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"*Legally* eHealth"

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ASPECTS OF COMPETITION AND TRADE LAW

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OVERVIEW

Competition policy is one of the corner stones of the internal market, which is in itself one of the central *raison d'être* of the European Union. The concept of the internal market is to allow European businesses to compete on a level playing field between and across all the Member States of the Union. The role of competition policy and legislation is to ensure that such competition is allowed to prosper unhindered by anticompetitive practices on the part of companies, public bodies or national authorities. Its central purpose is to prevent one or more organisations from improperly exploiting an economic power over weaker organisations through an **abuse of a dominant position,** as well as to prevent Member States' governments from distorting competition through **State aid**. Its function, in short, is to encourage a market economy, while still safeguarding the interests of European consumers.

When eHealth services are offered on an open market by commercial undertakings they will, of course, be governed by the rules of competition law. Thus, if a company offers a diabetes monitoring service which incorporates a physical device and a web-based monitoring service to people suffering from diabetes directly on the open market, then such a company will be subject to the rules on abuse of dominant position and on State aid.

On the face of it, this should not cause any problem since an eHealth company is not necessarily any different from a hotel group or a car manufacturer. However, the context in which eHealth organisations operate might make them significantly different to other organisations, not least because an eHealth company will, in many cases, be selling its services not directly to the consumer, but to a public health services provider who in turn makes the eHealth services available to patients and citizens, in the course of their usual provision of care.

It should be noted therefore that historically and socially the provision of healthcare services has been 'hidden' from the purview of competition law not only because of its public nature, but also because healthcare is generally conceived of an intellectual service provided by professionals whose services comprise a range of skills not classified into separate activities subject to competition. As a result, healthcare has historically not attracted the attention of competition lawyers to any very significant extent.

Moreover, since health services are, in most EU countries, funded through some form of taxation and organised to some degree by public bodies, the extent to which competition law applies to them is somewhat unclear and may be limited. In particular, it is unclear in how far the rules of competition apply at all to publicly funded bodies, and in how far the concept of Services of General Interest apply to health services, and the extent to which health services are, on the basis of the rules on Services of General Economic Interest as provided for in the Treaty, exempted from the provisions of European competition law.

However, as healthcare services change to incorporate more and more technical services furnished by specialised providers who are not necessarily medical practitioners, the role of competition law will become more important as those providers seek to ensure that they function within an open market. Similarly as more and more health services are purchased by private individuals, especially in long term elderly care, a direct contractual relationship between the consumer and the health service provider will require that such care provision is amenable to the control of public competition authorities.

In this section we will therefore look at the core aspects of EU competition law, its application to healthcare and the further policy issues around health as a service of general interest.

The document is divided into four parts:

Part I: A summary description of the key principles of EU level trade and competition legislation. Here you will find an outline of the key principles of the legislation with some healthcare based examples.

Part II: A detailed step-by-step analysis of the key Treaty article covering a description of all the relevant articles of legislation as well as links and references to the source documents.

Part III: A case vignette, which shows the ways in which competition legislation might come into play in health services.

Part IV: A source reference list, where you will find links and reference to all the legal source documents discussed in Parts I, II and III.

PART I: INTRODUCTION AND BACKGROUND

The principles of free trade and competition are among the most important economic principles supported by the European Community. It is therefore not surprising that the European Community has adopted a wide range of legislation to support competition through a legal system prohibiting any disloyal practices that might restrict competition.

The basis of European competition law is found in article 3(g) of the Treaty establishing the European Community (TEC). The article aims to establish "a system ensuring that competition in the internal market is not distorted". In that context, the Treaty includes a number of articles that provide that agreements and concerted practices come within the jurisdiction of the European Community authorities if they affect trade between Member States. It is important to note here that the role of the European Community is limited to issues affecting intra-Community trade; consequently, the coexistence of Community and national competition law sometimes causes the two to be applied simultaneously.

European Community competition law is found in articles 81-89 of the Treaty and falls into the following categories:

- rules on 'undertakings' (articles 81-82);
- rules on specific sectors and Services of General Interest (article 86);
- rules on State Aid (articles 87-89); and
- rules on regulation of competition:
    - article 83 provides that the Commission shall propose Directives and Regulations to give force to article 81 and 82;
    - articles 84 and 85 specify the respective powers of the Commission and the authorities of the Member States to apply articles 81 and 82 during the transitional period, i.e. until the entry into force of the provisions adopted by the Council under article 83.

The core of European competition law is found in the rules applying to private firms or "undertakings" in articles 81 and 82. Article 81 prohibits **agreements and concerted practices** with an anticompetitive object or effect on the market, while article 82 prohibits **abuse of a dominant position**. Article 86(2) states that the rules on competition also apply to public undertakings as long as the "application of such rules does not obstruct the performance, in law or in fact, of the particular tasks assigned to them."

The law encapsulated in the key articles above, as well as a wide range of case law coming from the European Court of Justice (ECJ), is established to allow fair and open competition between undertakings operating in the European Union and with a potential effect on trade between the Member States. In order to understand the way in which it applies to healthcare, if at all, we must first establish what an undertaking is, since the law applies only to undertakings.

The first key question for the purposes of healthcare providers is therefore whether they are deemed to be undertakings - and therefore subject to competition - or of if they are public entities not subject to such regulation.

In order to clarify the current law we must ask three key questions:

- What is an "undertaking" and can a public body be classified as an undertaking?
- What is a Service of General Economic Interest and do the rules on Services of General Economic Interest apply to healthcare?
- What is State aid?

What is an 'undertaking' and can a public body be classified as an undertaking?

First, it is important to note here that the term undertaking is not defined in the EC Treaty but its meaning has been set out in Community case law. An undertaking includes any natural or legal person engaged in economic activity, regardless of its legal status or the way it is financed[1]. It includes companies, firms, businesses, partnerships, individuals operating as sole traders, non profit-making organisations and, in some circumstances, public entities that offer goods or services on a given market. The key consideration in assessing whether an entity is an undertaking is whether it is engaged in economic activity. Note also that an entity may engage in economic activity in relation to some of its functions but not others. Thus, one entity could be subject to competition law in some of its dealings but not in others.

