

The role of EU competition law in health care and the 'undertaking' concept

Johan van de Gronden and Mary Guy

I. Introduction

Competition in healthcare is a contentious subject and the EU's role in this adds to the controversy insofar as questions are raised of national versus EU competence, and social versus economic aims. Both questions have clear relevance to discussions of the future of EU health law and policy. In this article we examine landmark case law emanating from the Court of Justice of the European Union (CJEU), the General Court and the European Commission in a doctrinal legal analysis to clarify the parameters of the “undertaking” concept in applying competition law in healthcare cases. A doctrinal legal analysis focusing on the law, rather than on the broader context, may appear to offer quite limited insights for an interdisciplinary audience. However, precisely this level of examination of the law is needed to understand why competition reforms in healthcare are difficult to implement at a national level. We also employ a comparative approach in considering the implications of EU law at national level regarding the Netherlands, where marketisation reforms – including mandatory private health insurance and liberalisation of hospital service prices – were implemented in 2006. In addition, a doctrinal legal analysis allows us to sketch EU level-developments from a perspective which may be new to a health policy audience. The methods therefore help us address the aforementioned questions.

With regard to national versus EU competence, Member States are considered to have a certain degree of freedom in experimenting with market-based reforms, such as private sector delivery of healthcare services, or public-private arrangements (Andreangeli, 2016). However, this degree of freedom has long been deemed circumscribed: market-based reforms may have the unintended consequence of triggering the applicability of EU competition law (Prosser, 2010). At EU level, the possibility of divergent interpretations by National Competition Authorities raises concerns about consistency at EU level, potentially creating “Euro-national competition rules for healthcare” (van de Gronden, 2011; van de Gronden and Szyszczak, 2014). The need for direction and guidance to be set at EU level is also important because we know that England (UK) and the Netherlands – the two Member States to engage most actively with competition reforms of their healthcare systems – have created regimes which are heavily influenced by, and even borrow terminology from, EU competition law (Guy, 2019).

Questions of social versus economic aims emerge as the applicability of competition law to healthcare has featured in wider discussions of welfare state reform since the turn of the 21st century (e.g. Winterstein, 1999; Szyszczak, 2009; Sauter, 2013). Indeed, a recent question has been whether, if the healthcare sector is not fully immune from EU competition law, these rules can trigger the reorganisation of welfare states in the EU (van de Gronden and Rusu, 2017). In addition to any “unintentional” triggering of EU competition law by national reforms, questions of applicability of EU competition law are given additional momentum at present as competition reforms appear reflected in a range of Country-Specific Recommendations within the context of the European Semester (Guy, 2019). We therefore examine here the question of how the “undertaking” concept of EU competition law functions in healthcare and to what extent it pays due consideration to healthcare-specific features.

In this article, we adopt a broad definition of “EU competition law” from Treaty on the Functioning of the European Union (TFEU) provisions encompassing both the state aid rules (Articles 107-109), and the prohibitions on anticompetitive agreements and abuse of dominance (Articles 101 and 102), described collectively as “antitrust rules”. The state aid regime is designed to avoid distortions of competition within the EU internal market by imposing on Member State governments a prohibition (subject to exceptions) on granting economic benefits to particular operators. EU-level cases involving the antitrust rules specifically in the healthcare context (as distinct from cases involving sectors such as pensions or education which may have implications for healthcare as well) have included the Commission fining professional organisations of pharmacists in France for hindering entry of new laboratories (Case T-90/11, *ONP*), and the Commission and the EU courts taking action against excessive pricing in the pharmaceutical sector (Hancher and Sauter, 2012; Danieli, this issue). We also address the partial exception to the state aid and competition rules of an activity being classified as a Service of General Economic Interest (SGEI). Activities classified as SGEI in a healthcare context include emergency patient transport services (Case C-475-99, *Ambulanz Glöckner*), supplementary health insurance (Case 437/09, *AG2R*), the Dutch mandatory private health insurance scheme (Cases N541/2004 and N542/2004, *Zorgverzekeringswet*), and the Irish complementary insurance scheme (Case T-289/03, *BUPA*) (Hancher and Sauter, 2012 and van de Gronden, 2009).

Our discussion proceeds as follows.

Section 2 surveys EU competition law cases relating to healthcare and the parameters defining the “undertaking” concept up to the 2018 *DZP/UZP* case (Case T-216/15, *Dôvera zdravotná poisťovňa and Union zdravotná poisťovňa*) regarding Slovak health insurers.

Section 3 takes as its starting-point the 2017 *CEPPB* state aid case (Case C-74/16, *Congregación de Escuelas Pías Provincia Betania*) regarding state financing of religious educational establishments in Spain and the three-prong test identified from the judgment (van de Gronden 2018) in determining the applicability of competition law which offers a new direction for future cases. This three-prong test is applied here to the healthcare context for the first time.

Section 4 concludes with some considerations about the future of EU law and policy regarding competition in healthcare.

2. Overview of EU case law / developing interpretations of the “undertaking” concept

Although the state aid rules and “antitrust” rules are conceptually discrete, they share a common starting-point: for either to be applicable, there must be an “undertaking”, long defined as an “economic activity” (Case C-41/90 *Höfner*) of “offering goods and services on a market” (Case I 18/85 *Commission v Italy*). Whether or not there is an “economic activity” is a deceptively simple question, so has received varying responses over time and across different healthcare systems.

