community undertook to raise the average employment rate in the EU for men and women within the 55-64 age-group by 2010. This required policies addressing the specific health and safety challenges of integrating these workers into the labour market. The evaluation of the 2002-2006 strategy demonstrates the importance of developing a risk prevention culture in education and training programmes. To identify new risks, research priorities include psychosocial issues, musculoskeletal disorders, dangerous substances, knowledge of reproductive risks, occupational health and safety management, and the potential risks associated with nanotechnologies. [115]

[115] COM (2007) 62

DG Employment, Social Affairs & Equal Opportunities Health and Safety Legislation (by theme)
DIRECTIVES
Framework directive Council Directive 89/391/EEC EP and Council Directive 2007/30/EC
Workplaces and work equipment Council Directive 89/654/EEC (workplaces in general) Council Directive 89/655/EEC (work equipment) Modifications: Council Directive 95/63/EC, and EP and Council Directive 2001/45/EC Council Directive 89/656/EEC (personal protective equipment) Council Directive 92/29/EEC (medical treatment on board vessels) Council Directive 93/103/EC (fishing vessels) EP and Council Directive 1999/92/EC (explosive atmospheres) Council Directive 92/58/EEC (safety signs)
Sectors of activity Council Directive 92/57/EEC (mobile construction sites) Council Directive 92/91/EEC (mineral extracting industries) Council Directive 92/104/EEC (surface and underground mineral extracting industries)
Specific risks Council Directive 90/269/CEE (Manual handling of heavy loads) Council Directive 90/270/CEE (Visual display units)
Chemical agents Council Directive 98/24/EC (chemical agents) Commission Directive 91/322/EEC (indicative limit values) Commission Directive 2000/39/EC (indicative occupational exposure limits values) Commission Directive 2006/15/EC

Biological agents EP and Council Directive 200/54/EC
Physical agents Council Directive 86/188/EEC (noise) EP and Council Directive 2003/10/EC (noise) EP and Council Directive 2002/44/EC (vibrations) 04/40/CE (electromagnetic fields) EP and Council Directive 2006/25/EC
Asbestos Council Directive 83/477/EEC Modifications: Council Directive 91/382/EEC EP and Council Directive 2003/18/EC (asbestos)
Category of workers Council Directive 92/85/EEC (pregnant workers) Council Directive 94/33/EC (young workers)
Recommendations
Occupational diseases Council recommendation 2003/134/EC of 18 February 2003
Self-Employed Workers Commission Recommendation C (2003) 3297 of 19 September 2003
NON-BINDING GUIDELINES
Guidelines concerning the non-binding guide of good practice for implementing Directive 1999/92/EC of the European Parliament and of the Council on minimum requirements for improving the safety and health protection of workers potentially at risk from explosive atmospheres - COM(2003) 515

Communication from the Commission on the Guidelines on the assessment of the chemical, physical and biological agents and industrial processes considered hazardous for the safety or health of pregnant workers and workers who have recently given birth or are breastfeeding (Council Directive 92/85/EEC) (COM 2000/0466)
Health and Safety Strategy Communication from the Commission - Adapting to change in work and society: a new Community strategy on health and safety at work 2002-2006 Council Resolution of 3 June 2002 on a new Community strategy on health and safety at work (2002-2006) European Parliament resolution on the Commission communication: Adapting to change in work and society: a new Community strategy on health and safety at work 2002-2006 Economic and Social Committee opinion on the Communication from the Commission - Adapting to change in work and society: a new Community strategy on health and safety at work 2002-2006
Council documents Council Resolution of 27 March 1995 on the transposition and application of Community social legislation Council conclusions of 21 December 1992 on the effective implementation and enforcement of Community legislation in the area of social affairs Transposition table (For older versions please contact H&S team)

Non-Life Insurance Directive

In 1992 the EU enacted the Third Non-Life Insurance Directive (Insurance Directive) to ensure the free movement of health insurance services.[116] This directive does not apply to health insurance as a component of a social security scheme. The Insurance Directive covers all other forms of health insurance, which will be referred to as 'private health insurance'. Private health insurance is frequently defined as voluntary and paid for privately by individuals or employers on behalf of individuals. A wide range of entities both public and private provide private health insurance in the EU, including statutory 'sickness funds', non-profit mutual or provident associations and commercial for-profit insurance companies.[117] Markets for health insurance are often regulated to protect consumers and insurers from the potentially negative effects of market failures such as adverse selection and risk selection.[118] Without government intervention to correct market failures, health insurance would not be easily accessible to people at high risk of ill health, people already in ill health and people with low incomes. Most European governments ensure that health insurance is compulsory for the whole population, that contributions are based on income rather than ability to pay, and that publicly financed 'insurers' (whether sickness funds, private insurers or a national health service) cannot deny cover to any individual.

Despite these common principles, there is wide variation in the regulation of private health insurance across the EU. Prior to the introduction of the Insurance Directive in 1992, government intervention in health insurance markets was largely determined by the role of private cover within the health system. Thus, substitutive private health insurance in Germany

[116] Council Directive 92/49/EEC of June 1992 on the coordination of laws, regulations and administrative provisions relating to direct insurance other than life assurance (Third non-life insurance directive), OJ L 228(11.8.1992); 1-23

[117] Mossialos, E. and S. Thomson (2002). "Voluntary health insurance in the European Union: a critical assessment." *International Journal of Health Services* 32(1) : 19-88.

[118] Barr, N. (1998). *The Economics of the Welfare State (3rd edition)*. Oxford: Oxford University Press.

and the Netherlands tended to be relatively heavily regulated[119]. Over the last thirty years EU legislation has restricted Member States regulatory options through a series of directives aimed at creating an internal market in insurance services.[120]

For the first time, the Third Non-Life Insurance Directive created a framework for regulating health insurance, extending the application of internal market legislation to all types of risks, including mass risks such as health insurance. Under the third directive insurers have full freedom to provide services throughout the EU. Articles 9 and 17 initiate a single system for the authorization and financial supervision of an insurance undertaking by the Member State in which the undertaking has its head office; the mutual recognition of systems of authorization and financial supervision; and the harmonization of minimum solvency standards. The Insurance Directive changed two key rules for regulating private insurance. First, it requires governments to abolish existing product and price controls and deems market regulation redundant, and in some cases, illegal (Articles 6.3, 29, and 39). Second, it requires governments to open markets for private health insurance to competition at national and EU levels (Article 3). Member States do retain some power to protect policy-holders (Articles 40.5, and 54.1) and to protect the general good (Article 54.2). However, measures to protect the general good must be necessary and proportional, must not unduly restrict the right of establishment or the freedom to provide services, and must not discriminate against any insurers operating within the state. Although the

[119] Thomson, S. and E. Mossialos (2006). " Choice of public or private health insurance: learning from the experience og Germany and the Netherlands." *Journal of European Social Policy* 16(4): 315-327.
[120] First Council Directive 73/239.EEC of 24 July 1073 on the coordination of laws, regulations and administrative provisions relating to the taking-up and pursuit of the business of direct insurance other than life assurance, OJ L 228(16.9.1973): 3-19; Second Council directive 88/357/EEC of 22 June 1988 on the coordination of laws, regulations and administrative provisions relating to direct insurance other than life assurance and laying down provisions to facilitate the effective exercise of freedom to provide services and amending Directive 73/239/EEC, OJ L 172(4.7.1988): 1; Council Directive 92/49/EEC.

Insurance Directive has been amended several times, non of the proposals address uncertainties about how Member States may regulate private health insurance or protect consumers' rights.

Environmental Protection

The EU views health considerations as the primary driver of EU environmental policy. EU environmental policy recognizes the WHO's broad definition for 'environment and health' as including "both the direct pathological effects of chemicals, radiation and some biological agents, and the effects (often indirect) on health and well-being of the broad physical, psychological, social and aesthetic environment, which includes housing, urban development, land use and transport."[121] The Council and Parliament enacted Decision 1600/2002/EC to define the sixth Community Environment Action Programme (EAP).[122] The current EAP runs from 2002 to 2012 and identifies four priority areas: climate change, nature and biodiversity, environment and health, and natural resources and waste. The 6th EAP calls for the development of seven Thematic Strategies in the field of soil and the marine environment (in the priority area of biodiversity), air, pesticides and urban environment (in the priority area of environment, health and quality of life) and natural resources and waste recycling (in the priority area of natural resources and waste). The Thematic Strategies constitute the framework for action at EU level in each of the concerned priorities.

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[121] *Environment and health. The European Charter and commentary*. Copenhagen, WHO Regioinal Office for Europe, 1990 (WHO Regional Publications, European Series, No. 35).

[122] Decision No 1600/2002/Ec Of The European Parliament And Of The Council of 22 July 2002 laying down the Sixth Community Environment Action Programme, OJ L 242/1 http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:242:0001:0015:EN:PDF

In 2003, the Commission proposed a European Environment and Health Strategy to reduce diseases caused by environmental factors. The approach included five key elements known as SCALE, Science, Children, Awareness, Legal instruments, and Evaluation.[123] The strategy would be based on science compiled from a wide range of experts and stakeholders. Since children are particularly vulnerable to environmental hazards, it is essential to ensure that they have the opportunity to develop in a healthy environment. The strategy also would raise awareness of the interconnection between the environment and health, and would use the legal instruments derived from the treaty as the basis for actions at the EU level that target environment-related health problems in an integrated way. Finally, the strategy recommends including constant and continuous evaluation to verify the efficacy and cost-effectiveness of the actions in terms of the reduction of the environment-related health problems.

The European Health Environmental Action Plan for 2004-2010 proposes an integrated approach involving closer co-operation between the health, environment and research areas, to integrate information rendering the assessment of the environmental impact on human health more efficient. The Plan was based on an assessment of the current baseline knowledge in the areas of: integrated monitoring of dioxins & PCBs, heavy metals, endocrine disrupters; childhood cancer, neurodevelopmental disorders, respiratory health; and human bio-monitoring, environment and health indicators, research needs; as compiled by the different technical working groups. To meet these goals, the Plan proposed an Integrated Information System on Environment and Health and Human Bio-monitoring between Member States to render the assessment of the environmental impact on human health more efficient.[124]

The Action Plan identifies several actions with a focus on :improving the information chain by developing integrated environment and health information filling the knowledge gap by

[123] European Commission, COM (2003) 338
[124] http://ec.europa.eu/environment/health/index_en.htm

strengthening research on environment and health and identifying emerging issues,reviewing and adjusting risk reduction policy and improving communication. [125]

Proposed Legislation

Patients' Rights Directive

On the 29th of May 2008, the Commission finally published its proposal for a Directive on the application of patients' rights in cross-border healthcare. At the time of writing, the proposal was being reviewed by the European Parliament. The likelihood of passage is uncertain, however we raise many issues for debate that will need to be addressed prior to effective implementation of the proposed legislation in its current form. For the sake of clarity, our analysis of the proposed directive will be divided into three sections. Treatment issues will focus on what is covered, and how costs are defined and reimbursed, keeping in mind the challenges of transparency and innovation. Patient issues will focus on the informational issues facing patients choosing to receive treatment abroad through to the residual issues of continuity of care and dispute resolution in the event of harm caused by the medical treatment. Governance Issues range from the efficient organization and provision of services for the national health system to ensuring patient safety in the recognition of foreign prescriptions, to installing interoperable information technology.

Treatment Issues

European health systems have evolved over time in a variety of different ways depending on local political and social history. The EU Treaty respects Member States' responsibility to organize and provide health services based on local preferences. Thus each country defines its

[125] COM (2004)416 http://ec.europa.eu/environment/health/pdf/com2004416.pdf

own benefits packages, eligibility criteria, mechanisms for calculating costs, and financing structures. The proposed Treaty reaffirms that Member States define the medical treatments that are covered. Most European countries do not openly detail treatment costs and have adopted co-payments or other patient cost sharing schemes for medical treatment and/or pharmaceuticals. Limited transparency regarding which treatments are covered and at what cost poses a barrier to patient mobility.[126]

Uncertainty about whether treatment costs will be covered discourages patients from seeking care abroad. Article 6 (2) requires that the "costs of health care provided in another Member State shall be reimbursed by the Member State of affiliation in accordance with the provisions of this directive up to the level of costs that would have been assumed had the same or similar healthcare been provided in the Member State of affiliation, without exceeding the actual costs of healthcare received." Subsection 4 also requires that Member States have a mechanism for calculating costs of treatments to be reimbursed to the insured person. Calculating hospital treatment costs may be relatively simple in European countries given the trend towards reimbursing hospitals through activity-based payments such as diagnostic related groups (DRGs). However, in health systems where budgets are based on capitation and staff are paid by salary, as in the case of primary care in Sweden, it would be difficult for governments to calculate the cost of specific treatments. Countries such as Spain, Italy, Finland and Sweden also have decentralized significant health policy authority to regional or municipal governments. For the national governments, publishing lists of treatments and costs could be administratively difficult and could expose governments to criticism forcing expensive public debates, especially where there is regional variation within countries for types of treatments covered or costs. The directive does not address how the differing cost sharing arrangements will be addressed. Many countries have adopted exemptions based on income, age, or diagnoses of chronic illnesses. How will

[126] The Transparency Directive 89/105/EEC only covers costs of pharmaceuticals.

these exemption schemes be factored into costs and reimbursements? Where exemption criteria conflict which will apply? Therefore, although the requirement for a mechanism to calculate of costs for reimbursement may seem uncontroversial and easily met on its face, it could cause significant political and administrative complications if implemented.

