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EU competition law and health policy

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1. Introduction

Competition law has been an essential tool in the establishment of the single European market (SEM) and the European Community. The EC Treaty reflects the Community's evolution from an economic organization with extensive competence to regulate the SEM. Social policy, on the other hand, reflects the diversity of Member States' social systems and remains primarily the jurisdiction of national governments. EU policies reflect a balance between European welfare state principles of universal access to public services and social solidarity, and the competition law principles of market integration and economic freedom.

The enforcement of EC competition law by the European Court of Justice (ECJ) and national courts has been a significant driver pushing health policy onto the European Union agenda.¹ Community competition rules prohibit undertakings from participating in anti-competitive activities, such as agreements to set prices or abuse of dominant position.² Since the definition of an 'undertaking' focuses on the function of the organization rather than its status,³ it has been applied to both private and public health care services.⁴ Article 152(5) EC leaves health provision and financing squarely under the jurisdiction

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¹ M. McKee, E. Mossialos and R. Baeten, *The impact of EU law on health care systems* (Brussels: PIE-Peter Lang, 2002).

² Articles 81 and 82 EC.

³ Joined Cases C-159/91 and 160/91, *Poucet and Pistre* [1993] ECR I-637.

⁴ Case C-205/03, *Federacion Nacional de Empresas de Instrumentacion Cientifica Medica Tecnica y Dental (FENIN) v. Commission of the European Communities* [2006] ECR I-6295; Case T-289/03, *British United Provident Association Ltd (BUPA) and Others v. Commission* [2008] ECR II-81.

of Member States, as long as other EU laws, including competition rules, are followed.

Chapter 7 in this volume presented the context of this debate by analysing competition law and public services. This chapter will present specific cases where competition laws have been applied to the health sector, providing a basis for analysis of the current state of EU law and the indications for the road ahead. The most important Treaty provisions governing competition law are Articles 81, 82 and 86 EC, found in Section 1 of Title VI.⁵ Chapter 9 in this volume focuses on Section 2 of Title VI of the Treaty, which includes Articles 87–9 EC governing state aid and public procurement.

To determine whether competition law applies and whether there is a justification for state regulation restricting competition under Article 86 EC requires detailed case-by-case analysis. The jurisprudence has created legal uncertainty regarding the application of EU law to national health systems and raised questions as to the Community's role in further developing a European health policy. In 2006, the Commission conducted a consultation exploring Community action on health services.⁶ The two primary issues of concern were the legal uncertainty created by ECJ rulings and how the Community could support Member States in the health services sector. In response to the process, Member States expressed an interest in receiving clarification on cross-border care, but emphasized a preference for national control of health systems under the subsidiarity principle.⁷ Thus, the tension between competing interests has been building. Member States would prefer to protect national health systems from external interference, while the Commission tries to raise its profile and influence through the publication of consultations and Communications that attempt to clarify the EU's role in health policy. Meanwhile, the ECJ and national courts continue their case-by-case analysis, defining few general rules for national policy-makers to follow.

The EU is at a legal crossroads, where economic policy and social policy collide. The case-law of the European Court of Justice is at the centre of the conflict, since it has applied competition law to

⁵ Articles 83 through 85 EC detail the duties of the Council and the Commission, as well as the entry into force of the provisions.

⁶ European Commission, 'Consultation regarding Community action on health services', SEC (2006) 1195/4, 26 September 2006.

⁷ *Ibid.*

the health sector in several cases.⁸ The imbalance between strictly delineated economic laws and nationally-defined social policy goals has been characterized as ‘constitutional asymmetry’ by Scharpf.⁹ Traditionally, European governments have regulated the health care sector to ensure quality, efficiency and equity in health care provision and financing. Health system reforms have decentralized decision-making, encouraged greater competition on price and quality, and forced many European patients to exercise choice as consumers. The question arises, if Member States’ health systems incorporate market-based reforms, to what extent will competition law apply?

It is also important to note that EU laws apply uniformly across the Community regardless of domestic health care system structures.¹⁰ No two Member States share the same mechanisms for planning, financing and providing health services. European national health systems have evolved based on the unique political and economic development of each Member State. It is also irrelevant whether the patient pays for services and is later reimbursed by the state, or if the services are free at the point of use. Depending upon the degree to which Member States employ market-based mechanisms to finance, manage and provide health services, the impact of competition law will vary. This diversity further complicates any attempt to harmonize EU health policy legislation.

Since health care has the potential to be both commercial and international, it is a test case for the conflict between EU economic policy and the expansion of EU social policy into new areas, including health care financing and provision. This chapter will first explain the circumstances when EU competition law applies, and will introduce some of the complexities of defining undertakings caused by recent policy developments moving health services towards market competition. The following section considers Articles 81 and 82 EC, which prohibit undertakings from forming anti-competitive cartels and abusing a dominant position. Next, Article 86 EC will be introduced in order to discuss the limitations on Member State regulation

⁸ Case C-205/03, *FENIN*, above n.4; Case T-289/03, *BUPA*, above n.4, Case C-372-/04, *Watts* [2006] ECR I-4325.

⁹ F. Scharpf, ‘The European social model: coping with the challenges of diversity’, *Journal of Common Market Studies* 40 (2002), 645–70.

¹⁰ Case C-385/99, *Müller-Fauré v. Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen* [2003] ECR I-4509.

and the potential to use the ‘services of general economic interest’ exception to permit restriction of competition when providing health services. Lastly, the chapter reviews EU competition enforcement mechanisms that have increased scrutiny of health-related cases as a result of decentralized enforcement delegated to national competition authorities (NCAs). Where possible, examples from a wide sample of European countries are provided; however, this chapter is not a comprehensive analysis of the current state of affairs in all twenty-seven EU Member States.

2. When does competition law apply?

Article 81(1) EC 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’. As explained in greater detail in Chapter 7 in this volume, the concept of undertakings is not defined in the Treaty but by a series of ECJ cases. Undertakings are classified not by their structure but by their actions, the context in which they act, and the purpose and effect of their actions.¹¹ The definition evolves from the Court’s attempt to distinguish between government functions and the private sector. Activities that are an exercise of sovereign power or are social activities based on solidarity are exempted from competition law.¹² Undertakings engaged in economic activities are subject to competition law, unless the ‘services of general interest’ exemption applies.¹³

Since the 1980s, reforms intended to improve efficiency in the health sector have encouraged greater privatization of public services. The gradual introduction of market forces to particular health services makes the delineation of undertakings dependent upon the specific nature of the activities, the context in which the services are provided, as well as a consideration of how the services will be paid for and by whom. It is possible that a government-owned hospital could engage in economic activities as an undertaking by providing services

¹¹ Joined Cases C-159/91 and 160/91, *Poucet and Pistre*, above n.3.

¹² Case C-364/92, *SAT Fluggesellschaft v. Eurocontrol* [1994] ECR I-43.

¹³ Case C-475/99, *Ambulanz Glockner v. Landreis Sudwetpflaz (Glockner)* [2001] ECR I-8089; Case T-289/03, *BUPA*, above n.4.

to private patients. Similarly, a private clinic could be entrusted by the government to provide certain health services that would be protected from competition law as a social activity based on the principle of solidarity.

Competition law does not apply to governments exercising sovereign powers under the principle of *imperium*.¹⁴ Acts emanating from the state's *imperium* are unique to sovereign governments and include defence, environmental surveillance or granting a licence.¹⁵ By analogy, it could be argued that a ministry of health exercises sovereign authority when setting public health priorities, defining the scope of practice for health professionals and setting tariff rates for public health services. Each of these non-economic activities is exempted from competition law, even though they have an impact on the health care market. However, this is not a blanket exception. If the state engages in economic activity, such as trading in products or services, alongside private undertakings, the sovereign exemption does not apply.¹⁶ In order to determine whether the state is exercising public powers or carrying on economic activities, it is necessary to conduct a case-by-case analysis.¹⁷ For example, the municipality granting a license to sell tobacco is acting in its public authority capacity,¹⁸ while a public clinic selling flu shots is engaged in an economic activity.

Entities are not undertakings if the services provided meet the criteria for social activities set out by the ECJ in the *Poucet and Pistre* case¹⁹ and its progeny. In this case, the plaintiffs challenged the monopoly rights of two social security schemes in France. The schemes were based on the principle of solidarity, since membership was compulsory; contributions were calculated based on income regardless of the member's state of health; and all members received the same benefits. As such, these schemes were fulfilling an exclusively social function in the discharge of their legally defined duties. Similarly, in *INAIL*, the Court found that a compulsory scheme providing workers'

¹⁴ Case C-343/95, *Cali & Figli v. Servizi Ecologici Porto di Genova (Cali)* [1997] ECR I-1580.

¹⁵ A. Winterstein, 'Nailing the jellyfish: social security and competition law', *European Competition Law Review* 6 (1999), 324–33; *ibid.*

¹⁶ Case C-41/90, *Hofner and Elser* [1991] ECR 1979.

¹⁷ Case 118/85, *Commission v. Italy* [1987] ECR 2599.

¹⁸ Case C-387/93, *Banchemo* [1995] ECR I-4663.

¹⁹ Joined Cases C-159/91 and 160/91, *Poucet and Pistre*, above n.3.

compensation insurance operated on the principle of solidarity, since the benefits and contribution levels were defined by law.²⁰ Therefore, this state-regulated insurance fulfilled a purely social purpose and was not an economic activity.

The Court has reviewed the activities of both health insurers and health providers to determine whether their activities violate competition law. In Germany, sickness funds jointly set maximum fixed amounts payable for some prescription medications, known as reference pricing. Pharmaceutical companies complained that the sickness funds were colluding to fix prices. In *AOK*,²¹ the ECJ held that the sickness funds were not undertakings, since they were organized under the solidarity principle and performed a purely social function. Employees are obliged to be insured by the statutorily regulated sickness funds. The fact that the funds compete to attract members did not override the social nature of the insurance schemes. The Court also found that setting reimbursement rates was an integral part of limiting costs for state-mandated benefits.

In the process of performing social functions, health care providers must naturally engage in some economic activities. In the *FENIN* case, an association of businesses complained that hospitals in the Spanish national health service were in violation of competition laws by delaying to pay invoices, and that this was an abuse of their dominant position. The Court of First Instance found that the hospitals were not undertakings, as they are funded through social security contributions and provide health services free of charge based on the solidarity principle. The ECJ then upheld the reasoning of the lower court, concluding that the purchasing activity was not economic, since the goods purchased would be used to provide public services and would not be resold in the market. It follows that, where the purchasing function is part of the process to provide social services, it should not be judged as an economic activity merely because the goods must be purchased from the market.²² Thus, even though an organization does engage in some economic activities, competition law may not apply to its social activities based on the solidarity principle.

