Prior and Subsequent Authorization of Cross-Border Healthcare under Directive 2011/24/EU

The Significance of the WO Case for EU Law and for Hungarian Law

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Abstract

The article deals with the specific issue of cross-border patient movements. It examines the feasibility of maintaining prior authorization schemes, which aim to ensure that only insured persons who have prior authorization are reimbursed for healthcare provided in another Member State. The focus is on Directive 2011/24/EU and the case law of the CJEU, in particular on the WO and Vas Megyei Kormányhivatal case. The article both describes the current legal developments and provides an insight into the internal Hungarian legal framework surrounding the still pending WO case. The article highlights the extreme complexity of the area where individuals might find it difficult to enforce their rights. The article argues that the case law of the CJEU has overstepped the formal condition of prior authorization and advocates for common interpretative rules at EU level which could facilitate the implementation of the notions stemming from the case law.

Keywords: prior authorization, cross-border health care, WO, Torubarov, Directive 2011/24.

1. The Free Movement of Cross-Border Healthcare and Services

In 1986, the CJEU ruled in *Luisi and Carbone*[1] that the freedom to provide services includes the right of recipients of services to travel to another Member State in order to receive services without being prevented from doing so by any restrictions, including restrictions on payments. Tourists, persons receiving medical treatment and persons travelling for the purpose of education or business are to be regarded as recipients of services.[2] The basis for the use of the service is Article 18 TFEU, which states that "Within the scope of application of the Treaties, and without prejudice to any special provisions contained therein, any discrimination on

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1 Judgment of 31 January 1984, *Joined Cases C-286/82 and C-26/83, Luisi and Carbone*, ECLI:EU:C:1984:35.

2 Id. para. 16.

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grounds of nationality shall be prohibited." Furthermore, with regard to the provision of services, the TFEU also specifically provides in Article 56 that

> "[…] restrictions on freedom to provide services within the Union shall be prohibited in respect of nationals of Member States who are established in a Member State other than that of the person for whom the services are intended."

Under the TFEU, the freedom to provide services has obtained a broad interpretation in the more than 60 years of development of EU law.[3] 25 years ago, the CJEU opened the way also for a person to travel to another Member State to receive healthcare under EU law.

1.1. The Kohll and Decker Cases

Luisi and Carbone did not yet involve what the CJEU first imposed in 1998 in *Kohll and Decker*,[4] namely, that the insurer of the recipient should reimburse that part of the cost of the care received which the insurer would otherwise have paid to the service provider or the insured on the basis of its own tariffs.[5] In both cases, the persons concerned received outpatient care in another Member State, received an invoice for the costs and subsequently claimed reimbursement from their own insurer in their Member State of insurance. The CJEU made it clear in both cases that reimbursement is due and cannot depend on the place where the service was received. However, already at that time, the CJEU indicated that there may be cases, types of care for which reimbursement does not automatically follow from the TFEU rules. There may be national restrictions which impose conditions on reimbursement and yet may be justified under the TFEU.

In *Kohll and Decker*, in 1998, Luxembourg law provided, in general terms, that the reimbursement of all care received abroad, with the exception of emergency treatment, was subject to prior authorization by the competent insurer for the person concerned to receive the care abroad.[6] In *Kohll*, the CJEU assumed that the service in question – a dental examination – was provided outside any hospital infrastructure and that making reimbursement subject to prior authorization would deter the insured person from seeking the service in another Member State.

3 Miklós Király, *Egység és sokféleség – az Európai unió jogának hatása a kultúrára*, Új Ember, Budapest, 2007. Many activities in the areas of family, language and culture also find their EU legal basis in the free movement of services.

4 Judgment of 28 April 1998, *Case C-120/95, Decker*, ECLI:EU:C:1998:167; Judgment of 28 April 1998, *Case C-158/96, Kohll*, ECLI:EU:C:1998:171.

5 Éva Gellérné Lukács, 'Ki fizeti a számlát? – a személyek szabad mozgása és az egészségügy kapcsolata az EU tagállamaiban', *Magyar Jog*, Vol. 49, Issue 8, 2002, p. 485.

6 *Case C-158/96, Kohll*, para. 6: "with the exception of emergency treatment received in the event of illness or accident abroad, insured persons may be treated abroad or approach a treatment center or center providing ancillary facilities abroad only after obtaining the prior authorization of the competent social security institution."
Id. para. 41: "it cannot be excluded that the risk of seriously undermining the financial balance of the social security system may constitute an overriding reason in the general interest capable of justifying a barrier of that kind."

