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Current trends and developments in competition law:

Panel III: Competition in the healthcare sector

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The Importance of the health sector in the EU

Definitions:

The "**healthcare sector'** is defined as 'an economic and social sector concerned with the provision, distribution and consumption of healthcare services and related products'.

Healthcare services and related products is a broad concept. It encompasses 'any intervention that may be used to promote health, to prevent, diagnose or treat disease or for rehabilitation or long-term care. This includes pharmaceuticals, medical devices, procedures and organisational systems used in healthcare.

See, '**Health Technology Assessment (HTA) Glossary**', First edition. Stockholm: edited by Topfer, L.A., and Chan, L. on behalf of the International Network of Agencies for Health Technology Assessment INAHTA Secretariat, 2006.

Importance of the Health sector in the EU

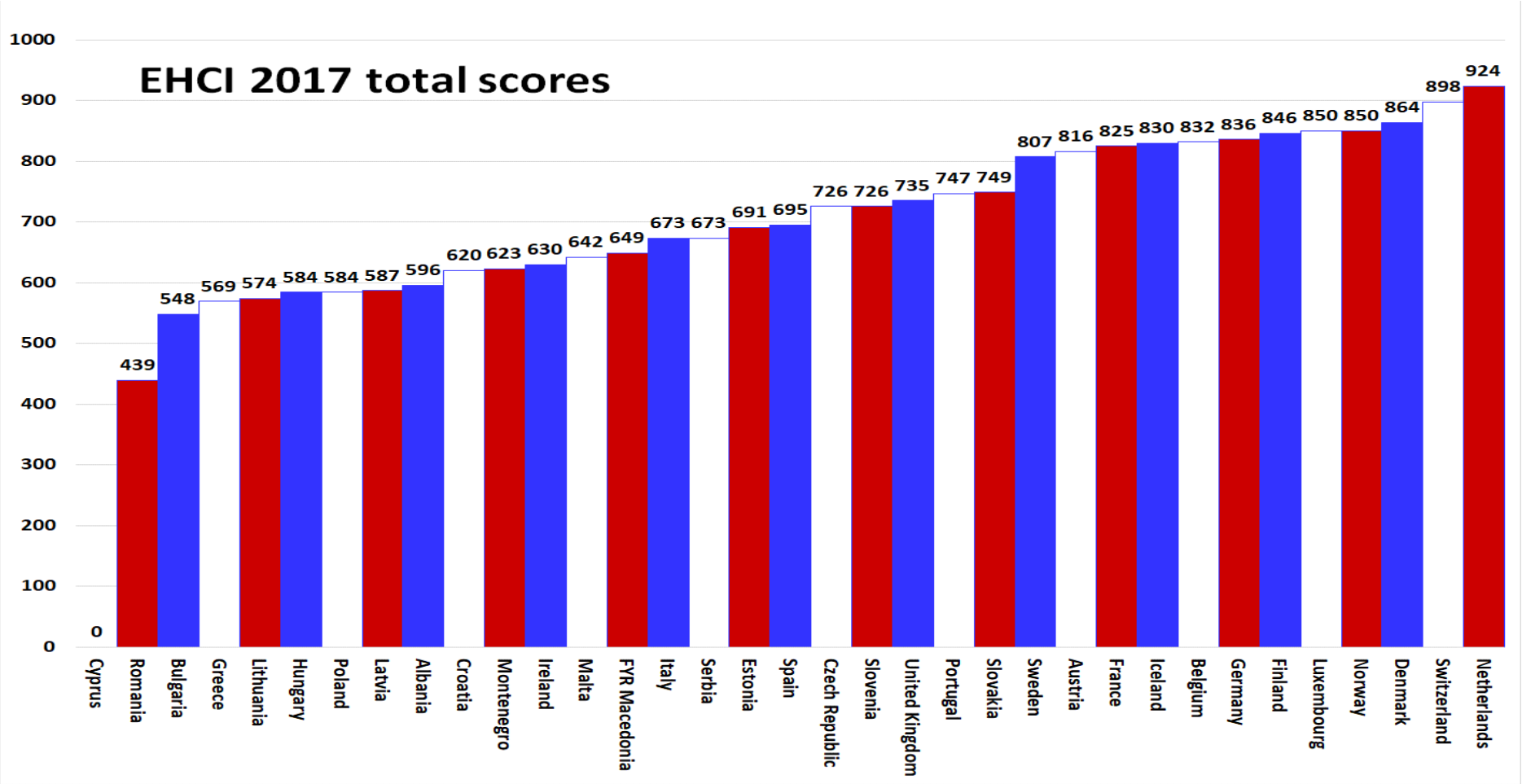
The citizens of the European Union spend more than 1 trillion euro a year on healthcare. This includes ‘any interventions that may be used to promote health, to prevent, diagnose or treat disease or for rehabilitation or long-term care such as pharmaceuticals, medical devices, procedures and organisational systems used in healthcare.