²⁰ Case C-218/00, *INAIL* [2002] ECR I-691.

²¹ Joined Cases C-264/01, 301/01, 354/01 and 355/01, *AOK Bundesverband v. Icbthyol-Gesellschaft Cordes (AOK)* [2004] ECR I-2493.

²² Case C-205/03, *FENIN*, above n.4.

On the other hand, the Court applied competition law in a case where social insurance institutions performed additional economic activities in competition with private insurance companies. It took this view in *Fédération française des sociétés d'assurance (FFSA)*,²³ involving a monopoly in the voluntary supplementary pension insurance sector. Even though the undertaking employed some elements of solidarity, the economic characteristics of the optional retirement scheme led to a finding that FFSA was an undertaking. The Court also deemed the insurance activity of compulsory, supplementary pension insurance funds to be economic in several cases, including *Albany*,²⁴ *Brentjens*,²⁵ *Bokken*²⁶ and *Pavlov*.²⁷ In each of these cases, the Court emphasized the fact that all these systems were financed according to the capitalization principle, whereby an explicit contribution to the budget is allocated to each member of the plan regardless of need.²⁸ Where the Court finds limited evidence of the solidarity principle due to the voluntary nature of the insurance scheme, competition law will apply.

It is difficult to derive a clear test from these cases. Determining the status of an undertaking and whether its activity is social or economic requires detailed analysis of the specific health programme and the circumstances of its operation. When competition law applies to a challenged activity, the Court will first decide whether the government is involved and the activity is exempted under the *imperium* principle. Then the Court will determine whether the actor is an undertaking engaged in an economic or social activity. The definition of undertakings that can be pieced together through the relevant ECJ judgments is an imprecise case-by-case approach that weighs several criteria. The most significant factors include: (a) whether the scheme is organized under principles of social solidarity, including legally standardized contribution and benefit levels free from risk selection; (b) whether membership in the system is compulsory; (c) whether the

²³ Case C-244/94, *FFSA* [1995] ECR I-4019, para. 17.

²⁴ Case C-67/96, *Albany* [1999] ECR I-5751, paras. 81 *et seq.*

²⁵ Case C-115/97, *Brentjens* [1999] ECR I-6025, paras. 81 *et seq.*

²⁶ Case C-219/97, *Bokken* [1999] ECR I-6121, paras. 71 *et seq.*

²⁷ Joined Cases C-180/98 to C-184/98, *Pavlov* [2000] ECR I-6451, paras. 114 *et seq.*

²⁸ N. Rice and P. Smith, 'Strategic resource allocation and funding decisions', in E. Mossialos *et al.* (eds.), *Funding healthcare: options for Europe* (Maidenhead: Open University, 2002).

scheme directly competes in the market with undertakings; and (d) whether the entity exercises independent discretion in providing services for profit or is following a delegated state mandate to provide public services. The Court will then analyse the nature of the activity itself, and whether it interferes with competition within the single market to the extent that it violates competition laws.²⁹

Applying the definition of undertakings to European health systems is complicated by the complex relationships between the public and private sectors. For example, if a municipality has contracted with a private service provider to manage a publicly-owned and funded facility that exclusively serves public patients, does that part of the provider's business qualify as a social activity exempted from competition laws? Alternatively, an organization that usually provides social services, such as a government-owned and operated public hospital, could engage in economic activity by providing services to private patients who pay directly for the treatments received. Reforms resulting in organizations that have mixed public and private funding and provide services to both public and private patients require detailed analysis to determine whether competition law applies. These situations also raise questions about state aid.³⁰ The important point here is that where the public entities are engaged in public-private partnerships, there is a risk that state aid prohibitions may be triggered.

To illustrate the complexity of the public-private and payer-provider relationships, one can consider the experiment with a general practitioner (GP) 'fundholding scheme' in the United Kingdom. GPs working as self-employed businesses consistently were recognized as undertakings providing medical services. The 1990 National Health Services and Community Care Act created a limited number of fundholding contracts between the National Health Service (NHS) and GPs for a range of medical services. These fundholders would then either provide the services themselves or contract with other providers for services not included in their practice, the idea being that the

²⁹ For further discussion on the topic of undertakings, see also Chapters 7 and 9 in this volume.

³⁰ The Treaty limits the granting of state aid to undertakings that distort competition in Article 87 EC. These issues are addressed in detail in Chapter 9 in this volume. The important point here is that where the public entities are engaged in public-private partnerships, there is a risk that state aid prohibitions may be triggered.

GPs would become price sensitive and more efficient. The question of whether to apply competition law is complicated by the type of contracts used between the NHS and the fundholders. While these contracts were legally enforceable, the subcontracts between the fundholders and NHS providers for additional services were ‘NHS contracts’, which are treated as public-service, intra-corporate agreements between a parent and its subsidiaries and therefore not legally enforceable and not covered by EU law.³¹ For the purposes of this discussion, the important point is that the fundholding system blurred the definition of GP practices. On the one hand, GP practices were private undertakings providing services as an economic activity. On the other hand, GPs were also treated as public contracting authorities purchasing social services for public patients on the basis of solidarity, an action that would be considered a social activity exempted from competition law. Since the scheme was short-lived, the courts never had the opportunity to scrutinize whether competition law would apply to the fundholding system, but it remains an interesting legal puzzle.

Another mixed public–private case arising in the United Kingdom was recently considered by the United Kingdom national competition authority, the Office of Fair Trading (OFT). The Bettercare Group complained that the North and West Trust was abusing its dominant position by purchasing services at an excessively low price. Trusts are organizations that are part of the NHS in each of the four nations of the United Kingdom. They purchase – and in some cases provide – primary health care and residential care services for patients within a defined geographical area.³² The North and West Trust provides residential care, and also contracts with the Bettercare Group to supply additional services. Thus, residents were offered a choice between publicly and privately provided services. It was this dual payer–provider function, creating competition between public and private facilities, that tipped the analysis towards the trust acting as an undertaking. On appeal, the Competition Appeal Tribunal (CAT) found that the

³¹ For more detailed analysis of the nature of these contracts, refer to P. Cohen, ‘The separation of purchaser from provider in health care systems and European Community law: the case of the British National Health Service’, LSE Discussion Paper No.1 (1994).

³² A. Talbot-Smith and A. Pollock, *The new NHS, a guide* (New York: Routledge, 2006).

Trust was an undertaking engaged in economic activities by providing services in the market, and sent the case back to the OFT to rule on the merits of the case. On remission, the OFT found that the Trust had not engaged in any abuse of dominance, since they did not have discretion to set prices. Further, the government bodies that set prices were not undertakings.³³ The fact that all of the services funded by the Trust were public services made the case difficult to reconcile with the ECJ ruling in *FENIN*. The OFT recognized that the application of the undertaking analysis may lead to a different result depending upon whether the entity also provides services in the market or merely purchases services.³⁴

The *Bettercare* case highlights the question of how the central government enforces EU obligations in a decentralized health system. Since the case was specific to a trust in Northern Ireland, applying the ruling to the other nations of the United Kingdom is difficult, as there are variations in the health system structure and the degree of private sector involvement. There are several different types of trusts in the United Kingdom health system that could be engaged in economic activities. The CAT held that the trust in the *Bettercare* case was an undertaking engaged in economic activities as a provider of services in the market. Most trusts, like primary care trusts (PCTs), fall within the NHS hierarchy and are managed by NHS employees. Some trusts function exclusively as payers contracting for services. Foundation Trusts (FTs) are hospitals that have been granted special status due to superior performance, placing them outside the NHS governance structure. FTs are public benefit corporations, ultimately accountable to the parliament, not the Secretary of State for Health. Both organizations contract with either NHS or private providers for services. FTs provide services to PCTs based on legal contracts, not public-service contracts. They have the discretion to set priorities, to dispose of property, to borrow funds from the private sector and to provide services to private patients.³⁵

Analysis regarding how competition law could apply to trusts in England's NHS is an open question worth further study. Initially,

³³ *BetterCare Group Ltd v. Director General of Fair Trade* (2002) 229 CAT 7.

³⁴ Office of Fair Trading (OFT), 'The Competition Act 1998 and public bodies', Policy Note 1/2004, OFT 443, August 2004.

³⁵ Talbot-Smith and Pollock, *The new NHS*, above n.32.

looking at the four part test for social activity detailed above, all NHS trusts are organized on the basis of social solidarity and provide services to all United Kingdom residents. However, there could be cases where the second two parts of the test may not be met. As discussed above, the Court would also consider whether the organization provides services that compete in the market and whether the organization's activities are narrowly defined by statute or if they enjoy independent discretion. FTs enjoy independent discretion to define business plans, to invest or dispose of assets and to enter into joint ventures with for-profit corporations for the sale of both NHS and non-NHS health care services, including private insurance.³⁶ On the other hand, they will be subject to government regulation, not within the NHS accountability framework like PCTs, but by an independent regulator.³⁷ Thus, whether the FT's activities were economic or social would depend on close scrutiny of the specific activities alleged to be anti-competitive.

Similarly, the Finnish Competition Authority (FCA) has investigated public hospitals for their expansion into private health services at below market rates. The Pirkanmaa Hospital District's Public Laboratory Enterprise was considered to be an undertaking with a dominant position in the market. The FCA warned the hospital district that 'when public production is marketized, the authorities should ensure that private players are provided with equal opportunities to compete in the field that used to be completely the responsibility of the public sector'.³⁸

Some statutory reforms adopted by national health systems also create new opportunities for challenges under competition law. For example, the privatization of hospitals could lead to the application of competition law. Germany, Austria and some new Member States have experimented with new forms of hospital ownership and management that establish complex public-private relationships. A study

³⁶ S. Boyle, 'What foundation trusts mean for the NHS', Report for the Overview and Scrutiny Committee of the Royal Borough of Kensington and Chelsea, January 2004, www.rbkc.gov.uk/howwegovern/yourcouncil/oscreport_foundationtrusts.pdf.

³⁷ Part 1, Section 2, The Health and Social Care (Community Health and Standards) Act 2003.