It therefore concluded that prior authorization is generally a barrier to the provision of the service. However, it accepted that, in principle, serious damage to public health or to the financial equilibrium of the social security system constitutes an overriding reason relating to the public interest which may justify a restriction on the freedom to provide services. In the specific case, however, it considered that dental treatment is not a matter of public health and does not jeopardize the financial equilibrium of the social security system.[7]

The interpretation of the concepts of the CJEU in *Kohll* took more than 10 years, with the scope of the restrictions being matured in a number of cases.[8] As regards prior authorization, the approach that prior authorization, as a general rule, conflicts with the principle of free movement of services has been established, but Member States may make the use of medical care provided in a hospital facility abroad subject to prior authorization.[9] Underlying this is the fact that the provision of care in such a facility must be planned by the Member States.[10] The CJEU literally ruled:

> "For one thing, such planning seeks to ensure that there is sufficient and permanent access to a balanced range of high-quality hospital treatment in the State concerned. For another thing, it assists in meeting a desire to control costs and to prevent, as far as possible, any wastage of financial, technical and human resources. Such wastage would be all the more damaging because it is generally recognized that the hospital care sector generates considerable costs and must satisfy increasing needs, while the financial resources which may be made available for healthcare are not unlimited, whatever the mode of funding applied. [...] From those two points of view, the requirement that the assumption of costs by the national system of hospital treatment provided in another Member State be subject to prior authorization appears to be a measure which is both necessary and reasonable."[11]

1.2. The Watts Case

Over time, it has become clear that the obligation to reimburse exists even where patients have access free of charge to care under the national law concerned, thus there is no invoicing and reimbursement of the kind that was involved in *Kohll*. In *Watts*, the issue of reimbursement arose in relation to the British healthcare system, which is similar in its main features to the Hungarian healthcare system. The British insured Watts had a hip replacement operation in Germany at her own expense and, when she returned home, she claimed reimbursement from her

7 Id. para. 42.

8 Judgment of 12 July 2001, *Case C-368/98, Vanbraekel*, ECLI:EU:C:2001:400; Judgment of 12 July 2001, *Case C-157/99, Smits and Peerbooms*, ECLI:EU:C:2001:404; Judgment of 27 October 2011, *Case C-255/09, Commission v Portuguese Republic*, ECLI:EU:C:2011:695.

9 Gabriella Berki, *Free Movement of Patients in the EU*, Intersentia, Belgium, 2018, p. 116.

10 *Case C-157/99, Smits and Peerbooms*, paras. 76-80; Judgment of 16 May 2006, *Case C-372/04, Watts*, ECLI:EU:C:2006:325, para. 107.

11 *Case C-372/04, Watts*, paras. 109, and 110.

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British insurer. The case reveals that "hospital care is provided free of charge" by the National Health Service (NHS) and its affiliated organizations

> "to all persons ordinarily resident in the United Kingdom, on a non-profit-making basis. [...] Treatment is funded directly by the State, essentially from general taxation revenue. [...] No patient co-payments are charged."[12]

Such a system is characterized by a strong sense of solidarity, its funding comes from a collective source ('collective input'), and individuals' access to health care is not affected by the extent of their individual contributions.[13] In that set-up, the doctrine established in *Kohll* and *Decker* and the idea that British insured would be reimbursed by the NHS seemed unrealistic.[14] *Watts* was closely followed in Hungary as well, since the Hungarian compulsory health insurance system[15] is similar to the British one, it provides access free of charge and there are no internal reimbursement mechanisms.

It is well known that the CJEU decided that

> "[...] Article 49 EC applies where a patient such as Mrs. Watts receives medical services in a hospital environment for consideration in a Member State other than her State of residence, *regardless of the way in which the national system with which that person is registered and from which reimbursement of the cost of those services is subsequently sought operates*."[16]

According to Spaventa, the CJEU has thus used a 'hermeneutic trick', *i.e*. an interpretative technique.[17] Her approach is akin to that of Shuibhne, who argues that the CJEU was already selective in setting the criteria when it brought health services within the scope of the Article of TFEU (then Article 49 EC) on the provision of services.[18] As regards the specific facts in the case, Tacconi complained that the CJEU did not take into account the fact that Mrs Watts had been prioritized by the NHS on the UK hip replacement waiting list, thus they were flexible in their response to her complaints. Therefore, in his opinion, the CJEU was guided all

12 Id. paras. 8-10.

13 Sylvia De Mars, 'Managing Misconceptions about EU Citizens' Access to Domestic Public Healthcare: An EU-Level Response?', *European Public Law*, Vol. 25, Issue 4, 2019, p. 718: "eligibility for care is not determined by individual contributions into the system."

14 Flaminia Tacconi, 'Freedom of Health and Medical Care Services within the European Union – Recent Jurisprudence of the European Court of Justice, with Particular Reference to Case C-372/04 Yvonne Watts', *ZaöRV*, Vol. 68, Issue 1, 2008, pp. 195-207.

