MEMBER STATES' REGULATORY AUTONOMY IN HEALTH SERVICES WITHIN THE INTERNAL MARKET: THE IMPACT OF THE EUROPEAN LAW

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Abstract

European Union (EU) law is based upon a liberalising imperative, the goal of which is to construct a single market between member states. Public healthcare is a fundamental task for the member states. However, its real character is ambiguous, though, on the one hand, healthcare is a cornerstone of social security and, on the other hand, it is an enormous economic sector. Legislation on the basis of the internal market can address numerous issues of pricing, accessibility of services and access to markets, competition and state aids, as well as consolidating and clarifying patient rights. Our study paper focuses on restrictive effects derived from EU law on national healthcare which requires stretching the basic distribution of powers between the EU and the Member States.

Keywords: healthcare, internal market, EU law, member states, health services, legislation

Introduction

The European Union in the last ten years has become seriously involved in healthcare systems. The organisation of public healthcare is one of the most delicate state tasks of current times. Healthcare is subject to various controversial factors and consequently causes serious disputes requiring critical decisions. The provision of sufficient and adequate healthcare is not only a question of political opportunism. Rather, healthcare constitutes a fundamental task of welfare states and affects fundamental rights including the right to life and the right to personal integrity. Therefore, the provision of healthcare is a constitutional issue.

After a series of reactive lawsuits over the last 20 years, EUs legislative and policy organs have entered a period of concern with the organization of national healthcare provision and the interaction of systems with each other. The importance of this can hardly be overstated. Healthcare systems are vast yet surprisingly fragile and embody one of their most defining, distinctive, and fundamental characteristics; that of solidarity. From a specifically European point

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ISBN 978-606-714-502-1 | ISSN 2393-2384 | ISSN-L 2392-8867

of view, involvement in healthcare offers the chance of a deepening of integration and an embedding of European policies in some of the most sensitive and protected national contexts, yet also risks a popular national backlash of hitherto unknown proportions. If the EU makes itself the patient's friend it has a lot to gain, but if it comes to be seen as a market-obsessed threat to patient welfare then this could be the issue that stops integration dead (Davies, 2006, p. 53-60).

Addressing healthcare therefore requires a strategic approach, in which legislative action is part of a long-term plan rather than being merely ad hoc specific problem solving. In developing such a strategy, a broad vision is required of where the EU wants to go, or wants its Member States to go. Yet, legal measures are likely to be found on specifically economic Treaty articles and to fall within the scope of the internal market.

Presently the European Union is formed of 28 Member States, and each state has a national healthcare system, which can in general terms be divided in two: the Bismarck systems (insurance based system which may have private or public provision of care or a combination of both) and the Beveridge systems (which are more likely to have public provision but may in part rely on private provision of care). Beveridge model is used in Great Britain, Italy, Greece, Finland, Spain, Norway, Sweden. The Bismarck model is a system inspired by German law. It is used in many EU countries, such as France, Germany, Austria, Belgium, the Netherlands and Romania.

Both systems are similar regarding the problems they face and they share (cost constraint; concerns about the affordability of care in the face of ageing populations; concerns about the technological developments and rising expectations; etc.)

If we assume that a healthcare system assigns access rights to healthcare to a particular target population and ensures the organization, notably the funding and delivery of such care the EU cannot be said to have its own healthcare system separately from the abovementioned national healthcare systems of the Member States. Instead it disposes of a number of fairly fragmented but complementary competencies and is responsible for a number of policies that affect the healthcare systems of the Member States either directly or indirectly without itself forming an EU healthcare system as such (Guy and Sauter, 2016, p. 4).

In most Member States, healthcare systems are undergoing reform as a result of economic and social pressures and an international healthcare market is something that we may expect to see slowly emerge in the coming years, rather than something which already exists. This suggests that market regulation undertaken today would have to be anticipatory, based on estimates of the shape of the market and its actors in the future.

