Research Paper

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Abstract: the provisions of EU law that are relevant to health insurance are either competition law and state aid, or public procurement. Which regime applies depends mainly on the definition of undertaking. At the same time the internal market rules are also relevant, notably the non-life insurance Directives which limit the ability of Member States to intervene in insurance conditions, but with an exception for schemes that substitute for social security. This reflects the balancing act between compulsory coverage and privatisation of risk that characterises the increasing importance of health insurance as part of the policy mix which Member States apply to problems of funding and guaranteeing the provision of healthcare.

JEL codes: I1; I18; K21; K23; K32
Keywords: health insurance and: competition law; state aid; public procurement

1. Introduction

Within the EU, health insurance is so far primarily a phenomenon of the Bismarck systems of which it forms the defining feature. In this paper the term health insurance covers publicly defined (minimum packages) of care as well as (often voluntary) supplementary insurance. In all cases health insurance involves third party payment of medical expenses as well as pooling of risks, in some cases based on solidarity within the population of the particular insurer, and sometimes between insurers if a system of risk equalisation is implemented.[1]

This paper will mainly examine which EU law rules apply to providers of health insurance and under which conditions. For this purpose, it is organised in two main parts:

— *Competition law:* first we will discuss the question when an insurance provider is classified as an undertaking, and when provided as a public service for the purposes of the competition rules. Next the implications of the rules on antitrust and on state aid are examined, as well as the exception for services of general economic interest (SGEI). It is in this context that risk equalisation is covered.

— *Internal market law:* second, we will look at the internal market rules that are specific to insurance and the conditions under which the various exceptions for public service, for the general good, and for healthcare apply. This also involves a concise examination of the direct effect and the horizontal effect of directives in this area. This is relevant inter alia to the question whether the Patients' rights directive restrictions on the use of prior authorisation requirements applies to insurance providers, or just to national authorities (or whether the latter are under instructions to prohibit the former from introducing such constraints). Next we look at public procurement and health insurance.

Finally some general conclusions will be drawn on the criteria applied and the links between them, as well as between the different areas of EU law involved.

2. Competition law

[*] Tilburg Centre of Law and Economics (TILEC) and Dutch Healthcare Authority (NZa). Leigh Hancher kindly provided comments on an earlier draft. The views expressed here are personal.

[1] A comparative view in F. Paolucci, A. den Exter and W.P.M.M. van de Ven, "Solidarity in competitive health insurance markets: analysing the relevant EC legal framework", (2006) Health Economics, Policy and Law 107.

2.1. Private undertakings or public service?

The competition and state aid rules apply exclusively to undertakings. This is in line with their purpose which is to complement the internal market freedoms that apply to the Member States' authorities in order to prevent barriers to trade levelled by the former from being resurrected by private constraints on competition. The locus classicus for the definition of undertaking is the 1991 *Höfner* Case in the context of executive job recruitment services, where the Court stated: "the concept of an undertaking encompasses every entity engaged in an economic activity, regardless of the legal status of the entity and the way in which it is financed".[2] In this context it was held immaterial whether there had been a public monopoly at a given time as such services were elsewhere and at other times performed competitively. An economic activity is in turn defined in the 2001 *Pavlov* Case (concerning supplementary pension schemes for medical specialists) as "any activity consisting in offering goods and services on a given market". [3]

The same observations were made in a number of insurance cases which however approached the question from the opposite angle, notably assessing the degree of solidarity by which the activity at issue was characterised. Some of the issues that will be raised are the following:

- How important is the question whether the entity concerned is profit-making or not?
- How important is who defines the benefits involved?
- Do we see parallels with the open enrolment requirement in SGEI cases?

First we summarise the main general insurance cases relevant tot the concept of undertaking under EU law. These demonstrate that the solidarity concept is associated less with not-for-profit activities than with standardised benefits independent from the amount of contributions paid. This is contrasted with undertakings providing benefits based on capitalisation.

<u>Poucet and Pistre</u>

Here (1993) mandatory social security contributions by self-employed persons to specific insurance schemes (sickness and maternity insurance as well as old-age insurance) were at issue.[4] Poucet and Pistre had wanted to contract their own, private, insurance for these risks. The Court held that the schemes concerned were non-profit-making, pursued an exclusively social objective and embodied the principle of solidarity. It observed that contributions were proportional to income but benefits were standardised and in some cases awarded to those who had not made contributions, and that there was some degree of cross-financing between different social security schemes to help those with structural financial difficulties. The funds were held to be unable to influence the amount of contributions, the use of assets or the level of benefits. In this context the system of compulsory contributions was indispensible for sustaining the principle of solidarity and the schemes' financial equilibrium. (As the Court held in its *García* Case of 1996: '(…) social security schemes (…), which are based on the principle of solidarity, require compulsory contributions in order to ensure that the principle of solidarity is applied and that their financial equilibrium is maintained.[5]) Hence the activity concerned was held not to be an economic activity and entities concerned not undertakings.

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[2] Case C-41/90, Klaus Höfner and Fritz Elser v Macrotron GmbH [1991] ECR I-1979, para 21.

[3] Joined cases C-180/98 to C-184/98, Pavel Pavlov and Others v Stichting Pensioenfonds Medische Specialisten [2000] I-6451, para 73.

[4] Joined cases C-159/91 and C-160/91, Christian Poucet v Assurances Générales de France and Caisse Mutuelle Régionale du Languedoc-Roussillon [1993] ECR I-637.

[5] Cf. Case C-238/94, José García et al. v Mutuelle de Prévoyance Sociale d'Aquitaine et al. [1996] ECR I-1673, para 14. Cf. A. Winterstein, "Nailing the Jellyfish: social security and competition law", (1999) European Competition Law Review 324.

FFSA

The *FFSA* case (1995) concerned a French supplementary old-age pension scheme which was optional but non-profit-making.[6] Apart from the optional nature of the scheme the Court focused on the fact that it was based on the principle of capitalisation, with a direct link between the individual entitlement and the amount of contribution paid as well as the financial returns of the investments made. Hence the entity concerned was held to constitute an undertaking for the purposes of the competition rules in spite of the existence of certain elements of solidarity such as temporary exemptions from paying contributions in case of illness and in spite of the fact that the entity was non-profit-making. It should be noted that neither in Poucet and Pistre nor in FFSA there was a public definition of the entitlements concerned.

Albany

In the *Albany* case (1999) the compulsory affiliation to a sectoral pension fund on terms that had initially been fixed by means of a collective agreement between employers and employees in the textiles industry in the Netherlands was at issue.[7] Here the Court also ruled that the collective agreements themselves did not fall within the scope of the competition rules as part of an exception for collective agreements that it derived from the context of the Treaty. (This was confirmed regarding a collective agreement involving compulsory health insurance in the 2000 *van der Woude* Case.[8]) The Court found that the pension fund operated based on the principle of capitalisation and engaged in competition with insurance companies. Hence neither the fact that it was non-profit-making nor that it pursued a social objective were held to be decisive and the fund was held to constitute an undertaking for purposes of the competition rules. However in the final analysis the award of an exclusive right to said fund was held to be justified for the performance of a SGEI with which it had been entrusted – opening the way for an exception to the competition rules.[9]

Cisal

In the *Cisal* case (2002) an Italian scheme providing compulsory insurance against accidents at work and occupational diseases was at issue.[10] The amount of benefits and the amount of contributions were subject to supervision by the State.

> (…) the activity of the INAIL, entrusted by law with management of the scheme in question, is subject to supervision by the State and (…) the amount of benefits and of contributions is, in the last resort, fixed by the State. The amount of benefits is laid down by law and they may be paid regardless of the contributions paid and the financial results of the investments made by the INAIL. Second, the amount of contributions, upon which the INAIL deliberates, must be approved by ministerial

[6] Case C-244/94, Fédération Française des Sociétés d'Assurance et al. v Ministère de l'Agriculture et de la Pêche [1995] ECR I-4013.