The judgment by United Kingdom's Competition Commission in the BetterCare[2] case would seem to suggest that contracting out services could bring the hospital into the realm of an undertaking. In that case, the BetterCare Group (a private company selling nursing and residential care in Northern Ireland) used the United Kingdom's competition law to challenge the contract price for private nursing home beds arranged with North and West Belfast Health and Social Services Trust (Northern Ireland's combined local commissioner for health and social care[3]). BetterCare alleged that the contract price was set too low, allowing the Trust to abuse its dominant market position, and was thus in breach of UK competition law. The Competition Tribunal noted first that the Trust was established to execute statutory duties of healthcare and was funded by a block grant from government in order to provide partially or fully funded long-term care to those people qualifying for such care. However, despite receiving such public finds, the Tribunal ruled that the Trust was acting commercially when contracting out because they negotiated contracts with service providers in order to get the best possible price/quality ratio. The Tribunal found generally that when public bodies enter into such partnerships with private bodies they are doing so in the spirit of enterprise and therefore they should be legally deemed to be acting as undertakings within the terms of Competition law. It found, therefore, that the Trust was acting in abuse of its dominant position (in this context an article 82-like prohibition of abuse).

However, the BetterCare issue was examined again at EU level in the recent case of FENIN (Federación Española de Empresas de Tecnología Sanitaria)[4]. In that case, the Court of First Instance of the EU found that a Spanish health service organisation, acting in a similar way to BetterCare, should *not* be deemed to act as an undertaking simply because it was purchasing large quantities of goods or services from competitive markets.

In the FENIN case, an association of businesses that market medical goods and equipment used in Spanish hospitals complained to the European Commission that several public bodies that run the Spanish national health system were abusing a dominant position by paying sums invoiced to them only after an average 300-day delay.

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[1] Case C-41/90 Höfner & Elser v Macrotron GmbH [1991] ECR 1- 1979

[2] BetterCare Group Limited v the Director General of Fair Trading Case no: 1006/2/1/01.Judgement dated 26 March 2002.

[3] A trust is a legal entity established under national law that comprises a number of healthcare delivery organisation in a geographical area including hospitals, primary care, long term care and ambulance services.

[4] Federación Nacional de Empresas de Instrumentación Científica, Médica, Técnica y Dental (FENIN) v Commission of the European Communities. Court of First Instance (EC), Case T-319/99 Court of Justice of the European Communities, Case C-205/03

In FENIN, the Court of First Instance held that the test to establish whether an organisation was acting as an undertaking in the terms of article 81 was **whether the purpose of the purchasing was to offer goods and services in a market**. The Court of First Instance found that, if an organisation is purchasing goods or services simply in order to deliver those services, then it is not acting as an undertaking. If, however, the goods or services are purchased in order to offer them to further purchasers as part of a commercial activity, then it is operating as an undertaking as accordingly the rules on competition do apply.

The European Court of Justice upheld the Court of First Instance ruling and thus provides that a purchasing activity is not subject to competition law if it is undertaken for a purely social purpose, rather than as an economic purpose, such as a supply of goods or services on a market. They therefore accepted the argument that in this case, the Spanish hospitals operated according to the principle of solidarity in that they were funded from social security and State contributions and provided free of charge services on the basis of universal cover, so they were found not to be engaging in economic activity. The Commission's argument summarised at paragraph 24 of the ECJ judgment (and accepted by the Court) makes the point in a concise way:

> '[It is] the act of placing goods or services on a given market which characterises the concept of economic activity and not purchasing activity as such".

It should be noted, however, that this issue is far from closed and settled. The FENIN case applies to its specific facts. The Court did not decide in general terms that a public organisation offering services on market would never be considered as an undertaking. This means that the position is not much clearer than it was before the judgment. Suppliers to the public sector may feel they have been left defenseless against large public purchasers, such as a national health system. However, public buyers have equally been left on shaky ground, especially those competing with private operators in the provision of goods or services.

Looking at the judgments in BetterCare and FENIN, Professor Tamara Hervey at Nottingham University has argued that hospitals, such as the Spanish hospitals in FENIN, may be regarded as having two legal functions[5]. On the one hand, they are health care providers and as such outside competition in any market. On the other, they are purchasers of goods and services, which may be regarded as a separate activity and which may take place within a market, if private actors are also present. Professor Hervey notes that if this approach is accepted, as implied by the FENIN ruling, and explicitly stated by the UK in BetterCare "then most health care purchasing bodies will fall within the scope of EU competition law. If EU competition law applies, then the body concerned may not 'abuse' its 'dominant position', for instance by keeping other actors out of the market through its contracting practices, or by keeping prices below 'competitive' levels".

[5] T. Hervey, EU law and national health policies: problem or opportunity? Health Economics, Policy and Law (2007), 2: 1–6.

The current situation is thus that most healthcare providers who are supplying goods or services

- in the execution of an exclusively social function
- on a non-profit making basis
- on the principle of solidarity, and
- where the entitlement to services is not dependent on the amount of contributions

are unlikely to be legally classified as an undertaking conducting an economic activity and thus their interactions with private bodies from whom goods or services are purchased for the purposes of providing healthcare will not be subject to the rules on abuse of dominant position. However, a healthcare provider operating outside those strict criteria could well be classified as an undertaking and therefore subject to competition law.

While this issue is at present still unclear, it is doubtful that will remain so indefinitely. As Europe ages and more and more long term care is provided on a public-private partnership basis in which the individual citizen will be participating in the costs, the distinction between public and commercial care will be blurred. It is to be expected that private parties providing services will no doubt seek to ensure that they are competing on an open and fair market. It is thus likely that more cases like BetterCare and FENIN will come to national and European Courts for a clear interpretation of the law in article 81-82 of the Treaty.