Considering potential cross-border economic activity in the healthcare sector of patients and healthcare providers, an obvious question arises as to the compatibility of national healthcare planning with European Union law. In our study we will analyse how national healthcare planning and is influenced in particular by rules of the internal market.

1. The limiting impact of EU law on Member States' healthcare planning

At first sight, the answer to the question of the distribution of powers between the EU and Member States in the field of healthcare cannot be given a simple answer. An absolute answer appears to be impossible since primary EU law does not provide for a definitive legal position. On the contrary, healthcare in general and healthcare planning in particular are part of the diverse and complex provisions of European constitutional law. For instance, due to its dual nature as social policy and public health, healthcare is linked to areas of "social policy" by Article 4 par. 2 lit. b) Treaty on the Functioning of the European Union (TFEU) and to the area of "common safety concern in public health matters" by Article 4 par. 2 lit. k) TFEU. Since both areas belong to the scope of shared competences between the Union and Member States, the Union enjoys pre-emptive rights. However, on closer examination, the legal position turns out to be quite the contrary. It may be concluded, for several reasons, that Member States can be regarded as principal legislators in the field of healthcare and healthcare planning. The TFEU limits the EU's competence explicitly. For example, Article 152 TFEU underlines "the diversity of national systems" and obliges the EU to respect Member States' autonomy. Moreover, initiatives taken by the EU "shall not affect the right of Member States to define the fundamental principles" of Member States' social security systems.[1]

Similarly, the TFEU restraints the EU's healthcare related competence. Forsooth, Article 4 TFEU conditions the competences of social policy and public health on "the aspects defined in this Treaty"[2] and Title XIV of the TFEU does not refer to "health" or "healthcare" in general, but targets just "public health". Public health differs from healthcare because it is solely concerned with human health protection, whereas healthcare refers to health services provided by health professionals to patients and the provision of medicinal products[3].

Article 168 par. 7 TFEU significantly delimits the EU's power to regulate healthcare. By this provision, primary EU law clearly assigns the general responsibility for healthcare and healthcare planning to the Member States. The article mentioned above states explicitly that, in principle, it is for the Member States to organise healthcare systems including all choices conceivable as for instance the scheme applicable. Certainly, the fact that the TFEU declares that healthcare is within the competence of Member States explicitly substantiates the principle of assignment in the field of healthcare and strengthens legal certainty in this domain[4].

[1] Treaty on the Functioning of the European Union (2007), art. 153 par. 4.
[2] Idem, Article 4 par. 2 lit. b) and k).
[3] Article 3 a) of Directive 2011/24/EU: healthcare means 'health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices'.
[4] Treaty on the Functioning of the European Union (2007), art. 5 par.2.

Thus, healthcare planning derives from the States' competence for social security in general and healthcare in particular. This coincides with Article 6(a) TFEU, which defines the protection and improvement of human health only as a supportive competence of the EU. According to Article 2 par. 5 TFEU, the Union's supportive competence does not supersede Member States' competence in this area, and binding acts of the Union do not entail the harmonisation of Member States' laws. Once more the very limited scope of EU competence becomes apparent; yet, the status of Member States as the competent legislators for healthcare is, in turn, limited by EU law. While to date the distribution of competences has been concerned with the basic question of the entity competent to legislate, law-making cannot be exercised without prejudice to EU law provisions. In fact, the Court of Justice of European Union (CJEU) gives emphasis in settled case law that "the special nature of certain services does not remove them from the ambit of the fundamental principle of freedom of movement". In other words, despite that Member States are authorised, for instance, to determine the conditions for entitlement to benefits based on their social security competence, national provisions have to comply with the rules of the internal market.[5] Therefore, the German government's argument in the Smits and Peerbooms case was rejected on the grounds that the "structural principles governing the provision of medical care are inherent in the organisation of the social security systems and do not come within the sphere of the fundamental economic freedoms guaranteed by the EC Treaty".[6] Certainly, the Court's decision to the benefit of EU law's reach is far-reaching. Considering the fundamental principles of validity and primacy of EU law in relation to national law, primary and secondary EU law limits Member States' room for manoeuvre as far as EU law is concerned. Thus, the CJEU's ruling on the application of the internal market rules to national healthcare planning reveals that it is also per se subject to noticeable limitations deriving from EU law, notwithstanding its "special" character as social security law.