[7] Case C-67/96, Albany International BV v Stichting Bedrijfspensioenfonds Textielindustrie [1999] ECR I-5751. Cf. the parallel cases Joined cases C-115/97, C-116/97 and C-117/97, Brentjens' Handelsonderneming BV v Stichting Bedrijfspensioenfonds voor de Handel in Bouwmaterialen [1999] ECR I-6025 and case C-219/97, Maatschappij Drijvende Bokken BV v Stichting Pensioenfonds voor de Vervoer- en Havenbedrijven [1999] ECR I-6121.

[8] Case C-222/98, Hendrik van der Woude v Stichting Beatrixoord [2000] ECR I-7111.

[9] See also the discussion in the AG2R, and BUPA Cases and the Commission Decisions on Irish and Dutch risk equalisation cases later in this section.

[10] Case C-218/00, Cisal di Battistello Venanzio & C. Sas v Istituto nazionale per l'assicurazione contro gli infortuni sul lavoro (INAIL) [2002] ECR I-691

> decree, the competent minister having the power to reject the scales proposed and to invite the INAIL to submit to him a new proposal taking account of certain information.[11]

In this context the Court found that the compulsory affiliation of the insurance scheme was essential for its financial balance and for application of the principle of solidarity, meaning the benefits paid were not strictly proportionate to the contributions paid by the beneficiaries. Hence such a body fulfilled an exclusively social function and accordingly did not carry out an economic activity for the purposes of competition law, meaning it was not an undertaking (and thus excluded).

Freskot

The 2003 case Freskot concerned compulsory insurance by agricultural holdings against natural risks in Greece.[12] The Court held that the social purpose of that compulsory insurance scheme was not, in itself, sufficient to preclude its activity from being classified as an economic activity. However it noted that both the benefits and the contribution, which were the two essential elements of that scheme, were set by law. Moreover the rate of the contribution was set and imposed by the State. Hence the insurance activity concerned was found not to be an economic activity: therefore the entity involved was not an undertaking for purposes of the state aid rules.[13] (Worth noting as an aside is that in Freskot the Court held that the concept of services that fall within the scope of the First non-life insurance Directive 73/239 is the same as that of Articles 56 and 57 TFEU.[14])

We therefore see the Court applying a loosely defined set of criteria revolving around the concepts of "undertaking" and "solidarity" with some variations but emphasising the question whether benefits are standardised across the pool of participants or personalised.

We will now look at *AOK* and at *AG2R* that because they specifically concern health insurance are discussed in greater detail. They are also of interest because in AOK the issue of risk equalisation was raised for the first time and in AG2R the most recent detail is given on the standard for SGEI. It should be noted that the assumption of the Court in AOK that risk equalisation testifies to the existence of solidarity to the exclusion of competition is the opposite from the findings of the Commission and the General Court in subsequent cases (such as BUPA) that present risk equalisation, conversely, as a precondition for competition.

AOK

In the 2004 AOK case the fixing of maximum contributions by the German health insurance funds towards the costs of medicinal products was at issue. The Court had been asked whether this was illegal under the competition rules.[15] The German system made it compulsory for

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[11] Ibid., para 43.

[12] Case C-355/00, Freskot AE v Elliniko Dimosio [2003] ECR I-5263.

[13] Ibid., paras 54ff.

[14] First Council Directive 73/239/EEC of 24 July 1973 on the coordination of laws, regulations and administrative provisions relating to the taking-up and pursuit of the business of direct insurance other than life assurance, OJ 1973, L228/3, last amended by Council Directive 2006/101/EC of 20 November 2006, OJ 2006, L363/238. The defining issue is that of remuneration agreed between two contracting parties.

[15] Joined cases C-264/01, C-306/01, C-354/01 and C-355/01, AOK Bundesverband et al. v Ichthyol-Gesellschaft Cordes, Hermani & Co. (C-264/01), Mundipharma GmbH (C-306/01), Gödecke GmbH (C-354/01) and Intersan, Institut für pharmazeutische und klinische Forschung GmbH (C-355/01) [2004] ECR I-02493. Cf. W. Sauter and J. van de Gronden, Taking the Temperature: A Survey of the EU Law on Competition and State Aid in the Healthcare Sector, TILEC Discussion Paper No. 2010-038.

employees to join the public law scheme but on the other hand the insurance premiums did not only depend on the income of the insured party but also on the rate set by the insurance company. There was a degree of rate competition between these insurers in order to gain the business of both those with compulsory insurance and customers who took out insurance voluntarily, with price differentials of up to 30% and up to 5% of customers switching insurers each year. The insurance funds also implemented a risk equalisation system (similar to the Irish scheme and the Dutch scheme that will be dealt with below) which made insurers with less burdensome risk profiles contribute to the financing of the funds that took care of insuring the more expensive risks. Benefits were "essentially identical" and could not be influenced by the individual health insurance funds.

Consequently, the Court held that the German health insurance funds fulfilled an exclusively social function based on the principle of solidarity and in the absence of any profit motive. In this context the health insurance funds form a collective that is based on solidarity (or "Solidargemeinschaft") which shares out costs and risks equitably.

> "The sickness funds are therefore not in competition with one another or with private institutions as regards grant of the obligatory statutory benefits in respect of treatment or medicinal products which constitutes their main function."

And:

> "The latitude available to the sickness funds when setting the contribution rate and their freedom to engage in some competition with one another in order to attract members does not call this analysis into question."[16]

This freedom and that element of competition were only seen as a way of pursuing an efficiency gain "in accordance with economic principles of sound management". Therefore the sickness funds were not considered to be undertakings, and as a result not to fall within the scope of the competition rules. Although it includes some obscure elements – such as regarding risk equalisation as the hallmark of a public scheme when in fact it enables private competition within a public context, and the lack of a clear definition of the benefits involved and how they were set – AOK now forms the outer boundary beyond which health insurers will be regarded as undertakings.

AG2R Prévoyance

The 2011 case *AG2R* concerned the compulsory affiliation in France to a specific insurer for healthcare costs that were themselves the subject of an agreement between the employers and employees in the traditional bakeries sector.[17] The Court held that, in line with the Albany case law,[18] agreements entered into within the framework of collective bargaining did not fall within the scope of the cartel prohibition. The fact that the affiliation was compulsory and did not provide for exemptions did not affect this conclusion. Nor was effet utile (public promotion of private illegal constraints) involved: because the agreement did not come within

[16] Ibid., paras 54 and 56.

[17] Case C-437/09, AG2R Prévoyance v Beaudout Père et Fils SARL, judgment of 3 March 2011.

[18] Case C-67/96, Albany International BV v Stichting Bedrijfspensioenfonds Textielindustrie [1999] ECR I-5751; Joined cases C-115/97 to C-117/97, Brentjens' Handelsonderneming BV v Stichting Bedrijfspensioenfonds voor de Handel in Bouwmaterialen [1999] ECR I-6025; Case C-219/97, Maatschappij Drijvende Bokken BV v Stichting Pensioenfonds voor de Vervoer- en Havenbedrijven [1999] I-6121.

the scope of the cartel prohibition, public authorities were free to make it binding on those concerned who has not been party to the agreement.

As regards the application of the abuse of dominance provision the Court set out by deciding whether or not an undertaking was involved here. Apart from having a social objective, which was held to be clear here, it had to establish whether, first, the scheme was governed by the principle of solidarity and, second, whether it was subject to public supervision.[19] The scheme was found to be characterised by a high degree of solidarity given that it was financed by fixed contributions which were not proportionate to the risk insured. Public supervision was found present in the legal basis necessary to make collective agreements compulsory although monitoring the functioning of the scheme had been devolved to representatives of the parties. However because AG2R moreover appeared to have a large margin of discretion in the way it carried out its functions and as regards the details of its designation it was held to be an undertaking engaged in economic activity.