What is a Service of General Economic Interest, and do the rules on Services of General Economic Interest apply to healthcare?

In the cases where a healthcare provider is classified as an undertaking, it might still be possible for the healthcare provider to operate outside the rules of articles 81 and 82 if it has been **entrusted** by a public body to supply Services of General Economic Interest. Article 86 of the Treaty provides for certain types of undertakings to be classified as providing Services of General Economic Interest (SGEIs) that may be exempted from the rules of competition **if** the application of the rules on competition would **obstruct** the performance, in law or in fact, of the particular tasks assigned to them.

The first step in applying the rules on SGEIs is to establish that the undertaking has been duly **entrusted** to provide Services of General Economic Interest. The act of entrustment may be by way of legislative measures or regulation. An undertaking may also be entrusted through the grant of a concession[6], or licence governed by public law.[7]

Next, we must establish if the service is a service can be classified as **SGEI.** The Treaty does not define SGEI. Instead, Member States define what they consider to be SGEI. The European Commission and Court will review the definition of a service as a SGEI only where they consider that a Member State has made a manifest error. A SGEI is usually a service

- that the market does not provide or does not provide to the extent or at the quality required by the State
- and that is in the general interest, i.e. it is delivered to the public at large and not to a specific sector of industry.

The service must be capable of being carried out on a commercial basis. Examples include public service broadcasting, public transport, postal services and the provision of gas, electricity and telecommunications services.

[6] Case C-159/94 and C-160/94 *EC Commission v the French Republic* [1997] ECR I-05815.
[7] Case C-393/92 *Municipality of Almelo and Others v NV Energiebedrijf IJsselmij* [1994] ECR I-1477.

Finally, the undertaking wishing to benefit from the exemption of competition law would have to establish that the application of the law to its provision of an SGEI would obstruct its ability to meet its duties as entrusted to it by a public body.

However, the issue is not closed with a discussion of the strict application of article 86. While the Treaty speaks only of Services of General **Economic** Interest, the European Commission has launched several communications and policy documents on **Services of General Interest** which include all public services whether of an economic nature or not. In general, the internal market and competition rules under the Treaty have no impact on services of general interest if these services constitute non-economic activities.

The European Commission has in recent years published several papers on the concepts of Services of General Interest and **Social Services of General Interest**[8], which include most social care services. It is important to note that to date the official Communications of the European Commission have **not** included health services within the definition of with Service of General Interest or Social Service of General Interest. The Commission has instead promised to issue specific guidelines on health services.

However, the European Parliament has in March 2007 adopted a report of MEP Joel Hasse Ferreira that calls for health services to be included in the definition of Social Services of General Interest (SSGI). According to MEPs, SSGI form one of the pillars of the European social model and "play an essential part in securing civic peace and the European Union's economic, social and territorial cohesion". Accordingly, an undertaking offering such a service should be able to benefit from the same exemption as do SGEIs. If this were accepted and health services were duly classified as SSGIs, then many private providers of eHealth services would find that they would not benefit from the protection of the law of competition to ensure that they can compete on an open market. On the other hand, such a classification would perhaps assist public bodies in long term health budget planning and control of services provision.

Thus, just as with the rules on undertakings, it remains unclear when a private undertaking offering health services, including eHealth services, may make use of the exemption in article 86 applying to SGEI and moreover it remains unclear whether a health service will be covered by proposed provisions on Services of General Interest.

What is State aid?

For the health sector it is important to think not only about the application of the rules on abuse of dominant position and the possible exemptions of SGEIs but also about State aid, since many health service providers will be funded directly through State aid. Thus if the State grants financial aid that includes special tax exemption, modification of credit conditions or State contribution to capital financing, to an undertaking entrusted with delivering SGEIs, then the State must comply with the rules as set out in article 87 of the Treaty.

[8] See Green Paper on Services of general interest (May 2003), the White paper on services of general interest (May 2004) announcing a more systematic approach in the field of social and health services of general interest. This systematic approach is proposed by a Communication from the Commission "Implementing the Community Lisbon programme: Social services of general interest in the European Union" on 26 April 2006. A conference to discuss the follow-up to the Communications scheduled for June 2007.

Article 87 states that any aid granted by a Member State or through State resources, in any form whatsoever, that distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods shall, insofar as it affects trade between Member States, be considered as incompatible with the common market.

Despite the categorical tone of article 87, the European Commission has the power to decide that a State aid having a social character granted to individual consumers or aids to repair the damages caused by natural disasters, will be considered as compatible with the common market. The Commission may also permit some specific aids.

In general any project of State aid must be notified in advance to the Commission. However, some State aids in the form of public service compensation granted to certain undertakings entrusted with the operation of services of general economic interest (e.g. hospitals) are not be considered as incompatible with the common market and need not be notified. A Commission Decision of 28 November 2005 sets out the conditions under which State aid can be considered as compatible with competition rules[9]. The conditions notably include: compensation of any amount given for **hospitals** and social housing, and to annual compensation of less than 30 million euros given to undertakings whose annual turnover in the last two financial years was less than 100 million euro provided that the service providers for delivering a SGEI. It does not, for example, apply to capital investment aid to those service providers.

If any one of these conditions is not met, then the payment or other benefit granted out of State resources is a State aid for the purposes of article 87(1) and, subject to the other provisions of article 87 and therefore not permissible.

As well as article 87 on State aid, it should be noted that article 10 of the EC Treaty requires Member States to take all appropriate measures to ensure the fulfilment of the obligations arising out of the Treaty and to abstain from any measure which could jeopardise the attainment of the objectives of this Treaty. Thus, if an undertaking is found to be in breach of articles 81 or 82, a Member State can be found to have infringed article 10 if the State favours or reinforces this anti-competitive agreement.