³⁸ Finnish Competition Authority, '2003 yearbook', www.kilpailuvirasto.fi/tiedostot/vuosikirja_2003_Englanti.pdf.

funded by the European Commission discovered that there were several reasons for public owners to privatize hospitals in Germany. Fiscal reasons included the need to reduce public debts and to be free of the responsibility to balance the financial deficits of hospitals, since the German financing system no longer guarantees full cost compensation. There is also external pressure from EU economic policies limiting public budget deficits. Public authorities following restrictive fiscal policies increasingly rely on privatizations to solve budget problems. These policies have led to both an increase in the number of private hospitals and a new type of hybrid, publicly-owned hospital with independent private status.³⁹ Whether these hybrid semipublic hospitals engage in social or economic activities must depend on the details of individual cases. These changes have also resulted in closer scrutiny by the German Competition Authority (GCA). The GCA has recently denied mergers in several cases where private hospitals have sought to acquire public facilities that could achieve excessive dominance in local hospital markets.⁴⁰ Similarly, in Austria, hospital reform has created publicly-owned but privately-managed hospitals. These reforms also have the goal of giving hospitals greater flexibility and independence from local political influence. Private managers outsource a larger portion of non-clinical services and establish public-private partnerships.⁴¹ This level of discretion and freedom to work with private patients could be characterized as economic activities subject to competition law.

Post-communist new Member States have gone through waves of health system reforms that also raise complex unanswered questions. Communist-era health systems were vertically integrated, and strictly

³⁹ Wirtschafts- und Sozialwissenschaftliches Institut (WSI), 'Liberalization, privatization and regulation in the German Healthcare Sector/ Hospitals', November 2006.

⁴⁰ German Competition Authority (GCA), Press Releases, 17 January 2008, www.bundeskartellamt.de/wEnglisch/News/2008_01_17.php; 29 April 2005, www.bundeskartellamt.de/wEnglisch/News/Archiv/ArchivNews2005/2005_04_29.php; 11 September 2006, www.bundeskartellamt.de/wEnglisch/News/Archiv/ArchivNews2006/2006_09_11.php; and 8 November 2006, www.bundeskartellamt.de/wEnglisch/News/Archiv/ArchivNews2006/2006_11_08.php.

⁴¹ A. Fidler *et al.*, 'Incorporation of public hospitals: a 'silver bullet' against overcapacity, managerial bottlenecks and resource constraints? Case studies from Austria and Estonia', *Health Policy* 81 (2007), 328–38.

state controlled. After the fall of the communist governments, the health systems required significant capital investment to facilitate reorganization and modernization. However, these reforms were further frustrated by high demand for services as was customary under the old system, and a lack of public confidence caused by corruption. Within this context, new Member States also experimented with reforms opening up public health services to the private sector, especially in the case of hospitals. In Estonia, hospital reforms from 1994 to 2001 altered the legal status of many hospitals under private law, leaving their status ambiguous and their public service mandate unclear.⁴² In Lithuania, hospitals underwent similar periodic reforms following the collapse of the former Soviet Union. Since 1996, the health care system as a whole has been moving towards using contracts, as many health care institutions have been redefined as public not-for-profit entities with independent boards.⁴³ Recently, public-private partnerships (PPPs) have become increasingly popular. Many municipalities have new responsibilities to manage health services provision within newly decentralized health system reforms. The local governments have struggled with a lack of capacity or authority to manage health clinics owned by the Ministry of Health. Complexities over the tendering and contract management processes have required the passage of new legislation to facilitate the new arrangements.⁴⁴ The resulting lack of oversight and coordination in these cases opens questions about whether the provision of care in these quasi-public facilities should be characterized as economic or social activities. In the health sector, there are many examples of health system reforms that could dilute the social aspect of public services towards more market-based provision of health services. This shift towards emphasizing economic activities could lead to more health care organizations being designated as undertakings and, consequently, additional legal scrutiny under EU law.⁴⁵

⁴² T. Palu and R. Kadakmaa, 'Estonian hospital sector in transition', *Eurohealth* 7 (2001), 3.

⁴³ Z. Logminiene, 'Hospital sector reform in Lithuania', *Eurohealth* 7 (2001), 3.

⁴⁴ K. Kerschbaumer, 'Public-private partnerships in Eastern Europe', *Eurohealth* 13 (2007), 7–10.

⁴⁵ As undertakings, they may also be subject to additional financial reporting requirements. Directive 2005/81/EC on the transparency of financial relations between Member States and undertakings, OJ 2005 No. L312/47, further clarified the specifics of reporting requirements. For any of the health

3. Prohibited conduct under competition law

Once competition rules apply, there are extensive rules protecting the neutral playing field of the internal market stemming from the EC Treaty and secondary legislation. Consistent with the principles of economic freedom, EU competition laws prohibit cartels and the abuse of a dominant position from negatively affecting competition within the single market. Here, the discussion will focus on the rules and cases most relevant to the health care sector.

A. Cartels

Unlawful cartels are formed by agreements between undertakings that ‘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’ (Article 81 EC). In other words, any form of collusion with the potential to negatively interfere with competition is prohibited. Article 81 EC continues with a brief list of some examples of prohibitive conduct, including price fixing, limiting production or sources of supply, or requiring supplementary contract terms extraneous to the essential agreement.

Traditionally, cases in this area involve markets for goods rather than service provision. In the health care sector, several cases have been heard in national courts concerning anti-competitive cartels dealing in pharmaceuticals, medical devices or related services.⁴⁶ In 1999, there was a case in Italy against two pharmaceutical companies for colluding to fix prices and coordinate market share.⁴⁷ Recently, in Germany, four pharmaceutical wholesalers engaged in a ‘discount battle’ after Andreae-Noris Zahn AG (Anzag) increased its discounts to expand its market share. After Anzag decided to end this price war, the wholesalers exchanged information about customer pharmacies and

organizations that could be engaging in economic activities as undertakings, the administrative burden alone of establishing separate accounting procedures will be extremely costly and time consuming. However, it is unclear when financial reporting rules apply, how they should be enforced and the extent of penalties for violations.

⁴⁶ For further analysis of the pharmaceuticals market, see Chapter 15 in this volume.

⁴⁷ Italian Antitrust Authority (IAA), Press Release, 22 July 1999, www.agcm.it/eng/index.htm.

monthly turnovers to redistribute the pre-existing market share. The German Competition Authority found that there was an intentional agreement constituting a quota cartel bordering on a price-fixing cartel and fined all four companies, as well as seven executives personally.⁴⁸ In France, the Competition Council fined two companies for colluding to share the market for medical devices during a public tender and reached a settlement with four pharmaceutical groups for anti-competitive agreements in the distribution of pharmaceuticals.⁴⁹ In Latvia, the Competition Council fined a medical gas monopolist for price discrimination ranging from 54% to 281%.⁵⁰ Similarly, in Italy, four medical device companies refused to present tenders in the colostomy device market for two years in an effort to drive up prices, demonstrating an anti-competitive agreement.⁵¹ In Hungary, the Hungarian Competition Council (HCC) found that three corporations cooperated in violation of 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 anti-competitive agreement, but disagreed on the extent of the infringement upon competition and reduced the fines by 10%.⁵² More recently, the HCC fined a medical equipment distributor for establishing an exclusive distribution scheme.

The Danish Competition Appeals Tribunal overruled a decision by the Danish Competition Council deciding that a vertical agreement between pharmaceutical wholesalers and insolvent retail pharmacies was insufficient to unlawfully infringe upon competition. The Danish Pharmaceutical Association entered into an agreement with wholesalers to help insolvent retail pharmacies with special

⁴⁸ German Competition Authority (GCA), Press Release, 19 April 2007, www.bundeskartellamt.de/wEnglisch/News/Archiv/ArchivNews2007/2007_04_19.php.

⁴⁹ French Conseil de la Concurrence (FCC), Press Releases, 30 October 2007, www.conseil-concurrence.fr/pdf/avis/07d22.pdf; 20 January 2003, www.conseil-concurrence.fr/user/standard.php?id_rub=127&id_article=243.

⁵⁰ A. Rubene, 'The Latvian Competition Council fines the medical gas monopolist for the application of an unfair and discriminating price', *e-Competitions Law Bulletin* No. 16460 (2006).

⁵¹ Italian Antitrust Authority (IAA), Press Release, 8 August 2007, www.agcm.it/eng/index.htm.

⁵² Hungarian Competition Council, Press Release, 21 February 2007, www.gvh.hu/gvh/alpha?do=2&st=2&pg=137&m166_act=3.

credit terms. Once a retailer entered into such an arrangement, the agreement prohibited the retailers from switching between suppliers. The Competition Council ruled that the insolvency scheme violated Article 81 EC as an anti-competitive agreement. While the Appeals Tribunal agreed with the Council, it extended the analysis to consider that the Danish pharmaceutical market was highly regulated and the wholesalers were limited to competing on service and cost-based discounts. The facts further demonstrated that the Pharmaceutical Association had forced the arrangement on the wholesalers, rather than the wholesalers having exploited the retailers' weak bargaining position. Thus, the Appeals Tribunal found that the agreement was anti-competitive on its face, but that the evidence did not prove that the agreement restricted competition in violation of Article 81 EC.⁵³ This case is of particular interest because the language of Article 81 does not require a finding of serious infringement, only that it may affect trade. The Appeal Tribunal could have ruled based on the second requirement of Article 81(1) – that the object of the agreement was not to distort competition but to prevent market consolidation. However, the Tribunal instead limited the scope of the article, increasing the burden of proof to include a showing of serious infringement.

In the area of health services, agreements among providers or professional associations could be construed as anti-competitive cartels. NCAs and national courts in several Member States have found cases of unlawful price fixing agreements made by professional associations. As early as 1992, the Finnish Competition Council found that the Finnish Medical Association and Dental Associations had violated the price cartel prohibition by recommending prices to members.⁵⁴ The Austrian Federal Supreme Court found that an association of pharmacists had violated competition law by producing and distributing a

⁵³ Danish Competition Authority, 'Decision by the Danish Competition Appeals Tribunal, the insolvency scheme of the pharmaceutical sector', Press Release, 8 June 2007, www.ks.dk/english/competition/national-judgments/national-judgments-2007/2007-06-08-decision-by-the-danish-competition-appeals-tribunal-the-insolvency-scheme-of-the-pharmaceutical-sector/.

