GABRIELLA BERKI [*]

Realistic Necessity or Outdated Leftover?

Thoughts about the Controversial Nature of Prior Authorisation Schemes of Planned Treatments Abroad

The union citizens' fundamental right to move freely within the European Union has been high on the political agenda for years now,[1] especially when it comes to access to welfare benefits in the hosting Member State.[2] Under the layer of political arguments, there are two clear sets of interests which collide here: (1) on the one hand, *the citizens' right to free movement and social protection* guaranteed by a number of human rights' treaties and the Union law,[3] which serves the purpose that the migrant persons do not lose their social rights by using their right to move freely, but can get access to social benefits in the hosting state under certain conditions; and (2) on the other hand, *the Member States' desire to keep control of their social spending and to safeguard the sustainability of their welfare systems*. The question manifests itself: how can a fine balance be found between these two?

In this paper, the focus is set on one specific group of social benefits, namely *healthcare services* and the question is addressed whether in the matrix of interests outlined above the *prior authorisation procedure* required by the Coordination Regulations[4] in case migrant

[*] PhD, Assistant Professor, University of Szeged

[1] The free movement debate reached its zenith in 2013 – ironically, in the year dedicated to European citizenship – and continues to raise major concerns EU-wide till today. In April 2013, four ministers of influential Member States addressed a joint letter to the Irish Presidency and "*launched a strong attack regarding the freedom of movement of EU citizens.*" YVES PASCOUAU: *Strong attack against the freedom of movement of EU citizens: turning back the clock*. 2013. http://www.epc.eu/pub_details.php?pub_id=3491 (11 January 2016). The ministers claimed that migrant EU citizens from other Member States "*avail themselves of the opportunities that freedom of movement provides, without, however, fulfilling the requirements for exercising this right*." http://docs.dpaq.de/3604-130415_letter_to_presidency_final_1_2.pdf (11 January 2016).

[2] See an analysis on the topic prepared by the European Parliamentary Research Service: EVA-MARIA POPTCHEVA: *Freedom of movement and residence of EU citizens*. 2014. http://www.europarl.europa.eu/RegData/bibliotheque/briefing/2014/140808/LDM_BRI(2014)140808_REV1_EN.pdf (11 January 2016).

[3] Inter alia, Article 22 of the UN Universal Declaration of Human Rights, Article 19 of the European Social Charter and Article 34 of the Charter of Fundamental Rights of the European Union.

[4] Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems (OJ L 166 of 30 April 2004) and Regulation (EC) No 987/2009 of the European Parliament and of the Council of 16 September 2009 laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems (OJ L 284 of 30 October 2009).

persons seek planned treatment abroad[5] is still necessary to be maintained among today's circumstances. The length of this paper does not allow an in-depth analysis of all related issues, thus it rather intends to reflect on the arguments used in this debate.

I. The nature of the prior authorisation requirement

The European Union has guaranteed the – rather limited – right to planned treatment abroad for decades in the framework of social security coordination.[6] The Coordination Regulation – which stems from the principle of *free movement of persons* – requires the patient to request prior authorisation from the competent institution before being able to obtain planned treatment.[7] This legislation provides the national administrations with considerable *discretionary power* and significantly reduces the freedom of patients. From the Member States' point of view, this administrative step has ensured the avoidance of the uncontrolled outflow of patients and the wastage of the national healthcare resources.

However, the legal rules related to scheduled healthcare were completely redefined by the Court of Justice of the European Union (CJEU), when it applied the fundamental principles of the *free movement of services and goods* for the sector of healthcare in two milestone cases[8] in the late 1990s. The CJEU made it clear that despite the limited EU competence in the field of healthcare,[9] healthcare provision is not "*an island beyond the reach of Community law*."[10]

The baseline of the patient mobility case law[11] was that the Treaty precludes national rules which have the effect of making the provision of services (and the consumption of services) between Member States more difficult than the provision of services purely within one Member State.[12] Nevertheless, after refusing a series of possible grounds for justification of restrictions,[13] the CJEU acknowledged that *planning objectives can justify the maintenance of prior authorisation schemes*.[14]

---

[5] Article 20 (2) of Regulation (EC) No 883/2004.

[6] The possibility to obtain non-planned medical care during a temporary stay abroad was already offered by the very first set of Coordination Regulations in 1958, whereas – as a rather progressive step at that time and that level of European integration – provisions on planned care were introduced in 1972 by Regulation 1408/71.