Summary

The discussion above has established that European Competition law may in some cases apply to the various actors in health services provision. It might, for example apply where a public hospital contracts out telemonitoring homecare services to a private company in order to meet the needs of its elderly patients. In such a case, the public hospital, if it is offering its home telemonitoring services as an additional service on the open market, may be considered as an undertaking and must therefore ensure that it allows free and open competition between all telemonitoring service providers who may wish to offer their services through the hospital.

We have also seen, however, that the hospital may be able to argue that its services, despite being purchased from a private provider, are offered without profit to its patients who pay for the service through their normal healthcare co-payment agreements and are therefore exempt from the rules of open competition between telemonitoring providers because the hospital is not acting as an undertaking. This was the argument made in FENIN. However, noting the argument

[9] Commission decision of 28 November 2005 on the application of article 86(2) of the EC Treaty to State aid in the form of public service compensation granted to certain undertakings entrusted with the operation of services of general economic interest, O.J., L 312 of 29 November 2005, pp. 67-73.

made in BetterCare we can see that this question is not entirely clear and may be re-opened as more private providers enter the health market.

We have seen also that the hospital could be granted special State aid to invest in purchasing telemonitoring hardware from private suppliers on the basis that the service it offers is a service of general economic interest.

Most importantly, however, the discussion above has shown that the law in this area is very unclear. While FENIN appears to state that public health systems are not acting as undertakings when purchasing services that they in turn provide to patients, the case was decided on its particular facts and does not apply categorically to all cases of public hospital outsourcing. Similarly in the context of rules on Services of General Economic Interest, we have seen a number of different interpretations of whether health services ever fall into this category. While on the one hand the Commission would seem to exclude health services from this category in its various papers on Services of General Interest and Services of Social Services of General Interest, in its Decision of 28 November 2005 on State Aid and Services of General Economic Interest, it clearly states that hospitals can be providers of Services of General Economic Interest.

In order to clarify the matter a little further Part II will consider the various Treaty articles outlined above in more detail.

PART II: ANALYSIS OF THE RELEVANT LEGAL TEXTS

A. Key concepts[10]

1. UNDERTAKING

Anti-trust and State aid rules apply only to "undertakings" in the meaning of competition law. Although the EC Treaty does not provide any definition of this concept, the ECJ has given various interpretations. Generally the term "undertaking" covers any entity, whatever its statute or type of financing, that is engaged in an economic activity consisting of providing goods or services on a given market.

This interpretation is quite broad and the classification does not depend on the form of the undertaking[11]. Therefore, this concept can include public entities or private corporations, non-profit-making organisations and even professional services like lawyers, notaries, architects or pharmacists[12].

Two conditions are relevant to understanding the concept of undertaking:

- the undertaking must be independent, and;
- it should perform an economic activity.

a. The undertaking must be independent

If the undertaking belongs to a group, the agreements adopted within the group will not be considered as an agreement between undertakings according to article 81 of the EC Treaty.

Moreover, an employee, subordinated and paid by an employer, could not be considered as an undertaking while someone who is self-employed may be an undertaking.

b. The undertaking must perform an economic activity

According to the ECJ, the legal status of the entity is not relevant, nor is the way in which it is financed[13]. The entity is an undertaking if it performs an economic activity.

A public body may be subject to competition law if it performs an activity that may be conducted by a private company or if there is no reason why a private company should not perform this activity[14]. The fact that the activity in question is carried out by private companies in certain Member States can therefore show its economic character[15]. Nevertheless, when the public authority performs activities that are typically those of a public authority, it will not be considered as an undertaking[16].

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[10] Further details on EU Competition law can be found at http://ec.europa.eu/comm/competition/index_en.htm and http://europa.eu/scadplus/

[11] *Höfner and Elser v Macrotron*, ECJ, 23 April 1991, C-41/90.

[12] See the Commission communication on 'Professional Services' of 5 September 2005, COM 2005/405.

[13] *Höfner and Elser v Macrotron*, op. cit.

[14] *Höfner and Elser v Macrotron*, EC, *idem.*

[15] Communication from the European Commission on Social services of general interest in the European Union, SEC 2006/516, p. 16.

[16] For instance, the ECJ stated that the control and supervision of air space is typically an activity of a public authority and therefore are not of an economic nature, *SAT Fluggesellschaft mbH v Eurocontrol*, 19 January 1994, Case C-364/92.

2. PUBLIC UNDERTAKING AND UNDERTAKING WITH SPECIAL OR EXCLUSIVE RIGHTS

A public undertaking is defined by the Transparency Directive 2000/52 as "any undertaking over which the public authorities may exercise, directly or indirectly, a dominant influence by virtue of their ownership of it, their financial participation therein, or the rules which govern it".

An organ of the State cannot be considered as a public undertaking. However, special or exclusive rights may be granted. Special rights are rights granted by a Member State to a limited number of undertakings and which limit to two or more the number of undertakings that are authorised to provide any of such services. An exclusive right is an authorisation for an undertaking to offer exclusively goods or services in a specific market (monopoly).

The authorisation criterion is hence not an objective, proportional and non-discriminatory one. Such privileges may be granted to private as well as to public undertakings.

3. RULES APPLYING TO UNDERTAKINGS

a. Article 81 TEC: Restrictive agreements and concerted practices

Article 81(1) of the EC Treaty prohibits agreements and concerted practices between firms that may affect trade between Member States and that may affect or seek to affect the prevention, restriction or distortion of competition within the common market.

A **restrictive agreement** is an arrangement between undertakings that seeks to limit or eliminate competition between them in order to increase the prices and profits of the undertakings concerned. In practice, these agreements will usually entail price-fixing; production quotas; sharing markets, customers or geographical areas; bid-rigging; or a combination of these practices. Such agreements are prohibited because they damage consumers and society as a whole since the undertakings involved will often set prices higher than they would in conditions of free competition, or undercut prices in order to distort competition. Note that such an agreement does not have be written or binding and could be based on a simple conversation between parties.