⁵⁴ Finnish Competition Authority (FCA), Press Releases, 3 November 1992 and 29 October 1993, www.kilpailuvirasto.fi/cgi-bin/english.cgi?sivu=cartels.

list of selling prices for pharmaceuticals and accessories.⁵⁵ Similarly, the Czech, Greek, Hungarian, Italian and Portuguese competition authorities each fined professional health associations for anti-competitive practices setting fees.⁵⁶ The Irish Competition Authority has settled collusion cases against the Dental Association, the Hospital Consultant Association and the Medical Organization prior to the Irish High Court reaching a judgment. All three of these cases involved the associations encouraging their members to threaten withholding services if their demands were not met.⁵⁷ The prevalence of cases against professional associations may be further evidence of the erroneous assumption that EU laws do not apply to the health sector.

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 included an anti-competitive restriction in their membership rules. The chemists' professional code of conduct included a provision restricting the advertising and sale of product samples, while other retailers are not similarly restricted. When the association discovered that a chemist was selling samples for a nominal fee, the association threatened to take legal action against him. The Court found that both the section of the professional code at issue and the threat of legal action violated German competition rules.⁵⁸ The French Constitutional Court was asked to strike down a French law that established a monopoly for

⁵⁵ Case 16 Ok 14/97, *Apotheker*, Austrian Federal Supreme Court, 23 June 1997, www.kartellrecht.at/OGH14-97.html.

⁵⁶ Czech Office for the Protection of Competition, Press Release, 17 February 2003, www.compet.cz/en/information-centre/press-releases/competition/czech-medical-chamber-fined-450000-czk/; Greece Competition Authority, 'Annual report on competition policy in Greece 2005', www.epant.gr/img/x2/news/news16_1_1190293793.pdf; Hungarian Competition Authority, 'Annual report on competition law and policy developments in Hungary 2005', www.gvh.hu/domain2/files/modules/module25/pdf/GVH2005AnnualReport.pdf; Italian Antitrust Authority, '2000 Annual Report', www.agcm.it/eng/index.htm; and Law Business Research, 'Portuguese Competition Authority fines professional associations', *Global Competition Review* 8 (2005), 45.

⁵⁷ Irish Health Insurance Authority, Press Releases, 28 April 2005, www.tca.ie/NewsPublications/NewsReleases/NewsReleases.aspx?selected_item=43; 28 September 2005, www.tca.ie/NewsPublications/NewsReleases/NewsReleases.aspx?selected_item=31; and 28 May 2007, www.tca.ie/NewsPublications/NewsReleases/NewsReleases.aspx?selected_item=196.

⁵⁸ *Re A Pharmacist's Sale of Stock*, [1994] ECC 275.

licensed opticians as anti-competitive. A distributor of contact lenses complained that the French law requiring that suppliers of optical care appliances be managed by qualified opticians enforced by the optician's trade association constituted either a concerted practice or an abuse of a dominant position violating Articles 81 and 82 of the EC Treaty. The French court rejected the argument and held that the sale of contact lenses may be restricted with the aim of protecting public health. The court also explained that professional persons or trade associations, such as the opticians, joining together to enforce the observance of laws favourable to them cannot, in the absence of specific allegations of discrimination, constitute a violation of competition laws.⁵⁹ These rulings demonstrate that national courts have permitted specific restrictions on competition as justified by public health concerns so long as the national court or ECJ finds that the means used to protect public health are proportional to the limit on trade.

More recently, the Belgium Supreme Court heard an appeal filed by a pharmacist who was sanctioned for violating a regulation of the local association of pharmacists by opening his pharmacy on a Saturday afternoon. The pharmacist argued that he was exercising his right to freely practice his profession and that the regulation prohibiting shops from opening during scheduled on-call service violated the Belgian Competition Act. The Court agreed – as an undertaking, the Order of Pharmacists should use on-call service to guarantee regular and normal administration of health care but must also be consistent with the Competition Act. The Court sent the case back to the Appeals Council to determine whether the opening of a pharmacy beyond normal opening hours 'disrupts or threatens the continuity of the administration of health care'.⁶⁰ Each of these cases found that domestic regulation of pharmacists was in conflict with competition law prohibiting anti-competitive collusion by cartels, as found in Article 81 EC.

The more complex cases for professional associations are agreements that raise barriers to entry. Professional associations often serve dual public and private functions. States may delegate the regulation of the profession to peer organizations that must maintain

⁵⁹ *Laboratoire de Prothèses oculaires v. Union nationale des syndicats d'opticiens de France* [1994] ECC 457.

⁶⁰ Joris Ballet, 'The Belgian Supreme Court held that obligatory opening and closing hours for pharmacists violate the Competition Act', *e-Competitions Law Bulletin* No. 15370 (2006).

minimum quality standards to protect the public from unskilled or inexperienced practitioners. These associations may also advocate for the business interests of their members who are undertakings, which could violate either the cartel restrictions or abuse of dominant position discussed below. Unfortunately, the case-law to date is thin on this complex topic.

Exclusions

The prohibition against anti-competitive cartels is inapplicable where the undertaking's actions are restricted by law. The cartel prohibition applies only to anti-competitive conduct displayed by undertakings on their own initiative.⁶¹ If the state has regulated the economy in the interests of public policy – by setting official prices, for example – the participation of an association in the scheme does not violate Article 81 EC.⁶² Notwithstanding the absence of a prohibited cartel agreement, the ECJ considered whether a Member State deprived any of its own regulations of their state character by delegating the responsibility for decisions affecting the economic sphere to private undertakings.⁶³ The association concerned cannot be accused of concluding an agreement in violation of Article 81 EC where the Member State transfers the responsibility for intervening in economic processes to the association. Consequently, the Member State is not allowed to delegate sovereign powers of economic regulation to an association.⁶⁴ In the *Reiff* and *Delta* cases, the Court found that, where the competent public authorities were experts in the field and were not bound to follow industry or association recommendations, and where the

⁶¹ Joined Cases C-359/95 P and C-379/95 P, *Ladbroke Racing* [1997] ECR I-6265, para. 33.

⁶² Case C-38/97, *Librandi* [1998] ECR I-5955, paras. 30 and 34; Case C-185/91, *Reiff* [1993] ECR I-5801, paras. 15–9; Case C-153/93, *Delta* [1994] ECR I-2517, paras. 15–8; Case C-96/94, *Centro Servizi Spediporto* [1995] ECR I-2883, paras. 22–5.

⁶³ Case C-38/97, *Librandi*, above n.62, para. 26; Case 267/86, *Van Eycke* [1988] ECR 4769, para. 16; Case C-185/91, *Reiff*, above n.62, para. 14; Case C-153/93, *Delta*, above n.62, para. 14; Case C-96/94, *Centro Servizi Spediporto*, above n.62, para. 21.

⁶⁴ H. Schröter, 'Kommentierung der Artikel 81–83 EGV', in H. von der Groeben and J. Schwarze (eds.), *Kommentar zum Vertrag über die Europäische Union und zur Gründung der europäischen Gemeinschaft*, Vol. 2, 6th ed. (Baden Baden: Nomos Verlag, 2003); see Case C-38/97, *Librandi*, above n.62, para. 26; Case 267/86, *Van Eycke*, above n.63, para. 16; Case

ministry retained final approval of the decision, the Member State had not delegated its authority.⁶⁵ In the *Centro Servizi Spediporto* and *Librandi* cases, the Court based its decisions on the fact that the competent public authorities sought the opinions of other public and private institutions prior to their approval of proposals, or even fixed the tariffs ex officio.⁶⁶ Similarly, an undertaking cannot be penalized for violation of Article 81(1) EC where the conduct was required by national legislation.⁶⁷ In *CIF*,⁶⁸ the Italian NCA was obliged to dis-apply national law that hindered competition by establishing an anti-competitive cartel. Although there are few cases arising from health sector regulation, these public transport cases are analogous.

Employing the principle of proportionality, the Court permits restrictions on competition to protect a legitimate national interest. Although the *Wouters* case concerns the Dutch bar association, the Court's analysis could easily be applied to the regulation of medical professions as well. Lawyers challenged the bar association rule prohibiting multidisciplinary partnerships between lawyers and accountants as a restriction of the creation of a new form of business in violation of competition law. The Court held that Article 81(1) EC does not apply, since the bar association was entrusted to ensure the proper practice of the legal profession and a multidisciplinary practice could create conflicts of interest for the lawyers' clients. The Court determined that national interests took priority over the limited restriction of competition, by applying a proportionality test.⁶⁹ Thus, the Court could strike a similar balance between narrow restrictions on competition law and specific categories of public service policies. In the health sector, there arises a similar conflict of interest where doctors are paid by private insurance for some patients and public insurance for others. Where the doctors have different incentives for

C-185/91, *Reiff*, above n.62, para. 14; Case C-153/93, *Delta*, above n.62, para. 14; Case C-96/94, *Centro Servizi Spediporto*, above n.63, para. 21.

⁶⁵ Case C-185/91, *Reiff*, above n.62, paras. 21–3; Case C-153/93, *Delta*, above n.62, paras. 20–2.

⁶⁶ Case C-96/94, *Centro Servizi Spediporto*, above n.62, paras. 27–30; Case C-38/97, *Librandi*, above n.62, paras. 31 and 35.

⁶⁷ Case C-198/01, *Consorzio Industrie Fiammiferi (CIF) Autorita Garante della Concorrenza e del Mercato* [2003] ECR I-8055.

⁶⁸ *Ibid.*

⁶⁹ Case C-309/99, *J. C. J. Wouters et al v. Algemene Raad van de Nederlandse Orde van Advocaten (Wouters)* [2002] ECR I-1577.

providing different treatments, conflicts could easily arise where the private patients could receive treatment earlier but at a higher cost, causing a welfare loss to the health market.

Though rare, the Court has also carved out an exception for one specific type of agreement relevant to the health care sector. Collective bargaining agreements between labour and management are not subject to competition law. The Court found that social policy concerns would be significantly compromised if management and labour were subject to Article 81(1) EC when negotiating and implementing changes to working conditions.⁷⁰ Scholars have argued that *Albany's* rationale is unique, in that the Court rarely singles out a narrowly specified type of agreement for special exceptions. Since this ruling is so narrowly tailored and the revised Article 152 EC on public health does not reference any analogous consideration, it is unlikely that the Court would choose to exclude a particular type of health sector agreement from competition law.⁷¹ But the ruling is relevant for health policy-makers to keep in mind when considering system reforms that may have an effect upon labour relations.