The trigger effect of the “undertaking” concept on competition law within the healthcare context can be understood in overview thus:

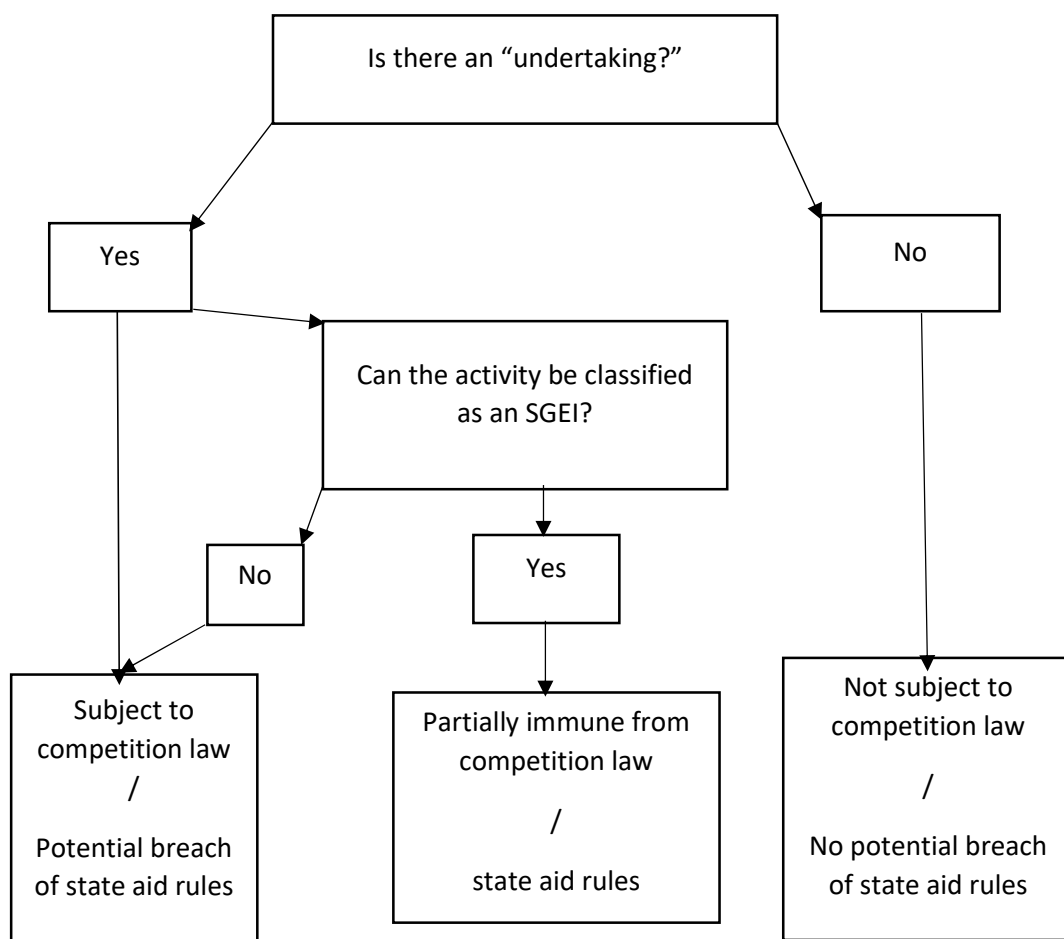


Figure 1: Overview of the operation of the “undertaking” concept within EU competition law and state aid rules.

The above diagram suggests that – regarding the “undertaking” concept – there are two ways in which activities in healthcare may be deemed immune from the competition rules. Firstly, by finding that the activity is not “economic” in nature (thus competition rules do not apply at all), and secondly, by finding that, although the activity is indeed “economic”, its classification as an SGEI means that it is treated as an exception, thus partly immune from the competition rules. Although our focus here is on the former, the latter can form an important exception mechanism in the healthcare context (see also Sauter 2013), because the SGEI concept entails balancing competition concerns and public interest values.

EU-level case law regarding healthcare has considered both “routes” to competition law immunity to varying degrees. As healthcare systems experiment more with private sector delivery of healthcare, or combined public and private arrangements, a tendency towards the “SGEI route” may be anticipated, insofar as this may reflect more easily the reality of healthcare provision and purchasing involving both “economic” and “non-economic” activities.

It has been considered that the “contours” of the EU’s approach regarding state aid are clearer than regarding competition law *sensu strictu* - i.e. the “antitrust rules” (Hancher and Sauter 2012). This is perhaps unsurprising if it is considered that there is greater scope for EU-level

intervention regarding state aid than activities which would fall within the purview of the antitrust rules.

Certainly the state aid rules may have wider implications for healthcare system design and government reform. An example is the classification of the Dutch risk equalisation scheme to ensure universal access as SGEI: universal access has been considered to form a “core” around which the Dutch competition reforms developed (Guy 2019). However, the effect of EU decisions in antitrust cases have also helped shape national reforms – as evidenced by the introduction of Article 122 Dutch Health Insurance Act 2006 to allow application of Dutch competition law to Dutch private health insurers, where the CJEU *AOK Bundesverband* judgment (Joined Cases C-264/01, C-306/01, C-354/01 and C-355/01, *AOK Bundesverband and Others*) suggests that EU competition law may not apply (van de Gronden and Szyszczak 2014).

2.1 The “abstract” and “concrete” tests in the case law

What has also emerged from the case law regarding the “undertaking” concept is the categorisation of analysis as an “abstract” test and a “concrete” test (van de Gronden 2004).

The “abstract” test is applied in the majority of the cases. The core question for qualifying an activity is whether the service or good at hand can potentially be supplied on the market, or can only be offered through the official authority of the State. The legal design of the supply of this service or good does not matter. If the activity under review cannot be performed without State intervention, it is not of an economic nature. In contrast, if the activity can potentially be carried out by providers on the market, it is of an economic nature irrespective of the fact whether its actual performance is in the hands of a State body. In other words, the test is performed wholly in the abstract, without reference to the national legal framework concerned. (van de Gronden 2018) Broadly speaking, the abstract test has been applied to healthcare providers, such as hospitals and physicians, and concerns the entities providing treatment as well as related services and goods to patients. This is logical: an “economic activity” is defined as “offering goods or services on a market”, which clearly references the activity of providing (such as supplying medical products and providing medical services), as distinct from purchasing. Thus, in a healthcare context, self-employed medical specialists who receive financial remuneration and bear financial risks in exercising their profession have been deemed “undertakings” (Joined Cases C-180/98 to C-184/98 *Pavlov*), as have standard and emergency patient transport services since – in a similar logic – these are provided for remuneration, thus do not have to be provided by public bodies.

In contrast, the “concrete” test is only applied in cases concerning social security systems, including healthcare schemes (van de Gronden 2018: pp. 203- 204). In this test, strikingly, the national legal framework is the starting-point. The review to be carried out revolves around the actual set-up of a social security scheme by a particular Member State and focuses on the bodies managing the scheme at hand. As a result, at the heart of the “concrete” test are organisations entrusted with the task of financing the social security schemes. If such a scheme is predominately solidarity-based, the body managing this is not engaged in an economic activity and does not, accordingly, qualify as an “undertaking” (Joined Cases C-159/91 and C-160/91 *Poucet*). The “concrete” test is not applied in the abstract of the applicable national

legal framework but, on the contrary, in close connection with this framework. It considers the national legal framework as a decisive factor in whether or not EU competition law applies (van de Gronden 2018 and 2004, Baquero Cruz 2005).