A **concerted practice** is minor restrictive agreement. It involves coordination among firms that falls short of an agreement proper. A concerted practice may take the form of direct or indirect contract between undertakings whose object or effect is either to influence market behaviour or to inform each other of the conduct they intend to adopt in the future.

Since it is not always easy to tell whether an arrangement between companies is a restrictive agreement or a concerted practice (or indeed neither) the European Commission has developed a broad overall policy that prohibits certain types of agreement almost without exception. The current public policy website SCADPLUS[17] lists the **prohibited agreements** as:

- horizontal or vertical agreements that fix prices directly or indirectly;
- agreements on conditions of sale;
- agreements that partition market segments, concerning price reductions, for example, or seeking to prohibit, restrict or, on the contrary, promote imports or exports;
- agreements on production or delivery quotas;
- agreements on investments;
- joint sales offices;
- market-sharing agreements;
- agreements conferring exclusive rights to public service contracts;

[17] http://europa.eu/scadplus/

- agreements leading to discrimination against other trading parties;
- collective boycotts;
- voluntary restraints (agreements not to engage in certain types of competitive behaviour)[18].

In this context, **horizontal agreements** are agreements between actual or potential competitors, i.e. between undertakings at the same stage in the production or distribution chain. Such agreements could have an effect on research and development, production, purchases or marketing. Horizontal agreements can restrict competition, particularly when they involve price-fixing or market-sharing, or when the market power resulting from such horizontal cooperation has a negative effect on prices, production, innovation or diversity and on the quality of the products. Horizontal cooperation can also be a means of sharing risks, cutting costs, pooling know-how and launching innovations on the market more rapidly.

Vertical agreements are agreements or concerted practices between two or more undertakings (each of which operates, for the purpose of the agreement, at a different stage of the production or distribution chain) that affect the conditions under which the parties can buy, sell or re-sell certain goods or services.

However, it is noteworthy that some of the activities described above are in fact common practice in commercial areas where co-operation between various vendors or service supplier is well established. This is because article 81(3) provides for certain conditions under which certain types of agreement may be exempted from the general prohibition in article 81(1).

b. Block Exemptions

The provisions in article 81(3) are known as "block exemption" regulations and include certain categories of vertical agreement, such as the regulations on supply and distribution agreements concerning final and intermediate goods as well as services, provided that the combined market share of the parties concerned does not exceed 30% of the relevant market[19]. Further rules in the regulation set limits on the size of undertakings to which the exemption applies (50 million euro annual turnover for supplier and 100 million euro annual turnover for suppliers) and also limit the range and nature of the agreement. Thus, in supply and distribution agreements, fixed resale prices are not permitted although recommended pricing structures are allowed.

While some of the "block exemptions" will apply to certain business practices, others are addressed to types of business. Thus Regulation (EC) No 1400/2002 addresses the application of article 81(3) of the Treaty to categories of vertical agreements and concerted practices in the motor vehicle industry. There are also block exemption regulations for certain categories of horizontal agreement, such as the regulations on technology transfer agreements, and research and development agreements.

Even if a specific exemption regulation has not been adopted under article 81(3), an agreement may be exempted by an individual exemption if its restrictive effect on competition is counterbalanced by the contribution it makes to the general welfare (improved production, technical or economic progress and advantages to consumers).

[18] http://europa.eu/scadplus/leg/en/lvb/l26055.htm

[19] Regulation (EC) No 2790/1999 on the application of article 81(3) of the Treaty establishing the European Community to categories of vertical agreements and concerted practices.

c. Article 82 TEC: Abuse of a dominant position

Article 82 of the Treaty states that "any abuse by one or more undertakings of a dominant position within the common market or in a substantial part of it shall be prohibited as incompatible with the common market in so far as it may affect trade between Member States". A **dominant position** is a situation of economic power held by a firm that allows it to hinder effective competition in the relevant market.

The concept of a **relevant market** is further defined by legislation, notably Regulation (EC) No 1/2003, which set out methods to be used by the Commission to define a relevant market on a case-by-case basis. This incorporates both the product and the geographical dimensions of the relevant market, which are used to determine whether there are actual competitors and to assess the degree of real competition on the market.

Article 82 provides that there is an abuse of a dominant position when the conduct of an undertaking is such that it influences the structure of the relevant market or the degree of competition. It should be noted that the Commission can find that an abuse of dominant position is taking place even if such conduct is allowed by a provision of national law.
Such abuse of dominant position may consist in:

- directly or indirectly imposing unfair prices or other unfair trading conditions;
- limiting production, markets or technical development to the detriment of consumers;
- applying dissimilar conditions to equivalent transactions with other trading parties;
- making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which have no connection with the subject matter of such contracts.

It should be noted that article 82 does not provide for individual or block exemptions.

4. RULES APPLYING TO STATE AID

a. Article 87: State Aid

Restrictions on competition are not always the work of firms; such restrictions can also be created by governments, which grant public aid to businesses. Article 87 of the Treaty states that "any aid granted by a Member State or through State resources in any form whatsoever which distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods shall, in so far as it affects trade between Member States, be incompatible with the common market".

Any advantage granted by the State or through State resources is considered to be State aid where:

- it confers an economic advantage on the recipient;
- it is granted selectively to certain firms or to the production of certain goods;
- it could distort competition; and
- it affects trade between Member States.

The Commission and the European Court of Justice have placed a very broad interpretation on the concept of "aid". The Treaty refers to aid "granted … in any form whatsoever". The Commission and the Court will consider any public aid or any aid granted by a local or regional authority. The aid may come even from a private body, such as a private company or a publicly-owned company operating under private law, or from any other body over which central

government, a public institution or a local or regional authority exercises a dominant influence, directly or indirectly.

The ban catches a very large number of aid measures, whether direct or indirect, of all types. The form and purpose of the aid and the reason for it are irrelevant here; all that matters is the effect on competition. Therefore, not only positive contributions, such as subsidies, are considered as aid, but also any other measure which reduces the financial burden on a firm.