The Dutch Competition Authority (DCA) also found that agreements do not violate Article 81 where collective purchasing of goods or services enhances consumer welfare by containing costs while restricting competition. The DCA preliminarily ruled that an agreement between five Dutch health insurers designating preferred suppliers distorted competition between the insurers. The DCA was asked to provide an informal opinion regarding the pilot pricing policy. The policy focused on three groups of medicines and defined the maximum price for reimbursement. Since these health insurers compete with one another, the DCA reviewed the agreement to determine whether competition among the insurers was restricted. The DCA concluded that competition was not compromised since the scope of the programme was narrowly limited and policy holders would benefit from the savings.⁷² Unfortunately, the DCA has not reported any

⁷⁰ Case C-67/96, *Albany International v. Stichting Bedrijfspensioenfonds Textielindustrie* [1999] ECR I-5751.

⁷¹ P. J. Slot, 'Applying the competition rules in the healthcare sector', *European Competition Law Review* 24 (2003), 580–93.

⁷² Dutch Competition Authority (DCA), 'Permitted pharmaceutical preference pricing policy for health insurers', Press Release, 22 June 2005,

subsequent analysis evaluating the policy or indicating whether the policy has been extended beyond the pilot phase.

B. Abuse of dominant position

The EC Treaty prohibits an undertaking with a dominant position from exploiting its market power to distort or restrict competition. When the Commission seeks to establish an infringement of Article 82 EC, it must show the following: 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 that there is no objective justification for the abuse. There are issues for health systems at several points in this legal analysis.

First, the market must be defined in terms of product, geographic area and time frame. Although abuse must affect trade between states, there is no requirement that the geographical area must include more than one state. The Court has considered the port of Genoa to be a market sufficient for these purposes, because of its role in trade throughout the EU.⁷³ Defining the market could be as straightforward as utilizing the specifications for a medical device under an anti-competitive exclusive distribution agreement. In the area of pharmaceuticals, defining the market is particularly challenging, given that several arguments similar to those made for patent protection could distinguish between products, such as method of delivery, treatment pathway or mode of action.⁷⁴ Defining markets in health services cases can be particularly challenging. Patients select providers based on a number of objective and subjective factors. Due to the high set-up and labour costs, it is difficult for hospitals to adjust their product mix when competition is introduced. A recent analysis of the partially-privatized Dutch hospital market found that both traditional and new economic approaches to defining markets were inappropriate for the Dutch health care system. Both the unique relationships

www.nmanet.nl/engels/home/News_and_publications/News_and_press_releases/2005/05_21.asp.

⁷³ Case C-179/90, *Merci convenzionali Porto di Genova* [1991] ECR I-589, para. 15; and P. J. Slot and A. Johnston, *An introduction to competition law* (Oxford, Portland: Hart, 2006).

⁷⁴ See Chapter 15 in this volume for a more detailed discussion of the pharmaceuticals market.

between health insurance contracts and hospitals, as well as the difficulty of mapping patient preferences, influence how markets could be defined in the Dutch health system.⁷⁵

The next step in the analysis is an assessment of the undertaking's dominance in the market. Thus, the first two steps in the analysis are closely linked. As the definition of the market narrows, it is easier to show that the undertaking is dominant in that market. In the past, the Commission was criticized for blurring these issues by tailoring the definition of the market to facilitate a finding of dominance.⁷⁶ In response, the Commission adopted the 'market definition notice' approach, based on economic theory, and thus formalized its methodology.⁷⁷ The market definition notice approach analyses whether there is sufficient demand and supply substitutability so that no undertaking influences the price of the goods or services in question.⁷⁸ Once it has been established that the undertaking is dominant in the market, the question then turns to whether it has infringed competition by abusing its dominance. Abuse is often categorized as either exploitative or exclusionary. Exploitative abuse includes monopolistic behaviours, including price fixing, selective contracting, reductions in quantity or quality, and refusal to modernize production or service provision. Exclusionary abuse raises barriers to entry, limiting competitors' participation in the market, such as in cases of refusal to deal.

As an example of exclusionary abuse, the Dutch Competition Authority investigated a case where a group of pharmacies shared considerable market power as a result of their joint participation in an electronic filing system that included patient information. Rather than focusing on the issue of whether this was an anti-competitive cartel, the DCA found that the electronic system promoted efficiency for the health system and improved services for patients. The anti-competitive

⁷⁵ M. Varkevisser *et al.*, 'Defining hospital markets for antitrust enforcement: new approaches and their applicability to the Netherlands', *Health Economics Policy and Law* 3 (2008), 7–29.

⁷⁶ L. Gyselen and N. Kyriazis, 'Article 86: the monopoly power measurement issue revisited', *European Law Review* 11 (1986), 134; S. Baker and L. Wu, 'Applying the market definition guidelines of the EC Commission', *European Competition Law Review* 19 (1998), 273–81.

⁷⁷ European Commission, 'Notice on the definition of relevant market for the purposes of Community competition law', OJ 1997 No. C372/5.

⁷⁸ For a more in depth discussion of these legal issues, see G. Monti, *EC competition law* (Cambridge: Cambridge University Press, 2007), Chapter 5.

behaviour was found to be an abuse of dominant position for the arbitrary exclusion of new pharmacies. Initially, the decision on whether to admit a pharmacy to the system was conducted by a vote among the participating members, without objective and transparent criteria or any procedure for appeal. This exclusion functioned as a barrier to entry into the market. As a result of the DCA's investigation and statement of objections, the pharmacists voluntarily adapted their admission rules. The DCA was sufficiently satisfied with the changes in the admission procedures to close the file.⁷⁹

Predatory pricing is another form of exclusionary abuse. As with all cases, the first step requires defining the market. In pharmaceutical markets, there are several possible approaches to defining markets, such as arguments made for patent protection or in pricing policies, distinguishing factors such as treatment pathways and modes of action. A recent case before the French Competition Council demonstrates how far the competition authority may stretch the market definition analysis when it is concerned about anti-competitive activities. The French NCA found that GlaxoSmithKline France (GSK) was liable for abuse of dominant position through predatory pricing in a market where Glaxo was not dominant. The Council's investigation determined that GSK sold Zinnat, an injectable antibiotic 'at a price below costs so as to deter generic drug manufacturers from effectively entering the hospital market'.⁸⁰ The Council also found that GSK was dominant in the market for injectable aciclovir (an antiviral drug) sold to hospitals. Rather than finding that there were associative links between the two markets, the Council found abuse of dominance because the predatory pricing was part of a global intimidation strategy to discourage generic manufacturers from entering other GSK hospital markets.⁸¹

In another predatory pricing case, an English firm, Napp, used market segmentation to become super-dominant in the supply of

⁷⁹ Dutch Competition Authority, Press Release, 6 June 2003, www.nmanet.nl/engels/home/News_and_Publications/News_and_press_releases/2003/03_22.asp.

⁸⁰ See also Chapter 15 in this volume. French Conseil de la Concurrence (FCC), Press Release, 14 March 2007, www.conseil-concurrence.fr/user/standard.php?id_rub=211&id_article=695.

⁸¹ A. Schulz and J. de Douhet, 'French Competition Council vs. GSK France: who is the predator?', eSapience Centre for Competition Policy, June 2007.

morphine tablets and capsules. Napp offered prices below costs to the hospital segment of the market, capturing more than 90% of the hospital market. Although the hospital segment is only 10–4% of the total market, it has greater strategic importance than the community segment, since it is the access point for new patients. The United Kingdom OFT found that Napp's pricing policy had foreclosed the hospital market, excluding competitors from entry into both market segments.⁸² Similarly, the OFT awarded damages to Healthcare at Home, an in-home care provider, against the pharmaceutical company Genzyme, for abuse of dominant position for bundling the price for Cerezyme services to include the cost of providing home delivery.⁸³

In another example, the DCA reviewed a complaint of exploitative abuse filed by physiotherapists and GPs against Dutch health insurers. The health providers alleged that the insurers abused their dominant position by refusing to negotiate the terms of the contract and to increase the fees paid to the professionals. The DCA found that there is no duty to negotiate, so long as the procurement procedures were objective, transparent and non-discriminatory. These findings were further supported by the problem that there was an oversupply of physiotherapists, undermining their request for increased fees.⁸⁴

In some cases, selective contracting could be another example of exploitative abuse that could lead to an anti-competitive complaint. In some social health insurance systems, insurance funds are monopolists with a dominant position in the market to contract with providers. If the funds are engaged in economic activity warranting an application of the status of an undertaking, then they could be at risk of abuse of dominant position. When there is an insufficient supply of doctors or hospitals, the funds can contract with all providers available. The funds may have significant leverage as monopolists in defining contract terms, which could lead to an abuse of a dominant position. Alternatively, where there is an oversupply of providers and the funds must restrict the number of contracts or the number of

⁸² *Napp Pharmaceutical Holdings Ltd v. Director General of Fair Trading* [2002] Comp. AR 13.

⁸³ Case No. 1016/1/03, *Genzyme Limited v. Office of Fair Trading* [2004] CAT 4.

⁸⁴ Dutch Competition Authority, Press Release, 27 May 2005, www.nmanet.nl/engels/home/News_and_publications/News_and_press_releases/2005/05_16.asp.

procedures to contain costs, a question arises as to the process used to select providers. There could be another risk of abuse of dominant position through a refusal to contract with particular providers if decisions are made subjectively or arbitrarily. Payers should use transparent criteria for contract selection, such as national standards of minimum quality, or maximum prices. A question as to whether physicians or hospitals should have due process rights to appeal cases terminating or rejecting their contracts could also arise. Ultimately, the social health insurance fund may not be held responsible for abuse of dominant position if their activities are justified as a service of general economic interest (discussed in the next section).

C. State regulation and services of general economic interest

While Articles 81 and 82 EC define the rules to limit an undertaking's anti-competitive behaviour, Article 86 EC applies when Member States interfere with a market by granting exclusive rights (Article 86(1)), or by entrusting an undertaking with the operation of a service of general economic interest (SGEI) (Article 86(2)). The liberalization of state monopolies is encouraged in Article 86(1). Decisions of the European Court of Justice that provide interpretations of this provision show the development of criteria to test whether a state monopoly is lawful.⁸⁵ In short, firms must meet efficiency standards and the state must limit grants to avoid awarding excess monopoly power that could have additional anti-competitive consequences. One such case arose in Germany, where the *Land* of Rheinland-Pfalz granted an undertaking (*Ambulanz Glockner*) the exclusive right to provide ambulance services in a rural area, giving the company a dominant position in the market. In *Glockner*, the ECJ was asked whether the provision of services under the grant abused its dominant position or was justified by public policy concerns under the SGEI exception found in Article 86(2).⁸⁶ Although there is no precise regulatory definition of SGEI, the Courts and the

⁸⁵ Case C-41/90, *Hofner and Elser v. Macrotron* [1991] ECR I-1979; Case C-179/90, *Merci Convencionali Porto di Genova v. Siderugica Gabrielli* [1991] ECR I-5889; Case C-475/99, *Glockner* [2001] ECR I-8089; Case C-18/88, *Regi des telegraphes et des telephones (RTT) v. GB-Inno-BM SA* [1991] ECR-5941; and Case C-320/91, *Corbeau* [1993] ECR I-2533.