Proposed Article 6 (3) prohibits discrimination against patients from other Member States but allows the same conditions, administrative formalities and eligibility criteria for receiving healthcare and reimbursement of costs to be applied to all patients. The proposal's introductory section provides the example that GPs could still play a gate keeping function so long as the procedures are "not discretionary or discriminatory." Therefore these rules must be applied in an objective transparent way, known in advance, based primarily on medical considerations, and must not require any additional requirements for patients seeking care from another state.[127] This provision raises a number of questions. Which eligibility criteria are permissible? Are national policies that employ residency requirements to assist in the organization and distribution of health resources unlawful? Is everyone who is deemed eligible entitled to the same level of benefits? Could a GP from the Member State of affiliation conduct the initial examination required for a referral to a specialist in another state? Or could a GP in another Member State make a referral to a specialist in the patient's country of affiliation? Must the criteria for GP referrals to specialists also be published in advance?

Rearticulating ECJ case law, Article 7 simply states that non-hospital care shall not be subject to prior authorization. Both case law and the explanatory memo suggest that the reason for this is the low financial burden of non-hospital care on the overall health system. There are several situations where local budgets, especially in border regions, may be disproportionately affected if

[127] Proposal Introduction, EC Commission: Proposal for a Directive on the application of patients' rights in cross-border healthcare, Explanatory Memorandum, COM(2008)414. Brussels; 2008, paragraph 28.

a significant number of patients cross the border to receive expensive diagnostic tests or pharmaceuticals. In some border regions, bi-lateral agreements between governments have assisted in addressing these specific issues [128], however, the proposal does not address these types of arrangements that could both facilitate cross-border treatment and lead to preferential treatment of those covered by the agreements over nationals from other states.

Since the Court has distinguished between hospital and non-hospital care, European health systems have wrestled with categorizing treatments under each category. What is the definition of a hospital? For example, Finnish polyclinics that primarily provide out patient care, but have bed spaces and overnight staff available for certain cases. Would these facilities meet the definition of a hospital? Proposed Article 8 clarifies that hospital care requires overnight accommodation and would grant the Commission authority to draft a definitive list of other treatments requiring highly specialized and cost-intensive medical infrastructure or particularly risky treatments that would also qualify as hospital care. This list shall be regularly updated. Once again many vital details remain unclear. What process would the Commission use to draft this list? Would private industry have an opportunity to offer opinions on or proposals for the list? What is the threshold cost or type of risk that would be necessary to meet the hospital care definition? How often would the list be updated? Many states employ lengthy health technology and cost effectiveness analyses prior to approving new treatments for coverage. What if the ruling on new treatments as to whether the treatment would be covered by the State of affiliation is still under evaluation?

Patient Issues

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[128] Osterle A Health care across borders: Austria and its new EU neighbours, *Jounal of European Social Policy* 2007; 17(2): 112-124.

Although the title of the proposed directive focuses on patients' rights, the document only addresses patients' issues indirectly, without listing legally enforceable rights. For example, rather than establishing a patients' right to receive a copy of her medical records, Article 6(5) requires Member States to guarantee access to medical records. Currently, in most European countries patients do not have the right to a copy of their medical records. Article 10 requires that Member States establish mechanisms to provide patients with information on healthcare in other Member States, including patients' entitlements, procedures to receive those entitlements and systems of redress if those services are denied. Again, this access to information is not drafted in terms of patients' rights, but Member States obligations. The proposed directive does not address how health providers and systems must cooperate to ensure continuity of care. Once a patient has received treatment abroad and returns home, who is responsible for the follow-up care? What if there are complications from a treatment not provided in the patients home country?

The most novel of the directive's proposals are national contact points (NCP) suggested by Article 12. Member States would create NCPs that serve as a clearinghouse of information about cross-border healthcare for patients both from their home state of affiliation as well as other states. The scope of information should include quality and safety information, procedures for complaints and means of redress, and information about international out-of-court settlement bodies. These NCPs should work closely with domestic health authorities and their counter-parts in other Member States. Article 12 instantly raises four major challenges. First, there are the administrative issues of providing health system information on 27 Member States in the EU's 23 different official languages. The time and expense necessary to maintain this database and keep it up to date would be extremely resource intensive. There would be significant time lags between the time when a state legislates health system reforms to the point that these changes would trickle down to NCPs as practical information for patients.

Second, what information about the quality of care should the NCPs provide? The explanatory memo suggests that NCPs should be "facilities to provide information on the main aspects of cross-border healthcare and provide practical assistance to patients if needed." Some Member States have limited published information on quality indicators or standards, especially at the level of rating particular hospitals or practitioners. Undoubtedly, patients would ask for

information regarding referrals to specific providers. Would 'practical assistance' include such level of detail? Politically, publishing quality information could be controversial and could undermine patient confidence in the domestic health system. For these reasons, recommendations to publish information for the benefit of cross-border health services that may not outweigh significant negative consequences on the domestic system.

Third, there is a complex cluster of problems arising out of the need to procedures for dispute resolution and means of redress if a patient suffers harm either from the denial of treatment, or when receiving treatment that falls below a standard of care. Each Member State has its own judicial system, rules of civil procedure, and laws regarding medical malpractice. Thus the NCP would have to have to be well versed in the health systems and the legal systems of 27 Member States to provide the level information recommended by Article 12. Subsection 3 explains that NCPs should have information about out-of-court settlement procedures and facilitate co-operation with those bodies. However, not all Member States have mechanisms for out-of-court settlement in the area medical malpractice. Furthermore, subsection 3 encourages the development of an international out-of-court settlement scheme for dispute resolution. Medical malpractice attorneys could write books on the legal complexity, expense, and administrative difficulties of attempting to create such an international scheme. Legal issues range from determining jurisdiction, rules for discovery of evidence, to standards of care and the burden of proof for negligence. Each country has its own legal history and culture that would not easily be harmonized. A study commissioned by the European Committee on Legal co-operation concluded that the significant differences in the definition of the Standard of Care and the procedural aspects of medical liability that are significant obstacles to developing an international

legal instrument in the area of medical liability.[129] In June 2008 the Council hosted a Conference on "The Ever-growing challenge of medical liability: National and European Responses." The conference report concluded that Member States have different priorities and mechanisms for addressing medical liability and found that alternatives to court procedures varied and should not preclude the pursuit of a remedy in court.[130]

Fourth, the broad scope of the NCP's mandate creates conflicts of interest. The NCP would simultaneously have the duty to cooperate (Article 13) with other Member States and to assist with dispute resolution in cases of conflict. What is the scope of this duty? To whom is this duty owed, to Member States or to patients? All patients should be treated equally, regardless of state of affiliation. This becomes more difficult when disputes arise. What redress would patients have if the NCP fails to meet its duty to cooperate and provide information?

Governance Issues

The issues raised in the context of treatments and patients lead to more complex questions for governments as to how health systems are planned and financed, how quality and safety are measured and monitored, and how governments should be held accountable when their duties are unfulfilled. Article 5 suggests a number of Member State responsibilities to ensure that providers meet defined standards of quality, systems of professional responsibility are appropriate to the nature of the risk, and patients enjoy equal treatment free from discrimination. Some Member States have employed a variety of mechanisms to ensure quality and safety in health care, but there is little consistency or coordination regarding the training of health

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[129] Nys H: Report on Medical Liability in Council of Europe Member States, A Comparative study of the legal and factual situation in Member States of the Council of Europe. *CDCJ* 2005; 3: 1

[130] Kilby E, General Rapporteur, The Ever-growing challenge of medical liability: National and European Responses: Conclusions of the Conference. Strasburg. June, 2008 CONF; 2008.

professionals, patient safety programs or clinical guidelines.[131] Given the wide variety of health systems across the EU, it is difficult to envision how broad provisions such as this will work in practice. What is the timeframe within which states would need to develop these standards and monitoring mechanisms? Who determines whether the existing national policies are sufficient and adequate? There are many positive aspects of encouraging health systems to develop these high standards, in theory. In practice, there is insufficient detail to make these goals actionable. There is no mention of the potential for incremental development of policies in countries that have yet to establish quality mechanisms in all areas.

Article 9 addresses procedural guarantees for prior authorization of medical treatment abroad. These sections are broadly drafted in reflection of existing ECJ case law and ensure that patients have the right to appeal administrative decisions. Article 13 extends a duty to cooperate to facilitate cross-border health care provision at the regional and local level. At the risk of sounding repetitive, it should be emphasized again that the scope of this duty is unclear and would need to be defined. The article does not indicate to whom the duty is owed and how a failure to meet this obligation would be challenged or enforced. As mentioned earlier, the decentralization of authority within health systems may frustrate the central government's ability to ensure that local administrations comply with EU law. It is unclear whether local governments also have an independent duty to facilitate cross-border health care and will also be held accountable to EU legal standards.

Another issue addressed by the directive is recognition of prescriptions issued while the patient receives care abroad, proposed in Article 14. It states that

'prescriptions issues by an authorized person in another Member State for a named patient, can be used in their territory and that any restrictions on recognition of individual prescriptions are prohibited unless they are limited to

[131] Legido-Quigley H, McKee M, Walshe K, Sunol R, Nolte E, and Klazina N. How can quality of health care be safeguarded across the European Union? In *British Medical Journal*. 2008; 366:920-923.

what is necessary and proportionate to safeguard human health, are non-discriminatory or are based on legitimate and justified doubts about the authenticity or content of an individual prescription'.

There are a number of logistical challenges with fulfilling this requirement due to the differences in language; scope of practice of health professionals; and pharmaceutical markets; and differences in dosage and packaging of medicines across Member States. Who would have the responsibility and the expertise required to verify the authenticity of foreign prescriptions, and to determine the appropriate treatment details? The Commission would be granted authority to develop measures for verification, to ensure correct identification and dispensing, and to exclude specific categories of medicinal products. This is another instance where the practicalities of establishing standardized mechanisms to address pharmacy procedures from 27 countries seem unworkable. Furthermore, the introductory section of the proposed directive fails to clarify the scope of this provision and seems to go beyond the language of Article 14. It states that patients have a right 'to receive any medicinal product authorized for marketing in the Member State where healthcare is provided, even if the medicinal product is not authorized for marketing in the Member State of affiliation". [132] Does this right include reimbursement? If so, patients whose home country excluded a particular pharmaceutical from their reimbursement lists could circumvent that decision by shopping around the European Union. This could undermine pricing and reimbursement policies intended to control costs or improve efficiency. Thus, the administrative and economic impact of the mutual recognition of prescriptions could lead to greater confusion and health risks, rather than improving efficiency.

Article 15 discusses European Reference Networks that will concentrate expertise on particular medical specialties or treatments with the Commission orchestrating from the hub. Establishing a coordinated system of specialty hospitals, or units or experts has the potential to

[132] Proposal introduction, EC Commission: Proposal for a Directive on the application of patients' rights in cross-border healthcare, Explanatory Memorandum, COM(2008)414. Brussels; 2008, paragraph (27) p. 26.

expand access to innovative treatments to patients who live in areas without the capacity to provide such services. However, as will other sections of the proposal there are numerous obstacles to instituting this proposal, such as logistical problems of covering set-up, maintenance, and treatment costs, and defining referral procedures; political issues regarding the selection and prioritization of patients to receive treatment; as well as complex continuity of care and liability issues. These would each need to be addressed in a multi-lateral context to ensure fairness, and to avoid discrimination. The Commission would again have a primary role in establishing the regulations necessary to overcome these challenges, without clear channels for accountability and public oversight.

The directive closes with a number of proposals requiring significant financial investment to develop and adopt of new information technologies. Some of these proposals are already being developed in some countries, but the breadth and scope of technologies discussed in the proposal approaches the proverbial pie in the sky. Article 16 discusses interoperable information and communication technology commonly known as E-health. Article 17 requires Member States to improve their information collection monitoring mechanisms to better document cross-border health services. Finally, Article 18 encourages the development of a network connecting national authorities responsible for health technology assessment for improved information sharing. For countries where health records are not kept electronically, or there is not uniform interoperability between information systems at different facilities, this level of sophisticated integration seems a long-term goal at best. These sections would impose a number of burdens on health systems. The explanatory memo fails to explain how these additional, resource-intensive obligations, further limiting governments' policy options to plan for care and contain costs will actually benefit access cross-border healthcare.

Finally, health policy makers will also observe that many of the proposals touch upon difficult areas, such as equity and distribution of resources to ensure quality, that health ministries struggle to resolve on a domestic level. Yet the Commission would be granted authority to address these issues on a multi-lateral level to encourage cross-border access to health services. Some of these policy areas, such as patient safety and quality of care, have already been approached by soft law mechanisms, with varying degrees of success.[133] The benefit of soft law policies is that they may be sensitive to the differences within and among countries, allowing for flexibility, experimentation, and incremental changes. The ultimate difficulty with promoting quality and safety through a directive based on internal market legislation is that the directive applies uniform, legally enforceable responsibilities on all Member States, without regard for unique local circumstances. Member States will have difficulty agreeing to such commitments when the financial, legal, and practical consequences are so uncertain.