2. The scope of application of EU legislation

Looking at primary EU law as the first source of law with possible relevance for national healthcare planning, Article 35 of the Charter of Fundamental Rights of the European Union is a pertinent starting point. This Article grants everyone the right of access to medical treatment. However, the material scope of Article 35 EU Charter is remarkably limited. First, the provision itself clearly restricts the right of access to medical services to "conditions established by national laws and

[5] CJEU, 11 September 2008, C-141/07 European Commission v. Federal Republic of Germany [2008] ECR I-6935, para. 23 (retrieved from https://curia.europa.eu/en/content/juris/c2_juris.htm).

[6] CJEU, 12 July 2001, C-157/99 B.S.M Geraets-Smits v. Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Groep Zorgversekeringen [2001] ECR I-5473, para. 51: '[…] Member States may be required […] to make adjustments to their national systems of social security, but […] it does not follow that this undermines their sovereign powers in the field'(retrieved from https://curia.europa.eu/en/content/juris/c2_juris.htm).

practices". The Charter emphasizes Member States' individual power to determine healthcare policies and hereby coincides with Article 52, par. 6 of the Charter[7]. Hence, the European right of access to medical services is a relative right only. Second, Article 35 of the Charter is addressed to the Member States when they are implementing Union law. Since healthcare planning constitutes primarily a Member States' task, the application of Article 35 of the Charter appears limited once more. It therefore is no wonder that the Court of Justice of the European Union has not yet based its healthcare related case law on Article 35 EU Charter.

Notwithstanding, the CJEU construes the material scope of the fundamental freedoms in national healthcare cases extensively. This concerns all freedoms particularly relevant to healthcare from an economic point of view, i.e. the free movement of persons including the freedom of establishment, the free movement of services and finally the free movement of goods.

The most significant decision on the application of Article 56 TFEU on national healthcare organisations still had to be made because the latter varies in fundamental ways. In particular, the crucial question to be settled was still whether the freedom of services of Articles 56 and 57 covered all methods of funding, i.e. not only remuneration but also benefits-in-kind and national healthcare schemes. Since Member States' healthcare systems are diverse and do not require direct payment by patients, the vital point was whether the condition of "remuneration", within the meaning of Article 57 TFEU, was met. Indeed, pursuant to the Court's case law, remuneration requires, generally, a direct economic link between the service provided and the payment rendered. Therefore, it can be doubted whether health services provided free of charge fall within the scope of freedom of services. However, the Court of Justice was, and is, willing to overrule any objections to the applicability of Article 56 and 57 TFEU on all variations of healthcare planning schemes (Walus, 2015, p. 60). According to Article 57 TFEU does not require that payment has to be made by the recipient of services.

Looking to other fundamental freedoms of the internal market, the same pattern can be seen in the CJEU case law on the freedom of establishment and the free movement of goods. In the Hartlauer[8] and Decker[9] judgments, the Court of Justice followed its approach in interpreting the material scope of the freedoms broadly, and applied them to national healthcare laws with the requirements of prior authorisation and a needs test for the establishment of medical facilities as well as national healthcare laws on the reimbursement of medical products. The freedom of establishment grants companies, in particular, the right to set up undertakings, as well as agencies, branches or subsidiaries; and self-employed

[7] Article 52, par. 6 of the Charter of Fundamental Rights of the European Union states: 'Full account shall be taken of national laws and practices as specified in this Charter'.

[8] CJEU, 10 March 2009, Case C-169/07, Hartlauer Handelsgesellschaft mbH v. Wiener Landesregierung and Österreichische Landesregierung [2009] ECR I-1721 (retrieved from https://curia.europa.eu/en/content/juris/c2_juris.htm).