An absolute ban on State aid would be impossible since article 2 of the Treaty states that one of the Community's tasks is to "promote throughout the Community a harmonious, balanced and sustainable development of economic activities", and, given that economic development differs from one Member State to another and from one region to another, this task may require specific government intervention. Accordingly, articles 87(2) and (3) provide for a number of exceptions.

The following are thus deemed compatible with the internal market:

- State aid having a social character, granted to individual consumers, provided that it is granted without discrimination related to the origin of the products concerned;
- aid to make good the damage caused by natural disasters or exceptional occurrences;
- aid granted to areas of Germany affected by the division of the country.

The Commission may also declare the following to be compatible with the internal market:

- aid to promote the development of certain activities or regions;
- aid to promote the execution of an important project of common European interest or to remedy a serious disturbance in the economy of a Member State;
- aid to promote culture and heritage conservation;
- other categories of aid specified by the Council.

The Commission must ensure that the Member States grant only aid that is compatible with the common market. Based on article 88 of the Treaty, **Regulation (EC) No 659/1999 on State Aid**[20] provides that all aid measures or schemes must be notified to the Commission and approved by it *before* being implemented.

5. EXCEPTION REGARDING THE APPLICATION OF THE COMPETITION RULES FOR UNDERTAKINGS ENTRUSTED WITH THE OPERATION OF SERVICES OF GENERAL ECONOMIC INTEREST (SGEI)

With regard to public undertakings and undertakings to which Member States have granted special or exclusive rights, **article 86(1)** of the Treaty prohibits Member States from enacting or maintaining in force any measure contrary to the rules contained in the Treaty, in particular the rules on competition.

However, **article 86(2)** allows some exceptions to the general rules of the Treaty. It provides that enterprises entrusted with the operation of **Services of General Economic Interest** are subject to the rules on competition only "insofar as the application of such rules does not obstruct the performance, in law or in fact, of the particular tasks assigned to them".

The definition of services considered to be "of general economic interest" is generally left up to the Member States. It is well accepted that all basic infrastructure services are covered, e.g., electricity, telecommunications, postal services, transport, water and waste removal services.

[20] Council Regulation (EC) No 659/1999 of 22 March 1999 laying down detailed rules for the application of article 93 of the EC Treaty (now article 88).

In recent years, as liberalisation of these markets has occurred, the Commission has developed the concept of separating infrastructure from commercial activities, in which the infrastructure becomes a means of creating a market for competing services. Thus, while in some Member States the right to exclusive ownership may persist as regards the infrastructure (the telephone or electricity network, for example), monopolists must grant access to third parties as regards the services offered (telephone communications or supply of electricity).

6. MERGERS

Many mergers have been completed during the 1980s. An important example in the pharmaceutical sector is the merger between Glaxo Welcome and SmithKline Beecham. Mergers allow companies to create economies of scale, increase their market power or increase the management quality. However, mergers can obviously create or strengthen a dominant position, which may give rise to abuse. This risk has justified advance vetting of mergers by the EC authorities. The principles of this control are set in the Regulation (EC) No 139/2004.

The regulation addresses different types of mergers, like full mergers or takeovers. The question is whether an enterprise acquires the possibility of exercising a decisive influence over another company. The purpose of this regulation is not to prohibit any merger but to prevent those that would significantly impede effective competition.

Therefore any concentration with an EC dimension in the eHealth sector must be notified to the Commission. During the analysis of the proposed merger agreement by the European Commission, the merger process is suspended. The Commission will assess whether the concentration is compatible with the common market and whether the concentration will be allowed.

Conclusion

APPLICATION OF COMPETITION RULES TO THE VARIOUS ACTORS OF EHEALTH

Competition rules do not apply in the same way to all the different actors playing a role in eHealth activities. Indeed, public organs that perform a typical public kind of activity are not subject to articles 81 and 82 but will be subject to the rules applying to Member States.

Other actors, such as public or private entities, may be subject to competition rules if they are considered as "undertakings". Two conditions are considered by the ECJ: the independence and the performance of an economic activity.

The condition of independency is not easy to apply to eHealth service providers. For example, doctors may work in hospitals as self-employed or as employees. Since the national criteria to distinguish self-employed from employees are not taken into account, this is a question of fact. The ECJ takes into account the means of payment and the extent of individual freedom to seek the level of independence. It may not be easy to find a difference between those situations. Indeed, medical decisions are subjective and so complex that it can become difficult to sustain that a doctor is supervised or subordinated[21]. However, the ECJ stated that self-employed medical specialists are undertakings when they are paid by their patient for the services they provide and therefore assume the financial risk attached to the pursuit of their activity[22].

[21] Jason Nickless, *The consequences of European competition law for social health care providers*, Antwerp, Maklu, 1998, pp. 17-18.

[22] *Pavel Pavlov and Others v Stichting Pensioenfonds Medische Specialisten*, 12 September 2000, Joined cases C-180/98 to C-184/98, n°76-77.

The ECJ refused in some decisions to consider some potential eHealth actors as undertakings performing an economic activity. Indeed, the ECJ refused to consider bodies managing mandatory public social security systems as undertakings. The argument was that this kind of activity has an exclusive social function, is non-profit making and is based on the principle of national *solidarity,* which implies that the benefits paid are statutory benefits bearing no relation to the amount of the contributions[23]. Therefore, providing a technical e-platform in order to register a doctor or to organise the welfare payments may not be considered as an economic activity. Nevertheless, when the amount of contribution has a relation with the benefits, such as private health insurance systems, competition rules do apply. This is the case even if some national public services duties that render the activity less competitive have to be respected.

Other eHealth care providers, like public or private hospitals, self-employed doctors, dentists, surgeons, etc., should be regarded as undertakings as defined by ECJ. Indeed, the financing of health services should be distinguished from the health services as such. The eHealth care providers perform an economic activity and the fact that some hospitals are public does not change anything since their health care activities may be provided on the private market. Therefore, the fact that health care provision is often deeply linked to a social security system does not alter the economic nature of the services provided.