Lisbon Reform Treaty

Although the future of the proposed Lisbon Treaty is uncertain, modifications are proposed for three treaty sections that may impact on Member States Health systems if the Treaty is ratified and enacted. The Article on public health, currently known as152, would be modified to emphasize physical and mental health, cross-border care, and to encourage OMC and other soft law mechanisms. A new point shall be inserted in paragraph 4 that recommends the adoption of "measures setting high standards of quality and safety for medicinal products and devices for medical use." While these issues are already addressed by internal market

[133] McGill, L. **Patient Safety–A Priority for the European Commission**. EU HealthPolicy Forum, 28 November 2007, Brussels. http://ec.europa.eu/health/ph_overview/health_forum/docs/ev_20071128_co05_en.pdf; and Mrs Katja Neubauer, **EU activities on patient safety and quality of care**. Health and Consumers Directorate-General European Commission, Kranska Gora, 5 June 2008.

legislation, the additional emphasis here acknowledges the need to give quality and safety standards greater weight. The proposal also changes the wording of the subsidiarity language in subsection 5 to:

"Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organization and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. The measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood."

Although the new language specifies additional details regarding the nature of the duties of Member States, it is difficult to predict how this language would affect the division of authority between the Community and the Member States in practice.

As mentioned above, the services of general economic interest language is an important mechanism for Member States to protect health system policies from the application of competition rules. The proposed Treaty modifies the language of SGEI in the current Article 16 and adds a Protocol on SGEI. The language of Article 16 would be amended to specify that Member states shall take care that such services operate on the basis of principles " and conditions, particularly economic and financial conditions," in addition to fulfilment of their missions. This additional language gives Member States more guidance towards ensuring that SGEI policies are economically viable. The Protocol rearticulates established ECJ case law on SGEI. It emphasizes that not only the central government has the discretion to define SGEI, but also regional and local authorities commissioning and organizing SGEI. However, this proposal fails to provide the additional clarity sought by legal analysts and policy makers.

Soft Law Processes - Open Method of Coordination

Since the Community's legislative authority is limited to the scope of the Treaty, the Commission has pursued alternative 'new governance' or 'soft law' strategies to keep issues such as health policy on the EU's agenda. As an evolving process for consensus building, soft law is

difficult to define. In contrast to specifically detailed legislative procedures, new governance techniques involve a broader representation of government officials and stakeholders in a more flexible, non-hierarchical deliberation where informative agreements and policy declarations encourage cooperation. Since the 2000 Lisbon summit, soft law has been closely associated with the Open Method of Coordination (OMC), which facilitates the sharing of best practices, setting of guidelines indicators and benchmarks, and encourages self-monitoring and peer review. The flexibility and lack of legally enforceable prescriptions are well suited to social policy issues where Member States wish to preserve local autonomy and fear externally imposed harmonization.

The narrow scope of policy options permitted by Article 152 coupled with the legal uncertainty and administrative difficulty of patient mobility issues meant that the Commission was obliged to act but lacked the means to do so. The 2002 European Council of Ministers agreed that health care systems share common principles of solidarity, equity, and universality. Rather than agreeing to take particular action, they emphasised that patient mobility 'presents particular challenges in terms of the need to exchange clinical and other information'[134]. Due to the lack of consensus, the most the Council could do was to invite the Commission to organize a 'high-level process of reflection' as part of the Lisbon process, a softer legal process would be difficult to imagine. The Commission proposed the Services Directive in January 2004. After intense lobbying from a wide range of health-related groups, the European Parliament voted to exclude health care services. The Commission was left with few policy-making options beyond high-level group meetings and reflection.

The Council did not extend formal Social OMC procedures to include health and long-term care, managed by the Social Protection Committee (SPC), until 2005. The SPC also adopted a three-year cycle with National Strategic Reports submitted in the first year and in-depth

[134] Conclusions of the Health Council, 26 June 2002, http://ec.europa.eu/health

analysis and mutual learning activities during the intervening years.[135] The 2007 Joint Report covered the first European plans on healthcare and long-term care. Member States identified four priority areas including: equal access for all; reduction of health inequalities in outcomes; guarantee safe and high-quality care; and manage the introduction of new technology for health and independent living.[136] The 2008 Joint Report, focusing on child poverty, access to health care, evolving long-term care needs, longer working lives and privately managed pensions, reflects the greater emphasis on policy implementation.

The 2008 Commission Communication on Social OMC proposes a new commitment to social Europe that would strengthen the OMC process by setting targets, improving reporting, communication and dissemination as well as improving mainstreaming and horizontal coordination (see OMC box below). The Commission seems to be interested in expanding its influence towards lower levels of government and local stakeholders through increased involvement of regional and local authorities and other relevant actors involved in implementation of policies. The Commission's proposals focus on four objectives: 1) increasing political commitment and the visibility of the process; 2) strengthening the positive interaction with other EU policies; 3) reinforcing the analytical tools underpinning the process, with a view to moving towards the definition of qualified targets and enhancing evidence-based policymaking; 4) increasing ownership in Member States, by boosting implementation and enhancing mutual learning.[137]

International Agreements

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[135] COM(2008) 418, 2.7.2008.
[136] Joint Report on Social Protection and Social Inclusion (2007) March 2007
[137] COM(2008) 418, 2.7.2008.

Depending on the sphere of competence, international agreements could either be concluded by the Community or jointly by the Community and Member States, with the latter only binding the EU institutions.

Framework Convention on Tobacco Control (FCTC)

To address the global expansion of tobacco use and the associated health risks, the World Health Organization developed the FCTC as the first global health treaty as a framework for countries to implement effective tobacco control strategies. The FCTC introduces a comprehensive ban on tobacco advertising and sponsorship, controls on the labelling of products, education programmes about the health effects of tobacco, tackles cigarette smuggling, and encourages measures to reduce exposure to second hand smoke and the availability of tobacco to young people. The European Commission ratified the convention as well as all EU Member States except for the Czech Republic.

International Health Regulation (IHR)

The primary legal framework on communicable disease control within which the EU and its Member States operate is governed by the International Health Regulations (IHR). These originated in the International Sanitary Regulations, agreed by governments meeting in Paris in 1851. In due course, responsibility for the regulations passed to the World Health Organization which, in 1969, consolidated and updated them, creating the International Health Regulations. By the end of the twentieth century it was apparent that they had failed to keep pace with changing circumstances. Specifically, they focused on a limited number of diseases (plague, yellow fever, cholera, and initially smallpox until it was eradicated), they depended on timely and accurate notification by government (despite growing evidence that some governments suppressed information to protect tourism and other economic interests), and they failed to address the need for rapid transmission of information.

The 2005 revision of the regulations addresses all of these concerns. Instead of verified cases of the three diseases, states are required to notify the WHO of any "public health emergency of international concern".[138] This is an event that constitutes a risk to other states and which may require a co-ordinated international response. Criteria for notification include the seriousness of the event, how unusual it is, its potential for international spread, and the possibility that restrictions on trade or travel may result. The IHR encompass not only communicable diseases but also toxic and other hazardous exposures. Linked to the implementation of the IHR, a Global Outbreak Alert and Response Network has been established, with its secretariat based within the WHO. It links a number of other networks, including the Global Public Health Intelligence Network, a web crawler that monitors emerging evidence suggestive of disease outbreaks. As with the earlier regulations, governments are limited in the actions they may take to impede trade and travel. Any action that "significantly interfere(s)" with international traffic, defined as refusing it or delaying it for 24 hours, must be justified on scientific grounds, as must any medical checks on potential travellers.

The revised IHR came into force on 15th June 2007, with 194 states as parties to the agreement. The regulations allow the WHO to make recommendations, including restrictions on travel and trade, but they incorporate no enforcement mechanism. There is, instead, a dispute resolution procedure. Prior to the coming into force of the IHR, it was possible for governments to register reservations. No EU Member State did so. The EU is not a party to the IHR[139] but all of its Member States are. Although the Commission claims that some matters within the IHR are matters of exclusive Community competence,[140] an alternative interpretation is that these are matters of shared competence between the EU and its Member States.[141] Article 57 of the IHR requires that "States parties that are members of a regional economic integration organisation shall apply in their mutual relations common rules in force in that regional economic integration organisation". Thus, should the WHO recommend a restriction on trade or travel, the EU would have to act collectively, following an initiative from the Commission. The European Commission has published a communication setting out the inter-relationships between the

[138] World Health Organization, International Health Regulations (2005). Geneva, World Health Organization.
[139] This reflects the EU's constrained competence in the field of health.
[140] For example, Article 26 IHR on protection of personal data; see COM(2006) 552 final Communication from the Commission to the European Parliament and the Council on the International Health Regulations.
[141] See Article 4 Treaty on the Functioning of the European Union, to enter into force if the Treaty of Lisbon is ratified by all the Member States.

IHRs and EU law and has proposed a series of working practices, with a 'memorandum of understanding' to clarify relationships and to ensure co-ordinated responses.[142] Consequently, the remainder of this section should be interpreted in the light of the Member States' international obligations under the IHR.

Multilateral Trade Agreements

The General Agreement on Trade and Tariffs (GATT) and the subsequent creation of the World Trade Organization provide legal norms and institutions used to liberalize international trade. The WTO has three primary functions: to promote the free flow of trade, to serve as a forum for trade negotiations, and to settle trade disputes. Trade in health services is also an inevitable consequence of the globalized economy and is governed by the General Agreement on Trade and Services (GATS).[143] GATS promotes the free flow of trade in service categorized by four types of modes. The first and second modes address cross-border delivery of trade and the movement of consumers receiving treatment abroad. The third mode is defined as commercial presence, or the foreign investment in health care services and treatment centres. The fourth mode includes the movement of health personnel to work in foreign markets. GATS creates two types if legal obligations for member countries, conditional and unconditional. Unconditional rules apply to all signatories, requiring states to treat other members with "most favoured nation status" and to maintain transparent trade policies.[144] Once a country has chosen to open a sector or a sub-sector to trade, the commitment must specify: which modes of trade

[142] Commission of the European Communities (2006). Communication from the Commission to the European Parliament and the Council on the International Health Regulations, COM(2006) 552 final. Brussels.
[143] M. K. Ranson and R. Beaglehole, c. Correa, Z. Mirza, K. Buse, and N. Drager, (2002) "The public health implications of multilateral trade agreements," Chapter 2 in Health Policy in a Globalizing World. Eds Kelly Lee, Kent Buse, and Suzanne Fustukian. University Press: Cambridge, UK.
[144] L. Belsky and F. Lie, A. Mattoo, E. Emanuel, and F. Sreenivasan, (2004) "The General Agreement on Trade in Services: Implications for Health Policy Makers," *Health Affairs*; 23 (3) 137-146.

will be included; whether the commitment will be applied horizontally across all modes; whether public and/or private services will be included; and the timeframe for implementation. These conditions could allow countries to formulate policies with some degree of flexibility, including the right to treat foreign service providers differently than domestic ones.[145]

Under the Common Commercial Policy, the EU is a single actor for trade negotiations and WTO membership, representing the European interests on behalf of all Member States. The legal basis for the EU's trade policy is Article 133 of the European Community Treaty. The Commission negotiates on behalf of the Member States, in consultation with a special committee, "the Article 133 Committee". The 133 Committee is composed of representatives from the 27 Member States and the European Commission. Its main function is to coordinate EU trade policy. In the "health related and social services sector" the Commission did not propose any commitments, and reserved the rights of Member States to determine the most appropriate commitments for their health systems.[146]

[145] J. Nielson, (2006) " Ten Steps to Consider before making commitments in health services under the GATS," Chapter 4 in International Trade in Health Services and the GATS: current issues and debates. Eds. Chantal Blouin, Nick Drager, and Richard Smith. World Bank: Washington DC.
[146] Summary of the Commission's proposal for the EU's Services Offer, April 29, 2003, (last accessed July 2008), http://trade.ec.europa.eu/doclib/docs/2004/march/tradoc_116490.pdf

Health Related Objectives of the OMC for Social Protection and Social Inclusion
I. The overarching objectives of the OMC for social protection and social inclusion are to promote:
a. Social cohesion b. Effective and mutual interaction between the Lisbon objectives of greater economic growth and greater social cohesion, and sustainable development. c. Good governances, transparency, and the involvement of stakeholders in the design implementation and monitoring of policy
II. Accessible, High-quality and sustainable healthcare and long-term care by ensuring:
a. Access for all to adequate health and long-term care and that the need for care does not lead to poverty and financial dependency; and that inequities in access to care and in health outcomes are addressed; b. Quality in health and long-term care and by adapting care, including developing preventive care, to the changing needs and preferences of society and individuals, notably by developing quality standards reflecting best international practice and by strengthening the responsibility of health professionals and of patients and care recipients; c. That adequate and high quality health and long-term care remains affordable and financially sustainable by promoting a rational use of resources, notably through appropriate incentives for users and providers, good governance and coordination between care systems and public and private institutions. Long-term sustainability and quality require the promotion of health and active life styles and good human resources for the care sector.
III. Health Related Indicators for Monitoring the Social OMC
a. Healthy life expectancy- the number of years that a person at birth, at 45, at 65 is still expected to live in a healthy condition (not hampered in activities of daily living).

b. Self-reported unmet need for medical care - due to financial barriers, or waiting times, or too far to travel, by income quintile.
c. Total health expenditure per capita – in PPP.