In healthcare the “abstract” and “concrete” tests have resulted in a striking outcome in CJEU case law. The CJEU has consistently held that healthcare providers are undertakings and subject to EU competition law, irrespective of the national framework they operate in (whether an insurance-based or taxation-funded healthcare system). Conversely, managing bodies in either system type may escape these rules if the schemes at issue are predominately solidarity-based. As a result, in some national systems, the healthcare providers must observe EU competition law when entering into contractual relationships with managing bodies, although the latter are not bound by these rules. Furthermore, financing of such managing bodies by the State does not give rise to issues under the EU state aid rules, while the financial support given to the healthcare providers in the same system could be illegal under these rules. As the “concrete” test merits a detailed analysis of the healthcare scheme under review, we examine below how this test has played out in the national healthcare systems – both insurance-based and taxation-funded – in the case law.

2.2. The “concrete” test in insurance-based systems – AOK Bundesverband and DZP/UZP

AOK Bundesverband considered the compatibility of EU antitrust rules with German statutory provisions governing the collective determination by leading sickness fund associations of maximum amounts paid by sickness funds towards the cost of various medicinal products. The question of compatibility arose in challenges brought by pharmaceutical companies seeking compensation for losses suffered following the introduction of maximum fixed amounts.

In essence, at issue was whether German sickness funds were “undertakings” for the purposes of the anticompetitive agreements prohibition when they jointly determine the applicable level of uniform fixed amounts for medicinal products.

The CJEU found that sickness funds in the German statutory health insurance scheme were not “undertakings”. This was because their involvement in managing the social security system meant that they fulfilled an exclusively social function, which was founded on the principle of national solidarity and was entirely non-profit-making (*AOK Bundesverband*, para 51) a logic built on the earlier cases of *Poucet* and *Cisal* (C-218/00, *Cisal*). A further justification for this finding was that German law required the sickness funds to offer their members essentially identical benefits independent of the amount of contributions. This meant that the sickness funds had no possibility of influencing those benefits (*AOK Bundesverband*, para 52) and so were not in competition with one another or with private institutions vis-à-vis the grant of obligatory statutory benefits regarding treatment or medicinal products.

DZP/UZP was concerned with the coexistence of public and private bodies in the Slovak health insurance system, in which citizens choose between the state insurance provider and private insurance companies for compulsory health insurance. The private insurance companies alleged a breach of the state aid rules by the Slovak government making payments to the state health insurer linked with healthcare and health insurance reforms. The Commission considered that the measures did not constitute state aid because the

organisation of compulsory health insurance in the Slovak Republic could not be regarded as an “economic activity”. As a result, the state and private health insurers could not be classified as “undertakings” within the meaning of the state aid rules (*DZP/UZP*, para 21). The private health insurance companies appealed this decision on two grounds. Firstly, that the Commission erred in law by interpreting the “undertaking” concept too narrowly by limiting its review to the public and private health insurers’ activity to the single compulsory health insurance system and not their activities beyond this. Secondly, that the Commission made errors of law and assessment in finding that the public and private health insurers were not engaged in economic activities.

The General Court’s judgment in *DZP/UZP* drew on previous case law, including *AOK Bundesverband*, in defining the parameters of its considerations, such as no direct link between contributions paid and benefits received, compulsory and identical benefits for all insured persons, contributions proportional to income, application of the pay-as-you-go principle, and the impossibility for health insurance bodies to influence the nature and level of benefits set by law or the amount of the contributions paid by the insured persons (*DZP/UZP*, paras 52-3). In light of these factors, the conclusion that the insurers were not engaged in economic activities appeared justified, as the Slovak system was solidarity-driven. Nevertheless, the General Court did eventually find that the Slovak healthcare system was of an economic nature.

The General Court established the existence of an economic activity based on two factors (*DZP/UZP*, paras 62-66). Firstly, the health insurance companies’ profit-making ability, since they were clearly pursuing financial gains, as the Slovak health laws permitted them to use and distribute profits. Secondly, while the health insurance bodies were not free to determine the amount of contributions or formally compete via tariffs, Slovak legislation nevertheless introduced an element of competition on quality. This took the form of the insurers’ freedom to supplement compulsory statutory services with related free services, such as better coverage for certain complementary and preventive treatments, or an enhanced assistance service for insured persons (*DZP/UZP*, para 66).

Overall, the General Court concluded that the activity of providing compulsory health insurance in Slovakia is economic in nature (*DZP/UZP*, para 68). This is a striking finding because it focuses on the insurers’ profit-making ability and a wider definition of “competition” which includes quality as well as price. The General Court held that not-for-profit operators must ‘by contagion’ be considered to be an undertaking, if other companies they compete with do seek to make a profit (*DZP/UZP*, para 69). Although such considerations were absent in *AOK Bundesverband*, they featured in the aforementioned Commission Decision in the Dutch health insurance state aid case, and in other, non-healthcare-related cases (e.g. Case C-49/07 *MOTOE*, para 27).

Following the General Court’s judgment, the Commission and the Slovak Republic have appealed to the CJEU, suggesting that the General Court committed an error of law by misinterpreting the notion of “undertaking” within the meaning of the state aid rules. In particular, the Commission appeared to take issue with the General Court finding “that the mere presence of for-profit insurers in Slovakia transform the state insurers by contagion into undertakings within the meaning of the [state aid rules]” (C231/15 Official Journal of the European Union 2.7.2018), and how it uses this to disregard previous case law which

established that “a health insurance scheme that is predominantly solidarity-based and whose economic features were introduced to ensure the continuity of the scheme and the attainment of the social and solidarity objectives underpinning it is non-economic in nature...”. It is striking to note that the Commission had previously found that the Dutch healthcare system includes solidarity features such as open enrolment and community rating, but nevertheless considered that Dutch insurance companies engaged in economic activities because they were allowed to seek profit (Cases N541/2004 and N542/2004 para 3.1).