[7] Article 20 of Regulation (EC) No 883/2004.

[8] C-158/96 Raymond Kohll v Union des caisses de maladie [1998] ECR I-01931 and C-120/95 Nicolas Decker v Caisse de maladie des employés privés [1998] ECR I-01831.

[9] Article 168 (7) of the Treaty on the Functioning of the European Union.

[10] YVES JORENS – MICHAEL COUCHEIR – FILIP VAN OVERMEIREN: *Access to health care in an internal market: impact for statutory and complementary systems.* Bulletin luxembourgeois des questions sociales 18/2005. p 2.

[11] http://ec.europa.eu/social/main.jsp?catId=572&langId=en (14 January 2016).

[12] C-381/93 *Commission v France*, 17; C-158/96 *Kohll*, 33; C-368/98 *Vanbraekel*, 44; C-157/99 *Geraets-Smits and Peerbooms*, 61; C-8/02 *Leichtle*, 37; C-372/04 *Watts*, 94; C-444/05 *Stamatelaki*, 25; C-211/08 *Commission v Spain*, 55; C-490/09 *Commission v Luxemburg*, 16, 33.

[13] In the early patient mobility cases, the Member States came up with four possible grounds of justification, consistently rejected by the CJEU one by one, namely (1) the control of the health expenditure, (2) safeguarding the financial balance of the social security system, (3) protecting public health by supplying goods and providing services by persons authorised by law to pursue the profession, and (4) a balanced medical and hospital service accessible to all.

[14] This argument first occurred in the *Geraets-Smits and Peerbooms* judgement, and was then confirmed on several occasions. C-157/99 *Geraets-Smits and Peerbooms*, 76, 78-80; C-385/99 *Müller-Fauré and Van*

Opening up the possibility for the Member States to make reimbursement of medical costs incurred abroad subject to prior authorisation eroded the patients' rights to cross-border treatments. Moreover, the Patient Mobility Directive (PMD),[15] which intended to incorporate the findings of the CJEU on the provision of healthcare services[16] and to clarify its relationship with the existing framework of social security coordination, took it a step further, and introduced grounds for justification – based on the protection of public health – which were not even verified by the CJEU.[17] As a consequence, the cross-border mobility of European patients is more restricted today than it was at the end of the 1990s.

II. Arguments on the patients' side

It is established that the great majority of European patients prefer to use healthcare facilities which are close to their home and which they are familiar with.[18] Hence, no indicators suggest that cross-border patient movements can be expected to grow into a mass phenomenon in Europe:[19] as it seems now, patient mobility will remain limited, although very important in certain areas and certain cases.[20] Nevertheless, the Member States' vehemence with which they guard their national healthcare (authorisation) schemes against border-crossing patients hardly correlates with the figures on the current volume of cross-border patient movements.[21]

Thus, it might be the right time to question whether the authorisation mechanism is still necessary and proportionate. What would the implications be of the *removal of the prior authorisation requirement*? One might wonder what the impact of the full liberalisation of cross-border patient mobility, which would allow insured persons to obtain healthcare in any Member State of their choice, might be.

Riet, 77–81; C-56/01 *Inizan*, 56; C-145/03 *Keller*, 62; C-372/04 *Watts*, 108-110; C-173/09 *Elchinov*, 43; C-512/08 *Commission v France*, 33-42.

[15] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare. OJ L 88 of 4 April 2011.

[16] In the Council Conclusions the European Council expressed its firm opinion that *developments in this area should result from political consensus and not solely from case law*. Therefore, it was of high priority for the European Commission to develop a Community framework for safe, high quality and efficient health services including the relevant case law of the Court. European Council: *Council Conclusions on Common values and principles in European Union Health Systems*. OJ C 146 of 22 June 2006. 29.

[17] Article 8 (2) (b) and (c) PMD.

[18] Inter alia, WILLY PALM et al.: *Implications of recent jurisprudence on the co-ordination of health care protection systems*. Association Internationale de la Mutualite, 2000. p. 7 and IRENE A. GLINOS and RITA BAETEN (2006): *A Literature Review of Cross-Border Patient Mobility in the European Union.* Brussels: European Observatory on Health Systems and Policies, Europe for Patients Project, 2006. p. 6. See also European Commission: *Communication from the Commission: A Community framework on the application of patients' rights in cross-border healthcare*. COM (2008) 415 final, 2. 7. 2008, p 8 and Recital 39 of the PMD.