The third element of the case was the question whether the exception for services of general economic interest applied. Not much was made of the need for a formal act of entrustment or of the role of AG2R in negotiating the scope of its public service obligations. Essentially the constraints of the fixed nature of the contributions and the obligation to accept all risks, which made it less competitive than insurance companies, were held to justify the exclusive right concerned. With this, the French system was upheld.

2.2. Analysis

Based on the above cases we can draw the following conclusions with regard to the question whether in the case of health insurance undertakings are involved:

- Public or private status and for-profit or non-profit-making status are not an issue
- Potential competition may suffice to assume the existence of undertaking
- However (*AOK* shows) some competition may be compatible with solidarity

Crucial in this context are the following:

- (Publicly) defined benefits (sometimes in combination with defined contributions)
- State involvement as final decision making (since *AG2R*)
- The notion that solidarity entails compulsory affiliation to avoid the bad risks crowding out the good
- In the context of SGEI (which by definition involves undertakings) the converse is true, with a central role awarded to open enrolment in order to avoid risk selection weeding out the bad risks.

Admittedly the case law is not unambiguous on what degree of public involvement in setting benefits and supervision is required, although in itself the broadening of the criteria beyond solidarity to include public supervision is to be welcomed not just as a guarantee of good governance but also because it clarifies the nature of the public involvement required.

Are there healthcare specific characteristics in all this? It seems that so far both the classic theme of the Solidargemeinschaft and the more modern one of risk equalisation are not perhaps unique to health insurance but certainly play a larger role there than in the economy at large, or even in insurance at large. Hence it is not surprising that the latter theme has been taken up vigorously in the context of the application of the state aid rules to health insurance.

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[19] With reference to Case C-350/07, Kattner Stahlbau GmbH v Maschinenbau- und Metall-Berufsgenossenschaft [2009] ECR I-1513.

3.1. Prohibitions on cartel and dominance abuse
So far the application of the antitrust provisions to healthcare insurance has been minimal. In arguably the most important case, *AOK*, concerning collective fixing of purchasing prices for medicinal products, the entities concerned were found not constitute undertakings because they could not influence the benefits concerned and were engaged in risk and cost equalisation – meaning (in this case) that they were not in competition.[20]

The main exception to this finding is *AG2R*, where a possible abuse of dominance under Article 102 TFEU based on a system of compulsory affiliation to a scheme for supplementary insurance in the traditional bakery sector was involved.[21] However in this case it was more the principle of awarding a monopoly in this area that was examined than that any allegations of actual misconduct by the undertaking concerned were at stake. Moreover as we have seen in the end the Court found that the exemption for SGEI of Article 106(2) TFEU applied and consequently no breach of Article 102 TFEU was established.

3.2. State aid and SGEI
The EU law implications concerning health insurance in the State aid sector have been more important than so far in antitrust. In state aid the most contentious issue has been the practice of risk equalisation.[22] This is a method whereby insurers compensate each other either upfront or after the fact (or both) for any significant differences in the risk profile of their respective populations. This is generally introduced at the instigation of, or imposed by, public authorities. Although a restriction of competition in the dimension of selecting the healthiest consumer population, risk equalisation at the same time enables competition "on the merits" such as on costs by means of more efficient purchasing, managed care and prevention. Because state funds are generally involved risk equalisation is relevant to the application of the state aid rules.

Before discussing risk equalisation the main features of the state aid prohibition and the Altmark exception are briefly recalled here. It is settled case law that this prohibition applies if a national measure meets four cumulative conditions:

1. Aid must be granted by the state or through state resources
2. It must confer an advantage to particular (selected) undertakings
3. The aid must affect trade between the Member States
4. And it must distort competition in the internal market.[23]

Especially the second of these conditions (advantage/selectivity) has been controversial.

In the *Altmark* Case (concerning a regional transport license awarded in Germany)[24] the Court determined that if the undertaking concerned performed a universal service in exchange for

[20] Joined cases C-264/01, C-306/01, C-354/01 and C-355/01 AOK, above note 15.
[21] Case C-437/09 AG2R, above note 17.
[22] Cf. Paolucci et al., above note 1 and W.P.M.M. van de Ven and R.P. Ellis, "Risk adjustment in competitive health plan markets", in A.J. Culyer and J.P. Newhouse (eds), Handbook of Health Economics, vol. 1A (North-Holland, Amsterdam 2000), Chapter 14, 755.
[23] Cf. Case C-475/99, Firma Ambulanz Glöckner v Landkreis Südwestpfalz [2001] ECR I-8089.
[24] Case C-280/00 Altmark Trans GmbH and Regierungspräsidium Magdeburg v Nahverkehrsgesellschaft Altmark GmbH, and Oberbundesanwalt beim Bundesverwaltungsgericht (Altmark) [2003] ECR I-7747. This pursued the line set out in CaseC-53/00, Ferring SA v Agence centrale des organismes de sécurité sociale (ACOSS) [2001] ECR I-9067.

the financing provided there could be no question of state aid but only of compensation for performance of a service. Four cumulative conditions apply:

1. The undertaking must have clearly defined universal service obligations to discharge.
2. The compensation parameters must be set out in advance, objective and transparent
3. Compensation cannot exceed universal service and reasonable rate of return
4. The undertaking must be selected by public procurement procedures, or meet the standard of a comparable efficient undertaking.

In *BUPA* (2008) the General Court stated that the concept of public service obligations corresponds to that of SGEI under Article 106 paragraph 2 TFEU .[25] If these conditions are not met there may be a finding of state aid but there is still a possibility that this aid can be declared compatible with the internal market based on the SGEI exception of Article 106(2) TFEU. In 2005 the Commission clarified its policy with regard to the application of Article 106(2) TFEU to compensation in the state aid context by means of its so-called SGEI package. This consists of a Commission Decision and a Framework. This framework was subject to a (2010) Commission consultation which also looked at the relationship between aid, compensation and public procurement.[26]

We will now discuss at greater length three cases concerning state aid and health insurance, in the last of which (BUPA) the Altmark framework was applied (and amended). They show that the Commission and the General Court are permissive of far-reaching restraints on competition on the theory that on the one hand the net effect is one of liberalisation, and on the other, the restraints involved are in proportionate measure to the legitimate public interests involved. Note that risk equalisation between insurers is at the cutting edge of balancing solidarity and competition as a mechanism enabling competitive provision of a publicly defined basic health insurance package. Finally these rulings by the Commission, respectively the General Court, contrast with the ECJ's 2004 finding in *AOK* (discussed above) where risk equalisation was cited as proof of the absence of "real" competition.

Risk equalisation Ireland

This 2003 case concerned the Irish system of risk equalisation between private providers of supplementary healthcare insurance who were subject to a public framework of open enrolment, lifetime cover, community rating and minimum benefits.[27] According to the Commission the risk equalisation system in principle met the four conditions for state aid in Article 107(1) TFEU. Although this concerned transfers between the insurers these were regarded as concerning state resources because it concerned contributions that were imposed by public law and managed and distributed by the State in accordance with those legal instruments.[28] As this Decision was drafted prior to the Court's findings in *Altmark* the Commission based itself on an early version of the compensation doctrine outlined in *Ferring*,[29] which set less strict conditions than Altmark. Although an explicit act of entrustment setting out a SGEI was absent in the relevant Irish laws, the Commission was

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[25] In case T-289/03 British United Provident Association Ltd (BUPA) et al. v Commission [2008] ECR II-81.

[26] 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 OJ 2005, L312/67; Community framework for State aid in the form of public service compensation, OJ 2005, C297/4.

[27] Decision of the Commission of 13 May 2003 with regard to state aid N 46/2003 – Ireland – risk equalisation scheme in the Irish health Insurance market.

[28] Cf. Case C-114/91 Criminal proceedings v Gérard Jerôme Claeys [1992] ECR I-6559; Joined cases C-114/91 en C-145/91 Gilbert Demoor en Zonen NV et al. v Belgium [1992] ECR I-6613.