It is to be hoped that the CJEU and Advocates General engage with this ground of appeal in particular and offer further clarity about what might be considered a “tipping point” in determining applicability of competition law: whether or not economic features introduced to ensure continuity of schemes underpinned by social and solidarity objectives do not detract from the solidarity basis (so operate as a means to the end of providing a solidarity-based healthcare system) or fundamentally change this (thus represent an end in themselves in the form of a system change).

2.4. The “concrete” test in taxation-funded systems – FENIN

Thus far, a single case has considered the applicability of EU competition law in a taxation-funded system. *FENIN* (Case C-205/03/P *FENIN*) involved an eponymous association of companies supplying medical goods and equipment used in Spanish hospitals to management bodies of the Spanish national health service (SNS). FENIN submitted a complaint to the Commission alleging that the SNS management bodies abused their position as a dominant buyer by making systematically delayed payments. The Commission dismissed the complaint on the basis that the SNS management bodies’ activities vis-à-vis the public health service were not economic in nature, and secondly, that their capacity as purchasers could not be dissociated from the use made of the medical goods and equipment following their purchase. FENIN then appealed to the General Court, which similarly dismissed the complaint on the grounds that the SNS operated according to the principle of solidarity, being funded from social security contributions and other State funding, and providing services free of charge to members on the basis of universal cover (*FENIN*, para 8). FENIN argued that Spanish public hospitals sometimes also provide care for patients not covered by the SNS, such as foreign visitors, so charges for these. The General Court dismissed this on procedural grounds and effectively upheld the Commission’s finding that the SNS managing bodies were not undertakings subject to competition law. FENIN then appealed to the CJEU, which upheld the findings of the Commission and the General Court.

The distinctive feature of the reasoning in *FENIN* emerges in the question of whether the activity of purchasing can be dissociated – or not – from the ultimate purpose of the purchase (to provide healthcare within a solidarity-based system). While this “dissociation” logic has been criticised (Sánchez Graells, 2015; Hancher and Sauter, 2012), it appears consistent with the definition of an “undertaking” as clearly focusing on provision rather than purchasing. There is also logic in examining the purpose of a purchase within a system where distinctions between public and private healthcare exist, such as England, where some private providers deliver services for National Health Service (NHS) patients, but others serve private patients exclusively (Guy, 2019).

The effect of the *FENIN* judgment is that it has been recognised as avoiding any (inappropriate) application of competition law “by the back door” (Krajewski and Farley, 2007), and as suggesting that the public procurement rules and state aid rules may be necessary as these serve to discipline the exercise of public purchasing power (Hancher and Sauter, 2012, para 8.18, p. 230).

It has been considered that, while the *FENIN* logic is freestanding, its ramifications are best understood when juxtaposed with the findings of the UK Competition Appeal Tribunal (CAT) in the contemporaneous *BetterCare* case (Case 1006/2/1/01, *BetterCare Group Limited v Director General of Fair Trading*) (Dunne, 2010; Sinclair, 2014). The CAT found that the purchase of care home places by the Northern Irish NHS constituted an economic activity, and upheld the complaint of a private provider (BetterCare). This conclusion was reached by the CAT approaching the “undertaking” concept from an “economic, rather than a legal perspective”, but was nevertheless cited with approval by Advocate General Maduro in *FENIN* (Case C-205/03 P *FENIN*, *Opinion of AG Maduro*) and arguably continues to be regarded as good law within the UK (Sinclair, 2014). These differing conclusions can perhaps be explained by the fact that the purchasing body in *BetterCare* was also actively engaged in providing services, whereas the purchasing body in *FENIN* was not.

2.5. A “concrete” test for cases involving managing bodies: identifying common themes for the “undertaking” concept in healthcare?

The broad distinction in healthcare system typology between a taxation-funded system and an insurance-based system can determine the scope for competition. Put simply, there is greater scope for competition within an insurance-based system because there is greater scope for demand-driven competition, as distinct from the supply-driven nature of a taxation-funded system where governments are likely to determine the precise levels of benefits (Hancher and Sauter, 2012, para 8.25, p.232). Some of the reasoning within *AOK Bundesverband, Zorgverzekeringwet*, and *DZP/UZP* reflects this with regard to the freedom (or not) of health insurers to determine benefits. However, a closer look at the case law reveals that the distinction between tax-based and insurance-based systems is less than suggested. Whether there is room for competition in a system can be answered in a flexible way.

To start with, there have been attempts to “square the circle” arising from the *FENIN* and *BetterCare* judgments by emphasising *actual* or *potential* making of profit, with even the latter proving sufficient to trigger applicability of EU competition law (Sinclair, 2014). Furthermore, while emphasis on a widened definition of “profit-making” is clearly a defining feature of the *DZP/UZP* judgment, the General Court appears to add another dimension with a widening of the definition of “competition” to include quality, as well as price.

Consequently, a very sophisticated approach is being developed for determining what competition is. In both tax-based and insurance-based systems, profit-making and competition on price as well as quality can occur, thus arguments for finding the competition rules applicable are similar in both systems.

It is curious that the discussions of *DZP/UZP* have been confined to the initial question of whether an undertaking exists – with no suggestion that the issue of allocating an SGEI

function may also be relevant. This in itself would appear to mark a departure from state aid cases concerning Dutch and Irish risk equalisation schemes since these function as a mechanism to support a solidarity-based system and have been classified as SGEI, thus partially immune from the competition rules. The appeal in *AOK Bundesverband* was framed as two questions: firstly, whether an undertaking existed, and secondly, whether the SGEI exception was relevant. It should be kept in mind that solidarity objectives could be achieved on competitive markets by partly allowing some restrictive practices and measures (cf. Davies, 2010).

All in all, cases dealing with managing bodies show that the levels of competition and solidarity are key features that must be scrutinised in order to find whether competition law applies. The development of additional considerations regarding these aspects in *DZP/UZP* demonstrates that the approach applied to managing bodies is more complex, in contrast to the simpler, “abstract” test applied to healthcare providers. In the “concrete” test, the specific features of healthcare schemes are closely examined: the “concrete” test, as deployed in the case law, allows for accommodating healthcare-specific concerns in the review and places a strong emphasis on solidarity, a core value in (many) national healthcare systems. Such considerations are absent from the “abstract” test, so no detailed analysis of the healthcare providers’ activities is made, nor is the role of solidarity considered.