[19] The generally low willingness of insured persons to move across borders in order to obtain healthcare does not prognosticate a radical change in this respect.

[20] GEORGE FRANCE: *Cross-border flows of Italian patients within the European Union - An international trade approach*. European Journal of Public Health, 7/1997. Suppl 3, p. 18. See also PALM et al. 2000. p. 7.

[21] JOZEF PACOLET and FREDERIC DE WISPELAERE: *Planned cross-border healthcare*. 2014. Report prepared for the European Commission. http://ec.europa.eu/social/main.jsp?catId=1154&langId=en (14 January 2016).

Since factual evidence does not support the Member States' argument that the current volume of patient movements would constitute *a major risk to their healthcare systems*, the justification that prior authorisation should be maintained *in meeting the desire to control costs and to prevent, as far as possible, any wastage of financial, technical and human resources*[22] is hardly valid in today's circumstances. It can thus be argued that *the prior authorisation requirement should be erased from the Regulations*. Nevertheless, upon the occasion of abolition of prior authorisation schemes, a practical *counterbalance* should be introduced into the protection of national healthcare systems against any possible extreme change in patient mobility trends.[23] An *'in case of emergency' (ICE) clause* could be inserted into the Regulations – similar to the one which has been applied to the free movement of workers in the newly accessed Member States – indicating that *when a Member State undergoes or foresees disturbances in its national healthcare system which could seriously threaten the standard of healthcare provision or the national healthcare scheme in the given Member State, that Member State shall inform the Commission and other Member State thereof and shall supply them with all relevant particulars. On the basis of this information, the Member State may request the Commission to permit certain restrictions in order to restore to normal the situation in the healthcare system concerned*.[24]

This way, the burden of proof would be shifted: instead of the patient being required to request an authorisation from the competent institution in advance and meet the conditions laid down in the legislation in order to receive an authorisation, the Member State has to provide evidence that patient movements put its system at a considerable risk. If such evidence cannot be given, patients are free to access healthcare in any other Member State. Such an incentive would remarkably improve the patients' social status and insure a higher level of protection.

III. Arguments on the Member States' side

As opposed to the patients' view summarised above, there are a number of arguments which the Member States could (and definitely would) put forward against the idea of removing prior authorisation. Besides (1) the argument that such a measure jeopardises their *healthcare planning*, (2) Member States would play the '*combating fraud*' card and (3) would argue that the maintenance of prior authorisation also serves the purpose of *safeguarding quality* in the national healthcare schemes. One might wonder whether any of these causes could justify this restriction of free movement of patients for the following reasons:

---

[22] C-157/99 *Geraets-Smits and Peerbooms*, 76, 78-80. On this issue see also C-385/99 *Müller-Fauré and Van Riet*, 77-81; C-56/01 *Inizan*, 56; C-145/03 *Keller*, 62; C-372/04 *Watts*, 108-110; C-173/09 *Elchinov*, 43; C-512/08 *Commission v France*, 33-42.

[23] After all, it does not serve patients' interest if national healthcare systems get hamstrung.

[24] See by analogy, for instance, the Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded – Annexes to the Act of Accession – 1. Freedom of movement for persons, Article 7.

(1) I have already dealt with the justification based on planning objectives in the previous section, where I stated that it is doubtful that the current features of patient movements would significantly influence national healthcare planning objectives. If so, and the individual Member State provides hard evidence on that, necessary and proportionate restrictions might indeed be permitted by the Commission on the grounds of the aforementioned *ICE clause*. However, this restriction might not necessarily be the reinvention of prior authorisation.

(2) It is undoubtable that another argument to be included in any discussion about liberalising healthcare provision is *how fraud and abuse can be prevented and combated*. Although this is a very complex topic,[25] it must nevertheless be underlined that *more freedom on the one hand requires more control on the other*. Without going into detail, I would like to point out that – in my view – controlling mechanisms should be developed at least on two levels, namely concerning fraudulent and abusive behaviours of both (a) patients and (b) providers.

(a) To prevent patients who *lack entitlement* from exercising cross-border healthcare rights, it should be made possible that healthcare providers anywhere in Europe are able to check patients' entitlements. A *European database* available to each registered and accredited, legally functioning healthcare provider could tackle this problem.[26] However, considering the difficulties of the EESSI project,[27] it is highly questionable whether such a database could be put in place in the near future.