⁸⁶ Case C-475/99, *Ambulanz Glockner v. Landreis Sudwetpflaz (Glockner)* [2001] ECR I-8089.

Commission have specified that, for Article 86(2) to apply, the public service mission must be clearly defined and explicitly entrusted through an act of public authority.⁸⁷ A series of Court cases have interpreted this section in detail. First, the service must be ‘entrusted through an act of public authority’, including legislative regulations, ‘non-exclusive licences’ or ministerial orders. Second, the SGEI must be widely available to the community and it cannot be concerned with private interests, such as copyrights.⁸⁸ Beyond these basic characteristics, Member States have discretion to define the services that would not be satisfactorily provided by the market, also within Article 16 EC.⁸⁹ This exception should not be seen as a free pass to violate competition laws. Similarly to the analysis in *Wouters*, the Court applies a proportionality test. The restriction on competition must be necessary and proportionate for the undertaking to perform its task. If there is a less restrictive means to achieve the same public interest goals, then the exception would not apply.⁹⁰

Traditionally, the Court would narrowly apply the SGEI exception to cases where the economic conditions in which the undertaking operates necessitate an exception from competition laws. In *Almelo*, the Court decided that it was permissible for a regional distribution company to have exclusive purchasing and sales contracts for electricity. The suspension of competition rules was necessary for financial stability; if competition were permitted, it would be impossible for the undertaking to perform its public service task.⁹¹ The Court then expanded the SGEI exception to also consider non-economic factors. In *Glockner*, the Court found that the company was an undertaking

⁸⁷ European Commission, ‘Communication from the Commission, accompanying the Communication on “a single market for 21st century Europe” services of general interest including social services of general interest a new European commitment’, COM (2007) 725 final, 20 November 2007; and Case C-280/00, *Altmark Trans GmbH* [2003] ECR I-7747.

⁸⁸ Case C-127/73, *Belgische Radio en Televisie et Societe Belge des Auteurs, Compositeurs et Editeurs v. SV SABAM et NV Fonior* [1974] ECR 313; and Case C-66/86, *Ahmed Saeed Flugreisen and Silver Line Reisebuero Bmbj v. Zentrale sur Bekampfung unlaurteren Wettbewerbs e V* [1989] ECR 803.

⁸⁹ Communication from the Commission – services of general interest in Europe, OJ 2001 No. C17/4.

⁹⁰ D. Chalmers *et al.*, *European Union law* (Cambridge: Cambridge University Press, 2006), p. 1138.

⁹¹ Case C-393/92, *Municipality of Almelo and Others v. NV Energiebedrijf Ijsselmij* [1994] ECR I-1477.

since ambulance facilities had not always been provided by public authorities. The *Land* argued that the grant of exclusive rights was necessary to ensure ambulance services were available, since it was otherwise unprofitable to offer emergency transport. Although the grant of exclusive rights put the company at risk of abusing its dominant position, the restriction on competition did not violate competition rules. First, the Court found that the grant of exclusive rights was justified, since the service would not be economically viable without the restriction on competition. Thus, the grant of exclusive rights served as a cross-subsidy to other parts of the business to make the company more economically viable.⁹² The Court went on to reason that the SGEI exception was also necessary to ensure the quality and reliability of the ambulance services.⁹³

The Court's analysis and judgment in the *Glockner* case recognizes the reality of public service financing and the state's need to balance a number of factors when making health policy decisions. Prosser (Chapter 7 in this volume) sees this case as an expansion of the Court's analysis to include broader public values, in addition to economic benchmarks to judge whether the SGEI exception applies.⁹⁴ If the quality and reliability of public services should be considered when carving out exceptions to competition law, one might ask whether these factors should carry equal or greater weight than the economic factors, especially in the context of health services. It could be argued that health services are unique among public services on economic grounds due to the complexity and difficulty of overcoming market failures, and on public interest grounds due to the fundamental importance of health care.

States may delegate important public services to independent agencies that could result in anti-competitive activities. For example, a case of abuse of dominant position arose where the Government of Malta entrusted the National Blood Transfusion Centre (NBTC) with the collection and management of sensitive materials such as blood products. Under regulations enacted in 2003, the NBTC also was required to commercialize the distribution of its products, in addition to its traditional function as the official regulator of blood products.

⁹² T. Prosser, *The limits of competition law* (Oxford: Oxford University Press, 2005), p. 288.

⁹³ Case C-475/99, *Ambulanz Glockner v. Landreis Sudwetpflanz (Glockner)* [2001] ECR I-8089.

⁹⁴ Prosser, *The limits*, above n.92.

The NCA in Malta, the Maltese Commission for Fair Trading (CFT), found that the NBTC conducted activities as a government regulator and as an undertaking. By capitalizing on this dual role, the NBTC was restricting or distorting competition in the health care market, since patients faced a choice of either opting for a private hospital and paying for the blood products, or going to a public hospital where they would not be charged for blood.⁹⁵ Articles 82 and 86 EC preclude Member States from granting undertakings the power to regulate or set standards in a market where they also compete.⁹⁶

In the most recent case, *BUPA*, the Court of First Instance upheld the Irish Government's regulation of the health insurance market, using a risk equalization scheme, under Article 86(2).⁹⁷ This case and other issues of private health insurance are addressed in more detail in the chapter by Thomson and Mossialos (Chapter 10). It is worth mentioning here that the Court applied the *Altmark* test to determine whether the Commission was accurate in its conclusion that the risk equalization scheme was not a grant of state aid, finding that there was an act of public authority entrusting the entity with an SGEI mission and the universal and compulsory nature of that mission. The Court also found that the Commission was correct in its assessment that the regulation of the market was necessary and proportionate to the goal of providing all Irish residents access to a minimum level of private health insurance services at the same price.⁹⁸ Finally, it should be mentioned that the Court affirmed that Member States have wide discretion to define what they regard as SGEIs and that the definition of such services by a Member State can be questioned by the Commission only in the event of manifest error.⁹⁹

In November 2007, the Commission published its views on the proposed Protocol on Services of General Interest, annexed to the Treaty of Lisbon, with specific analysis of the particular situation of health services.¹⁰⁰ The Communication essentially summarizes the existing

⁹⁵ European Competition Law Review, 'Malta, Abuse of Dominant Position – Blood', Case Comment, *European Competition Law Review* 28 (2007), 120–1.

⁹⁶ Case C-18/88, *Régie des télégraphes et des téléphones (RTT) v. GB-Inno-BM SA* [1991] ECR-5941.

⁹⁷ Case T-289/03, *BUPA*, above n.4. ⁹⁸ *Ibid.*

⁹⁹ Case T-289/03, *BUPA*, above n.4, para. 166.

¹⁰⁰ European Commission, 'Services of general interest, including social services of general interest: a new European commitment', COM (2007) 724 final, 20 November 2007.

jurisprudence of the European Court of Justice interpreting Article 86 EC. In a specific section on health services, the Commission reiterates the balancing of Member States' responsibilities with its own interest in setting out a framework for safe, high-quality and efficient cross-border health care services. Thus, in the area of health care in particular, Member States can continue to regulate health services as long as they also meet the requirements of Article 86(2) as interpreted by the Court, especially the proportionality principle.

Efficient operator

If Member States were to declare that all health services qualified as SGEI, would health systems enjoy a blanket exemption from competition law? Thus far, the Court has not provided a clear answer. Under the *Altmark* decision, the Court requires that in cases where the public service obligation has not been chosen by competitive tender, the level of compensation defined by the contract should depend upon an analysis of the costs of a 'typical, well-run undertaking'. Thus, the Court would look for a measure of efficiency, to draw a comparison with an 'efficient operator'.¹⁰¹ As discussed at length in the *BUPA* case, the Commission was satisfied that the compensation paid to some insurers and not others as a result of the risk adjustment scheme did not create the possibility of offsetting costs that might result from inefficiencies on the part of an insurer subject to the scheme. The Commission appropriately found that the scheme took into account the costs of an insurer's average claim, so that insurers were not allowed to keep the benefit of their own inefficiencies.¹⁰²

This efficiency requirement indicates a preference for some type of tender process that rewards a firm that could provide the public service obligation efficiently. Once a firm provides SGEI, the state may have an ongoing responsibility to monitor the SGEI to determine whether the provider continues to supply services efficiently over time. This standard would require a significant administrative burden on the Member State. In the *BUPA* case, the Court of First Instance focused on whether the Commission satisfied its burden to identify whether the scheme resulted in a grant of state aid. It is unclear whether the Irish Government is required to review the insurers to determine whether

¹⁰¹ Case C-280/00, *Altmark Trans GmbH* [2003] ECR I-7747.

¹⁰² Case T-289/03, *BUPA*, above n.4.

they provide the SGEI efficiently. The *Altmark* efficient operator principle could be one of the hurdles used to raise the level of scrutiny of Member State SGEI awards in an area where the Commission otherwise would have to respect their wide discretion.

4. Enforcement of competition law

Enforcement of EU competition law is diffused among EU institutions, national courts and national competition authorities. Prior to the modernization of the competition law enforcement system in 2004, the Commission was unable to address the growing number of complaints of anti-competitive behaviour. Council Regulation 1/2003/EC delegates authority to investigate, regulate and enforce competition law to NCAs. Since enactment of the reforms, the number of cases in the health care sector has increased substantially, due to the NCAs' proximity and familiarity with domestic legislation and policies, and the Commission's focus has shifted to sector-wide investigations and coordination of NCAs. Several NCAs, including those of Finland, Germany, Italy, the Netherlands and the United Kingdom, have paid special attention to the health care sector. However, NCAs will only be effective if they have adequate financial resources, staff expertise and independence. Consequently, the level of NCA scrutiny of competition in the health sector varies widely.