[9] CJEU, 28 April 1998, Case C-120/95 Nicolas Decker v. Caisse de maladie des employés privés [1998] ECR I-1831 (retrieved from https://curia.europa.eu/en/content/juris/c2_juris.htm).

professionals are entitled to take up and pursue an activity. Thus, in addition to the freedom of services which covers temporary services, health service providers are protected by internal market rules, even if they provide healthcare services permanently. As a consequence of the case law referred to above, the Court of Justice decided categorically in favour of the material application of internal market rules to Member States' healthcare systems. This was undoubtedly motivated by the wish to ensure a uniform application and an effective use of these freedoms. Either way, these judgments undoubtedly mark a breakthrough in the relationship between Member States' healthcare planning and European Union law (Walus, 2015, p.61). Since all healthcare schemes are considered to fall within the material scope of the fundamental freedoms, generally speaking Member States' healthcare law needs to comply with the internal market rules.

The same approach can be identified in the CJEU's ruling on the personal scope of application of the internal market rules in the context of national healthcare law. Indeed, the extension of the personal scope of the freedom of services from providers of services to recipients of services has one of its roots in the CJEU case law on cross-border healthcare. The Luisi and Carbone case proved to be a landmark decision, since here the Court opened the freedom of services to service recipients[10]. In the Court's view, the freedom to receive services is the "necessary corollary" to the freedom to provide services[11]. The reach of the judgment is certainly quite wide since it acts, as will soon be seen, as a gateway for further influences on national healthcare planning deriving from EU law. From the internal market perspective, the Court's case law on the freedom of establishment complements the wide range of the internal market's personal scope of application that is relevant to national healthcare planning. Considering the Court's acknowledgment that the freedom of establishment is applicable to providers of healthcare services, the personal scope of the internal market rules now covers both natural and legal persons, both as active actors, companies and self-employed individuals; and as passive actors, particularly patients.

At this point, it is worth taking a look at the configuration of the material and personal scope of EU legislation on healthcare. Here, as regards both the material and personal scope of application, Directive 2011/24/EU and Regulation 883/2004/EC differ widely from primary EU law – the different personal focus stands out in particular. Both laws only aim to protect the rights of health service recipients, namely patients, at least as regards direct protection. As Regulation 883/2004/EC concerns the coordination of social security rights of individuals in cross-border activity, it is designed, primarily, to protect Member States' citizens who wish to

[10] CJEU, 31 January 1984, Joined cases 286/82 & 26/83 Graziana Luisi and Giuseppe Carbone v. Ministero del Tesoro [1984] ECR 377; see also CJEU, 4 October 1991, C-159/90 SPUC v. Grogan, C-159/90 [1991] ECR I-4685 (retrieved from https://curia.europa.eu/en/content/juris/c2_juris.htm).

[11] CJEU, 31 January 1984, Joined cases 286/82 & 26/83 Graziana Luisi and Giuseppe Carbone v. Ministero del Tesoro [1984] ECR 377, par. 10; see also, CJEU, 5 October 2010, C-512/08 European Commission v. French Republic [2010] ECR I-1297, par. 32 (retrieved from https://curia.europa.eu/en/content/juris/c2_juris.htm).