An improved version of the European Health Insurance Card (EHIC) should continue to serve as a universal European document incorporating entitlement to cross-border healthcare. Fraudulent usage of the EHIC (e.g. forged or fake cards or usage by someone else than the person the card was issued for) must be reported and investigated in each case.

(b) The providers must be closely monitored in terms of *quality*, but also their *pricing practice* and their *administrative mechanisms* should be checked by independent institutions. It must be ensured that providers respect the principle of equal treatment and comply with the European rules of (cross-border) healthcare provision.

Although there is no dispute that cross-border fraud must be prevented and tackled, the methods might be different. I cannot share the opinion that prior authorisation is an appropriate tool for that purpose.[28] I agree with DEL SOL on the idea that the key to effectively fighting fraud and abuse in the field of healthcare is in an *efficient inter-institutional cooperation*.[29]

---

[25] On the topic see, inter alia, ARASH RASHIDIAN, HOSSEIN JOUDAKI and TARYN VIAN (2012): *No Evidence of the Effect of the Interventions to Combat Health Care Fraud and Abuse: A Systematic Review of Literature.* PLoS One, 8/2012. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3427314/ (20 June 2014) and MARION DEL SOL: *Taking Measures Against European Healthcare Fraud*. In: SYLVIE HENNION and OTTO KAUFMANN (eds.): Unionsbürgerschaft und Patientenfreizügigkeit. Springer, Berlin, Heidelberg, 2014.

[26] Similar databases on a national level, where providers can – or are even obliged to – check the entitlement of patients, exist in most Member States.

[27] http://ec.europa.eu/social/main.jsp?catId=869 (14 January 2016).

[28] The CJEU is reluctant to easily accept the argument of the fight against or the prevention of fraud and abuse of rights as proper justifications for impediments on free movement in relation to non-corporate entities. See, inter alia, the Court cases C-200/02 Kunqian Catherine Zhu and Man Lavette *Chen* v Secretary of State for the Home Department [ECR 2004 Page I-9925], where the CJEU refused the UK's argument that the appellants in the main proceedings were not entitled to rely on the Community provisions in question, because Mrs Chen's move to Northern Ireland with the aim of having her child acquire the nationality of another Member State

(3) Member States argue that prior authorisation systems do not only enable them to control costs and avoid wastage of resources but also to *safeguard the quality of healthcare services,*[30] thus to protect both public health and the health of individual patients.[31] As described *supra*, these arguments came up at an early phase in the healthcare case law,[32] and although the CJEU declined them, they survived and became legal grounds of justification of prior authorisation in the PMD.[33] The questions which must be raised here are whether the authorisation system is the right measure to maintain quality, and how the removal of the prior authorisation requirement could be compensated for in this respect.

I share the opinion of the CJEU that the angst related to the quality of services on a more liberal healthcare market cannot justify the restriction of patients' movements. Instead, any entities providing healthcare services on the territory of the Union should be closely monitored. European institutions[34] and responsible national authorities should effectively cooperate to ensure that in all Member States patients receive good quality healthcare services. To this end, quality standards should be harmonised[35] and a *European registration and accreditation scheme for healthcare providers* should be developed. This way, it could be ensured that persons and institutions providing healthcare services in the Union meet the universal minimum standards set up on EU level. Furthermore, it must be frequently checked whether those standards are maintained throughout the daily functioning of the healthcare provider. I would find it laudable if a separate supranational institution, a *European Monitoring Centre for Healthcare Provision,* were established to carry out this task.

---

constitutes an attempt to improperly exploit the provisions of Community law (34.); and C-577/10 European *Commission v* Kingdom of *Belgium* [ECR 2012 Page 00000], where the CJEU expressly declared in relation to a prior declaration requirement for foreign posted employed and self-employed workers that a general presumption of fraud was not sufficient to justify a measure which compromises the objectives of the TFEU (53.). Furthermore, see on this topic RITA DE LA FERIA and STEFAN VOGENAUER: *Prohibition of Abuse of Law. A New General Principle of EU Law?* Hart Publishing, Oxford, 2011.

[29] DEL SOL 2014, pp 346-349.

[30] The issues related to the quality of healthcare services and patient safety are highly relevant in a cross-border context. See HELENA LEGIDO-QUIGLEY et al.: *Assuring the quality of health care in the European Union*. European Observatory on Health Systems and Policies, Brussels, 2008 especially chapter III titled *Patients, quality of care and cross-border care in the European Union*.