Chapter 3

Health Programmes and Initiatives

1. Public Health Programme and Planning

In 1998 The Commission expressed its view of the Community's role in public health in a Communication on the development of public health policy in the European Community.[147] As confirmed in the circulating draft of the Amsterdam Treaty, the Community would focus on three strands of action: to improve information for the development of public health, to react rapidly to threats to health, and to tackle health determinants through health promotion and disease prevention. The first Public Health Framework Programme (2003-2008) was based on those three priorities, which were set out as the programme's general objectives in Article 2 of its enabling instrument, Council and Parliament Decision 1786/2002/EC.[148] Each general objective was to be pursued by "actions" reflecting public health concerns of the health systems of the Member States at the time. For instance, "rapid response to health threats" includes exchange of information on strategies to counter health threats from physical, chemical or biological sources in emergency situations, including those relating to terrorist acts. Other examples include developing strategies for reducing antibiotic resistance, implementing strategies on life-style

[147] Communication from the Commission on the Development of public health policy in the European Community, 14.4.1998. http://ec.europa.eu/health/ph_overview/Documents/com_98_230_en.pdf
[148] European Union (2002). "Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008) - Commission Statements." Official Journal of the European Communities OJ L 271(9.10.2002): 1-12.

related health determinants, and exchanging information on genetic determinants and the use of genetic screening.

The "actions" are implemented with EU-level support for "activities", in cooperation with the Member States. "Activities" may implement all or part of an action, and may be combined. The complex arrangement of "objectives", "actions" and "activities" reflects a compromise position between those legislative actors who wished to place more constraints on the funding of the EU public health programme, and those who valued flexibility. Broadly speaking, the European Parliament sought greater flexibility, while the Council sought to impose constraints on the disbursement of EU finances for the public health programme. "Activities" fall into four categories, related to: monitoring and rapid reaction systems; health determinants; legislation; and consultation, knowledge and information. The last includes matters such as developing and maintaining networks for exchange of information on best practice in public health and the effectiveness of health policies.[149]

Since 1 January 2005, the detailed running of the public health programme was been carried out by an executive agency, on behalf of the Commission.[150] The Commission commenced negotiations over the second Public Health Programme (though the word 'public' has now disappeared from its title) in April 2005.[151] The Commission's bold proposal aimed to merge "public health" and "consumer protection" into one joint programme, and the text of the

[149] Ibid.

[150] Commission of the European Communities (2004). "Commission Decision of 15 December 2004 setting up an executive agency, the 'Executive Agency for the Public Health Programme', for the management of Community action in the field of public health — pursuant to Council Regulation (EC) No 58/2003 ." Official Journal of the European Communities L 369/73.

[151] European Union (2005). "COM(2005) 42 final Proposal for a Decision of the European Parliament and Council establishing a Programme of Community action in the field of Health and Consumer Protection 2007-13."

proposal tied this explicitly to "what citizens want".[152] The Commission proposed three core objectives for the programme. The programme would "protect citizens from risks and threats which are beyond the control of individuals, and that cannot be effectively tackled by individual Member States alone; increase the ability of citizens to take better decisions about their health and consumer interests; and it would mainstream health and consumer policy objectives across all Community policies in order to put health and consumer issues at the centre of policy-making'.[153] Had these objectives, especially the third, been adopted, this would have given DG SANCO a stronger position within broader EU policy-making that it does not currently enjoy. The objectives were to be met by six "strands" of the programme: the existing three of health information, health threats, and health determinants, and three new ones – response to threats, disease prevention and co-operation between health systems. The proposed financial framework was €1 203 million.[154]

The integration of health and consumer protection did not survive long. In June 2005, the Conference of Presidents[155] decided to split the proposal into two programmes [156]. The European Parliament proposed eight objectives for the health programme. These included improving

[152] 'EU citizens want to live healthily and safely wherever and whoever they are and to have confidence in the products and services they consume. They also want a say in the decisions that affect their health and consumer interests. The EU, national and regional authorities, businesses and civil society must play a part to respond to these concerns, but there are common health and consumer policy challenges that only EU level action can tackle' COM(2005) 42 final, p 1.
[153] Ibid.
[154] Ibid.
[155] The Conference of Presidents consists of the President of the European Parliament, and the chairpersons of the political groups within Parliament. It is responsible, inter alia, for relations between the European Parliament and other EU institutions.
[156] European Parliament (2005). "Draft European Parliament Legislative Resolution on the proposal for a decision of the European Parliament and of the Council establishing a programme of Community action in the field of health and consumer protection (2007-2013) - Health aspects (COM(2005)0115 – C6 0097/2005 – 2005/0042A(COD))."

efficiency and effectiveness in health systems, tackling health inequality, and empowering citizens by facilitating patient mobility and increasing transparency between the various countries' health systems, all of which would again have suggested a significant change of focus from the current programme. The latter objective arose from the activity of various EU institutions and actors[157] following the *Kohll* litigation on free movement of patients[158].

Parliament proposed a budget – solely for the health programme strand, excluding the consumer protection elements of the original proposal – of €1 500 million. Following the inter-institutional agreement on the EU's future Financial Framework 2007-2013[159], in May 2006, the Commission amended its original proposal, taking account of the fact that under the new financial settlement, the budget available for health was about one third of that originally envisaged. The proposed budget was €365.6 million. The Commission added new focuses on health inequalities, promoting healthy ageing, and addressing children's health and gender questions, some of which reflect the European Parliament's proposed amendments[160]. Council reached political agreement (unanimously) on a common position[161] which endorsed this budget and these three objectives[162] in November 2006.

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[157] Such as the High Level Group on Health Care and Medical Systems.

[158] Hervey, T. K. (2006). The European Union and the governance of health care. New Governance and Constitutionalism in Europe and the US G. De Burca and J. Scott. Portland, OR, Hart Publishing: 179-210.

[159] European Union (2007). "Interinstitutional Agreement between the European Parliament, the Council and the Commission on budgetary discipline and sound financial management." Official Journal of the European Communities C 139(14.06.2006).

[160] Ibid.

[161] Council of the European Union (2007). Common Position adopted by the Council with a view to the adoption of a Decision of the European Parliament and of the Council establishing a second programme of Community action in the field of health (...-2013) 6 March 2007, 16369/06, Interinstitutional File: 2005/0042 A (COD).

[162] Article 2: Aim and objectives 1. The Programme shall complement, support and add value to the policies of the Member States and contribute to increased solidarity and prosperity in the European Union by protecting and promoting human health and safety and improving public health. 2. The objectives to be pursued through the actions set out in the Annex shall be: 1) to improve citizens'

The latest stage in the legislative process, Parliament's second reading, in July 2007[163], made a few further changes. By this stage, it was obvious that the programme could not begin until January 2008. Parliament sought to bring health inequalities further to the fore, by including this explicitly within the second objective which then read "to promote health, including in the reduction of health inequalities". The financial envelope was reduced to reflect the reduction in running time of the programme to €321.5 million. The Final 2008-2013 Together for health: Health Programme objectives include:

- To improve citizens' health security;
- To promote health, including the reduction of health inequalities; and
- Health information and knowledge.

Resources available under the Public Health Programme 2008-2013

OPERATIONAL OBJECTIVE 1: Citizen's health security: EUR97.572 million.

- Action 1: Protect citizens against health threats : EUR 65.048 million -Action 2: Improve citizen's safety: EUR 32.524 million

OPERATIONAL OBJECTIVE 2: Promote health: EUR 113.834 million.

- Action 1: Foster healthy, active ageing and help bridge inequalities : EUR 42.281 million
- Action 2: Promote healthier ways of life by tackling health determinants : EUR 71.553 million

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health security; 2) to promote health; and 3) to generate and disseminate health information and knowledge.The actions referred to in the first subparagraph shall, where appropriate, support the prevention of major diseases and contribute to reducing their incidence as well as the morbidity and mortality caused by them.

[163] European Parliament (2007). European Parliament legislative resolution of 10 July 2007 on the Council common position for adopting a decision of the European Parliament and of the Council establishing a second programme of Community action in the field of health (2007-2013) (16369/2/2006 – C6-0100/2007 – 2005/0042A(COD)).

OPERATIONAL OBJECTIVE 3: Generate and disseminate health knowledge : EUR113.82 million.

- Action 1: Exchange knowledge and best practice : EUR 48.78 million
- Action 2: Collect, analyse and disseminate health information: EUR 65.04 million

The Public Health Executive Agency has recently been given a new role. In June 2008, the Commission decided to prolong the mandate of the Agency until 2015 and entrust it with the implementation of the new EU Health Programme and give it responsibilities in the filed of consumer protection and food safety as well.[164] The agency will also have a new name as the Executive Agency for Health and Consumers (EAHC). The EAHC will also manage the "Better Training for Safer Food" initiative which includes food law, feed law, animal health and animal welfare rules, and plant health rules.

2. Health Topics

A. Information- surveillance, monitoring, and E-Health

To better monitor and assess the successes and deficiencies of health systems WHO, OECD as well as the EU have tried to define comparable health statistics and indicators. The eEurope initiative was launched in 1999 in collaboration with DG information society. The eEurope Action Plan included policy actions such as:

Ensure that primary and secondary healthcare providers have health telematics infrastructure in place including regional networks;

[164] http://ec.europa.eu/phea/index_en.html

Best practice in electronic health services in Europe identified and disseminated, benchmarking criteria set;

Establish a set of quality criteria for health-related websites;

Establish health technology and data assessment networks; and

Publish a Communication on « Legal Aspects of eHealth.

In 2004 the Commission proposed a new e-Health Action Plan[165], given the difficulties of developing and the costs of implementing such a grand plan, the Communication focuses on soft law techniques to encourage the use of health technology through disseminating best practices, benchmarking, and international collaboration. The Commission has the expectation that health technology will be utilized by professionals, patients and citizens throughout the Community and that will soon support the realization of health care objective.

The Programme for 2003-2008 included actions to improve health information such as the European Public Health Report Series (EPHRS)[166] and the production of European Community Health Indicators (ECHI). The EPHRS have included special reports on Major and Chronic Diseases, Rare Diseases, Alcohol, mental health, tobacco, nutrition, inequalities, and musculoskeletal problems. For over 30 years, surveys conducted by Eurobarometer have been conducted twice a year to guage the European public's opinions on European integration and the activities of European institutions.[167] There have been several surveys specifically focused on gathering information on health issues such as smoking, mental health, patient safety and health status. The Commission has recently funded research on healthy life years and a global report on the health status of the EU both due to be published by the end of the year. As mentioned in the

[165] Communication on e-Health- making healthcare better for European citizens: aN action plan for a European e-Health Area, COM (2004) 356, 30.4.2004

[166] http://ec.europa.eu/health/ph_information/reporting/community_en.htm

[167] http://ec.europa.eu/public_opinion/index_en.htm

previous chapter, the SPC recently adopted a set of indicators as part of a new commitment to social Europe. The overarching indicators that will be used to health aspects of social OMC are:
Health life expectancy = the number of years that a person at birth, at 45 and at 66 is still expected to live in a health conditions;
Self-reported unmet need for medical care= Total self-reported unmet need for medical care due to "financial barriers" or "waiting times" or " too far to travel", by income quintile; and
Total health expenditure per capita.[168]
While these statistics may provide some interesting information for comparison, they will not reach issues of quality, safety, or efficiency of the health system.

B. Threats/Security

Following the terrorist attacks in the United States in September 2001, the EU reassessed its preparedness to support Member States in dealing with deliberate attacks through the use of biological, chemical or nuclear agents. In 2001 the Health Council developed a health security programme to establish health expert consultations, strategies on availability of key pharmaceutical treatments, and a European network of experts for evaluating, managing, and communicating risks. The EU also joined the Global Health Security Initiative along with eight countries as an informal group to fill a gap for like-minded countries to address health issues of the day, such as global health security.[169] In 2002 a Task force on Bio-terrorism was created. The SARS epidemic in 2003 raised awareness of additional disease-related threats that should be addressed in health security planning. The Commission then began to research the development of a general plan covering a wide range of public health emergencies, including medical counter-

[168] COM(2008) 418
[169] http://www.ghsi.ca/english/index.asp

measures, public order measures, civil protection measures, and external affairs measures. In 2005, the Commission published a Communication on "Strengthening coordination on generic preparedness planning for public health emergencies at the EU Level"[170] The commission identified six key components to preparedness planning: information management; communications; scientific advice; liaison and command and control structures; preparedness of the health sector; and preparedness in all other sectors and inter-sectorally. The framework for cooperation includes: sharing of national plans, examining the role of Community legislation and measures, and evaluating implementation to improve interoperability. As part of the health security programme the commission will operate the ARGUS system of Community rapid alert crisis coordination centre.

In 2007 the Commission adopted a Green paper on bio-preparedness. The aim of the paper is to stimulate a debate and launch a process of consultation at European level on how to reduce biological risks, and to enhance preparedness and response capabilities. The European Commission sought stakeholders' opinions on the existing mechanisms and frameworks and what their possible shortcomings may be. Bio-preparedness stakeholders include national authorities responsible for risk prevention, investigation and response, human, animal and plant health, customs, civil protection, law enforcement authorities, the military, bio-industry, epidemiological and health communities, academic institutions and bioresearch institutes. At the time of writing, the Commission's public health web page included no further updates on the bio-preparedness programme.

C. Disease prevention/ health promotion

1. Blood

[170] COM (2005) 605, 28.11.2005.

In 1958, the Council of Europe adopted Agreement No 26 as the first step in regulating the cross-border exchange of therapeutic substances of human origin. In 1964 the Council established the European Pharmacopoeia Convention to harmonize the official technical rules on the quality of medicinal products including blood. Fears about blood contaminated with HIV undermined public confidence in the blood supply pressured the Community to adopt Directive 89/381/EEC to define measures to prevent the transmission of infectious diseases. Article 152 of the Treaty of Amsterdam provided the legal authority for subsequent legislation setting high standards of quality and safety for substances of human origin, without limiting Member States from introducing more stringent measures.