In The EU the healthcare sector is organised in intricate and country-specific systems in which the governments hold competence in the field of health policy. Roles and responsibilities within the healthcare sector are split between regulators, payers, healthcare providers, the industry (suppliers) and patients (consumers).

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.

Indicators of the healthcare system 2010	Slovakia	EU average
Total health expenditure as % of GD	9%	9%
Public expenditure as % of total health spending	64%	73%
Private insurance as % of total health spending	0%	4%
Private-out-of-pocket as % of total health spending	26%	21%
Organisation of the healthcare system		
Social insurance or tax-based system? Gatekeeping by a general practitioner (GP)? How are physicians paid? (e.g. salary, fee-for-service, capitation)	**Social insurance compulsory Capitation**	
Patient organisation involvement (3=good, 2=intermediary, 1=not-so-good)	3	

Source Study on Corruption in the Healthcare Sector HOME/2011/ISEC/PR/047-A2 October 2013 European Commission – Directorate-General Home Affairs
https://ec.europa.eu/home-affairs/sites/homeaffairs/files/what-is-



Health Consumer Powerhouse

EHCI 2017 sub-disciplines

Sub-discipline	Weight (Red = full score)	Doing well
Patient rights, information and e-Health	125	Netherlands, Norway
Waiting times / Access	225	Switzerland, Slovakia
Outcomes	289	Finland, Norway
Range & Reach of services provided	125	Netherlands, Sweden
Prevention	119	Norway
Pharmaceuticals deployment	89	Germany, Netherlands

Health Consumer Powerhouse

EU HEALTH POLICY

Article 152(5) provides that Community action in the field of public health must fully respect the responsibilities of the member states for the organisation and delivery of health services and medical care.

Public health bodies hold a position of special responsibility in national health markets. In many cases, they enjoy a position of dominance in domestic health markets through the intervention of state legislators and governments. All dominant undertakings are subject to special responsibilities.

Articles 10, 3(g) and 82 and national health markets

In EU law, public health bodies may be considered to be emanations of state by reference to the degree of control exercised over them by domestic governments or parliaments. In situations where a dominant public health body is considered not to fall within the direct scope of article 102 by reference to the decision of the Court of Justice in FENIN, article 10 of the EC Treaty requires member states to abstain from any measure which could jeopardise the attainment of the objectives of the Community's competition rules.

EU HEALTH POLICY

Regardless of whether or not the conduct of public health bodies is directly subject to the requirements of article 102, member states must at all times dutifully ensure that competition in upstream or downstream markets is not distorted by their emanations of state in contravention of the requirements of articles 3(g), 10 and to "a system ensuring that competition in the internal market is not distorted".

The meaning of ‘Undertakings’ in EU Competition Law

The understanding of the concept of undertaking is vital to the application of EU competition law. it can be considered as the first important step in a competition assessment because for an agreement to fall within the scope of EU competition law it must meet four criteria in which the two are relevant to the term of undertaking. They include : ”there must be an agreement or a decision by an association of undertakings or a concerted practice' and that “the agreement! decision or concerted practice must be between undertakings'.

However, althought Article 101 of the TFEU, Article 102 TFEU and Article 106 TFEU mention undertaking the Treaties do not provide a definition of the term.