However, article 137(4) of the EC Treaty states that the choice of the fundamental principles of the social security systems belongs to Member States and European law shall not affect this right. This principle may have some limits on the competition possibility in the health sector. Indeed, some national systems limit competition by imposing the choice of the health care provider (the patient must go to a particular doctor or hospital) or limit competition on prices (when prices are fixed or entirely paid by the State without any transparency for the patient).

Technical suppliers, like software or hardware providers, will, among other regulations, also be subject to competition rules.

When the technical activity consists partially or completely in the provision of electronic communication networks or services, it will also be governed, in addition to general competition rules, by sector specific regulations aiming at protecting competition in this sector[24]. Those rules address mainly the relationship between electronic communication providers (like, for instance, to force a dominant undertaking to give access to its network at a reasonable price for his competitors). The electronic communication framework *does not cover the content of services delivered over electronic communication networks using electronic communication services*[25]. Since they do not concern directly as such the eHealth content or eHealth service providers, they are therefore not analysed in this report.

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[23] *Poucet and Pistre v Assurances Générales de France and Others*, ECJ, 17 February 1993, Joined cases C-159/91 and C-160/91. On the question of the application of competition rules to Social Security bodies, see *also Fédération Française des sociétés d'assurance, Société Paternelle-Vie, Union des Assurances de Paris-Vie and Caisse d'Assurance et de Prévoyance Mutuelle des Agriculteurs v Ministère de l'Agriculture et de la Pêche*, 16 November, C244/94*, Pavel Pavlov and Others v Stichting Pensioenfonds Medische Specialisten*, 12 September 2000, Joined cases C-180/98 to C-184/98; *Cisal di Battistello Venanzio & C. Sas contre Istituto nazionale per l'assicurazione contro gli infortuni sul lavoro (INAIL)*, 22 January 2002, C218/00.

[24] See more information on http://ec.europa.eu/information_society/policy/ecomm/index_en.htm

[25] Recital 2 of the Directive 2002/21/EC of the European Parliament and of the Council of 7 March 2002 on a common regulatory framework for electronic communications networks and services (Framework Directive).

PART III: CASE VIGNETTE

Introduction

We have so far provided a general overview of the aspects of competition and trade law having a potential impact on the implementation of eHealth (Part I) and a detailed analysis of the key legislation (Part II). Part III will look at those principles and definitions in practice by using a compilation case vignette.

The case vignette has been constructed on the basis of fictional case histories to outline the way in which legislation might be applied in practice. The compilation is not a 'real' case as such but is informed by reports of real cases and grounded in the reality of medical practice.

In order to make best use of the stories, the reader should refer back to Part II to ensure that a correct interpretation of the legal terms is understood.

Case Vignette 1

SoftMicro Ltd, multinational software specialists have a division called International Medical Records Coordinators (IMRC) Ltd, which provides record scanning services and which they acquired in 2005 as the beginning of a healthcare strategy roll-out.

Founded by Dr. Gautam Gandhi, a practicing physician in the UK, IMRC's business was based on Dr Gandhi's connections between the UK and India. IMRC scans patient records in a mobile unit stationed outside British practices, sends them to IMRC offices in India for data entry to populate a data base hosted on a UK website.

Business developed well over the first eighteen months, when suddenly and without warning, the National Health Service began to offer the same service to physician practices, at one-third the price. The NHS had bought out a British record-scanning company in order to offer the service cheaply and accelerate the number of records being scanned in the UK.

Dr Gandhi's personal financial situation was considerably weakened and most of his employees had to be let go. IMRC and SoftMicro wondered if the NHS entry in the scanning market in this way was legal at a European level.

SoftMicro, fearing the loss of its healthcare business and disposing of important cash reserves, decided to target the up and coming monitoring sector. SoftMicro had heard that PhysioImplant and other Finnish companies had interesting potential. PhysioImplant's owners were ready to sell, because of recent product liability issues, but they assured SoftMicro of their interesting Research and Development pipeline of products.

SoftMicro, found that there was indeed extraordinary monitoring expertise in Finland and, bought up 90% of the market through four purchases. The Finnish Health Minister did not agree that a foreign company dominate the implantable monitoring sector in Finland and was determined to submit the case to the European Court of Justice.

Legal Analysis

This case raises at least two questions:

- the lawfulness of the NHS' services competition,
- the acquisition of 90% of the Finnish medical monitoring market.

LAWFULNESS OF THE NHS' PROPOSED SERVICE

This issue comes from the fact that IMRC has to compete with the new NHS service offered at one-third the price. IMRC is quite surprised by the NHS' possibility to offer this service at such a low price. IMRC wants to know if this price is not unfair and did not result from an abuse of dominant position from NHS.

In order to answer this question, we have to check first whether the NHS' activities fall within the scope of competition rules.

The NHS will have to comply with competition rules if it is considered to be an undertaking as defined in the Community Treaty. The answer will depend on the considered activity. In other words, the NHS might be considered an undertaking for some of its activities, and in other cases for other activities, it might not be considered as such.

In this case, we must examine the provision of record scanning services performed by the NHS, and determine whether this service should be considered an economic activity, in which case the NHS would fall under the definition of an undertaking as per the Treaty.

A public body may indeed be considered to be performing an economic activity, when (if) it performs an activity that may be conducted by a private company or when (if) there is no reason why a private company should not perform this activity. The fact that the activity is carried out by a private company (IMRC in this story) in certain Member States shows the economic character of this activity.

Therefore, we may consider in this case that the record scanning service is an economic activity, that the NHS is thus an undertaking for this activity, and that competition rules do apply to it for this activity.