15 Hungarian Act LXXXIII of 1997 on the Services of the Compulsory Health Insurance System.

16 *Case C-372/04, Watts*, para. 90 (emphasis added).

17 Eleanor Spaventa, *Free Movement of Persons in the European Union: Barriers to Movement in Their Constitutional Context*, Kluwer Law International, 2008, p. 56.

18 Niamh Nic Shuibhne, *The Coherence of EU Free Movement Law. Constitutional Responsibility and the Court of Justice*, Oxford University Press, Oxford, 2013, p. 66: "incompleteness of reasoning and the selective citation of existing authority."

along by the objective of ensuring that patients are mobile enough to seek medical treatment in another Member State.[19]

In its judgment the CJEU did not go into the taxonomic details but held that NHS had an obligation to reimburse. It considered it a technical issue how a free-of-charge based scheme would be able to implement the reimbursement obligation. Furthermore, the CJEU confirmed the application of the same restrictive set of criteria for prior authorization to publicly funded free-of-charge based systems, such as the British and Hungarian systems.

The CJEU has always been the engine and catalyst of EU law and it has presented national courts seeking preliminary rulings with challenges with its interpretation of the law.[20] Some of its decisions have caused tension, including *Kohll, Decker* and *Watts* relating to health care. These tensions center around solidarity versus individualism in health care. The cornerstones of publicly funded systems are the principle of universal access, the principle of health as a public good, and that all patients receive the same care according to their needs, on the basis of universality.[21] Financial resources are limited, therefore any expenditure not directed to the publicly funded service providers reduces the amount allocated to the publicly funded service providers. Those arguing for solidarity claim that it is unfair to take an individualistic approach, favoring those who, on the one hand, are well-informed (or better informed) and, on the other hand, are better-off and able to advance costs in other Member States.

Considering how strong the critical spirit was around the time when the case law was established, over time it has changed. A more economic, cost-benefit analyses have emerged that examined whether the reimbursement scheme could have advantages in the state of origin of the patient (the state which is responsible for reimbursement).[22] According to Rieder, the cost-per-patient at macro level could be reduced by treatment received abroad, thus achieving a status where there is virtually no significant impact of the reimbursement rules (*i.e.* a 'no-impact-approximation' status can be achieved).[23]

19 Tacconi 2008, p. 203: "The ECJ seems to strongly defend the position of the citizen in order to ensure free mobility of patients having the possibility of undergoing treatment abroad."

20 Réka Somssich, *Egységes jog – egységes értelmezés? Az uniós jog értelmezése a tagállami bíróságok szintjén*, ELTE Eötvös, Budapest, 2016, p. 12.

21 A complex analysis of this system of principles can be found in Kenneth Veitch, 'Juridification, medicalisation and the impact of EU law: patient mobility and the allocation of scarce NHS resources', *Medical Law Review*, Vol. 20, Issue 3, 2012, pp. 362-398; Christopher Newdick, 'Citizenship, free movement and health care: cementing individual rights by corroding social solidarity', *Common Market Law Review*, Vol. 43, Issue 6, 2006, pp. 1645-1668.

22 Some argue that there is no overall loss in the operation of the Directive. *See* Clemens M. Rieder, 'Cross-Border Movement of Patients in the EU: a Re-Appraisal', *The European Journal of Health Economics*, Vol. 24, Issue 4, 2017, pp. 390-413.

23 Id. pp. 398-402, and 409. The no-impact issue was brought up in relation to 2011/24/EU Directive, more than 10 years from *Kohll*. It can be mentioned here as a point of interest that expenditure relating to the 2011/24/EU Directive is negligible in Hungary, which is probably due to the fact that the price level in Hungary is lower than in other Member States. *See* Éva Lukács Gellérné & Brigitta Paragh, 'A magyar biztosítottak részvétele az európai uniós szintű betegmozgásokban – tervezett egészségügyi szolgáltatások igénybevétele', *Munkajog*, 2020/4, pp. 27-36.

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2. The Elchinov Case

The different cases of the CJEU relating to cross-border healthcare and prior authorization have largely followed the lines described so far. On the one hand, they have dealt with the characteristics and scope of the healthcare that can be subject to prior authorization, and, on the other hand, with the legality and justification of individual decisions by Member States' authorities refusing individuals' requests for treatment in another Member State.

Elchinov[24] was the first case in which the CJEU considered whether reimbursement was due in the absence of a decision on prior authorization, because the authority had not yet taken a decision to grant or deny treatment abroad when the treatment was sought. In previous cases the CJEU examined whether the refused authorization and refused reimbursement should have been granted to the patient.[25] In *Elchinov*, the Sofia Administrative Court initiated a preliminary ruling on whether reimbursement would be due if the patient had submitted a request, he just did not wait for the decision and as such there was an ongoing administrative procedure when the treatment abroad was sought.