The meaning of 'Undertakings' in EU Competition Law

The general understanding of the term was given by the European Court of justice (ECJ) in Höfner and Elser v Macrotron. It defines an **undertaking** to be all entities which are engaged in economic activities not withstanding the legal standing of it and the method it is financed.

The next point is to look at what constitutes an economic activity. In Pavlov and others, it was stated that "any activity consisting in offering goods and services on a given market is an economic activity"

The starting point of these definitions is the fact that the legal status is irrelevant. Further, it is also not necessary for the entity to make profits.

Inn addition SELEX also makes it clear that an entity may not be subject to competition law in respects to all of its activities but for some.

It is also vital to note that the general principle that the exercise of powers relating to public authorities tend not to be governed by competition law.

Concept and organisation of public undertakings

The concept of public undertaking covers very different situations, primarily because of the many different reasons that have justified, for more than a century, the creation of public undertakings in European countries.

Various definitions of public undertakings exist ; The European Commission in Directive 80/723 of 25 June 1980 concerning the transparency of financial relations between Member States and public undertakings defines a public undertaking 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'.

It follows from this definition that dominant influence of a public authority and not public ownership is now considered to be the main criterion of the public undertaking, influence being exerted, irrespective of ownership, through the power to appoint top decision-makers in the undertaking or the ability to control major decisions through special rights for public authority representatives.

Competition law applies to **undertakings**, that is, bodies engaged in **economic activity**

A body can act as an undertaking in respect of **some of its functions** in respect **of its functions** and not in respect of others

Conduct amounts to economic activity when the body is: (a) **supplying a good or service,** and (b) that supply is of a **commercial nature**

- Exercise of certain **public powers** are deemed not to involve a supply of goods/services are deemed not to involve a supply of Goods/services
- **Profit-making activities** in competition with private sector will be commercial
- **Non-profit making activities** can also be commercial if they could be provided by the private sector
- **Upstream purchasing** is an economic activity if the purchased g/s are subsequently used to conduct economic activities downstream.

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Conduct will not amount to economic activity if it is of a **wholly social** nature

- Activities that **could not conceivably be carried out for profit** by a private sector body may be wholly social
- Redistributive activities carried out according to principles of ' **solidarity** ' may be wholly social

Identifying 'economic activity'

Whether a particular activity carried on by a public body is treated as an economic activity necessarily depends on the specific facts at hand. For this reason, past cases may provide only limited wider guidance to public bodies seeking to apply legal precedent to their own specific circumstances.

In broad terms, the following questions for each activities separately are relevant:

- Is the supply of good or service, as opposed to, for example, exercising a public power ?
- is that offer or supply of a 'commercial' – rather than an exclusively 'social' – nature?

If the answer to both these questions is yes, then – **for the purposes of that activity (and any related upstream purchasing)** – the public body is likely to be regarded as an undertaking subject to EU competition law .

Economic activity

….Any activity consisting in offering goods and services on a given market.”

In the FENIN, . The Commission rejected the complaint on the ground that the alleged bodies were not acting as undertakings when they purchased medical goods and equipment from FENIN. The ECJ held that ”an organisation which purchases goods - even in great quantity - not for the purpose of offering goods and services as part of an economic activity, but in order to use them in the context of a different activity, such as one of a purely social nature, does not act as an undertaking simply because it is a purchaser in a given market ” .

It is also important to note that this 'functional' approach means that a public body may act as an undertaking – and therefore be subject to competition law – in respect of some of its activities, but not in respect of others.

Social activity not economic activity

Joined cases C-159/91 and C-160/91, Poucet and Pistre : The ECJ held that “Fulfilled an exclusively social function based based on the principle of national solidarity and is entirely non-profit making “.

Commercial activity

Where goods or services are offered or supplied by the public body, is that offer or supply of a 'commercial' nature, as opposed to an exclusively 'social' nature?

The provision of goods or services on a 'commercial' basis will constitute economic activity. The clearest example of this is an activity undertaken for profit in direct competition with private sector .

However, the concept of 'commercial' activity should not be considered limited to such examples : importantly, an activity need not in fact generate a profit . For example, in the case of a public body providing employment recruitment services free of charge , the EU courts found that those services were an economic activity, as they could be (and had previously been) provided by private sector companies.