The Community's legislative framework related to blood and plasma donations for transfusion or as the basis for manufacturing plasma-derived medicinal products addresses the quality safety and efficacy requirements. Directive 2002/98/EC defines requirements for the collection, testing, processing, storage, and distribution of human blood and blood components. As soon as the components are manufactured into medicinal products, pharmaceutical legislation becomes applicable. Member States are obliged to transpose the Directive's requirements into law including:

Collection of information from all prospective blood and plasma donors;

Data protection and confidentiality;

Traceability of blood and blood components;

Labelling that complies with established identification system; and

Penalties for violations of the national laws that comply with the Directive and their enforcement.

The third meeting of the "Competent Authorities on blood and blood components" was held in October 2007. The new EUBIS project (European blood inspection system) was introduced.

The mission of EUBIS is to develop and implement commonly accepted criteria and standards to ensure equivalent recognition of inspection of blood establishments among Member States.[171] The project is implemented through four working groups focusing on quality management system evaluation, donor recruitment and blood collection, processing and testing, and blood component issuing, storage, and logistics.

2. Tissue

Human tissue is defined as a functional group of cells, such as cartilage, arteries, skin, nerve cells or cornea. These raw materials are used to restore or replace damaged tissues, but pose a risk of transmission of diseases to the recipient, including infectious diseases, cancer, or genetic diseases. There are a number of complex and interrelated activities involved in the procurement, implantation or graft, or the manufacturing of human tissue. Directive 2002/98/EC sets standards of quality and safety and the subsequent procedures similar to the regulation of blood. Similar to the blood directive, Member States must transpose the Directive's requirements into law, for example:

Ethical principles, such as voluntary unpaid donation, and the non-profit procurement of tissues and cells;

Anonymity of both donor and recipient;

Establishment of national structures in charge of accreditation designation and authorization of the conditions for the procurement of human tissues and cells; and

A European register of all authorized centres.

The first meeting of "Competent Authorities on Tissues and Cells" was held in February 2007. They discussed the transposition and implementation of the Tissue directive, reported the

[171] http://www.eubis-europe.eu/index.php

current practices for voluntary and unpaid donation of tissues and cells, as well as special issues related to the directive.[172]

3. Organs

The least developed of the three areas, regulation of organ donation and transplantation has not been harmonized despite the existence of cross-border exchanges of organs for use in therapy and transplantation. The risks of transmission of diseases, and the potential for trafficking of human organs by organized criminal groups pose significant risks to the health and safety of EU citizens. The Commission conducted an impact assessment and published a Communication demonstrating the need for further regulation to establish guidelines for the quality and safety of the use of human organs.[173] The biggest challenge inhibiting the promotion of health in the area of organ transplantation in the EU is the server shortage of organ donors. The gap between supply and demand creates a market for both criminal activity and transplant tourism.

In 2003, the Commission conducted a survey on legal requirements related to organ transplantation in the EU which found discrepancies in quality and safety requirements within Member States. In June 2006, the Commission carried out an open consultation on organ donation and transplantation forming the basis for the Communication's recommendations. Several measures should be initiated at every stage of the transplant process in order to improve the quality and safety of organs. These safety procedures range from pre-transplant evaluation of potential donors to developing a system for traceability from donor to recipient to detect and investigate serious or unexpected adverse events. Member States could share expertise to increase organ donor rates through public awareness campaigns, and the establishment or improvement of transplant systems ensuring that the organs of people willing to donate are

[172] SANCO C6 CT/ges D(2007) 360063
[173] COM(2007)275

identified, tested, and transferred to the most suitable recipient as efficiently and quickly as possible. The Commission identified three main areas of action:

To define a legal framework on quality and safety for human organs with the cooperation of Member States in the compilation of information;

To promote the training of professionals based on best experience to expand the pool of organ donors; and

To identify the most efficient systems, share experience and promote best practices in accordance with local characteristics.

To initiate these actions, the Commission proposes the development of an Action plan on strengthened cooperation between Member States and a new legal instrument on quality and safety of organ donation and transplantation.

BLOOD	TISSUE	ORGANS
Directive 2002/98/EC Setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Dir 2001/83/EC	Directive 2004/23/EC Setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage, and distribution of human tissues and cells.	Commission Communication on Organ Donation and Transplantation: Policy actions at the EU Level COM (2007)275 Concluded that there is a need for a directive
Commission Implementing Directive 2004/33/EC Technical requirements for blood and blood components	Commission Implementing Directive 2006/17/EC Technical requirements for the donation, procurement and testing of human tissue and cells.	

Commission Implementing Directive 2005/62/EC Community standards and specifications relating to a quality system for blood establishments	Commission Implementing Directive 2006/86/EC Regards traceability requirements, notification of seriouc adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells.	

4. HIV/AIDS

The EU has conducted activities to combat the HIV/AIDS epidemic since the 1980s. But it was not until 2004 that the council called for actions to address the situation affecting neighbouring countries as well. In 2005 the Commission proposed a strategy for combating HIV/AIDS within the EU and neighbouring countries for 2006-2009.[174] The main areas of action include: leadership and advocacy; involvement of civil society; Surveillance; prevention of new infections; and treatment, care, and support; research. The Commission has established several coordinating structures to formulate and implement HIV/AIDS activities in Europe.[175]

HIV/AIDS networking structures

HIV/AIDS Think Tank	The HIV/AIDS Think Tank is a forum to exchange information

[174] Commission Communication, "On Combating HIV/AIDS within the EU and in the neighbouring countries, 2006-2009, COM (2005) 654, 15.12.2005.

[175] http://ec.europa.eu/health/ph_threats/com/aids/aids_en.htm

	between the Commission, the Member States, Candidate and EEA countries (Lichtenstein, Iceland and Norway). Relevant international and regional organisations and pan-European NGOs are invited to the meetings.
HIV/AIDS Civil Society Forum	The HIV/AIDS Civil Society Forum (CSF) is an informal advisory body established in 2005 by the European Commission to facilitate the participation of NGOs and networks, including those representing People Living with HIV/AIDS, in European policy development and implementation as well as to exchange information.
Inter-service group (ISG) on HIV/AIDS	The ISG is a forum for coordination and cooperation between all relevant Commission Directorate Generals.
HIV/AIDS Task Force	In April 2004 the Directorate General Health and Consumer Protection established HIV/AIDS Task Force within the Directorate for Public Health and Risk Assessment. This Task Force draws resources from different units in the Directorate thus bringing diverse expertise within the group. At the moment ten members of the staff in the Directorate are attached to the Task Force and two of them work only on HIV/AIDS issues.

D. Health Determinants- Healthy Lifestyles

Nutrition and Physical Activity

Poor nutrition, overweight and obesity are increasing and post serious public health problems in Europe because it increases significantly the risk of many chronic diseases. In May 2007 the Commission published "A Strategy for Europe on Nutrition, Overweight and Obesity related Health Issues.[176] The Commission emphasized that any Community action must consider three factors: 1) the individual is ultimately responsible for his lifestyle; 2) a well-informed consumer can make rational decisions; and 3) optimal nutrition policies will look at both vertical and horizontal approaches. Actions to promote the EU nutrition policy focus on six themes. 1) Informing consumers through improved nutrition labelling, regulation of the claims made by producers and addressing food advertising and marketing, especially to children. 2) Making health options available to consumers, which requires action by the Common Agricultural Policy (CAP) and the Common Market Organization (CMO) for fruit and vegetables to encourage consumption especially in schools. There is also interest in reducing the disparities across the EU in the composition of manufactured foods to reduce levels of fat, saturated and trans fats, salt and sugar. 3) Encouraging physical activity including organized sports and "active commuting". 4) Priority groups and settings requires the targeting of research and programs to low socio-economic groups and children. 5) Developing the evidence base to support policy making including evidence about the determinants of food choices and consumer behaviour. 6) Developing monitoring systems that will analyze consistent comparable national data on overall progress indicators related to diet and physical activity such as the prevalence of obesity.

Consistent with this call to action on nutrition, the Commission also proposed wide-ranging reforms to the CMO for fruit and vegetables to bring the sector into closer line with the rest of the reformed CAP by encouraging increased consumption and organic production while

[176] White Papter COM (2007) 279

abolishing export subsidies[177]. As part of these CMO reforms, the Commission proposed amending Regulation 1182/2007to establish a "School Fruit Scheme". This policy will supply fruit and vegetable products to pupils in educational establishments which will have a range of benefits from reducing health inequalities to encouraging healthy eating habits.[178] The scheme would include three elements: the free distribution of fruit and/or vegetables in schools; a series of accompanying measures such as public health and education strategies; and monitoring and evaluation.

Injury Prevention

Injuries remain a leading cause of death among the European population. There are significant differences in rates of accidents and injury across the EU and within national populations. In 1999, the commission adopted the Injury Prevention Programme. In 2003 the Public Health Programme incorporated injury prevention activities among the other priorities. In June 2006 the Commission published a Communication and proposed Council recommendations to address injuries by: quantifying the size and impact of injuries, disseminating evidence-based prevention strategies, and educating the public how to make safer choices.[179] The proposed Council Recommendation suggests a strategic framework to help Member States prioritize their actions in reducing accidents and injuries. Priority areas include the safety of children, adolescents, the elderly and vulnerable road users; and the prevention of sports injuries, injuries caused by products and services, self-harm and interpersonal violence.

[177] EC (European Commission) (2007) Commission Press Release: "CAP reform: Fruit and vegetable reform will raise competitiveness, protect producers from crisis, increase consumption, improve environmental protection and simplify rules," Press Release, Brussels 24 January 2007, IP/07/75.
[178] COM (2008) 442 final
[179] Communication on Actions for a Safer Europe COM(2006) 328 23.6.2006; and Proposed Council Recommendations COM(2006) 329, 23.6.2006.

This broad scope of priorities does not seem to lend itself well to focusing on specific root causes or effective short-term strategies, which may explain the delay in adoption.

E. Control of Harmful products

1. Tobacco

Since the EACP, EU tobacco policies have been criticized for the inconsistent objectives of reducing the negative health impacts of tobacco while simultaneously subsidizing tobacco farmers and protecting tobacco industry jobs. The EU is one of the largest cigarette manufacturing regions in the world, including an extensive export market, and may subsidize tobacco farmers up to €337,937,000,000 in 2008. The Common Agricultural Policy that manages the tobacco subsidy is encouraging sustainable economic development by rewarding the transition to healthy products and developing alternative sources of income and economic activity, while the subsidies are being phased out by 2010.[180] This shift towards public health policies taking precedent over agricultural interests may be due to the fact that tobacco related diseases are the single largest cause of death in Europe.[181]

After the first wave of tobacco control legislation, including directives on regulation, taxation, and the attempted ban on advertising the tobacco industry implemented their own comprehensive lobbying strategy.[182] The industry's well-funded and multi-dimensional approach included the creation of the Confederation of European Community Cigarette Manufacturers,

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[180] EC (European Commission) (2008) Commission Press Release: "Commission proposes to continues financing Community tobacco fund to pay for awareness raising on dangers of tobacco," http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/178&format=HTML&aged=0&language=EN

[181] ASPECT Consortium (Analysis of the Science and policy for European Control of Tobacco). (2004). "Tobacco or Health in the European Union, past, present, and future," http://ec.europa.eu/health/ph_determinants/life_style/Tobacco/Documents/tobacco_fr_en.pdf

[182] Gilmore, Anna and Martin McKee. (2004) "Tobacco-Control Policy in the European Union," In Eric A Feldman and Ronald Bayer (Eds.), Unfiltered, Conflicts over Tobacco Policy and Public Health, (pp.219-370) London: Harvard University Press.

the funding smokers rights groups, and the support of research facilities. Tobacco industry documents later revealed close associations with both national government officials and EU level staff. In particular, tobacco lobbyists encouraged and supported the German government's successful legal challenge overturning the first EU Tobacco Advertising Directive. The German government complained that the official legal basis for the Directive was regulation of the internal market did not support a total tobacco advertising ban. The European Court of Justice agreed and found that the Treaty did not provide legal authority to justify the ban on public health grounds. (see the Politics of Tobacco Control text box for more details)

Currently, the primary laws regulating the tobacco market in the EU are the new Advertising Directive from 2003 and the Products Directive enacted in 2001. The Products Directive requires high visibility, hard-hitting health warnings on all tobacco products sold in the EU; bans misleading descriptors such as "light", "ultra light" and "mild" that give the impression certain types of cigarette are less dangerous; and regulates maximum levels of tar, nicotine, and carbon monoxide in cigarettes.[183] The Advertising Directive bans all tobacco advertising on the radio, internet and in the print media in EU countries; and prohibits tobacco sponsorship of cross-border events. The directive is limited in that it does not cover advertising in cinemas, on billboards, or at strictly local sporting events.[184] In April 2006 the Commission sent formal notice of non-compliance to the Czech Republic, Italy, Hungary, and Spain for failure to enforce the Tobacco Advertising Directive. These Member States must bring their legislation into

[183] CEU (Council of the European Union) (2001). Directive concerning the manufacture, presentation and sale of tobacco products. Directive 2001/37/EC 2002 IP/02/1383 CEU, Brussels
CEU (Council of the European Union) (2001). Directive concerning the manufacture, presentation and sale of tobacco products. Directive 2001/37/EC 2002 IP/02/1383 CEU, Brussels
[184] CEU (Council of the European Union) (2003). Directive relating to the advertising and sponsorship of tobacco products. Directive 2003/33/EC 2003 IP/02/1788 CEU, Brussels

conformity with the directive, or face infringement procedures.[185] For a detailed comparison of the recent progress in tobacco control legislation in thirty European countries refer to the report written by Luk Joossens and Martin Raw in 2007. As of 2007 all EU members have signed the Framework Convention on Tobacco Control and all but 2 have ratified the convention.