[31] To the argument of protecting public health via the supply of goods and the provision of services by persons authorised by law to pursue the profession, the CJEU answered that *since the conditions for taking up and pursuing regulated professions have been harmonised on Community level, the provision of a treatment by a healthcare provider established in another Member State provides guarantees equivalent to those provided by a healthcare practitioner established in the national territory*. C-215/87 *Schumacher*, 20; C-62/90 *Commission v Germany*, 18; C-120/95 *Decker*, 41-45; C-158/96 *Kohll*, 44-49; C-145/03 *Keller*, 50, 52; C-444/05 *Stamatelaki*, 37.

[32] The argument first appeared before the CJEU at the end of the 1980s.

[33] See footnote 17.

[34] There is a number of Union institutions with a wide range of tasks related to healthcare among which they also have responsibilities in human health and safety protection. The most notable of these agencies are the European Medicines Agency, the European Monitoring Centre for Drugs and Drug Addiction, the European Centre for Disease Prevention and Control and the European Chemicals Agency. On this topic, see GOVIN PERMANAND and ELLEN VOS: *EU regulatory agencies and health protection*. In: ELIAS MOSSIALOS et al. (eds.): Health Systems Governance in Europe – The Role of European Union Law and Policy. Cambridge University Press, New York, 2010.

[35] Harmonising measures concerning special fields of healthcare already exist in several healthcare-related field, such as medical devices, medicinal products for human use, human blood and blood components, human tissues and cells, quality and safety of human organs intended for transplantation.

IV. Conclusion

In the current state of European social security legislation, the abolishment of the prior authorisation would require a drastic makeover which should come hand in hand with the rethinking of the financing mechanisms as well. Furthermore, today such a measure would fail the feasibility test both from a legal, political and economic perspective. The Member States would possibly heavily object to any measures that loosened their control over patient movements. Therefore, any alteration requires the careful consideration of the interests of each party involved in order to reach a substantive solution.

Although – as I see it – it is doubtful that a radical positive change in European cross-border healthcare policy is just around the corner, there are alternatives to the current politically burdened, incomplete freedom for patients. The suggestion concerning the abolishment – although maybe overambitious under the current circumstances – aims at such a positive shift towards a (more) Social Europe.[36]

BERKI GABRIELLA

REÁLIS SZÜKSÉGSZERŰSÉG VAGY IDEJÉTMÚLT JOGINTÉZMÉNY?

Gondolatok a tervezett külföldi gyógykezelés előzetes engedélyeztetésének ellentmondásos természetéről

(Summary)

Az uniós polgárok szabad mozgása és a szociális ellátásokhoz való hozzáférésük a befogadó tagállamban az utóbbi években a figyelem és a politikai viták középpontjába került. Jelen tanulmány ennek a témakörnek egy speciális szegmensére, az egészségügyi szolgáltatásokhoz való külföldi hozzájutásra koncentrál. A területet szabályozó koordinációs rendeletek szabályait véve alapul arra a kérdésre keresi a választ, vajon a tervezett egészségügyi ellátás külföldi igénybevételének feltételéül támasztott előzetes engedélyezési eljárásnak van-e létjogosultsága napjainkban.

A kérdés meglehetősen sok vizsgálati szempontot vet fel, amelyeket két csoportba sorakoztatva tárgyal a tanulmány: a két – eltérő érdekek mentén működő – érdekcsoport, a betegek és a nemzeti kormányok érveit veszi górcső alá. Habár hosszabb kifejtésre a terjedelmi korlát okán nincs lehetőség, mind az engedélyezési eljárás eltörlése, mind a fenntartása mellett számos indok merül fel.

Az a következtetés vonható le, hogy hiába javítaná a betegek joghelyzetét egy radikálisabb szabály-módosítás, a tagállami kormányok hajlandóságának hiánya, a politikai, jogi és gazdasági környezet alapján drasztikus változás a közeljövőben nem várható e területen.

[36] It is promising that the EU Commissioner responsible for healthcare issues, Vytenis ANDRIUKAITIS, envisages "*a single market for health services*" and said that "*moving around Europe is taken for granted, so systems should be in place that can take care of everyone wherever they are*." Peter O'DONNELL (2014): *Andriukaitis calls for an EU health system to take care of everyone, wherever they are.* http://www.europeanvoice.com/article/andriukaitis-calls-for-an-eu-health-system-to-take-care-of-everyone-wherever-they-are/ (5 December 2014).