Exercise of 'public powers'

The exercise by a body of powers which are 'typically those of a public authority' (that is, where it carries out State prerogatives or essential functions of the State) are deemed no t to involve the offer or supply of goods or services on a market.

Case C-343/95 *Diego Cali & Figli SrL v Servizi Ecologici Porto di Genova Spa* [1997] ECR I- 1547 (' *Diego Cali* '), paragraphs 22 to 23.

Purchase of goods or services

Competition law may apply to agreements and conduct relating to a public body's **purchasing** activities (whether individually or jointly with others). However, in determining whether a public body is acting as an undertaking in relation to such purchase of goods or services in a market, the economic or non-economic nature of that purchasing activity depends on **the end use to which the public body puts the goods or services bought .**

NB. Public bodies should, even where they are carrying out essential functions of the State, or merely purchasing goods, their conduct may — even if not subject to the EU competition law prohibitions may be subject to other legal controls, including administrative or procurement laws..

State bodies

State body

“the classification as an activity falling within the exercise of public powers or as an economic activity must be carried out separately for each activity exercised by a given entity”. Case C-49/07, MOTOE

Exercise of public authority

ECJ found Article 101 not apply to agreements concluded by bodies “acting in their capacity as public authorities and undertakings entrusted with the provision of a public service” (Case 30/87, Bodson**)**

Public services

Public services are not defined by specific ownership arrangements but by their function: for the public authorities, this function consists of ensuring that citizens have access to services of an economic nature which meet essential general interest requirements and that cannot be satisfactorily met by private initiatives;

the services are defined, organized and regulated by the authorities which generally grant them special rights which are perceived as necessary for the service provision.

Public services exist whenever a political community decides that a particular economic activity which is vital for the general interest cannot be provided by the market alone.

Public services

At the same time, a public undertaking must have:

(1) a degree of autonomy vis-à-vis the public authorities;

(2) an economic purpose: i.e. to produce and sell goods or services;

(3) operating methods similar to those of private undertakings.

Public services are not to be confused with public undertakings, which may carry out activities which are devoid of any general interest .

'Social' activity

By contrast, where public bodies carry out an activity of an exclusively social nature, neither that activity, nor the bodies' purchase of goods or services for the purpose of that activity, will generally be treated as an economic activity.

Any assessment of whether an activity is of an exclusively social nature will necessarily be fact specific, and must take account of all aspects of the activity in question.

Past case law on this issue provide certain principles:

- The activity must be **exclusively** social;
- Activities which by their very nature could not be carried out for profit without State support;
- In the context of social security and insurance schemes, the operation of a scheme according to certain wholly 'uncommercial', redistributive principles (known as ' **solidarity** ') has been considered to be an exclusively social activity.

'Social' activity

However, it can be seen in FFSA and Albany that the CJEU in these cases rejected the solidarity arguments although there were elements of it as the benefits were dependent on the results of investments made.

In a controversial case involving this area the UK, the CJEU suggested a broader interpretation to the idea of an undertaking as compared to previous C-EU cases# In

In the Spanish Health Service, the CJEU held that the GC was right in taking the view that although the Spanish Health Service purchased large amounts of goods it cannot be considered to be an economic activity as it has to take the view of ***where the goods were put to use in, how it was funded and whether its services were provided free***. Thus, even though the Spanish Health Service could exert great economic power it could not be classified as an undertaking.

However, the Court has held that non-profit-making organisations, contributing to the management of the social security system and subject to the solidarity principle, could be considered to be carrying out an economic activity .

Undertakings in the health sector

Moving to the health services and sector, the European Courts have developed a concept which to determine what types of activities in these sectors should be excluded from competition rules.

The concept of solidarity was first discussed in the Poucet and Piste case. in this case two people wanted to opt out of the French system for certain benefits that required mandatory payments and they claim that this was in breach of competition law. The CJEU in this case held that these schemes were not economic activities as they were of a social nature and were thus based on the solidarity principle. The principle in this case was that the scheme was financed proportionally by incomes of the people that paid them and identical benefits were given to all those that are entitled to it.