[29] Case C-53/00 Ferring, above note 24.

prepared to derive this (implicitly) from the general regulatory context. The public service obligation was found to have been formulated in the obligations cited above, and the Commission also held that apart from the classical SGEI where a single undertaking is charged with providing public services in an entire national territory at comparable rates and quality, it was also possible to impose public service obligations on all the operators in a particular market. This meant the Irish government had not committed a manifest error in designing its system of supplementary health insurance.

According to the Commission, the risk equalisation system that was being examined also met the requirements of necessity and proportionality, the latter because a certain incentive towards efficiency had been retained by the fact that compensation was based on the market average (making it attractive to perform better than average) and because new entrants were granted a holiday from contributing during their first three years in the market. Hence the Commission concluded (i) that compensation was involved, rather than selective advantage, and therefore no state aid was found to exist, but (ii) that if the latter were to be found to exist anyway the aid concerned would be compatible with the internal market based on Article 106 paragraph 2 TFEU. This decision was to be tested before the General Court in the BUPA Case that will be discussed below.[30]

Risk equalisation and reserves the Netherlands

In this 2005 Case the new Dutch framework for health insurance was under evaluation, specifically the aspects whereby private insurers would cover the entire population in the context of the application of a risk equalisation system, and where moreover the formerly public or cooperative insurers when being transformed into private entities would be allowed to keep their financial reserves.[31] In contrast to the Irish system that was fully based on private insurance premiums the Dutch insurers receive half their financing from a public fund which is fed by income related social insurance contributions that are withheld at the source. The relevant framework was that of publicly defined minimum benefits, public supervision, national coverage, open enrolment and community rating. In this system the risk equalisation system compensates for the open enrolment obligation, at 50% of the expected costs, and ex post. The Commission took a positive view on this. Normally ex ante compensation is desirable in order to retain incentives for efficiency and any ex post compensation should be limited to the necessary minimum. Here instead ex post compensation was seen as part of a system of double solidarity: among the insured population and between persons with various income levels (progressive financing). The capital requirements were linked to solvability ratios imposed on private insurers.

The Commission decided that in this case (unlike in AOK, discussed above) the risk equalisation system did not restrict competition but instead promoted it. When it applied the Altmark criteria however it found that the fourth (efficiency) condition had not been met, because in principle all insurers received compensation, irrespective of their efficiency.

Because the risk equalisation system was consequently considered as aid, this case was dealt with based on the SGEI exception in Article 106(2) TFEU. Just as in the Irish Case that was just discussed the Commission was prepared to derive the existence of a SGEI from the general legal and regulatory context, although in this case it explicitly held that the Member State tried to realise its public objectives by means of obligations and objective constraints

[30] Case T-289/03 BUPA, above note 25.

[31] Decision of the Commission of 3 May 2005 with regard to state aid N 541/2004 en N 542/2004 – The Netherlands – risk equalisation system and retention of reserves.

that it imposed on the undertakings involved.[32] It also held that the risk equalisation system was necessary to maintain stability in the market and to guarantee universal access to affordable healthcare. Because the compensation involved would be limited to the necessary minimum the proportionality test was met as well.

The retention of their financial reserves by those insurers who were switching from public to private status as part of the reform of the Dutch system was evaluated based on Article 107(3)c TFEU (aid for the development of certain types of economic activity). On this count the Commission held that the retention of the reserves on the one hand had only limited negative effects on competition and on the other hand formed an essential element of the liberalisation of the health Insurance markets in The Netherlands. Hence the Commission rules that the Dutch measures were compatible with Article 106(2) respectively 107(3) TFEU.

BUPA

The *BUPA* case was decided by the General Court in 2008.[33] BUPA was a private health insurer that entered the Irish market for voluntary supplementary private health insurance which covered some 50% of the population and was dominated by VHI, a former monopolist. Although BUPA was much smaller than VHI the risk equalisation system that the Commission had approved in its Decision on the Irish scheme that was discussed above was triggered to the advantage of VHI. Consequently BUPA both challenged the Commission's Decision before the General Court and appealed the relevant Irish decisions before the Irish courts. The Commission Decision was upheld by the General Court based on belt and braces approach, i.e. not only with respect to the Altmark criteria (as the applicability of the latter had not been limited in time in the Altmark judgment) but also based on the SGEI criteria. Not much later the Irish Supreme Court found the risk equalisation system unconstitutional. BUPA was not much aided by this as it withdrew from the Irish market.

As regards the Altmark criteria it is noteworthy that the General Court in relation to the first criterion (the existence of a public service obligation) did not demand that the service concerned was available to the entire population of the Member State concerned: instead the obligation to deal with all comers at standard conditions (open enrolment) was considered sufficient to find the existence of a universal service. The fact that different services with price differentiation were concerned did not mitigate this consideration, nor did even the fact that not all consumers (in fact almost half of the population) either could or would pay for these services. The second criterion requires clearly defined parameters for compensation and was not contested. The necessity and proportionality of the compensation were more difficulty to establish in the absence of a direct link between the universal service and the need for compensation. Here the General Court accepted that the arrangement was "consistent with the purpose and the spirit of the third Altmark condition in so far as the compensation is calculated on the basis of elements which are specific, clearly identifiable and capable of being controlled".[34] Likewise with respect to the fourth Altmark condition the General Court formulated an alternative version because it would not be possible to determine in advance which insurer had a right to compensation and therefore to compare its costs with those of an efficient competitor. Because compensation was based on the average costs in the market (and not on those of the individual competitor) an incentive toward efficiency would be retained.

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[32] With reference to Case C-157/94, Commission v the Netherlands (Almelo) [1997] ECR I-5699, para 40.

[33] Case T-289/03 BUPA, above note 25. Annotated by W. Sauter in (2009) Common Market Law Review 269.

[34] Ibid., para 237. This meant applying almost the exact same test as under the second Altmark criterion.

In this manner the General Court substantially amended the relatively recent Altmark criteria in the first important case where they were applied – in the sense that it broadened their scope. By contrast several other aspects of the case, such as the scope for market entry, and the undesirable effects of ex post compensation, were not addressed. In any event, by moderating the fourth Altmark condition the General Court has put pressure on the approach that the Commission adopted in its health insurance decisions discussed above. In these decisions the Commission started from a strict reading of the criterion of the costs of a well-run company. As long as the ECJ has not shed any light on this matter, it remains unsolved whether this condition should be applied in a strict or lenient manner.

3.3. Analysis

As we have already seen, the effective impact of the competition and state aid rules hinges in large part on the application of the Altmark test and the scope for SGEI. However the *BUPA* case illustrates that the case law in this area is still far from settled. It does appear that the Court is on the whole well disposed towards private undertakings discharging public tasks, and notably the concept of risk equalisation – even though in the context of *AOK* it was still seen as evidence of the absence of "real" competition rather than as a precondition for competition on the merits.[35] This perspective appears to have changed radically in the *BUPA* Case before the General Court but it has not yet been confirmed by the ECJ.

4. Internal market

In principle the relevant freedoms are that of establishment and the freedom to provide or receive services in Articles 49 and 56 TFEU. At the same time there is specific secondary (harmonisation) legislation for insurance in place, which to a certain extent limits direct recourse to the Treaty freedoms. The second leg of internal market legislation that may be relevant to health insurance (depending on whether of not "contracting authorities" are involved) is public procurement. The general Services Directive however does not apply to (health) insurance as it is explicitly excluded from its scope.[36]

4.1. The EU insurance legislation

Over time the EU has adopted four directives that are relevant to non-life insurance activities. The most important of these is the 1992 Third non-life insurance Directive,[37] and the most recent is the 2009 Solvency II Directive.[38] The Third non-life insurance Directive is designed to give insurers full freedom to provide their services throughout the EU. The relevant mechanisms are home country control as well as a single system for authorisation and financial supervision by the Member State which is the seat of the head office. The Third non-life insurance Directive also provided for the harmonisation of solvency requirements which is now spelled out in detail in the abovementioned Solvency II Directive.[39] The latter are not discussed here as they are too technical and specific for purposes of this study.

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[35] Cf. Paolucci et al., above note 1.