We consider now whether a less simple test for determining the applicability of competition law to healthcare providers may also be appropriate, in view of the healthcare providers’ role being more complicated than simply providing services for remuneration. We suggest that such a test may emerge from the *CEPPB* state aid case.

3. The new three-prong test in CEPPB from a healthcare perspective: a new test for healthcare providers?

It is apparent from the above analysis that so far in healthcare the discussion has focused on qualification of managing bodies, such as health insurance companies. Their position has given rise to heated debate both in case law and legal doctrine. The qualification of healthcare providers, as counterparts of the managing bodies in many healthcare systems, has been relatively neglected until now. In our view this is because the CJEU has consistently held that the mere fact that providers receive remuneration for their activities suffices for qualifying them as “undertakings”. This raises the question whether this does justice to the complex and significant task they perform. A common thread running through assessments under competition law is that a profound understanding of the economic and legal context is essential (Cases 96-102, 104, 105, 108 and 110/82 *IAZ* para 25, and Case C-8/08 *T-Mobile* para 27). The CJEU has stressed the merits of a close examination of all issues and circumstances at play in interpreting competition law (Case 67-13, *Cartes Bancaires*). In fact, the sophisticated approach developed towards the “undertaking” concept in cases involving managing bodies testifies to this. Would it be possible for the CJEU to moderate its straightforward approach towards healthcare providers and to incorporate in its case law elements that accommodate concerns and values related to these providers? In our view, important lessons may be learned from the *CEPPB* judgment, which developed important principles for the “undertaking” concept.

3.1. The test developed in the *CEPPB* judgment

This case concerned tax exemptions for religious institutions in Spain. The Congregación de Escuelas Pías Provincia Betani (hereafter the Congregación) was refused this exemption for the use of its school hall. The municipal authorities argued that EU state aid rules prevented them from giving financial support to the Congregación. One of the questions to be addressed was whether the Congregación, which operated a primary school, was an “undertaking” for the purposes of EU competition law.

The CJEU addressed this question by recalling its case law on free movement and educational systems. At the heart of this is whether a particular activity is a “service” within the meaning of Article 57 TFEU, which would mean that services are normally provided for remuneration. It is apparent from free movement and education case law that as soon as economic consideration is given for an individual service, the Treaty provisions on free movement apply (Case C-76/05, *Schwarz and Gootjes-Schwarz*, Case C-318/05, *Commission v Germany* and Case C-56/09, *Zanotti*). In contrast, if education is organised in a collective way, the fees due are not considered to be payment in exchange for services rendered, so the EU free movement rules do not apply (Case 263/86 *Humbel* and Case C-109/92, *Wirth*). This approach comes down to verifying whether an educational institution is predominately financed by the State or by private means. If State financing is dominant, the educational activities are not of an economic nature, whereas a prominent role of private financing suggests that educational services are economic.

In *CEPPB* the CJEU recycled this free movement case law in order to address the question as to whether the Congregación was an undertaking when operating a school and offering services closely related to this. It was held that a school predominately financed by the State, fulfilling its social, cultural and educational duties towards the population, is not an “undertaking”. By contrast, educational services do constitute economic activities if they are financed by private funds (students, parents or other private players). Consequently, the approach adopted in *CEPPB* in order to qualify an activity under the competition rules was identical to that developed in EU free movement cases. Furthermore, the CJEU pointed out that an entity could be engaged in both economic and non-economic activities. In other words, although the operation of a primary school is likely to be non-economic, the use of the school hall for activities, such as offering private courses, can definitely be of an economic nature. In such circumstances, an entity must be severed in two parts.

The emphasis put on the level of the public financing reveals that State involvement is one of the key elements in establishing whether an educational institution is an “undertaking”. This involvement underlines the collective organisation of the educational system. No individual services are provided to specific persons; rather, it is guaranteed that a collective group of citizens is granted access to education. This means that the supply of services concerned is dependent on State intervention. Without public funding these services are not supplied. In contrast, some educational services, such as after-school tutoring, could be provided to specific persons in return for remuneration. Consequently, the mere existence of public funding does not suffice for carving out particular activities from the scope of EU competition law. The question to be answered is whether the supply of a service or a good can *only* be

guaranteed through public funding. In other words, taxpayers' money is needed to provide these services and goods for the public benefit. This means that solidarity is the principle underpinning the State intervention by means of public funding, as through taxation, wealth is redistributed in order to guarantee access for all to essential services. Concerns of solidarity justify that, in some cases, the competition rules do not limit the room for manoeuvre for Member States when organising their welfare schemes, including national healthcare systems (Ross, 2010)

If this is true, the CJEU's decision in *CEPPB* sheds new light on the issue as to whether healthcare providers must be regarded as "undertakings". Above, it was pointed out that the principle of solidarity is one of the key elements for qualifying bodies managing social security systems, including healthcare schemes, as "undertakings". In fact, the prominent role of solidarity prevents these bodies from being qualified as "undertakings". The characteristics of the activities concerned does not justify market forces playing a role. In the same vein, it could be argued that some health services are provided in a solidarity-driven framework, which makes it problematic to accommodate market dynamics in their supply. In fact, inherent in the assessment carried out in *CEPPB*, which concerned the provision of educational services, is the principle of solidarity.

Allowing consideration of solidarity-based concerns in the assessment under the competition rules would imply the "undertaking" concept must be (slightly) moderated. Admittedly, the "concrete" test is specifically developed for striking a balance between EU competition law and social security. The status of healthcare providers is assessed in accordance with the "abstract" test. In our view, however, solidarity is also an important element in the "abstract" test. As noted above, the exercise of official authority does not amount to an economic activity because this kind of State involvement is closely related to solidarity-based values: if there is no market, it does not make sense to apply the competition rules. Market players are not capable of delivering certain 'public goods', and so the State carries out certain tasks, such as policing, or issuing passports. In the same vein, some health services cannot be provided without public funding. In the public benefit the State finances the provision of the services that cannot be provided in the marketplace.