Undertakings in the health sector

It is therefore clear from the case-law that the social aim of a health insurance scheme is not in itself sufficient to exclude classification as an economic activity. It must also be examined whether that scheme can be regarded as applying the principle of solidarity and is subject to the supervision of the State which established it. Those factors are liable to preclude a given activity from being regarded as economic (see judgment of 3 March 2011, AG2R Prévoyance, C-437/09, EU:C:2011:112, paragraphs 45 and 46 and the case-law cited).

For the purposes of that assessment, first, it must be noted that characteristics of social security schemes applying the principle of solidarity include, inter alia, an obligation on health insurance bodies to be affiliated with the scheme, a lack of any direct link between contributions paid and benefits received, compulsory and identical benefits for all insured persons, contributions proportional to the income of insured persons and application of the pay-as-you-go principle

Undertakings in the health sector

Second, characteristics of social security schemes subject to State supervision include, inter alia, an obligation for health insurance bodies to offer compulsory benefits to insured persons and an impossibility for health insurance bodies to influence the nature and level of the benefits set by law or the amount of the contributions paid by insured persons .

(see, to that effect, judgments of 17 February 1993, Poucet and Pistre, C-159/91 and C-160/91, EU:C:1993:63, paragraphs 9 to 12; of 22 January 2002, Cisal, C-218/00, EU:C:2002:36, paragraphs 34 to 43, and of 16 March 2004, AOK Bundesverband and Others, C-264/01, C-306/01, C-354/01 and C-355/01, EU:C:2004:150, paragraphs 52 and 53).

(see also judgments of 22 January 2002, Cisal, C-218/00, EU:C:2002:36, paragraphs 43 and 44; of 22 May 2003, Freskot, C-355/00, EU:C:2003:298, paragraph 78, and of 16 March 2004, AOK Bundesverband and Others, C-264/01, C-306/01, C-354/01 and C-355/01, EU:C:2004:150, paragraph 52).

Specific exclusions from competition law

Article 106(2) TFEU, exclude from the application of the EU competition rules undertakings that are entrusted with providing ***'services of general economic interest***' or that are ***'revenue-producing monopolies***', insofar as those prohibitions would obstruct, in law or in fact, the performance by those undertakings of the particular tasks assigned to them.

These exclusions therefore seek to ensure that the application of competition law does not prevent the effective provision of important public services or the proper operation of fiscal monopolies.

State regulation and services of general economic interest

Article 106 EUFT applies when Member States interfere with a market by granting exclusive rights (Article 106(1)), or by entrusting an undertaking with the operation of a service of general economic interest (SGEI) (Article 106(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. In short, terms 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.

The consequences for public bodies of engaging in economic activity

The fact that a public body acts as an undertaking and is subject to EU competition law does not necessarily mean that it will have to amend its practices.

Compliance with competition law should not materially impede public bodies' efficient exercise of their functions. Instead, public bodies need to self-assess whether their conduct is compliant with competition law to determine whether any amendments are required.

Enforcement of competition law

Variations in the level of national enforcement.

Cartels

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

German Competition Authority (GCA), Press Release, 19 April 2007,.

French Conseil de la Concurrence (FCC), Press Releases, 30 October 2007, w

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

Italian Antitrust Authority (IAA), Press Release, 8 August 2007.

Hungarian Competition Council, Press Release, 21 February 2007,

Enforcement of competition law

Abuse of dominance

Definition of relevant market : 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.Case C-179/90, Merci convenzionali Porto di Genova [1991] ECR I-589,para. 15;

Dutch Competition Authority, Press Release, 6 June 2003,

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'.

The Council also found that GSK was dominant in the market for injectable aciclovir . 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

the DCA's investigation and statement of objections led the pharmacists voluntarily adapted their admission rules.

Advocacy by NCAs

NCAs in some EU countries have commented on proposed or enacted health legislation or have advocated in favour of improving competition in the organization of national health systems

The rising cost of pharmaceuticals has increased pressure on Member States to initiate 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.

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.

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Thank you