Recently, the EU has sponsored significant anti-smoking media and education campaigns. From 2002 to 2004 the €18 million "Feel Free to say No" anti-smoking campaign included television advertising geared toward adolescents. The evaluation of the campaign disclosed the need for more narrowly targeted strategies and greater focus on the independence of youth and the risks of addiction.[186] In 2005 the Commission launched a new campaign, "HELP- For a Life without Tobacco" with a €72 million budget. This multi-media Europe-wide campaign includes web based advertising, more nationally tailored messaging and information about the dangers of exposure to environmental smoke. At the time of writing the Commission had not published an evaluation of the HELP campaign.

Recent policy trends have focused on encouraging member states to enact legislation expanding smoking bans in public places and requiring health label to include color pictures.
In an Annex to Commission Decision 2003/641/EC in accordance with Article 5 of the products directive, the Commission adopted a library of forty-two selected source documents and technical specifications for printing combined pictorial and written warnings.[187] Member States have also been encouraged to use combined warnings with quit-line phone numbers,

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[185] EC (European Commission) (2006). Press Release: Tobacco advertising: European Commission takes action against four non-compliant Member States. IP/06/435. April 4, 2006.
[186] Evalua, "Evaluation Process for the Commission, Tobacco Prevention Media Campaign, 'Feel Free to say No', Evaluation Report" December 15, 2003)
http://ec.europa.eu/health/ph_determinants/life_style/Tobacco/Documents/evalfeelf_151203_en.pdf
[187] CEU (Council of the European Union) (2003). Commission Decision on the use of colour photographs or other illustrations as health warnings on tobacco packages. 2003/641/EC Sept. 5, 2003.

internet addresses or other visual elements informing about the support available to whose who want to stop smoking. By autumn of 2008 only Belgium, Romania, and the UK will have implemented combined pictorial warnings.[188]

In 2007, the Commission published a Green Paper examining the health and economic burdens associated with passive smoking, public support for smoking bans, and the measures taken so far at national and EU level.[189] The Commission invited stakeholders' views on the scope of measures to tackle passive smoking and the most appropriate form of EU intervention. The responses to the consultation verified that only a full smoking ban in all enclosed workplaces and public places can adequately protect the health of citizens and workers. Mechanisms to achieve this goal should be addressed at both the Member State and the EU level. The report concluded that the EU should provide support in cases where national governments have encountered political difficulties introducing comprehensive smoke-free legislation in the hospitality and leisure sector.[190]

Cigarette smuggling into and across the EU has continued to be a problem since the creation of the Single European Market. On March 18, 2008, the European Anti-Fraud Office (OLAF) announced the arrest of twenty-six people in Poland and Germany, including the presumed main organizers of an international criminal gang responsible for smuggling millions of cigarettes into the EU from former Soviet Union countries and China. In addition to the arrests, the authorities in Poland seized nearly seven million cigarettes, a truck that was in the process of being loaded with contraband cigarettes, nearly three million euros in cash and nine

[188] EC (European Commission) (2007) Commission Report: Second Report on the Application of the Tobacco Products Directive. COM(2007) 754 final, Nov. 27, 2007. CEU, Brussels.
[189] EC (European Commission) (2007) Commission Green Paper: Towards a Europe free from tobacco smoke: policy options at EU level. COM(2007) 27 final, Jan. 30, 2007. CEU, Brussels.
[190] Ibid.

kilos of gold and jewelry following a series of coordinated searches in warehouses and private dwellings.[191]

The Politics of Tobacco Control in the EU

In December 1997, the Council of Ministers agreed to support a directive banning advertising of tobacco products after protracted negotiations where the UK government changing its position with the election of a Labor government. Germany and Austria opposed the legislation, while Spain and Denmark abstained. Germany and several British tobacco companies filed a legal challenge in the ECJ on the grounds that the Treaty provided no legal basis for the directive. Since the public health Article of the Treaty explicitly prohibited the harmonization of laws for public health purposes, the directive was enacted as an internal market measure.[192]

Once secret tobacco industry documents indicate that the tobacco industry lobbied politicians and used third party organizations to undermine and eventually overturn the first Advertising Directive. The industry's effort to influence EC policy focused on lobbying government officials and industrial groups within a number of key EC Member States, including Germany, the UK, the Netherlands, and Denmark. Germany has been a strong and consistent ally of the tobacco industry in its efforts to defeat the Advertising Directive within the EC and through litigation at the level of the ECJ. The tobacco industry influenced officials at the highest levels of European politics, including former German Chancellor Helmut Kohl.[193]

The Court upheld the challenge and annulled the first directive, ruling that it went beyond the legal basis on which it was enacted.[194] In its decision the Court offered a suggestion for tobacco legislation that would be supported as a regulation of the internal market by limiting

[191] OLAF (European Anti-Fraud Office) (2008) Press Release: International Cigarette Smuggling Ring Dismantled. OLAF/08/04 March 18, 2008, Brussels. http://ec.europa.eu/anti_fraud/press_room/pr/2008/4_en.html

[192] Gilmore, Anna and Martin McKee. (2004) "Tobacco-Control Policy in the European Union," In Eric A Feldman and Ronald Bayer (Eds.), Unfiltered, Conflicts over Tobacco Policy and Public Health, (pp.219-370) London: Harvard University Press.

[193] Bitton, A, M Neuman and S Glantz. (2002). "Tobacco Industry Attempts to subvert European Union Tobacco Advertising Legislation", The Lancet 359:1323-30.

[194] Case C-376/98, Federal Republic of Germany v. European Parliament and Council of the European Union. (2000) ECR I-8419

the ban to cross-border advertising. The Commission quickly drafted a new directive that was submitted to the Parliament and Council for approval. Negotiations were again strained with Germany firmly supporting the tobacco industry's interests. Philip Morris persuaded Britain's opposition through its close relationship with Kenneth Clarke, who had been health minister and health secretary.[195] Agreement on the new directive was not reached until November 2002 when the Parliament passed watered down draft. Directive 2003/33/EC was ultimately adopted without Germany and the UK's support. The Court rejected Germany's second legal challenge ruling that the measures were appropriate for achieving their objective.[196]

2. Alcohol

The EU is the heaviest drinking region of the world at 11 liters of pure alcohol drunk per adult per year. [197] Alcohol has been produced and consumed in Europe for thousands of years and is deeply intertwined with many local cultural traditions. Prior to the major EU expansion in 1995, the Commission defined alcohol either as and industrial or an agricultural product. Only distilled spirits were regulated as an alcoholic beverage, but the powerful Amsterdam Group representing large international alcohol corporations has effectively protected the industry's interests for many years.[198]

The European Court of Justice has also played an active role in the harmonization of Member States alcohol control regulations. In cases concerning the 1994 Swedish Alcohol Act, and the French ban on alcohol television advertising the Court held that the Member States could justify

[195] Gilmore, 2004

[196] Case C-380/03, Federal Republic of Germany v. European Parliament and Council of the European Union, (Germany) (2006) ECR I-8419

[197] Anderson, Peter and Ben Baumberg. (2006) Alcohol in Europe, a Public Health Perspective: a report for the EU Commission, June 2006. http://ec.europa.eu/health-eu/news_alcoholineurope_en.htm

[198] Kurzer, Paulette. "Alcohol policy in Sweden and Finland: Challenges for the future," Scandinavian Review, Autumn 1998 http://findarticles.com/p/articles/mi_qa3760/is_199810/ai_n8818952/pg_2

legislation regulating the alcohol industry in order to protect public health and safety.[199] However, in other cases, the Court has ruled that the means used to regulate the alcohol market were not proportionate to attain the objective of protecting young persons from the harmful effects of alcohol.[200] Under Swedish law, private individuals must apply to the Swedish retail monopoly, called Systembolaget, to import any alcoholic beverages not available through the State run stores. The Court held that the prohibition was a quantitative restriction on the free movement of goods that could not be justified on public health grounds, since it failed to demonstrate that the process was necessary to prevent under-age drinkers from getting access to alcohol.

The increased attention of alcohol related harms encouraged a belated discussion of the public health aspects of underage and excessive alcohol consumption. In 2001, a Council Recommendation recognized that alcohol was a key health determinant and invited the Commission to develop a comprehensive strategy to reduce the negative health impacts. Accordingly the Commission began public consultations and solicited reports to analyze the problem. One study estimated the economic cost of alcohol attributable crime to be thirty-three billion euros in 2003. Alcohol is also responsible for about 195,000 deaths in the EU each year.[201] Based on these reports and public consultations the Commission published its strategy for reducing alcohol related harm in the EU in a 2006 Communication.[202] The Strategy focuses on three main areas: harmful alcohol consumption by youth, alcohol-related traffic accidents, and

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[199] Ibid.; and Case C-262/02 and C-429/02, Commission v. France, Bacardi v. France, (Bacardi) joined cases, (2004) ECR I-6569

[200] Case C-170/04, Klas Rosengren and Others v. Riksaklagaren, (Rosengren) (2007) ECR I-1251

[201] Anderson, Peter and Ben Baumberg. (2006) Alcohol in Europe, a Public Health Perspective: a report for the EU Commission, June 2006. http://ec.europa.eu/health-eu/news_alcoholineurope_en.htm

[202] EC (European Commission) (2006) Communication from the Commission: EU Strategy to support Member States in reducing alcohol related harm. COM (2006) 625 final, Oct. 24, 2006.

alcohol-related harm among adults, including the negative impact on the workplace. The Commission defined its role: first, to inform and raise awareness of the major public health concerns and to cooperate with Member States in addressing these; second, to initiate action at the EU level through public health programs; and third, to support and help coordinate national actions by identifying and disseminating good practices across the EU.

In June 2007, the European Alcohol and Health Forum was established to facilitate the implementation of the Communication on alcohol related harm.[203] Forum members include European umbrella organizations capable of playing an active role in reducing alcohol related harm in the EU, and willing to engage in concrete and verifiable commitments to reach this goal. The forum meets twice a year and focuses on concrete actions to protect children and young people and to prevent irresponsible commercial alcohol communication and sales. It created two task forces to focus on youth specific aspects of alcohol consumption and on alcohol marketing communications respectively.

3. Drugs

Due to the local nature of illicit drug use and related crime, there is wide variation in national legislation, policies, and expenditures. There are no Directives specifically regulating drugs from a public health perspective. The EU coordinates information gathering and dissemination, as well as the identification and sharing of best practices for drug treatment and control. In 2003, the Council Recommendation on the prevention and reduction of health related harm associated with drug dependence focused on the need for Member States to actively

[203] EC (European Commission) (2007) Commission Press Release: "European Commission, businesses and NGO's create Forum to battle alcohol-related harm," June 7, 2007, http://europa.eu/rapid/pressReleasesAction.do?reference=IP/07/774&format=HTML&aged=0&language=EN&guiLanguage=en

address the problem, reflecting the diversity of drug related health issues at the state and local level.[204]

The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) compiles and reports data regarding the problem of illicit drugs in the EU, but has no regulatory authority. The Centre helps to develop national monitoring systems based on common methodologies and standards, providing an evidence base for policy-makers at the national and European levels. Generally, cannabis use seems to have leveled off, while cocaine use is on an upward trend. Intervention in the 1990s were effective at controlling the spread of HIV among infected drug users in most of Europe, but it is still prevalent especially in the Baltic states. Hepatitis C rates are high among injecting populations and studies have shown that young injectors continue to acquire the disease relatively quickly, making early intervention crucial. The downward trend in drug-related deaths also seems to have leveled off. This appears to be caused by a rise in over-doses by young users.[205]

The comparative information generated by the EMCDDA, has contributed to the development and implementation of the EU Drugs Strategy. The Strategy for 2005-2012 defines the twin aims of reducing demand and supply of drugs with a budget of € 21,350,000.[206] Due to the EU's limited competence to work in this field the strategy primarily focuses on research, information dissemination and evaluation. At the EU level, the Horizontal Working Party on Drugs a coordinating committee within the Council, will monitor the implementation of the actions set out in EU Action Plans on drugs and coordinate other Council working groups with drug-related

[204] CEU (Council of the European Union) (2003). Council Recommendation on the prevention and reduction of health-related harm associated with drug dependence. 2003/488/EC. June 18, 2003 CEU, Brussels.