[36] Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market, OJ 2006, L376/36, Article 2(1)b.

[37] Council Directive 92/49/EEC of 18 June 1992 on the coordination of laws, regulations and administrative provisions relating to direct insurance other than life assurance and amending Directives 73/239/EEC and 88/357/EEC (third non-life insurance Directive) OJ 1992, L228/1.

[38] Directive 2009/138/EC of the European Parliament and of the Council of 25 November 2009 on the taking-up and pursuit of the business of Insurance and Reinsurance (Solvency II), OJ 2009, L335/1. See section 5 on health insurance in Annex III.

[39] S. Thomson and E. Mossialos, "Private health insurance and the internal market" in E. Mossialos et al. (eds) Health systems governance in the Europe: the role of European Union law and policy (Cambridge University Press, Cambridge 2010), p 427.

We will primarily discuss whether the relevant regimes are applicable, instead of the respective rules e.g. on home country control, authorisation and supervision themselves which would require a degree of detail for which space is not available. In this context it is important that The Directive contains three relevant exceptions to its standard regime which is based on the premise that Member States may not interfere in setting rates of conditions. These are:
— The social security exception in Article 2(1)d
— The general good exception in Article 28
— The health insurance exception in Article 54.

Each of these is now discussed briefly. Next Article 206 of the Solvency II Directive is discussed which deals with private health insurance as an alternative to social security.

Finally we will look at the question of which activities insurances undertakings may pursue.

The social security exception

Article 2(1)d of the First non-life insurance Directive provides for an exception for "insurance forming part of a statutory system of social security".[40] It remains unclear under what conditions an insurer is covered by this exception. In Case C-206/98 *Commission v Belgium* the Court holds that Directive 92/49 EC is "applicable to insurance forming part of a statutory scheme of social security offered by insurance undertakings at their own risk". Apart from suggesting that risk taking is key this begs the question what are "insurance undertakings".[41]

This question was answered in the so-called "Bolkestein letter" of 2003 dealt with below under the health insurance exception, but its status as well as the accuracy of some of the views stated there remain open to doubt. Some of the literature cites the Cases Garcia and Commission v France in support of a three-pronged test whereby only insurance undertakings operating at their own risk following insurance techniques and on the basis of contractual relationships governed by private law are covered by the Directives.[42] However we have not found a basis for this view in the cases cited, nor for a similar statement in the Bolkestein letter (see further below).

In this context the ruling in *Freskot* is relevant where the Court held that the scope of the definition of a service in the context of the First no-life insurance Directive and of Articles 56 and 57 TEFU is the same: the concept of consideration is key as is the question who decides on the levels of the rates concerned.[43]

Our proposed solution is finding that if the entity concerned is both (i) an undertaking providing insurance services in a market i.e. in exchange for consideration (consistent with *Freskot*) and (ii) is doing so at its own risk (consistent with *Commission v Belgium*) then regardless whether it forms part of a statutory scheme or is governed by public law it would

[40] First Council Directive 73/239/EEC of 24 July 1973 on the coordination of laws, regulations and administrative provisions relating to the taking-up and pursuit of the business of direct insurance other than life assurance, OJ 1973, L228/3 (last amended by Council Directive 2006/101/EC of 20 November 2006, OJ 2006, L363/238).

[41] Case C-206/98, Commission v Belgium [2000] ECR I-3509, para 44.

[42] Thomson and Mossialos, above note 39, at 427, citing Case C-238/94 García, above note 5, and Case C-299/98 Commission v France [2000] ECR I-3025.

[43] However if insurable natural risks are concerned undertakings established in other Member States may nevertheless challenge the legality (and proportionality) of the restrictions involved under the freedom to provide services. Case C-355/00 Freskot, above note 12, paragraphs 56-60; 63.

be covered by the Non-life insurance Directives. Otherwise choosing a public law regime would simply remove even competitive insurance schemes from the scope of the Directives on purely formal grounds, which is at odds with the general functional and teleological approach to EU law.

The general good exceptions

Article 28 of the Third non-life insurance Directive provides that insurance contracts shall be freely concluded unless there is a conflict with legal provisions protecting the general good:

> The Member State in which a risk is situated shall not prevent a policyholder from concluding a contract with an insurance undertaking authorized under the conditions of Article 6 of Directive 73/239/EEC, as long as that does not conflict with legal provisions protecting the general good in the Member State in which the risk is situated."

This general good criterion is also incorporated in article 54(1) of the Directive that relates specifically to health insurance. Elucidating both provisions is a Commission Communication of 2000.[44]

The general good is not defined in EU law. Accordingly the categories that the general good may cover are in principle not limited and may be determined at national level. Relying on the general good exception requires that the measures concerned must:[45]

(i) operate within an area that is not already harmonised;
(ii) pursue on objective of the general good;
(iii) be non-discriminatory;
(iv) be objectively necessary;
(v) and proportionate to the objective concerned.
(vi) in addition it is necessary that the general good objective is not already safeguarded by rules set in the Member State of establishment.[46]

The absence of harmonisation is key. Because the health insurance exception is specifically harmonised in Article 54 of the Third non-life insurance Directive we may assume that as a consequence it is in principle no longer possible to invoke, in addition or in the alternative, the general good exception in Article 28 thereof. However the general good conditions listed above apply equally under Article 54 of the Directive where the general good criterion was incorporated too, albeit in this case restricted to health insurance (an example of the specific rule trumping – or absorbing – the general rule).

The health insurance exception

Article 54 of the Third non-life insurance Directive provides an exception to the principle of non-intervention in the setting of insurance premiums and conditions.[47] It regards insurance agreements that "may serve as a partial or complete alternative to health cover provided by

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[44] Commission interpretative communication, Freedom to provide services and the general good in the Insurance sector, OJ 2000, C43/5.

[45] This is in line with standard case law: e.g. for services Case C-76/90 Manfred Säger v Dennemeyer & Co. Ltd. [1991] ECR I-4221; Case C-55/94; for establishment, Case C-55/94 Reinhard Gebhard v Consiglio dell'Ordine degli Avvocati e Procuratori di Milano (Gebhard) [1995] ECR I-4165.

[46] Interpretative communication on the general good, above note 44, pp 16-17.

[47] This Article is materially identical to Article 206 of the Solvency II Directive 2009/138/EC, above note 38. See Annex III.

the statutory social security scheme". This means that it should be seen as an exception that covers alternative and not supplementary or complementary types of health insurance.[48]

At the time it was adopted Article 54 was tailor-made for number of Member States operating private health insurance systems as (partial) substitute for public schemes: Ireland, the Netherlands, and Germany. The permissible conditions listed in Article 54 paragraph 2 and in recital 24 of the Directive closely match the conditions in place in these Member States. The question is whether this will slowly turn into a straitjacket as new modes of regulation develop. However at least the clarification of this provision in 2003 by the so-called "Bolkestein letter" (after the then internal market Commissioner who hailed from the Netherlands) concerning the reforms of the Dutch healthcare system shows that the room for intervention at national level may be considerable.

The Bolkestein letter stated that the Dutch regime characterised by open enrolment, mandatory coverage, uniform rates (at a level freely determined by the insurer) and a risk equalisation fund could be justified under article 54 of the Third non-life insurance Directive as these principles appeared necessary to ensure the legitimate objective of the Dutch government. The legitimate objective in this context was to guarantee healthcare as a basic social right. Hence all residents were to have access to health insurance guaranteeing a basis package of essential care for an acceptable premium. However the letter stressed that the measures concerned must be limited to what was objectively necessary.[49] In addition it suggested that the risk insurance scheme might need to be considered under the state aid rules (as indeed they were: see above under state aid).

It is worth noting that the letter does not recoup the six general conditions of the general good that Article 54 paragraph 2 already listed nor does it state that given prior harmonisation the permissible deviations from the general rules of the Directive found in Article 54 paragraph 2 are exhaustive so the general good is unable to accommodate further variations at Member State level. Instead an assessment is made that relies on criteria set out in recital 24 of the Preamble to the Directive: open enrolment, rating on a uniform basis according to the type of policy and lifetime cover; and to participate in loss compensation schemes.