Which test must be carried out in order to determine whether a certain healthcare provider is an "undertaking" for the purposes of competition law? It is clear from the approach developed by the CJEU in *CEPPB* that the first condition requires the supply of the services by a certain provider to be mainly dependent on State funding. Furthermore, given the role of solidarity, the second condition is that the funding is geared towards achieving a public interest objective: accordingly, financial State intervention is necessary. As a close relationship should exist between the public interest objective and the public funding, the third condition is that the healthcare provider's activities are closely related to this objective. In other words, when it comes to healthcare providers, our proposal is to carry out the following three-prong test (van de Gronden, 2018) comprising cumulative (not alternative) elements:

- 1) the supply of the services or goods of these providers is mainly dependent on public funding;
- 2) the aim of this funding is the attainment of an objective of public interest; and
- 3) the activities concerned are closely related to this objective.

It is clear from the outset that the second and third conditions relate to solidarity. The State intervenes in order to make the supply of services and goods available for its citizens. The first condition of the test, however, merits further clarification. It cannot be excluded with regard to cost-intensive services and goods that some end-users are prepared to pay a high sum of money for e.g. highly-specialised medical treatment. However, this does not mean in itself that such services or goods can be offered on the market by economically viable companies. This depends on the expenses incurred by the operators in the supply and the number of customers willing to spend the great sum of money needed. If these expenses are very high and only a limited number of customers can make purchases, the services or goods concerned cannot be offered viably given the 'lack of critical mass on the demand side'. In other words, in these circumstances no real business case exists for enterprises supplying the services and goods concerned. Given the characteristics of these services or goods, the majority of customers cannot afford to purchase them and consequently, collective funding is required to ensure that the goods and services that play an essential role in society are provided.

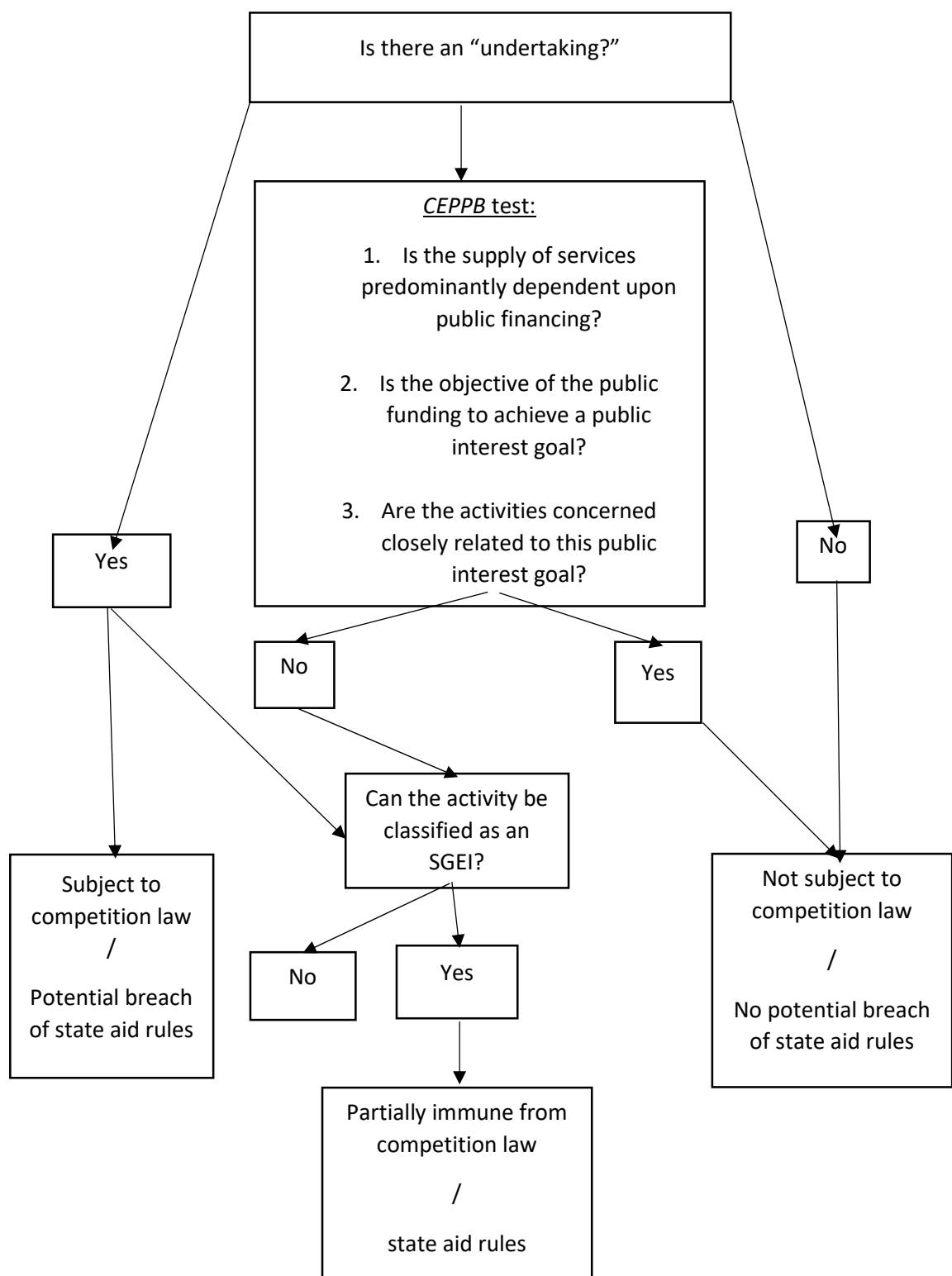


Figure 2: Overview of the possible operation of the “undertaking” concept regarding healthcare providers in light of the CEPPB test.

A clear example of healthcare provision falling outside the scope of competition law is offered by certain types of specialist treatment. For example, where certain types of specialist treatment can only be provided to citizens because of public funding, the first condition is likely to be satisfied. The expenses for such treatment are so massive that only a very small group of patients can afford this, which entails that no real business case exists for commercial operators. Taxpayers' money is, therefore, required and, accordingly, State intervention based on solidarity is justified (van de Gronden, 2018). The second criterion is satisfied by the existence of the objective being set out in national legislation (for example, to ensure public health), and the third by demonstrating a close connection between the activity (provision of certain specialist healthcare services) and the public interest objective. As regards the second and third criteria, the State funding is based on solidarity, i.e., the rationale of this intervention lies in the need to provide universal access to the medical treatment concerned.