[205] EMCDDA (European Monitoring Centre for Drugs and Drug Addiction) (2007) Annual Report 2007: The state of the drugs problem in Europe. http://www.emcdda.europa.eu/html.cfm/index419EN.html

[206] CEU (Council of the European Union) (2004). General Secretariat Communication to European Council on the EU Drugs Strategy (2005-2012). 15074/04, November 22, 2004 CEU, Brussels.

issues. The report divides the strategies into demand and supply issues. Demand side strategies focus on the development and implementation of integrated and comprehensive knowledge-based demand reduction systems including treatment, harm reduction, and rehabilitation and social integration. Supply side strategies involve several branches of EU institutions. EU legislation provides a framework for the control of trade in the chemical precursors for drugs both within the Community and which third countries, enforced through the Commission's Environment Directorate-General (DG). With regard to money laundering, Community legislation sets out a number of measures to prevent the laundering of drugs proceeds. (see Third Directive on Money Laundering[207]) The DG for justice and home affairs encourages cooperation between police, customs and judicial authorities. Finally, in the area of external relations the EU takes international action with a combination of political initiatives, like the action plans and dialogue on drugs with various regions of the world, as well as assistance through development programs. The evaluation of the strategy and the Action Plans on Drugs is planned for 2008 and should be conducted by the Commission, in cooperation with the EMCDDA, Europol and the Member States.

In 2006, the Commission published a Green Paper on the Role of Civil Society in drugs policy. The DG for Justice and Home Affairs organized the Civil Society Forum for Drugs, and called for interested civil society organizations to formally express their interest in taking part in such a forum.[208] The December 2007 meeting addressed current issues arising from the EU Action Plan, as well as the Progress Review carried out by the Commission. The forum provides a channel for exchanging views, ideas and information between the Commission and civil society

[207] CEU (Council of the European Union) (2005) Directive on the prevention of the use of the financial system for the purpose of money laundering and terrorist financing. Directive 2005/60/EC 2005 OJ L 309 , 25/11/2005 P. 0015 - 0036 CEU, Brussels

[208] EC (European Commission) (2006) Commission Green Paper on the role of civil society in drugs policy in the European Union. COM (2006) 316 final, June 26, 2006.

organizations as well as providing for civil society input on the policy development and reflection process at the European level. The April 2007 Commission Report on the implementation of the 2003 Recommendation on the prevention and reduction of health-related harm associated with drug dependence provides the current status of implementation across EU to be used as a baseline for comparison with future studies.[209] The Commission proposes that the action plan for 2009-2012 include a Council Recommendation on reduction of drug related harm in prisons, and a report on drug treatment programs for the purpose of an exchange of good practice information.

TOBACCO	
Tobacco Products Directive 2001/37/EC	Directive on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products.
Tobacco Advertising Directive 2003/33/EC	Directive on the approximation of the laws regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products.
Commission Decision 2003/641/ec	Commission Decision on the use of color photographs or other illustrations as health warnings on tobacco packages.
Council Recommendation 2003/54/EC	Council Recommendation on the prevention of smoking and on initiatives to improve tobacco control
Council Decision	Council Decision concerning the conclusion of the WHO

[209] EC (European Commission) (2007) Report to the Council and the European Parliament On the implementation of the 2003 Council Recommendation on the prevention and reduction of health-related harm associated with drug dependence reports on the status of implementation across EU. COM(2007) 199 final, April 18, 2007. CEU, Brussels.

2004/513/EC	Framework Convention on tobacco Control
Commission Green Paper January 2007	Towards a Europe free from tobacco smoke: policy options at EU level
ALCOHOL	
Council Recommendation 2001/458/EC	Council Recommendation on the drinking of alcohol by young people, in particular children and adolescents
Commission Communication COM(2006) 625	Commission Communication on an EU strategy to support Member States in reducing alcohol related harm
DRUGS	
Council Recommendation 2003/488/EC	Council Recommendation on the prevention and reduction of health-related harm associated with drug dependence
Commission Green Paper COM(2006) 316	The Role of Civil Society in Drugs Policy in the EU

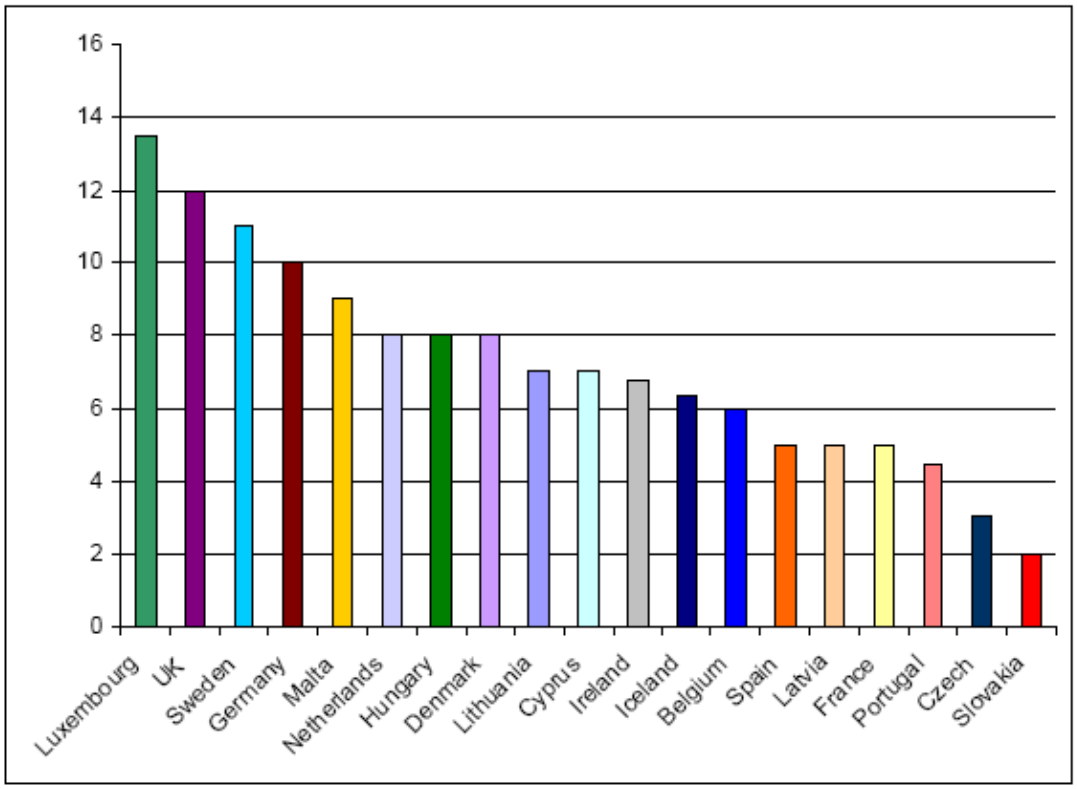
F. Mental Health

Mental health has been on the Community's health policy agenda since 1997. However, critics would be quick to point out that a comprehensive strategy on mental health still does not exist. In 2000 The Community's Framework Programmes for Research funded a project to assess mental health in Europe. In January of 2005, the WHO European Ministerial Conference on Mental Health established a framework for comprehensive action. Later that year the Commission published a green paper on improving the mental health of the population, focusing on four priorities: 1) promoting the mental health of all; 2) addressing mental ill health through preventative action; 3) improving the quality of life of people with mental ill health or disability through social inclusion and the protection of their rights and dignity; and 4) developing a mental health information, research, and knowledge system for the EU. The consultation process to develop an EU strategy for mental health is ongoing and

includes: a forum for Member States to exchange information, a platform for cross-sectoral cooperation and consensus on mental health, and an interface between policy and research on mental health. In June 2008 the Community health a health-level conference "Together for Mental health and Well-being". Participants agreed to a European Pact for Mental Health and Well-being which identifies five priority areas: 1) prevention of depression and suicide; 2) mental health in youth and education; 3) mental health in workplace situations; 4) mental health in older people; and 5) combating stigma and social exclusion. The Commission plans to propose a council Recommendation on Mental health and Well-being during 2009.

Mental Health Expenditure in European Economic Area Countries

(% of total health expenditure)



Source:

Mental Health Economics European Network (2004)

3. Health System Support & Research Initiatives

A. Patient Safety and Quality Measurement and Improvement

Although Member States have primary responsibility for health systems there are several areas where the EU has sought to provide support through soft law mechanisms such as the Patient Safety Working Group (PSWG), and the European Network for Patient Safety. PSWG recommendations for the EU include: 1) develop the knowledge and evidence base for patient safety; 2) implement evidence-based reforms for safer care; and 3) engage and involve stakeholders. The EU Network began a 30 month project in February 2008 focusing on four vertical frameworks: 1) reporting and learning systems; 2) education and training of professionals; 3) patient safety culture; and 4) pilot testing of medication safety interventions. The Commission is currently working on a communication regarding patient safety and hospital infectious diseases.

B. Inequalities – Research & Structural Funds

The Commission has been concerned about the inequalities in health status that exist across and within European countries. To reduce the gaps, Structural Funds are invested to improve health infrastructure and human capacity to maintain a healthy workforce.[210] The Commission has sponsored research into the socio-economic related health inequalities. One of the most recent projects is called DETERMINE (2007-2010). DETERMINE is an EU wide

[210]For examples of projects see: http://ec.europa.eu/regional_policy/projects/stories/search.cfm?LAN=EN&pay=ALL&region=ALL&the=21

initiative to stimulate action on the social and economic determinants of health inequities.[211] The project involves over 50 health related organizations from 26 European countries. The goal of the project is to raise awareness and capacity amongst decision makers to consider health and health equity when developing policy. Specifically, the project aims to:

identify effective national level policies and practices that promote health equity and undertake a cost-effectiveness review;

seek innovative approaches to improve the health of disadvantaged groups, and implement small scale pilot projects in this area; and

design and implement awareness raising and capacity building activities.

EuroHealthNet, in collaboration with the Czech Institute of Public Health (contract holder), coordinates the project. Several other organizations are also involved in leading and implementing the projects.

C. Rare Diseases

Rare diseases require special efforts in research, diagnosis and treatment due to the low prevalence of less than 5 per 10,000 persons in the European Union. These diseases could be life-threatening or chronically debilitating, and may be of genetic origin. From January 1999 to December 2003, the Community action programme on rare diseases focused on improving knowledge and facilitating access to information about these diseases. Under the new action programme from 2008-2013, DG SANCO's Work Plans include:

Improving the exchange of information using existing European information networks on rare diseases, and promoting better classification;

[211] http://www.health-inequalities.eu/?uid=12e0f5547c8fa0f54ec26397c7a55c66&id=home

Developing strategies and mechanisms for an exchange of information between people affected by a rare disease, volunteers, and professionals;
Defining relevant health indicators and developing comparable epidemiological data at EU level;
Organizing the Fourth European Conference on Rare Diseases in 2007;
Developing the concept of European Centres of Reference for Rare Diseases; and
Supporting the exchange of best practice and developing measures for patient groups.
The 2007 Conference highlighted new research and multidisciplinary techniques for treating rare diseases. The Conference was organized by European Organization of Rare Disease (EURODIS) is a network of 200 rare disease associations. The Commission plans to present a Communication on European action on Rare Diseases in late 2008.[212] Related to DG SANCO's work coordinating EURODIS and other stakeholders, DG Enterprise and the EMEA implement policies encouraging research and development of Orphan Drugs. The Orphan Regulation[213] sets criteria for orphan designation and describes incentives (10-year market exclusivity, protocol assistance, access to the Centralized Procedure for Marketing Authorization) to encourage the research, development and marketing of medicines to treat, prevent or diagnose rare diseases.

4. Pharmaceuticals & Medical Devices

The Pharmaceutical and Medical device industries play a vital role in the delivery of health care and clinical research and innovation. Both types of products are indispensable public goods, that could restore health and wellbeing while posing significant risks to health if poorly

[212] 4th European Conference on Rare Diseases, "Patients at the Heart of Rare Disease Policy Development", Lisbon 2007.
[213] Regulation 141/2000 of the European Parliament and the Council of 16 December 1999 on orphan medicinal products.

regulated or inappropriately used.[214] This section will introduce the major issues facing the EU in the manufacture, regulation, and reimbursement for both types of products and treatments. Striking a balance between the economic and health objectives of the pharmaceutical and medical device sectors has been particularly challenging for European governments. Table 2 offers an overview comparison of industrial, healthcare, and public health policy issues for the two related sectors.

A. Pharmaceutical Regulation

The pharmaceutical industry is one of the most heavily regulated markets, where health policy and industrial policy objectives are often at odds. Cost containment strategies may not be the a primary health policy objective, but it is one of the tools used by governments in an effort to improve efficient use of resources. However, governments must also encourage drug research and development and balanced trade since the pharmaceutical industry is also a significant provider of employment and economic growth. EU laws and policies touch upon many different aspects of the pharmaceutical sector. Here, we will discuss pricing and reimbursement, parallel imports, generic policy, competition, and market authorization.

Price and/or volume control policies attempt to correct for market imperfections and control other factor that increase drug expenditures. Mechanisms used to regulate pharmaceutical products differ across Europe due to distinct national policy priorities. For example, some policies control prices directly by negotiating prices, fixing maximum prices, international price comparisons, and price cuts or freezes. Indirect pricing schemes regulate profits, such as the now

[214] Altenstetter, C. and G. Permanand, (2007) "EU Regulation of Medical Devices and Pharmaceuticals in Comparative Perspective", Review of Policy Research, 24:5 pp. 385-405.

discredited UK 'Pharmaceutical Price Regulation Scheme' (PPRS), or set reimbursement limits known as reference prices.[215] The Transparency Directive 89/105/EEC[216]loosely governs the pricing of medicines and national reimbursement systems. Authorities must determine prices within 90 days of receiving adequate information and indicate how negative decisions are to be communicated. Price freezes must be reviewed annually to determine whether macroeconomic conditions support their existence. The directive further stipulates that pricing mechanisms must be explicit and must state the rationale for including medicines on positive or negative reimbursement lists. In addition to reimbursement decisions, several countries use economic evaluation data to determine pricing. Finland is the only country to have officially adopted economic evaluation guidelines as part of the price-setting mechanism.[217] In additional to containing costs, the determination of reasonable drug prices signal which drugs should be rewarded as being cost-effective innovations. It is debatable whether a single price control system for the EU is a viable alternative to nationally defined schemes. Member States vary in willingness to pay for a drug due to local epidemiology or patient valuations. While the pharmaceutical industry would prefer streamlined pricing procedures so long as the market for particular products did not become more restrictive.[218]

Recent Pharmaceutical Legislation

Transparency Directive 1989/105/EEC, 11.02.1989, OJ L40

Orphan medicinal products regulations No 141/2000, 16 Dec 1999, OJ L 18/1; and 847/2000, 27 April 2000, OJ L 103/5

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[215] Mrazek and Mossialos, (2004) "Regulating pharmaceutical prices in the European Union", in Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality. Elias Mossialos Monique Mrazek, and Tom Walley eds. Open University Press.
[216] OJ L40 11.02.1989
[217] Ibid.
[218] Ibid.