> "Whereas to this end some Member States have adopted specific legal provisions; whereas, to protect the general good, it is possible to adopt or maintain such legal provisions in so far as they do not unduly restrict the right of establishment or the freedom to provide services, it being understood that such provisions must apply in an identical manner whatever the home Member State of the undertaking may be; whereas these legal provisions may differ in nature according to the conditions in each Member State; whereas these measures may provide for open enrolment, rating on a uniform basis according to the type of policy and lifetime cover; whereas that objective may also be achieved by requiring undertakings offering private health cover or health cover taken out on a voluntary basis to offer standard policies in line with the cover provided by statutory social security schemes at a premium rate at or below a prescribed maximum and to participate in loss compensation schemes; whereas, as a further possibility, it may be required that the technical basis of private health cover or health cover taken out on a voluntary basis be similar to that of life assurance."

[48] However as we have seen, in Case T-289/03 BUPA, above note 25, supplementary insurance was found to be covered by a SGEI. This calls into question the abovementioned distinction.
[49] For a diverging view see Paolucci et al., above note 2.

In EU law generally the recitals of a Directive are only of interpretative value and do not form separate legal provisions that can be relied on. The approach in the present case was perhaps also based on the theory that the (limited) degree of harmonisation achieved allows for the abovementioned additional exceptions. This suggests the remaining scope for general good exemptions under Article 54 of the Third non-life insurance Directive at present is wide or even completely open-ended, constrained only by the proportionality test involved. Judicial clarification of this issue would be welcome.

The Bolkestein letter also details what it states is the line set out by the case law of the Court of Justice, according to which:

> "(…) insurance activities forming part of a statutory system of social security fall under the scope of the Insurance Directives when they are conducted by insurance undertakings at their own risk following insurance techniques and on the basis of contractual relationships governed by private law."

The legal form expressly stated in the Directives themselves, according to the letter, is immaterial as long as these three conditions are met. However it does not provide an uncontested definition of what defines the scope of the Insurance Directives. For starters as was noted above the relevant case law of the ECJ has not yet been identified – or perhaps materialised. Another caveat is in order because the status of the Bolkestein letter is no more than that of informal Commission guidance in a particular case and therefore not compelling and open to debate.

Line of business restrictions

The non-life insurance Directives apparently place line of business restrictions upon insurance undertakings that are relevant to e.g. healthcare insurers that want to participate in the activities of healthcare providers (also called vertical integration). Article 8(1) of the first non-life insurance directive provides:[50]

> "The home Member State shall require every insurance undertaking for which authorization is sought to: (...) (b) limit its objects to the business of insurance and operations arising directly therefrom, to the exclusion of all other commercial business."

However on the other hand article 18(1) of the same Directive states

> "Member States shall not prescribe any rules as to the choice of the assets that need not be used as cover for the technical provisions referred to in Article 15."

The case law of the ECJ makes clear that the first provision should be read as a limiting clause that refers to the level of the solvency requirements when carrying out its own business, not to the right to hold stakes in non-insurance undertakings:

> "(…) the purpose of the prohibition preventing insurance undertakings from carrying on commercial business other than insurance business, laid down in the amended Article 8(1)(b) of Directives 73/239 and 79/267, is in particular to protect the interests of insured persons against the risks which the exercise of such business could entail for the solvency of those undertakings. It follows that the aforesaid provision does not

[50] Council Directive 73/239/EEC, above note 40.

> prevent insurance undertakings from holding shares in public limited companies carrying on commercial business other than insurance business and to the assets of which the financial risks are confined."[51]

Similarly in the 2000 health insurance case *ABBOI* where mutual benefit societies were engaged both in health insurance and (other) commercial activities the Court held that:

> '(…) Article 8(1)(b) of Directive 73/239 does not preclude mutual benefit societies engaged in insurance business from participating, within the limits of their respective free assets, in a body with legal personality and legal autonomy which is involved in commercial business - such as an association of mutual benefit societies - provided that the financial risks inherent in such business attach only to the assets possessed by that body'.[52]

In sum it should be possible for a health insurer to belong to the same group as say a healthcare providers such as a hospital or a chain of pharmacies provided that at all time the solvency requirements for its insurance activities are met. Turning this around, and given that the Court in the abovementioned cases establishes the direct effect of said provisions (both article 18(1) and article 8(1)(b) of the Directive), health insurers may invoke the right to do so, for example against public measures designed to block vertical integration.[53]

Private health insurance and acceptable constraints

The recitals to the Solvency II Directive set out clearly the status of private health insurance in the context of public norms with regard to the risks to be insured.

> "(84) In some Member States, private or voluntary health insurance serves as a partial or complete alternative to health cover provided for by the social security systems. The particular nature of such health insurance distinguishes it from other classes of indemnity insurance and life insurance insofar as it is necessary to ensure that policy holders have effective access to private health cover or health cover taken out on a voluntary basis regardless of their age or risk profile. Given the nature and the social consequences of health insurance contracts, the supervisory authorities of the Member State in which a risk is situated should be able to require systematic notification of the general and special policy conditions in the case of private or voluntary health insurance in order to verify that such contracts are a partial or complete alternative to the health cover provided by the social security system. Such verification should not be a prior condition for the marketing of the products.
>
> (85) To that end, some Member States have adopted specific legal provisions. To protect the general good, it should be possible to adopt or maintain such legal provisions in so far as they do not unduly restrict the right of establishment or the freedom to provide services, it being understood that such provisions should apply in an identical manner. Those legal provisions may differ in nature according to the conditions in each Member State. The objective of protecting the general good may also be achieved by requiring undertakings offering private health cover or health

[51] Case C-241/97 Försäkringsaktiebolaget Skandia (publ) [1999] ECR I-1879, para 47.

[52] Case C-109/99 Association basco-béarnaise des opticiens indépendants v Préfet des Pyrénées-Atlantiques (ABBOI) [2000] ECR I-7247, para 64.

[53] Cf. E.H.M. Loozen, E.J. Schut and M. Varkevisser, 'Verticale integratie tussen zorgverzekeraars en zorgaanbieders', (2010) Markt en Mededinging 5.

> cover taken out on a voluntary basis to offer standard policies in line with the cover provided by statutory social security schemes at a premium rate at or below a prescribed maximum and to participate in loss compensation schemes. As a further possibility, it may be required that the technical basis of private health cover or health cover taken out on a voluntary basis be similar to that of life insurance."

This is detailed further in Article 206 of the Solvency II Directive on private health insurance as an alternative to social security. Here it is stated that such private schemes may be subject to general good conditions and prior public scrutiny as well as the requirement that they are operated on an actuarial basis similar to life insurance provided that certain conditions are met. These conditions concern mainly the actuarial nature on which the scheme is based as well as (inter alia) the right to carry over benefits to other providers.

4.2. Direct effect en horizontal direct effect

The doctrines of direct effect and horizontal direct effect are standard features of Community law. They can be relevant in the health insurance context. Primary and secondary EU law are said to have direct effect if they can be invoked directly by individuals. The standard category is vertical direct effect when EU rules are invoked by individuals against the different emanations of the Member States (or in theory the EU Institutions). There are separate rules on how this works for Decisions (where one must be the addressee or assimilated to that status), Regulations (which need not be transposed) and Directives, which normally require transposition into national law to become effective. However where Directives confer individual rights and are transposed late, incorrectly, or not at all, they may have vertical direct effect: to be invoked by the individual against the state.