In addition to the national court enforcement discussed above, supranational enforcement by the Commission under Article 85 (now Article 81) EC was originally set out in Regulation 17/62/EEC, following the German rules-based tradition. Various attempts to improve efficiency or to shift more cases to national systems were unsuccessful. For example, the Commission set *de minimis* rules to prioritize only significant violations of Article 81 EC. The modernization of competition enforcement defined by Council Regulation 1/2003/EEC came into effect in May 2004.¹⁰³ The Commission's new role includes setting priorities, enforcing state aid rules and ensuring consistent enforcement throughout the EU. The newly-established European Competition Network (ECN) is a framework for cooperation among

¹⁰³ Council and European Parliament Regulation 1/2003/EC on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty, OJ 2003 No. L1/1.

the NCAs, but has no independent legal authority. The Commission further controls the NCAs by reviewing all decisions prior to formal publication. At this point, the Commission may comment on the decision or override the relevant NCA's jurisdiction and open its own proceedings.¹⁰⁴ Although these mechanisms encourage uniform application of competition law, the potential for inconsistencies persists.

Post-decentralization, the volume of cases has increased and there are greater opportunities for variation in enforcement, despite the best efforts of the ECN. For example, the Latvian Competition Council was established in 1998, but only heard five cases of abuse of dominance in 2005 and eleven in 2006. The Council wants to continue to double the number of cases each year, at least through 2009.¹⁰⁵ Differences in resource allocation, experience and expertise among NCAs mean that there is wide variation in the level of enforcement within Member States. Some NCAs have relatively few staff and limited budgets, and may feel pressure to take only high profile cases that will result in significant fines generating revenue for their government. The European Bank for Reconstruction and Development has funded several projects in former communist countries to encourage the enactment of competition law and the development of institutions. Their indicators reflect that the new Member States' enforcement of competition law is improving and has encouraged actual market competition. However, one area of concern is the lack of effectiveness of the appeals process.¹⁰⁶ One researcher also argued that the appellate institutions' personnel lack sufficient training to reverse decisions of the NCAs.¹⁰⁷

Since Regulation 1/2003/EC came into force in May 2004, there has only been limited independent analysis of the implementation of the new enforcement scheme. It is clear, however, that a number of

¹⁰⁴ Monti, *EC competition law*, above n.78.

¹⁰⁵ Latvian Competition Council, 'Annual Report 2005'; Latvian Competition Council, 'Annual Report 2006', www.kp.gov.lv/?object_id=618; and A. Rubene, 'The Latvian Competition Council fines the medical gas monopolist for the application of an unfair and discriminating price', *e-Competitions Bulletin* No. 12435 (2006).

¹⁰⁶ See M. Vagliasindi and L. Campbell, 'The EBRD: promoting transition through competition', *Law in Transition* (2004), 35–45, at 41, Chart 6, www.ebrd.com/pubs/legal/lit041g.pdf.

¹⁰⁷ J. Rossi, 'Competition law enforcement mechanisms', *Law in Transition* (2004), 78–84, www.ebrd.com/pubs/legal/lit041m.pdf.

risks and uncertainties arise, leaving the full impact on both economic and social policy an open question. Wilks points out that there are a number of risks related to variation in a decentralized system where 'variations in application may be deliberate, inadvertent, or opportunistic as the regimes respond to differing sets of pressures'.¹⁰⁸ Concerns over accountability, forum shopping, vulnerability to lobbying and lack of competence all jeopardize the implementation and integrity of the new system. Wilks argues further that the Commission's successful centralizing and the increasing juridification of competition law result in economic policy enjoying excessive power and potentially 'becom[ing] a destructive force in the regulation of the European economy ... The law may require competition authorities to act in ways incompatible with national interests in employment, [and] social welfare.'¹⁰⁹ Overly rigid, legalistic rules that fail to take social policy priorities into account could undermine the solidarity principles inherent in national health policies.

Applying Wilks' analysis to the health sector, it is easy to imagine how NCAs could also be subject to both political and economic pressures. The health care sector is important politically and economically, features influential pharmaceutical industry lobbies, as well as being a sensitive election issue. The Italian NCA has adjudicated several cases against the pharmaceutical industry, commented on proposed financing legislation and criticized variations in regional health systems since the 1990s. By contrast, the Estonian NCA's annual reports and decisions are diplomatically constructed to avoid findings of anti-competitive behaviour in the health sector.¹¹⁰ Even though the United Kingdom Office of Fair Trading has dealt with a number of health-related cases, it has thus far refrained from challenging English National Health Service reforms – such as the economic activities of

¹⁰⁸ S. Wilks, 'Agency escape: decentralization or dominance of the European Commission in the modernization of competition policy?', *Governance: An International Journal of Policy, Administration, and Institutions* 18 (2005), 431–52.

¹⁰⁹ *Ibid.*, 449–50.

¹¹⁰ In the 2004, 2005 and 2006 annual reports from the Estonian NCA pharmacies, health insurance funds and a pharmaceutical cartel were investigated for anti-competitive activities, but none were held liable. Estonian Competition Board, 'Annual Report 2004'; Estonian Competition Board, 'Annual Report 2005'; Estonian Competition Board, 'Annual Report 2006', www.konkurentsiamet.ee/?id=11591.

foundation trusts – that have introduced market elements but have arguably not gone far enough to establish a competitively neutral environment for private providers.

In addition to variations in the level of enforcement, national governments differ in terms of designation of authority to NCAs. Many NCAs have multiple functional areas, including complaint investigation, consumer protection, enforcement and regulation. In some countries, such as Ireland, Finland, Denmark and Sweden, the NCA has an executive enforcement role, where it conducts research, provides recommendations, monitors transactions and, in some cases, files complaints. The NCAs of each of these countries have produced reports providing recommendations on how to improve competition in particular segments of the health services sector, such as the private insurance market in Ireland discussed earlier. Only the national courts in these countries have the jurisdiction to rule on competition cases. The separation of authority gives the Irish NCA, for example, more latitude to advise health officials. In other countries, such as the United Kingdom, the Netherlands, Portugal, Italy, Germany and France, the NCA plays both an adjudicatory and an advisory role. National courts are bound by the findings of the competition authority in some jurisdictions, such as the United Kingdom and Germany.¹¹¹ For example, in the United Kingdom, the OFT adjudicates violations of the Competition Act, in addition to its advisory role. If the NHS presented difficult competition issues to the OFT for advice it could potentially expose itself to litigation.

NCAs in some countries have commented on proposed or enacted health legislation or have advocated in favour of improving competition in the organization of national health systems. Health system reforms that have decentralized authority and decision-making to the regional or local level weaken the central government's control over specific health policies. In Italy, the NCA has commented on the anti-competitive aspects of proposed health legislation and of the implementation health policies. As early as 1998, the Italian Antitrust Authority (IAA) reported to government and parliament on local health boards' dual payer-provider function, creating an anti-competitive conflict of interest. Responding to a number of complaints by clinics, labs and patients regarding selective contracting

¹¹¹ Monti, *EC competition law*, above n.78, p. 435.

by local health boards, the IAA found that several regions had implemented the same health policies inconsistently and that the inconsistencies resulted in anti-competitive markets. Some local health boards focused on the patients' freedom to choose providers, while others focused on the planning of services, limiting choice in an attempt to contain costs, but failed to include incentives for efficiency. In 2005, the IAA again focused on local health boards that had individually interpreted national regulations, resulting in problems with accreditation of private providers and leading to selective contracting.

The Finnish Competition Authority supported legislative reforms that were enacted in 2002 requiring generic substitution of medicines, unless a physician specifically forbids the replacement. The FCA argued that the reform would encourage competition and control the increase of medicines expenditures, and went further in proposing additional amendments to the legislation to enhance economic incentives.¹¹² The Hungarian Competition Authority has weighed in on the health reform debates in Hungary, arguing that a balance should be found between a wholly state-run health sector and that of a fully competitive health market run by private insurance companies. The HCA presented a discussion paper that considers the areas for competition, why competition cannot solve existing regulatory problems and provides suggestions on where competition should be stronger.¹¹³

Similarly, the Swedish Competition Authority (SCA) has identified several local government policies that interfere with competition. In Sweden, county councils and municipalities are entrusted with health care provision and financing. Local governments plan for services based on local needs, and also regulate the private practitioners' market by approving the establishment and public reimbursement of local practices. Moreover, county councils own and operate most health care facilities.¹¹⁴ The diversity of local regulations makes it difficult for providers to expand into neighbouring markets. The SCA published a market analysis, which found that

¹¹² Finnish Competition Authority, '2003 yearbook', above n.38.

¹¹³ Hungarian Competition Council, Press Release, 13 April 2007, www.gvh.hu/gvh/alpha?do=2&st=2&pg=133&m5_doc=4521.

¹¹⁴ Health Systems in Transition (HiT) Summary, Sweden, 2005, www.euro.who.int/Document/E88669sum.pdf.

the tight regulation of the establishment of new local practices had resulted in a decline in the number of new doctors entering private practice, and that this barrier to entry in the market had significantly limited health services supply.¹¹⁵ Arbitrary local regulations infringe upon competitive neutrality. The SCA has argued that municipalities that simultaneously define health care budgets and provide health services substantially hinder price competition.¹¹⁶ With decentralized health systems, the question then becomes: what should the central government do to prevent local policies from interfering with competition? Could the benefits of decentralization, such as increased accountability and responsiveness, ever outweigh the benefits of competitive markets? Health policy-makers, national courts and the European Court of Justice may each find different answers to these questions.

Thus far, the Netherlands has gone the furthest among EU Member States towards incorporating competition policy when implementing health system reforms. In 2006, the Dutch Healthcare Authority (DHA) was established to implement health system reforms, paving the way for market forces to operate in the health care services sector. The DHA supervises both health care providers and insurers in the curative and long-term care markets. The Healthcare Inspectorate will monitor quality, while the DHA encourages competition based on quality.¹¹⁷ In preparation for this system-wide reform, the Dutch Government negotiated with the EU Commission for the authorization of a €15 billion grant of state aid for private health insurers to cover start-up costs. Pre-existing sickness funds were permitted to roll-over financial reserves as start-up capital while they transform into private insurers.¹¹⁸ It is still too soon to assess the successes and

¹¹⁵ Swedish Competition Authority (SCA), 'Assessment for improving consumer welfare in health and elderly care', English Summary (2007), www.kkv.se/upload/Filer/ENG/Publications/rap_2007-3_summary.pdf.

¹¹⁶ Swedish Competition Authority (SCA), 'Business as usual? Clearer demarcation between authorities and markets', English Summary (2004), www.kkv.se/upload/Filer/ENG/Publications/rap_%202004_4summary.pdf.