Clinical Trials Directive 2001/20/EC, 4 April 2001, OJ L 121/34-37.
Veterinary Medicines Codification Directive 2001/82/EC,6 Nov 2001, OJ L 311.
Herbal Medicines Directive 2001/83/EC, 31 March 2004, OJ L 136/85.
EMEA regulations No 726/2004, 31 March 2004, OJ L136/1.
Medicinal Products for Human Use Directive 2004/27/EC, 30 April 2004, OJ 2004 L 136/34

The European pharmaceutical market is traditionally characterized by competition between new, patented, innovative products (often referred to as therapeutic competition) and from generic products as well as parallel imports. Parallel imports relate to the purchase of medicines by a wholesaler at low prices in one country and their subsequent import and resale at higher prices in another country. European governments employ different pricing regulation policies, variable prices for a product exist throughout the EU. Commission appears interested in expanding its 'tool kit', to prevent certain industry practices intended to discourage generic competition. Therefore, the application of Article 82 EC (which prohibits the abuse of a dominant position) is now becoming of greater significance.[219]

Market Fragmentation & Parallel Imports

Although the Community has many policies to promote a single European market, pharmaceuticals remains a highly fragmented market due to national rules on market authorization, pricing, and reimbursement policies. Parallel imports occur where national prices are undercut by the importation of products from another country where the prices are lower. The Commission approves of parallel imports as a way of integrating the internal market in

[219] The following section is based on Leigh Hancher's chapter published in the forthcoming book on EU Law and Health systems.

pharmaceuticals. The ECJ's and national courts' reconsideration of dual pricing strategies, where research-based manufacturers seek to prevent parallel trade, suggests that parallel trade may not be protected in the future. Recent case law tentatively indicates that preventive strategies may be legitimately pursued under certain conditions, perhaps undermining the Commission's stance on parallel imports. For example, in its ruling in the GlaxoSmith Kline (GSK) case, the Court of First Instance (CFI) rejected the Commission's argument that GSK's policy had the object of restricting competition.[220] It held that the Commission should have fully examined the full regulatory and economic context. In the meantime, appeals to the ECJ have been lodged against the CFI ruling.

Market Authorization – Centralized & Decentralized systems

As discussed in the previous chapter, the EMEA conducts a centralized authorization process that underwent reforms in 2005. There are two methods for obtaining marketing approval of medicines. First, through a centralized application to the EMEA or a decentralized application for authorization in an individual state, which could be under mutual recognition procedure (MRP), governed by Regulation 726/2004. Alternatively, the Community Code relating to medicinal products for human use sets out the general rules applicable to medicinal products.[221] Under the MRP procedure, a national marketing authorization is filed in the reference Member State. If granted, other Member States must then approve the marketing authorization, if they fail to raise an objection after reviewing the assessment report from the reference Member State.

Generic medicines

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[220] Case T-168/01 GlaxoSmithKline Services/Commission [2006] II-2969.
[221] Directive 2004/27/EC amending directive 2001/83/EC on the Community code relating to medicinal products for human use, OJ 2004 L 136/34.

Generic competition is encouraged at European and national level.[222] However, the research-based industry is also insulated from generic competition by a number of legal and regulatory instruments which aim to encourage R&D by granting innovative products a de facto market exclusivity, for a limited period of time. Recent amendments to the European product licensing regime have introduced a new term – 'market exclusivity' to prevent the marketing of a generic drug during the two years following the expiry of the data exclusivity period. The new European legislation has lengthened the overall period of time that generic manufacturers must wait prior to registering their products. In addition, generic manufacturers claim that the registration and use of generic medicines is frustrated by the lack of EU-wide harmonization of indications of reference products (also known as 'originators') on which the generic applicant must base its common European-wide approval. This is, in part, attributed the extension of intellectual property rights protection (IPR) for some pharmaceuticals, through the combination of patent, trademark and copyright.[223]

Competition Law and IPRs

The Commission imposed a significant fine of €60 million against Astra Zeneca (AZ) in May 2006 for abusing its dominant position by delaying generic market entry of generic copies of its best-selling product, Losec (a proton-pump inhibitor).[224] AZ sought to obtain additional patent protection in a number of different countries to protect Losec's market position in Europe after expiry of the basic patent on the active ingredient. AZ's 'misleading representations' to the

[222] In its Communication of July 1, 2003, the Commission confirmed that "generic medicines can provide significant savings to healthcare providers. However, their use must be balanced with sufficient incentives to develop innovate products.
[223] E Larson, 'Evolution of IPR and Pharmaceutical Discovery and Development'. Presentation. Available at www.nationalacademies.org/step/Larson_ppt.ppt.
[224] Case Comp/A.37/37.507/F3.

patent authorities were found to be abusive, since they were part of a centralized strategy to discourage generic market entry. The Commission also condemned AZ's selective withdrawal of Losec's market authorization in favour of an improved version in the countries where generic competitors and parallel importers would have been able to launch generic copies unless the 'reference product' was made unavailable. As a result, regulatory reforms have been adopted that should prevent this type of conduct in the future.

The Astra Zeneca decision is the first time that the Commission has relied on Article 82 to punish conduct occurring under the jurisdiction of national patent offices and regulatory authorities responsible for marketing authorizations. The Commission drew an important distinction between marketing authorizations and patents. Market authorization merely grants the right to sell products, and is not intended to reward innovation like patents and data exclusivity. Currently, the decision is under appeal. Meanwhile, the Commission has initiated similar investigations into allegations of abusive conduct by other pharmaceutical companies.[225]

Commission Inquiry

The launch of the Commission's sector-wide inquiry of pharmaceutical competition 16 January 2008**,** were launched with dawn raids at the offices of at least eight major pharmaceutical companies. The inquiry will focus on two issues: cartel agreements and abuse of dominant position. Settlements of patent disputes are one example of anticompetitive agreements between pharmaceutical companies. When companies create artificial barriers to product entry, through misuse of patent rights, vexatious litigation or other means this is unlawful as an abuse of dominant position. The sector-wide inquiry signals the Commission's willingness to address the impact of competition on the patent strategies of the manufacturers, particularly towards the end of a product's patent life. Whether this new addition to the Commission's tool kit will be

[225] COMP/39.246, available at http://ec.europa.eu/comm/competition/antitrust/cases/decisions/39246/initiations.pdf.

effective will depend on the enforcement measures taken on completion of the Commission's final report, planned for spring 2009.

B. Medical Devices Regulation

Defining and classifying medical devices is one of the biggest challenges of effective regulation. EU law constructs a definition both in terms of what medical devices are, how they are used, and by distinguishing what they are not. Medical devices are not organs, transplants, human tissue-engineered products, cosmetics or prescription drugs. Medical devices can be used in clinical practice, research, laboratory testing, and patient care. They can be subdivided into medical-electrical devices; non-electrical products, implantables, and diagnostic products. There are three primary directives specifically regulating pre- and post- marketing requirements for medical devices:

Active Implantable Medical Device Directive (AIMDD) 90/385/EEC

Medical Device Directive (MDD) 93/42/EEC

In-vitro diagnostic Medical Devices Directive (IVDD) 98/79/EEC

With some borderline products, determining which of the directives to apply is less than straight forward. Classification of a medical device depends on the duration of contact with a person, degree of invasiveness, and the anatomy affected by the use or the potential hazard posed by the device.[226] Guidelines known as MEDDEV documents further assist members with interpreting medical device regulation, but are not legally binding. The Medical Device Expert Group (MDEG), a stakeholder group including industry associations, Member State representatives, and user associations, adopt the documents that are then published by DG Enterprise & Industry.

[226] Guidelines for the classification of medical devices, MEDDEV 2.4/1 Rev 8, July 2001

The medical devices directives address a wide range of issues including labelling, instructions for use, and rules clinical investigations. There are also several other directives that govern broader issues but also apply to medical devices such as the information technology equipment directive, liability for defective products, and general product safety.

Member States have considerable discretion to set prices, and to define monitoring and national enforcement procedures to ensure compliance with Community directives. Despite EC attempts to strengthen medical vigilance and the reporting of adverse incidents occurring during the deliver of medical treatments, wide variation in the level of safety enforcement persists.[227] Notified Bodies, certification organizations that conduct formal audits of products and quality systems, play a vital role in national regulation. They have a duty to be independent, competent, and impartial, which requires experienced and knowledgeable staff, who are in short supply in some Member States. Most countries have at least two Notified bodies, while Germany has at least 25.[228] Notified bodies coordinate their activities and judgments during meetings of the Co-ordination of Notified Bodies Medical Devices (NB-MED) group.[229] The EU regulatory scheme also includes post-marketing surveillance measures and a vigilance system, including a safeguard clause for incident reporting.[230] Guidelines emphasize the need to address consumer/patient safety and adverse incident reporting through a performance monitoring system internal to manufacturers and product field performance. Thus, manufacturers must comply with safety obligations at several points during the lifecycle of their products. If a regulator finds that a manufacturer is noncompliant with these obligations, the manufacturer may be required to take

[227] Altenstetter, C. (2003) "EU and Member State Medical Devices Regulation", International Journal of Technology Assessment in Health Care. 19:1, 228-248.
[228] Ibid, 241.
[229] COM (2003)386
[230] MEDDEV 3/93, rev. 2

corrective action or to withdraw and/or replace the device.[231] This regulatory framework has eroded the boundaries between EU and Member State competences and responsibilities. As Altenstetter concludes, "European regulatory processes and local decisions aimed at containing the rising costs of medical technology are becoming increasingly intertwined, and the era of looking at funding, coverage, and reimbursement issues solely through the lens of domestic politics and jurisdiction has definitely come to an end."[232]

[231] Group MB. (1998) Postmarketing surveillance: Preventative and corrective action. In J. Adcock, S. Sorrel, and J. Watts (eds) Medical Devices Manual (rev.) Haslemere: Euromed Communications Ltd; 20.1-20.16.
[232] Altestetter, 2003.

Table 2. Interface of Industrial Policy with Healthcare and Public Health Policy

	Medicinal products	Medical Devices
Health Care Policy	Cost Containment and improving efficiency in health care services & care Cost-effective medication Regulating Dr and consumer behaviour vis-à-vis medicines Generic promotion and/or substitution Improving prescribing Ensuring access to medicines	Cost-containment and improving efficiency using devices in medical-surgical procedures, assisting patients, and improving the efficiency of in vitro diagnostic tests Cost-effective medical-surgical procedures and diagnostic tests Regulating dr. consumer behaviour vis-à-vis medical devices Substituting medical devices for pharmaceutical treatment & vice-versa Improving the use of medical devices and diagnostic tests Ensuring access to innovations Improving clinical outcomes
Industrial Policy	Promote local research and development Intellectual property Supporting local scientific community Generating and protecting employment Promoting small and medium enterprises Contributing to positive trade balance Sustain the university (public sector) research base	Promote local research and development Protection of property rights, and special status on patenting in the EU Supporting local scientific community Generating and protecting employment Promoting small and medium enterprises Contributing to positive trade balance Sustain the university (public sector) research base
Public	Safe medicines	Safe medical devices, classified by risks

Health Policy	High quality preparations Efficacious treatment Innovative cures Patient access to medicines	High-quality devices performing throughout the life cycle of the product High-quality and reliable in vitro diagnostics Efficacious medical-surgical procedures 'Breakthrough' innovations, alternative treatments, and reliable diagnostic tests Patient access to innovative surgical procedures diagnostic tests and patient-assisting devices Safe use of medical devices Improving health and safety

Source Altenstetter and Permanand, 2007[233]

5. Conclusion

EU regulation of health policies and systems approaches from several different angles both direct and indirect. The Commission is the institution most actively engaged in health sector issues, but the ECJ also plays a crucial role in interpreting the application of EC laws to the health sector. However, there are many more actors who are formally or informally part of the EU system engaged in health policy from the EMEA to the European Public Health Alliance. The legal basis for these activities stems from the Treaty Establishing the European Community, but is limited to complementing national policies and cannot require the harmonization of national laws. A wide variety of EU regulations and directives also impact the

[233] Altenstetter, C. and G. Permanand, (2007) "EU Regulation of Medical Devices and Pharmaceuticals in Comparative Perspective", Review of Policy Research, 24:5 pp. 385-405.

health of Europeans to ensure the safety and quality of blood products, food, pharmaceuticals, while others aim to limit the harmful impacts of tobacco, alcohol and drugs.