Horizontal direct effect means that individuals may invoke EU law not against national or EU authorities, but directly against each other. This feature of EU law has so far mainly been restricted to primary EU law (and some Regulations) affecting employment relationships and gender discrimination.[54] Directives have generally been the least favoured category for the application of this concept.[55] However, where a Directive lacks direct effect national Courts must exert themselves to provide an interpretation that is consistent with Community law (also called "indirect effect').[56]

According to the 2003 "Bolkestein letter" cited above health insurers offering a standard policy should be considered as competent bodies in the sense of Regulation 1408/71 (and its implementing Regulation 574/72), now replaced by Regulation 883/2004.[57] This means that

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[54] Case 149/77 Gabrielle Defrenne v Société anonyme belge de navigation aérienne Sabena [1978] ECR 1365 ; Case C-281/98 Roman Angonese v Cassa di Risparmio di Bolzano SpA [2000] ECR I-4139; Case C-438/05, International Transport Workers' Federation and Finnish Seamen's Union v Viking Line ABP and OÜ Viking Line Eesti [2007] ECR I-10779.

[55] Case C-188/89 A. Foster and others v British Gas plc [1990] ECR I-3313; an exception is Case C-341/05, Laval un Partneri Ltd v Svenska Byggnadsarbetareförbundet et al. [2007] ECR I-11767 concerning Directive 96/71/EC on the posting of workers in the construction industry. Conversely, spelling out the absence of horizontal direct effect of the Third non-life insurance Directive 92/49/EEC is Case C-233/01, Riunione Adriatica di Sicurtà SpA v Dario Lo Bue [2002] ECR I-9411

[56] Cf. Joined cases C-397/01 to C-403/01 Bernhard Pfeiffer (C-397/01), Wilhelm Roith (C-398/01), Albert Süß (C-399/01), Michael Winter (C-400/01), Klaus Nestvogel (C-401/01), Roswitha Zeller (C-402/01) and Matthias Döbele (C-403/01) v Deutsches Rotes Kreuz, Kreisverband Waldshut eV [2004] ECR I-835.

[57] Now Regulation (EC) 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems, OJ 2004 L166/1, replacing Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families

they can set prior authorisation requirements for cross-border healthcare, subject to the undue delay provisions of the Regulation. As regards the Directive on patients' rights in cross-border healthcare the status of the health insurers is much less clear.[58] The 2011 Directive on patients' rights in cross-border healthcare addresses the Member States authorities, whereas in practice it may well be the insurers, not the Member States, who impose limitations such as prior authorisation requirements on the cross-border provision and receipt of services. There are essentially two ways of dealing with this:

— The assumption that the Member States have a duty to act and ensure that the conditions imposed by the health insurers within their jurisdiction are in accordance with the Directive. This could be based on the doctrine of "indirect effect".

— Applying the doctrine of horizontal direct effect against the insurers themselves on the assumption that the latter are addressed by the Directive because they exercise control over their insurers and that justiciable individual consumer rights are involved. Under EU law as it stands this would be hard to pull off and complainants are better advised arguing that the relevant health insurers fall under a broad interpretation of emanations of the state.

In the admittedly unlikely event that horizontal direct effect applies the next question is: can the relevant EU law exceptions (overriding reasons of public interest) be invoked by private health insurers as well? From a perspective of general consistency (more than based on specific case law on this issue) it appears logical that the answer should be yes.[59]

5. Public procurement

There is a link between the legal categories that were discussed at the outset of this paper and the current topic of public procurement.[60] That is, the concepts of undertaking and contracting authority are corresponding vessels: who is not subject to the rules on competition and state aid should be so to the procurement rules (and vice versa).

Public procurement is a purchasing method that promotes competition between potential providers. On the one hand participants may expect a fair chance of landing a contract while on the other hand contractors not only obtain savings but also ensure procedural guarantees are respected that will limit the risk of the award being legally contested. The EU encourages and enforces public procurement procedures as part of its internal market drive: because public contracts account for a significant share of the internal market the material scope involved is considerable. The principles of public procurement in the EU are objectivity, transparency and non-discrimination.

5.1. The award of public works, supply and services contracts

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moving within the Community (OJ 1971 L149/2), last amended by Regulation (EC) No 1992/2006 of the European Parliament and of the Council of 18 December 2006, OJ 2006 L392/1

[58] Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare, OJ 2011, L88/45.

[59] This would also be in line with private definition of SGEI objectives as in Case C-437/09, AG2R, above note 17; and Decision of the Commission of 28 October 2009 with regard to state aid NN 54/2009 (ex CP 244/2005) – Belgium – financing of public hospitals of the IRIS-network of the Brussels capital region.

[60] Cf. V. Hatzopoulos, "Public procurement and state aid in national health care systems", in Mossialos et al., above note 39.

The relevant public procurement Directive for health insurers is Directive 2004/18/EC on the coordination of the procedure for the award of public contracts.[61] These procurement rules only apply if the following three cumulative conditions are met:
— The awarding party qualifies as a contracting authority
— The value of the contract exceeds the threshold set in the Directive[62]
— None of the exceptions applies.[63]

Article 1 paragraph 9 of the Directive defines the first category as follows:

> "'Contracting authorities' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law.
> A 'body governed by public law' means any body:
> (a) established for the specific purpose of meeting needs in the general interest, not having an industrial or commercial character;
> (b) having legal personality; and
> (c) financed, for the most part, by the State, regional or local authorities, or other bodies governed by public law; or subject to management supervision by those bodies; or having an administrative, managerial or supervisory board, more than half of whose members are appointed by the State, regional or local authorities, or by other bodies governed by public law. (…)"[64]

It is clear that health insurers are potentially at least bodies governed by public law, given their likely public interest purpose, as well as possibly based on their funding or supervision arrangements. This is illustrated well by the 2009 Case *Orthopädie Schuhtechnik* where the abovementioned criteria were applied to statutory sickness insurance schemes in Germany.[65] The Court held that

> "(…) financing of a statutory sickness insurance scheme (…), which is brought into being by a measure of the State, is, in practice, guaranteed by the public authorities and is secured by methods of collection which fall under the provisions of public law, satisfies the condition of being financed, for the most part, by the State for the purposes of the application of the Community rules on the awarding of public contracts."[66]

And:

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[61] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts, OJ 2004, L134/114.
[62] I.e. €125.000 for central government contracts (subject to certain exceptions); €193.000 for inter alia Annex IIB contracts which are the ones that are relevant here (see further below); and 4.845.000 for public works contracts. Ibid., Article 7.
[63] Ibid., Section 2 on specific situations, article 10-18 lists the various types of excluded contracts including e.g. defence and security contracts or contracts awarded through a central contracting body that is itself in compliance with the Directive.
[64] Cf. Case C-380/98 The Queen v H.M. Treasury, ex parte The University of Cambridge [2000] ECR I-8035.
[65] Case C-300/07 Hans & Christophorus Oymanns GbR, Orthopädie Schuhtechnik v AOK Rheinland/Hamburg, judgment of 11 June 2009 (nyr).
[66] Ibid., para 57.

> "(…) there is financing, for the most part, by the State when the activities of statutory sickness insurance funds are chiefly financed by contributions payable by members, which are imposed, calculated and collected according to rules of public law such as those in the main proceedings. Such sickness insurance funds are to be regarded as bodies governed by public law and therefore as contracting authorities for the purposes of the application of the rules in that directive."[67]

A body governed by public law therefore is likely to exist where its existence and financing are governed by public law. Although the two sets of criteria involved are not a perfect match they are close enough for it to appear logical that such health insurers as benefit from the exception for insurance that forms part of a statutory social security system in Article 2(1)d of the First non-life insurance Directive would be regarded as contracting authorities for purposes of the public procurement rules. It should be noted that when the procurement rules do apply they still leave room for different methods of procurement such as open, restricted and negotiated procedures and of competitive dialogue.[68] These methods share the non-discriminatory treatment of participants and the transparency of the criteria applied, as well as their ex post verifiable nature.

5.2. Mild regime of the public procurement Directive

Based on article 21 juncto Annex IIB sub 25 the procurement Directive provides that healthcare (services) are subject only to the so-called "mild regime". This requires meeting European standards for technical specifications must be met and making public the results of the procedure (article 23 and 35 paragraph 4 of the procurement Directive). In addition the contracting party must treat economic operators equally and non-discriminatorily and act in a transparent way (article 2 procurement Directive).[69] For services in Annex IIB of the procurement Directive a turnover threshold of €193.000 applies.