In this regard it must be noted that an assessment based on the three-prong test could result in a part of the activities of a healthcare provider being considered economic and a part not. In that case this entity must be severed in two parts: one falling within the scope of the competition rules, and one falling outside. Thus, a hospital offering certain types of specialist treatment is not an "undertaking" for these purposes, but is engaged in economic activities when providing 'regular' medical services.

In our view, one of the advantages of the *CEPPB* test is that it allows due consideration of specific characteristics of the services of a healthcare provider. Rather than assuming that the exchange of payment for a service triggers the applicability of the competition rules (irrespective of the nature of this service), exploring the content and the financing of a healthcare service, including aspects of solidarity, should be decisive for establishing whether EU competition law applies. In our view, this would do justice to complex problems surrounding the provision of healthcare services. Ultimately, deciding on the applicability of the competition rules means asking whether the healthcare providers can operate on a genuine market.

3.2. The CEPPB three-prong test in healthcare: a Dutch case study

An interesting example of how the *CEPPB* test could work arises from a recent Dutch case about financing Non-Invasive Pre-natal Tests (NIPTs) (*Gendia v Dutch Ministry of Health, Wellbeing and Sport*).

At issue was a subsidy given by the Dutch government to a consortium including academic hospitals for offering the NIPT to every pregnant woman and her partner in order to detect Downs, Edwards and Patau syndromes. A Belgian company, Gendia, took the view that this subsidy was not in line with the EU state aid rules. Gendia claimed to be able to provide the NIPT to Dutch women at a price of €590, but Dutch academic hospitals could charge a fee of €175. Charging this lower fee was one of the conditions attached to the Dutch government subsidy. The Dutch appeal court found that the offering of a NIPT was designated as a SGEI in Dutch health law and financing this was, therefore, compatible with the state aid rules (OJ 2012 L7/3). Interestingly, the appeal court held that the market was not capable of offering the NIPT service in combination with counselling to all at affordable prices. In our view, it could have examined whether the services (NIPT test and counselling) offered were predominately dependent on public funding, as no viable business case existed for commercial

service provision. If so, the court could have ruled that offering NIPTs to (a wide range of) pregnant women does not amount to economic activities and for that reason the state aid rules were not violated. The consequence of this approach is that the aid given does not need to be compatible with the specific conditions for SGEI set out in EU law. It should be noted that the Dutch court referred to the Commission's SGEI Communication, which provides that an SGEI mission may not be assigned to operators if the market already provides, or can provide satisfactorily, the services in question (OJ 2012 C8/4, para 48). In our view a distinction must be made between services that cannot viably be provided by the market, and services that cannot satisfactorily be provided by the market (consistent with the public interest). The first group of services is non-economic, whereas the second group has an economic dimension.

Furthermore, the Dutch Authority for Consumers and Markets (ACM) has taken the view in its guidance (ACM 2010) that healthcare providers are engaged in economic activities, as they offer services, such as medical treatment, nursing care as well as laboratory and x-rays for other physicians, in exchange for payment. The ACM could reconsider its view on the "undertaking" concept in healthcare cases by paying attention to the *CEPPB* test. It could accommodate considerations related to the role of public funding by asking whether some specialist health services are provided for the sole reason that the State finances these services. In that case, no market exists and so it does not make sense to apply competition law, which constitutes the rules of the game for the market. The services rendered must be organised in a collective way, which does not justify the application of competition law.

4. Conclusions

In the case law on the "undertaking" concept and managing bodies much attention is paid to the healthcare-specific circumstances under which these bodies operate. Key issues are the level of competition and the role of solidarity. This case law has resulted in a sophisticated "concrete" test, which continues to give rise to legal debate and litigation at national and EU level. Nevertheless, healthcare-specific concerns are accommodated in the reviews in this test. To date those concerns do not play a role in cases concerning the "undertaking" concept and healthcare providers. In these cases, an "abstract" test is applied focusing mainly on whether a service or good is supplied in exchange for payment. This does not do justice to the complex healthcare services provided, which could, eventually, result in application of the competition rules where no genuine markets exist. In this paper we have proposed addressing this problem by applying a three-prong test to healthcare providers where: 1) the supply of the services or goods is mainly dependent on public funding; 2) the aim of this funding is the attainment of an objective of public interest; and 3) the activities concerned are closely related to this objective. This test pays due consideration to the specific features of the healthcare services and goods concerned. It should be noted that the test is still "abstract" as it takes potential competition as its starting-point: only if no viable business case exists, do the competition rules not apply. One of the core questions in this test is whether the market is capable of providing the services or goods under review. Whether this is the case may change over time. New technologies could make it possible that the costs incurred in providing services that were very cost-intensive at first decrease (massively). The emergence of ICT, such as techniques based on big data, is an example of this. In these circumstances the services concerned can be provided on the market and are, accordingly, transformed from non-

economic into economic activities, prompting the applicability of competition law. This does not, however, question the importance of solidarity. In order to strike the right balance between market forces and solidarity, deference must be made to the SGEI concept. Accordingly, the SGEI concept will remain an important alternative for achieving solidarity-based objectives in healthcare.

References

A. Andreangeli, 'Healthcare Services, the EU Single Market and Beyond: Meeting Local Needs in an Open Economy – How Much Market or How Little Market?' (2016) 43(2) *Legal Issues of Economic Integration*, 145.

ACM, *Richtsnoeren voor de zorgsector (Guidelines for the Healthcare Sector)*, March 2010.

J. Baquero Cruz, *Beyond Competition: Services of General Interest and European Community Law* in G. de Búrca (ed) *EU Law and the Welfare State: In Search of Solidarity*, Oxford University Press 2005.

G. Davies, *The Price of Letting Courts Value Solidarity: The Judicial Role in Liberalizing Welfare*, in: M. Ross and Y. Borgmann-Prebil (eds), *Promoting Solidarity in the European Union*, Oxford University Press, Oxford, 2010.

N. Dunne, 'Knowing when to see it: State Activities, Economic Activities and the Concept of Undertaking', 16 *Colum. J. Eur. L.* 427 (2010).

J.W. van de Gronden, 'Services of General Interest and the Concept of Undertaking: Does EU Competition Law Apply?', *World Competition* 41, no.2 (2018): 197-224.

--- 'The Treaty Provisions on Competition and Health Care' in Van de Gronden, J.W., Szyszczak, E., Neergaard, U., and Krajewski, M. (eds.), *Health Care and EU Law*, TMC Asser Press, The Hague 2011.