receive cross border medical treatment[12]. Similarly, not only is Directive 2011/24/EU called the Directive "on the application of patients' rights in cross-border healthcare"; its subject matter is also defined to facilitate access to cross-border healthcare and to clarify its relationship to Regulation 883/2004/EC "with a view to application of patients' rights". According to Article 4, par. 3 of Directive 2011/24 EU, Member States are obliged to ensure that the principle of non-discrimination "shall be applied to patients from other Member States". Certainly, it may be argued that patients' rights correlate with those of healthcare providers, as the CJEU stated that recipients' rights are the necessary corollary to the freedom to provide services. Likewise, the CJEU held, in other healthcare related cases, that the two groups are closely linked, as restrictions which apply to providers apply to both providers and patients. It is still noteworthy that the EU legislature does not pursue the protection of healthcare providers actively through legislative acts *expressis verbis*. In fact, the impact of EU healthcare legislation on the protection of healthcare service providers takes place rather indirectly through the provision of patients' rights only. Arguably, the restricted involvement of healthcare providers in EU secondary legislation may be regarded as quite weak since their rights merely reflect other groups' rights and thus are not independent. In any event, from an objective point of view, the legal design of Directive 2011/24/EU appears to be consistent. As the Directive only addresses access to cross-border healthcare services, its constitution is limited as such. In fact, the Patients' Rights Directive does not by any means codify the CJEU case law on Member States' healthcare in general. On the contrary, instead of affecting the Court's case law on the freedom of establishment of healthcare service providers, for instance, the Directive focuses on patients' rights solely from the perspective of the freedom of services and free movement of goods. In this sense the Directive at hand clearly goes one step further than the general Service Directive, which explicitly excludes healthcare services. However, contrary to the general Service Directive, which also regulates cross-border rights of establishment, this cornerstone does not fall within the personal and material scope of Directive 2011/24/EU. Thus, this Directive can instead be classified as sectorial legislation that only applies to patient consumers of medical services and to medical products. In contrast to the CJEU's broad interpretation of the scope of application of the fundamental freedoms, the impact of the legislation at hand is ultimately rather limited.

3. The negative impact of EU law on Member States' healthcare planning

The negative impact of EU legislation on national healthcare planning may be measured by the scope of the interdiction based on the internal principle market

[12] The personal scope of Regulation 883/2004/EC also covers stateless persons, refugees residing in a Member State as well as their families and survivors; see in detail, Pennings (2010). In a recent judgment the CJEU had to rule on the Regulation's distinction between 'residence' and 'stay', see CJEU, 5 June 2014, C-255–13 I v. Health Service Executive [2013] ECR I-1291.

rules. The issue is therefore what are the restrictions stemming from EU legislation and at the same time what regulatory measures adopted by Member States to address healthcare planning are facing prohibitive restrictions under EU law. As for the interpretation rules of the internal market in cases related to national health regulations, the CJEU takes a similar approach to the extent of prohibition on its approach to other cases cross-border economic activity. The Court adopts a market access approach and controls national healthcare planning in the light of its restrictive effect. In this sense, the main focus is to put into effect the national regulations of the Member States regarding the access to the market in order to make it more difficult for other Member States. This applies to all relevant freedoms in the cases of healthcare. As for freedom of services the Court has explicitly emphasized the interpretation of Article 56 TFEU, which precludes "any national regulation which has the effect of providing for that provision of services between Member States is more difficult than the provision of services only in one Member State"[13].

The scope of prohibition of the EU legislation is ruled by two distinctive main legal instruments. First, the Regulation 883/2004 / EC is limited to coordinating the application of the cross-border social security provision, meaning that the regulatory limitations of the Member States derive from their obligation to comply with the provisions of the Regulation. Second, the Directive 2011/24 / EU imply prohibitive rules, which is not surprising given its objective to also codify CJEU case law. However, the prohibitive effects deriving from the Directive are more complex than the case-law of the Court. Indeed, the scope of the prohibition is based on the harmonization effect of the Directive. As Member States have to adapt their legislation in line with the requirements of the Directive, they are also required to enforce provisions involving prohibitions. In other words, to the extent that the Directive contains rules on the requirements to be met for the application of regulatory measures, the legislators of the Member States are not entitled to circumvent these requirements.

The outlook on the negative impact of EU legislation on national health planning revealed several limitations for the latter. First of all, the general question of the fundamental relationship of both legal orders in the health field can be answered as follows: although ordinary legal architecture gives Members States the right to regulate healthcare planning in their territories, by differentiation from the exercise of competences, Member States are confronted with a regulatory autonomy due to their obligations to comply with the EU internal market law.

Secondly, combining the negative perspective with a comparative one, three different sources of EU legislation affecting the national healthcare planning

[13] CJEU, 28 April 1998, Case C-158/96 Raymond Kohll v. Union des Caisses de Maladie [1998] ECR I-1931, para. 33; CJEU, 12 July 2001, C-157/99 B.S.M Geraets-Smits v. Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Groep Zorgversekeringen [2001] ECR I-5473, par. 61 (retrieved from https://curia.europa.eu/en/content/juris/c2_juris.htm).