¹¹⁷ Dutch Health Authority, 'Strategy of the Dutch Health Authority', October 2006, www.nza.nl/7113/10118/NZA_Strategy-internet.pdf.

¹¹⁸ European Commission, 'State aid: Commission endorses €15 billion public funding for new Dutch health insurance system', Press Release No. IP/05/531, Brussels, 3 May 2005.

failures of this transformation. Other Member States should perhaps note that the Commission's support for Dutch market reforms may be a sign of its preference for comprehensive market reforms.

The rising cost of pharmaceuticals has increased pressure on Member States to define regulations that will improve efficiency and competition on the price of medicines. NCAs in several countries have weighed in on the debates in addition to strictly enforcing competition law against the pharmaceutical industry. NCAs in Denmark, Estonia, Finland, Italy and Sweden have conducted investigations into improving competition in this market, concluding that regulations of the distribution and location of retail outlets should be reformed. NCAs in Poland and Latvia have articulated concerns that the retail pharmacy market is becoming more concentrated.¹¹⁹ The Danish NCA advocated for greater price competition by setting maximum prices for reimbursement, rather than fixed prices.¹²⁰ The Italian authorities recommend the deregulation of retail pharmacy ownership and that automated over-the-counter (OTC) machines be allowed outside pharmacies.¹²¹ The Slovak NCA also found that restrictions in the Slovak Chamber of Pharmacists Code of Ethics contained limitations on the geographic location of pharmacies, unlawfully restricting competition.¹²² In the United Kingdom, the OFT has published a report with extensive recommendations for reforming the Pharmaceutical Price Regulation Scheme by replacing it with a value-based approach to pricing.¹²³

¹¹⁹ Polish Office for Competition and Consumer Protection, 'Pharmaceutical products market in Poland', Press Release, 7 December 2006, www.uokik.gov.pl/en/press_office/press_releases/art66.html; Latvian Competition Council, 'Annual Report 2005', www.kp.gov.lv/uploaded_files/KP%20parskats%202005%20En%20Final.pdf.

¹²⁰ Danish Competition Authority, '2005 Annual Report', Chapter 6, 'Pharmacies', English Summary, www.ks.dk/english/publications/publications-2005/2005-06-08-competition-report-2005/chapter-6-pharmacies/.

¹²¹ IAA, Press Release, 23 September 2005, www.agcm.it/eng/index.htm.

¹²² Slovak Competition Authority, 'Decision of the Association of Entrepreneurs – Slovak Chamber of Pharmacists', Press Release, 2002, www.antimon.gov.sk/eng/article.aspx?c=394&a=2129.

¹²³ Office of Fair Trading, 'The pharmaceutical price regulation scheme', February 2007, www.offt.gov.uk/shared_offt/reports/comp_policy/oft885.pdf.

Finally, the EU's new decentralized enforcement scheme allows for the possibility of damages claims, creating incentives for privately-filed actions. Even though the Court has affirmed the right of victims to compensation,¹²⁴ these cases are rare. Private litigation could serve to protect plaintiffs' rights and, by extension, consumer welfare, as well as to deter future anti-competitive behaviour. Unlike the Commission, victims may not be discouraged from filing claims simply to avoid politically sensitive issues. Naturally, there are a number of procedural challenges to private actions, such as the burden of proving both that the defendants' acts restrict competition and that the plaintiff has personally suffered a loss as a result. Variations in national civil procedures, available remedies and judicial expertise in competition law will lead to differences in the outcomes of competition law cases. But the Commission sees benefits in the filing of both 'follow on' claims after a competition authority has found a violation of competition law, and 'stand alone' cases where the private actor initiates proceedings in a fresh case, as was articulated in the 2005 Green Paper.¹²⁵ Refusal to deal with cases could be raised by undertakings that have tried to expand operations into markets dominated by the public sector and that have been slow to modernize in the wake of health system reforms. Similarly, competitors may raise an abuse of dominance claim in cases where mixed public-private funding and provision of care restrict market entry. If health care markets become more broadly European – and even global – plaintiffs may be persuaded to file claims against foreign companies operating in Europe as well. However, the political implications of filing against a national health service may discourage current contractors from raising controversial issues. But corporations seeking entry into closed markets could be expected to consider private actions to encourage the adoption of competitively neutral policies. In this light, *Bettercare* may not be seen as an anomaly, but as only one of the first attempts. So far, only ten of the twenty-seven Member States have had any private anti-trust cases, and in those courts litigation is still rare.¹²⁶

¹²⁴ Case C-453/99, *Courage and Crehan* [2001] ECR I-6297; and Joined Cases C-295/04 to 298/04, *Manfredi* [2006] ECR I-6619.

¹²⁵ Monti, *EC competition law*, above n.78.

¹²⁶ Centre for European Policy Studies, 'Making antitrust damages actions more effective in the EU: welfare impact and potential scenarios', Report for

The United Kingdom High Court recently ruled on the type of damages that are available to private plaintiffs filing ‘follow on’ claims under EU competition law in the United Kingdom.¹²⁷ The Commission fined several firms in the vitamins industry for anti-competitive agreements in setting prices and sales quotas. A group of purchasers filed ‘follow on’ actions requesting several types of damages, including compensatory, exemplary and restitutionary damages.¹²⁸ The High Court’s ruling limiting the remedy to only compensatory damages may discourage future claimants from bringing private claims in England.

On 2 April 2008, the Commission published a White Paper on damages actions for breach of the EC antitrust rules.¹²⁹ These long awaited proposals seek to protect the right of victims to full compensation for all damage suffered as a result of a breach of competition law. Other stated purposes include deterrence of future infringements and the preservation of public enforcement mechanisms.¹³⁰ One of the prohibitive hurdles in filing stand-alone, private anti-trust litigation is the difficulty of obtaining the relevant evidence to prove that unlawful activity has occurred and that the plaintiff has suffered harm. The Commission suggests some minimum *inter partes* discovery rules to facilitate the production of documents and prevent wholesale abuse. However, Member States have little incentive to enact a whole raft of discovery procedures that narrowly apply to competition litigation. The Commission also emphasizes the need for a ‘European approach’, implying that, although inspired by the United States enforcement record, the EU will find its own more balanced approach to private litigation. Thus, two complementary mechanisms for collective redress are proposed, adopted from the effectiveness of United States class action law suits. On the other hand, the proposal limits damages to compensatory awards, as in the recent United Kingdom case. Lack of harmonization on discovery, damage awards and attribution

the European Commission (2008), http://ec.europa.eu/comm/competition/antitrust/actionsdamages/files_white_paper/impact_study.pdf.

¹²⁷ *Devenish Nutrition Limited & Others v. Sanofi-Aventis SA (France) & Others* [2007] EWHC 2394 (Ch).

¹²⁸ *Ibid.*

¹²⁹ European Commission, ‘Damages actions for breach of the EC antitrust rules’, White Paper, COM (2008) 165 final, 2 April 2008.

¹³⁰ *Ibid.*

of court costs will inevitably lead to forum shopping and could result in inconsistent enforcement.

Although the Commission seems to have worthy objectives, the implementation of these changes appears unlikely. Civil procedure rules evolve within domestic jurisprudence and typically apply broadly to many, if not all, types of civil cases. To revise discovery rules exclusively for private competition litigation could open a legislative can of worms that could have unintended political consequences that legislators would prefer to avoid. Worse yet, even if implemented, the proposals fall short of providing sufficient incentive to encourage private litigation. In the United States, the possibility of recovering damages of up to three times the amount of the overcharge is the golden carrot that motivates anti-trust litigation. The Commission's 'European approach' to private litigation will need further development if it is to achieve its goals of encouraging victims to seek compensation for harm inflicted by anti-competitive activities.

5. Conclusions

Despite the EU's lack of explicit competence in the area of health, Member States' domestic health care systems do not enjoy immunity from the application of EU competition law. Even incremental reforms to improve efficiency based on market competition may open the door for competition laws to apply. This creates a tension between the EU's explicit goals to promote both economic and social progress, and legal uncertainty for health policy-makers. EU competition law governs the actions of undertakings and Member States. The complexity of the relationship between public and private funding and provision of health care services is but one example demonstrating how undertakings participate in the health services sector. Professional associations can no longer protect members by negotiating fees or disseminating price information without risking being fined as anti-competitive cartels – as has already occurred in at least nine Member States. The privatization of hospital ownership or management may expose health providers to the application of competition law. Similarly, large health organizations run the risk of abuse of dominant position charges if their expansion threatens price competition, as evidenced by the rise in the number of health sector merger cases investigated by NCAs. However, this chapter is not an exhaustive analysis of the wide range of

issues on the subject occurring in all EU Member States. The analysis presented merely outlines the depth and breadth of the issues beginning to surface.

Naturally, the majority of published cases originate from the pre-1995 Member States. What remains to be analysed in detail is how the newer Member States will address these issues and whether the Commission will use its scarce enforcement resources to encourage or coerce compliance with EU laws. Since the eastern European Member States' health systems were highly centralized under communism, the only direction for the reforms to go was towards increased competition, decentralization and privatization. These health systems have been under significant pressure to modernize quickly within constrained budgets. Whether their policies have been sensitive to European competition law prohibitions is yet another topic for further study.

Despite the fact that some national health officials still believe that health is a protected domestic issue,¹³¹ NCAs have focused on the economic aspects of health care, allowing greater EU involvement in health system organization despite the protection of Article 152(5) EC. NCAs are not charged with enforcing the Treaty as a whole, only competition laws. Therefore, the decentralization of enforcement has strengthened economic policy priorities to the detriment of social policy objectives. Many NCAs have limited financial resources and staff experienced in health sector issues. National autonomy on issues such as civil court procedures, the types of remedy available and political risks will limit the prevalence of private actions. Concerns over the accountability and independence of NCAs also have been raised. Thus, both the definition and the enforcement of competition laws when applied to health sectors is an evolving subject worthy of further consideration.

The only thing that is clear, based on the law presented here, is that each case must be analysed in detail. There are few bright distinctions between economic and social functions in mixed public and private health systems. Competition law will not necessarily apply, while the services of general interest exception will not always provide a

¹³¹ S. Greer, 'Choosing paths in European Union health policy: a political analysis of a critical juncture', *Journal of European Social Policy* 18 (2008), 219–31.

safe haven, allowing Member States to distort or restrict competition when regulating health services. The Commission continues to pursue legal clarity through attempts to develop a coherent European framework for health care. However, Member States have demonstrated little political will to support any European health policy that will interfere with their domestic policies.