5.3. Strict regime of the public procurement Directive

In the event that health insurers qualify as contracting authorities they are however most likely not covered by the limited set of provisions for public service contracts on healthcare (services) but instead by those on insurance based on article 20 juncto Annex IIA sub 6 of the procurement Directive (again the €193.000 threshold applies). This is because it must be concluded that "healthcare" in the context of the public procurement Directive concerns the provision of healthcare services and not insurance to meet the cost of such services. This in turn means that the full gamut of the rules for public service contracts from articles 23 through 55 of the procurement Directive applies to health insurers. This concerns e.g. technical specification, subcontracting, contract award criteria, use of electronic auctions, how to deal with abnormally low tenders and verification of the suitability and choice of participants as well as the award of contracts. The logic involved is that because the contracting authorities are not undertakings and as they are therefore not disciplined by their competitors, nor by the EU competition rules, they need to be controlled at least as concerns their purchasing behaviour. In this context it is relevant that the Commission has proposed clarifying the Altmark framework in particular in relation to public procurement.[70]

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[67] Ibid., para 59.

[68] Directive 2004/18/EC, above note 61, article 28ff.

[69] For mixed contracts (Annex IIA and Annex IIB services the greater value of the two components determines which regime applies. Cf. e.g. Case C-160/08 Commission v Germany, judgment of 29 April 2010 (nyr).

[70] Commission staff working document, Guide to the application of the European Union rules on state aid, public procurement and the internal market to services of general economic interest, and in particular to social services of general interest, SEC(2010) 1545 final.

5.4. General principles of EU law and the interpretative Communication
According to the case law of the ECJ the general principles of non-discrimination and equal treatment, transparency, proportionality and mutual recognition even apply to contract awards not or not fully subject to the provisions of the public procurement directives.[71] In these cases the relevant distinction is whether or not contracting authorities are involved.

The Commission's 2006 interpretative Communication on this matter – which is partly based on the transparency case law of the ECJ – concerns the advertising and award of the contract as well as judicial protection.

> That obligation of transparency which is imposed on the contracting authority consists in ensuring, for the benefit of any potential tenderer, a degree of advertising sufficient to enable the services market to be opened up to competition and the impartiality of procurement procedures to be reviewed.[72]

The rules set out in the Communication also apply to contract awards below the turnover threshold of the public procurement Directive (€193.000 as mentioned above) and to awards above the thresholds to which only the mild regime applies:

> "(…) although certain contracts are excluded from the scope of the Community directives in the field of public procurement, the contracting authorities which conclude them are nevertheless bound to comply with the fundamental rules of the Treaty."[73]

Hence contracts concluded by providers of healthcare services who qualify as contracting authorities are also subject to the rules in the interpretative Communication that express the core of the abovementioned general principles of EU law.

In this context a core requirement is to ensure that interested parties from other Member States can also take notice of the contract award and participate in it. For instance qualifications and diplomas from other Member States must be recognised as equivalent and the timeframe for reaction needs to be long enough for reactions from other Member States.

5.5. Health insurance and procurement law
In summary there are two possible answers to the question whether health insurers are subject to the procurement rules, depending on the facts at hand:

(i) Either the insurers concerned meet the conditions to constitute contracting authorities and the procurement rules apply:
— Health insurers are subject to the strict regime of article 23-55 (based on article 20 and Annex IIA of the procurement Directive.

[71] Case C-324/98 Telaustria Verlags GmbH and Telefonadress GmbH v Telekom Austria AG [2000] ECR I-10745; Case C-231/03 Consorzio Aziende Metano (Coname) v Comune di Cingia de' Botti, [2005] ECR I-7287; Case C-458/03 Parking Brixen GmbH v Gemeinde Brixen and Stadtwerke Brixen AG [2005] ECR I-8585. Cf. Commission interpretative communication on the Community law applicable to contract awards not or not fully subject to the provisions of the Public procurement directives, OJ 2006, C179/2.
[72] Case C-324/98 Telaustria, above note 71, para 62.
[73] Communication on contract awards, above note 71, para 1.2; Case C-59/00 Bent Mousten Vestergaard v Spøttrup Boligselskab [2001] ECR I-9505, para 20.

— They are also subject to the transparency case law of the ECJ and the interpretative Communication of the Commission – including public advertising.

(ii) Or the procurement rules do not apply because the health insurers concerned are not contracting authorities. For example where they are undertakings providing services at their own risk and in competition and are not funded or supervised under public law. In this case the transparency case law does not apply either.

The logic of this is that in the undertakings concerned will be disciplined by the market and corrected, if necessary, by the competition rules. The contracting authorities on the other hand re not subject to this market discipline and must be subjected to the public procurement rules.

5.6. Recent trends

Finally it is worth mentioning that a recent policy trend is developing concerning procurement law that may affect in particular health insurance schemes that are framed by public policy:

— First, in the 2010 Monti report on the functioning of the internal market the Commission was advised to promote the integration of the EU's policy goals in public procurement policy. This relates to linking the public procurement and state aid policies (Altmark), which would seem to go in the direction of ensuring that those entities that are not caught as undertakings are at least subjected to the public procurement rules (as already suggested above).[74]

— Second a subsequent 2010 staff paper by the Commission on SGEI and social services of general interest attempts to flesh out this notion.[75] Disappointing many ardent advocates of exceptions for public services this does not appear to mean a relaxation of the present strict regime for contracting authorities awarding SGEI and social services of general interest mandates but instead to spell out in some detail that the procurement rules (as they were already discussed above) in fact do apply. This is likely to feed into an ongoing review on the Altmark package.

The general theme in both cases is to achieve greater coherence between the state aid, competition and procurement rules of the EU on the one hand, as well as between the former and the exceptions for SGEI and social services of general interest on the other.

6. Conclusion

The system of EU law on competition and the internal market as applied to health insurance can be summarised as follows. If health insurance is governed by solidarity (notably by the socialisation of risk and state supervision) it is outside the scope of the competition and state aid rules. If to the contrary health insurers are undertakings the competition and state aid rules apply. If they qualify as contracting authorities they are subject to the public procurement rules. Finally there is harmonised internal market legislation in place on insurance.

In order to determine where they are located within the EU legal system it is therefore important for health insurers to know whether they fall under the pertinent categories of EU law – e.g. undertaking, contracting authority – or whether they are an entity characterised by solidarity and state supervision, or part of a statutory system of social security.

[74] A new strategy for the Single Market: at the service of Europe's economy and society. Report to the President of the European Commission, José Manuel Barroso, by Mario Monti, 9 May 2010.

[75] SEC(2010) 1545 final, above note 70.

There is a link between the different categories in that an entity that is an undertaking will be subject to the competition and state aid rules, with the possibility of an exception if it is entrusted with the provision of a SGEI. In a number of cases the provision of health insurance subject to an open enrolment obligation and a prohibition of premium differentiation has been considered to fall under the latter exception.

However as was mentioned entities characterised by a combination of (a sufficient degree of) solidarity and state supervision may be immune to the competition and state aid rules, but by the same token they are subject to the public procurement regime – in its full force (i.e. not the mild regime that applies to healthcare providers). An intermediate system is provided by the Non-life insurance Directives which set limits to the degree of intervention in the conditions applied by private health insurers that public authorities are allowed to implement but provide a public good exception for healthcare which – by the expansive interpretation of the Commission's informal view in the 2003 Bolkestein letter – allows for far reaching exceptions to the principles of commercial freedom on the setting of rates and conditions.

This means that EU law is both important for health insurers and in spite of its complexities shows a degree of internal coherence that makes classifications under one part of the system increasingly significant to the classification under other parts – thus for whether EU law imposes conditions or allows exceptions. Most significant in this context is likely to be the way in which the application of SGEI develops – a system which is currently under review.

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