A further step must be considered: article 86.2 EC provides for the possibility of derogation from competition rules for undertakings that are entrusted with the provision of services of general economic interest or having the character of a revenue-producing monopoly. It states that those undertakings are subject to the rules contained in the Treaty, in particular to the rules on competition, insofar as the application of such rules does not obstruct the performance of the particular tasks assigned to them. On the other hand, the development of trade must also not be affected to such an extent as would be contrary to the interests of the Community.

In the present case, we assume that the application of competition rules does not obstruct the performance of the record scanning services. Derogation from competition rules is therefore not possible (i.e., competition rules apply).

Having established that, for this activity, the NHS is an undertaking, we need to examine whether it is abusing its dominant position when charging for its services a price inferior to that of its competitors. In order to do so, we have to identify the **relevant product**[26] and the **geographic market**[27]. This step also is done on a case-by-case basis, with instruments such as "price effect analysis" (to determine the impact on consumers).

To assess dominance, two elements are generally analysed: the type of entry barriers and the importance of market shares. Some very important market shares may be considered as a dominant position (e.g. 75% or more). A typical case of a dominant position is when an undertaking has a significant market share and there are high entry barriers. The existence of a dominant position is not forbidden as such. It is only the abuse of this position that is unlawful. Considering this, the application of an unfair price could be qualified as an abuse of dominant position if the low price is not justified. It would be up to the NHS to convince the courts that the low price it proposes is justifiable.

The opposing party might also investigate whether unlawful public aid has benefited the NHS's provision of this service. Public aid as such is acceptable, notably when the purpose is social aid[28], but this is an argument that could enter into the debate.

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[26] A relevant product market comprises all products and/or services that are regarded as interchangeable or substitutable by the consumer by reason of the products' characteristics, their prices and their intended use.
[27] A relevant geographic market comprises the area in which the concerned firms are involved in the supply of products or services and in which the conditions of competition are sufficiently homogeneous.
[28] Public aid is also lawful in other notable occasions, such as important projects of common European interest or any other category of aid specified by the Council on proposal from the Commission (cf. Commission Decision of 28 November 2005).

Finally, however, it must be remembered that Community action, including competition rules, has to respect the Member States' responsibilities for the organisation and provision of health services and medical care, as per article 182 of the Treaty.

THE ACQUISITION OF 90% OF THE FINNISH MEDICAL MONITORING MARKET

Again, the first step will be comprised of checking whether European competition rules apply, and verifying that the activity defines the company as an undertaking. In this case, the answer should be positive.

If the acquisition of 90% of the Finnish medical monitoring market constitutes a concentration with an EC dimension, the merger should be notified to the Commission, which will verify that it would not significantly impede effective competition, as per Regulation (EC) No 139/2004.

Owning 90% of the Finnish medical monitoring market will very likely be viewed as a dominant position. Again, while a dominant position in itself is not illegal, abusing it is. This may take the form of an excessive price, or non-interoperability with other services. Therefore, while SoftMicro cannot, according to European law, be stopped from acquiring 90% of Finland's medical monitoring market, the Minister of Health of Finland will likely monitor carefully that SoftMicro does not abuse of its dominant position in any way, submitting the case to the Finnish Courts or complaining to the European Commission if it notices any wrongful behaviour.

PART IV: LEGAL SOURCES

Legally binding texts:

- Article 81 of the Treaty establishing the European Community prohibiting agreements and concerted practices between undertakings with an anticompetitive object or effect on the market;
- Article 82 of the Treaty establishing the European Community prohibiting the abuse of undertakings in a dominant position that affects free trade;
- Article 86.1 of the Treaty establishing the European Community on the liability of Member States for unlawful practices made by public undertaking or undertaking which received special or exclusive rights;
- Article 86.2 of the Treaty establishing the European Community providing exceptions on the application of the competition rules for undertaking entrusted with the operation of general economic interest;
- Article 87 of the Treaty establishing the European Community prohibiting direct or indirect State aid that may distort competition by favouring certain undertakings;
- Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings (the EC Merger Regulation);
- Commission decision of 28 November 2005 on the application of article 86(2) of the EC Treaty to State aid in the form of public service compensation granted to certain undertakings entrusted with the operation of services of general economic interest, O.J., L 312 of 29 November 2005, pp. 67-73.

Commission communications:

- Communication from the European Commission on Social services of general interest in the European Union, SEC 2006/516.
- Commission communication on 'Professional Services' of 5 September 2005, COM 2005/405.

Some of the relevant case law of European Court of Justice (ECJ):

- *United Brands v. Commission*, 14 February 1978, Case C-27/76;
- *Höfner and Elser v Macrotron*, ECJ, 23 April 1991, Case C-41/90;
- *Poucet and Pistre v Assurances Générales de France and Others*, ECJ, 17 February 1993, Joined cases C-159/91 and C-160/91;
- *SAT Fluggesellschaft mbH v Eurocontrol*, 19 January 1994, Case C-364/92.
- *Fédération Française des sociétés d'assurance, Société Paternelle-Vie, Union des Assurances de Paris-Vie and Caisse d'Assurance et de Prévoyance Mutuelle des Agriculteurs v Ministère de l'Agriculture et de la Pêche*, 16 November, Case C-244/94;
- *Pavel Pavlov and Others v Stichting Pensioenfonds Medische Specialisten*, 12 September 2000, Joined cases C-180/98 to C-184/98;
- *Cisal di Battistello Venanzio & C. Sas contre Istituto nazionale per l'assicurazione contro gli infortuni sul lavoro (INAIL)*, 22 January 2002, Case C-218/00.
- *Federación Española de Empresas de Tecnología Sanitaria (FENIN), formerly Federación Nacional de Empresas de Instrumentación Científica, Médica, Técnica y Dental, v. Commission of the European Communities*, 11 July 2006, Case C-205/03 P
- Competition Act 1998 Decision of the Office of Fair Trading No CA98/09/2003 BetterCare Group Ltd/North & West Belfast Health & Social Services Trust (Remitted case), 18 December 2003 (Case no CE/1836-02).