--- 'Financing Health Care in EU Law: Do the European State Aid Rules Write Out an Effective Prescription for Integrating Competition Law with Health Care?' (2009) 6(1) *CompLRev*, 5-29.

--- 'Purchasing Care: Economic Activity or Service of General (Economic) Interest?' 25 *Eur. Competition L.Rev.* 87 (2004).

J.W. van de Gronden and C.S. Rusu, 'EU competition law and policy and health systems', Chapter 11 in Hervey, T.K., Young, C.A., and Bishop, L.E. (eds.), *Research Handbook on EU Health Law and Policy*, Edward Elgar, Cheltenham 2017.

J.W. van de Gronden and E. Szyszczak, 'Introducing Competition Principles into Health Care Through EU Law and Policy: A Case Study of the Netherlands', (2014) 22(2) *Medical Law Review*, 238.

M. Guy, *Competition Policy in Healthcare: Frontiers in Insurance-Based and Taxation-Funded Systems*, Intersentia, Cambridge 2019.

L. Hancher and W. Sauter, *EU Competition and Internal Market Law in the Health Care Sector*, Oxford University Press, Oxford 2012.

M. Krajewski and M. Farley, 'Non-economic activities in upstream and downstream markets and the scope of competition law after FENIN', *European Law Review* (2007).

T. Prosser, 'EU competition law and public services' in Mossialos, E., Permanand, G., Baeten, R., and Hervey, T.K. (eds.) *Health Systems Governance in Europe: The Role of European Union Law and Policy*, Cambridge University Press, Cambridge 2010.

M. Ross, *Solidarity – A New Constitutional Paradigm for the EU*, in: M. Ross and Y. Borgmann-Prebil (eds), *Promoting Solidarity in the European Union*, Oxford University Press, Oxford, 2010.

A. Sánchez Graells, *Public Procurement and the EU Competition Rules*, 2nd edn., Hart Publishing, Oxford 2015.

W. Sauter, 'The Impact of EU Competition Law on National Healthcare Systems' (2013) 38(4) *European Law Review*, 457.

D. Sinclair, "'Undertakings" in competition law at the public-private interface – an unhealthy situation', (2014) 35(4) *European Competition Law Review* 167.

E. Szyszczak, 'Modernising Healthcare: Pilgrimage for the Holy Grail?' in Krajewski, M. et al, *The Changing Legal Framework for Services of General Interest in Europe – Between Competition and Solidarity*, TMC Asser Press, The Hague 2009.

A. Winterstein, 'Nailing the Jellyfish: Social Security and Competition Law'(1999) 6 *ECLR*, 324

Treaty on the Functioning of the European Union (TFEU) – Article 101, Article 102, Articles 107-109

Commission Decision on Public Service Compensation (OJ 2012 L7/3)

Communication of the Commission on Services of General Economic Interest (OJ 2012 C8/4)

EU cases

Case T-216/15, *Dôvera zdravotná poisťovňa and Union zdravotná poisťovňa*, 5 February 2018, ECLI:EU:T:2018:64

Case C-74/16, *Congregación de Escuelas Pías Provincia Betania*, 27 June 2017, ECLI:EU:C:2017:496

Case C-67/13, *Cartes Bancaires*, 11 September 2014, ECLI:EU:C:2014:2204

Case T-90/11 *ONP*, 10 December 2014, ECLI:EU:T:2014:1049

Case 437/09 *AG2R Prévoyance v Beaudout Père et Fils SARL*, 3 March 2011, ECLI:EU:C:2011:112

Case C-56/09, *Zanotti*, 20 May 2010, ECLI:EU:C:2010:288

Case C-8/08, *T-Mobile*, 4 June 2009, ECLI:EU:C:2009:343

Case T-289/03, *British United Provident Association Ltd (BUPA) et al v Commission*, 12 February 2008, ECLI:EU:T:2008:29

Case C-49/07, *MOTOE*, 1 July 2008, ECLI:EU:C:2008:376

Case C-76/05, *Schwarz and Gootjes-Schwarz*, 11 September 2007, ECLI:EU:C:2007:492
Case C-318/05, *Commission v Germany*, 11 September 2007, ECLI:EU:C:2007:495
Case C-205/03 P, *FENIN v Commission*, 11 July 2006, ECLI:EU:C: 2006:453
Commission of 22 December 2005 on the introduction of a risk equalisation system in the Dutch Health Insurance Act, N541/2004 and N542/2004 – C (2005) 1329 fin
Case C-205/03 P, *Federación Española de Empresas de Tecnología Sanitaria (FENIN) v Commission of the European Communities*, Opinion of Mr Advocate General Poiares Maduro delivered on 10.11.2015, ECLI:EU: C:2005:666
Joined cases C-264/01, C-306/01, C-354/01, and C-355/01, *AOK Bundesverband and Others*, 16 March 2004, ECLI:EU:C:2004:150
C-218/00, *Cisal* ECLI:EU:C:2002:36
Case C-475-99, *Ambulanz Glöckner*, 25 October 2001, ECLI:EU:C:2001:577
Joined Cases C-180/98 to C-184/98 *Pavlov* [2000] ECR I-6451; [2001] 4 CMLR 1.
Joined cases C-159/91 and C-160/91, *Poucet*, 17 February 1993, ECLI:EU:C:1993:63
Case C-109/92, *Wirth*, 7 December 1993, ECLI:EU:C:1993:916.
Case C-41/90, *Höfner*, 23 April 1991, ECLI:EU:C:1991:161
Case 263/86, *Humbel*, 27 September 1998, ECLI:EU:C:1988:451
Case 118/85, *Commission v Italy*, 16 June 1987, ECLI:EU:C:1987:283
Joined cases 96-102, 104, 105, 108 and 110/82, *IAZ*, 8 November 1983, ECLI:EU:C:1983:310

National cases

Gendia v Dutch Ministry of Health, Wellbeing and Sport, Case No. 200.225.476/01, Gerechtshof Den Haag, 11 December 2018, ECLI:NL:GHDHA:2018:3331.
Case 1006/2/1/01 *BetterCare Group Limited v Director General of Fair Trading* [2002] CAT 6, [2002] Comp.A.R. 229