(primary EU law, coordination law and the Patients' Rights Directive)- ultimately have different influences on national healthcare legislation.

While the personal and material scope of the Treaties' freedoms are interpreted and applied broadly by the Court of Justice, the EU legislature has limited the scope of application of Regulation 883/2004/EC and Directive 2011/24/EU primarily to protect individuals who wish to receive cross border health services and to purchase medical products. Similarly, a broad scope of prohibition follows from the internal market freedoms due to the Court's strict restriction test. Hence, from a comparative perspective, the three sources certainly vary in terms of the intensity of their impact. While Regulation 883/2004/EC respects the Member States' healthcare competence, Directive 2004/24/EU goes one step further by providing for harmonization; some authors therefore conclude that the Directive leads to a "Europeanisation" of national health policies.

However, since the Directives' harmonizing scope is rather limited, CJEU case law exerts the strongest influence. Nevertheless, the limiting influence of EU law loses its overall importance because of its inconsistency. Since all sources vary and have varying grades of impact, national healthcare law faces unclear and widespread boundaries deriving from EU law. Different personal and material scope as well as the different scope of prohibition inevitably leads to a weakening of the limiting strength of EU law. Particularly in terms of the protection of healthcare providers, national healthcare planning is limited by a casuistic protection provided by CJEU case law of the freedom of services and freedom of establishment, as well as indirectly by the provisions of Regulation 883/2004/EC and Directive 2011/24/EU. Also, as regards personal scope, the Court's case law still does not feature the application of Article 18 TFEU on rights based on EU citizenship. In spite of this weakness; considerable limitations to national healthcare planning derive from EU law as a consequence of the Court's case law. Since national regulatory measures often fall within the scope of application and scope of prohibition, Member States' healthcare planning generally requires justification. For this reason, the following section examines how the Court relieves Member States from justifying their healthcare planning when it interferes with EU law (Walus, 2015, p.66-67).

Conclusions

Summing up we can speak of several key conclusions that can be drawn from this conceptual view of the impact of EU legislation on Member States' regulatory autonomy in the field of healthcare. A negative perspective analysis has shown that the Court of Justice has developed some outstanding constraints on national healthcare planning. The ambiguous nature of healthcare – both social security and the economic sector – has allowed the Court to make a decision in principle. On the basis of the economic relevance of healthcare, the CJEU advocated the application of internal market rules and therefore obliged the Member States to respect fundamental freedoms. In addition to that, despite the fact that Member States are the main legislators in the field of healthcare, their

restrictive planning requires justification from the CJEU, given the broadly interpreted and enforced domestic freedoms. Disadvantages arising from the differing scope of application and prohibition of EU legislation are affecting only patients and not the regulatory autonomy of the Member States. However, the positive outlook has revealed that the Member States' limited regulatory autonomy in healthcare also faces the protection and reinforcement effects derived from the CJEU case law. Indeed, the article revealed a judicial reconciliation of national planning in the field of healthcare and the internal market by the CJEU.

Various exceptions and allowances granted to Member States' health planning has considerably strengthened national legislation autonomy. Again, the ambiguous nature of healthcare is at the forefront. While the Court based its limitations on economic considerations, respect for healthcare planning followed from its social dimension. In fact, the CJEU has acknowledged that Member States have a great responsibility for maintaining high quality healthcare systems to meet their constitutional commitments to social security and fundamental rights. Because this constitutional task also requires huge financial expenses, the CJEU has taken this challenging topic into account and provided considerable flexibility to national healthcare policies. In view of legitimate purposes, the Internal Market Law of the EU has not posed major obstacles to the Member States to address this key policy. The throughout analysis of this article shows that without a full „Europeanization" of healthcare sector, it is still possible both to protect national and European interests at the same time.

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