The CJEU has ruled on three important points of principle that I henceforth call doctrine of urgency and inability or first Elchinov doctrine. *(i)* It is contrary to the freedom to provide services if the national legislation of a Member State completely excludes the possibility of reimbursement in the absence of authorization. Consequently, there must be a mechanism in national law for a substantive review of the substance of the request of the person concerned as to whether the substantive conditions for authorization are met, even if the request is submitted late. *(ii)* In the course of this examination, it should be borne in mind that not only those may be entitled to reimbursement of their costs who apply for and obtain the authorization in advance (a), or who apply for it in advance, it is refused, but it subsequently transpires that the refusal was contrary to EU law (b), but also someone who has made a request but could not wait for a decision (c), or who did not submit a request at all in advance because he or she was prevented from doing so (d);[26] and *(iii)* the CJEU confirmed that there was no proper

24 Judgment of 5 October 2010, *Case C-173/09, Elchinov*, ECLI:EU:C:2010:581. The Bulgarian insured Elchinov applied to his health insurance agency for authorization to undergo laser tumor cell removal in Germany as part of his ophthalmic treatment. He sought such a high-tech treatment at a specialized clinic in Berlin (Germany) that was not available in Bulgaria, where the tumor cells caused the entire eye to be surgically removed. He asked for authorization, but did not wait for the decision, he had the procedure done in Germany at his own expense and then, on his return home, he asked the Bulgarian insurer to reimburse the costs. In the meantime, but after the operation, the insurer refused the authorization and refused to pay on that basis.

25 Judgment of 13 May 2003, *Case C-385/99, Müller-Fauré*, ECLI:EU:C:2003:270.

26 "In the present case, it is clear that a national rule excluding, in all cases, payment for hospital treatment given in another Member State without prior authorization deprives the insured person who, for reasons relating to his state of health or to the need to receive urgent treatment in a hospital, was prevented from applying for such authorization or was not able, like Mr Elchinov, to wait for the answer of the competent institution, of reimbursement from that institution in respect of such treatment, even though all other conditions for such reimbursement to be made are met." *Case C-173/09, Elchinov*, para. 45.

justification for maintaining the prior authorization system where the person concerned could not wait for the decision or was prevented from doing so, because reimbursement in respect of such treatment is not likely to compromise achievement of the objectives of hospital planning, nor seriously to undermine the financial balance of the social security system, since such a reimbursement does not affect the maintenance of a balanced hospital service accessible to all, or that of treatment capacity and medical competence on national territory.[27]

Moreover, the CJEU ruled also on the specific treatment received by the Bulgarian insured in Germany. Elchinov received laser tumor cell removal which was not among the treatments listed specifically in the Bulgarian system. The CJEU stated that it was contrary to EU law that the Bulgarian insurer refused to grant authorization to Mr. Elchinov, because

> "in a situation where the treatment in question cannot be given in the Member State on whose territory the insured person resides and the benefits provided for by the legislation of that Member State are not given as an exact list of treatments or treatment methods but as a more general definition of categories or types of treatment or treatment methods",[28]

and the treatment proposed in the other Member State falls within one of these categories or types, the competent institution must grant authorization. This I call the second Elchinov doctrine.

Berki stated that the CJEU has gone a bit too far with the interpretation of the Bulgarian legislative provisions.[29] The CJEU did not take into account that the Bulgarian system had objective, transparent and non-discriminatory conditions for the authorization of medical treatment abroad, and the CJEU, instead of accepting that the Bulgarian system does not include expensive laser cancer cell removal surgery as part of the insurance package, placed the emphasis on the fact that this surgical technique was not specifically excluded, and, therefore, it had to be assumed that the insured person could ultimately have made a claim for this technique. Murphy also states that there is a risk that, by its decision, the CJEU will force Member States to follow a formalistic approach, *e.g.* to declare that only what is actually listed is eligible, and to blacklist all other treatments.[30] Furthermore, the CJEU has decisively not accepted as justification the purpose of planning in the case of a surgery for eye cancer, which was not a one day surgery in the Bulgarian system, only because it was not explicitly written in the Bulgarian system that the operation required a hospital stay.[31]

27 *Case C-173/09, Elchinov*, para. 46.
28 Id. para. 67.
29 Berki 2018, p. 107.
30 Ciara Murphy, 'An Effective Right to Cross-Border Healthcare?', *European Law Review*, Vol. 17, Issue 4, 2011, p. 554.
31 Tacconi 2008, p. 203: "The ECJ seems to strongly defend the position of the citizen in order to ensure free mobility of patients having the possibility of undergoing treatment abroad."

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3. Directive 2011/24/EU on the Application of Patients' Rights in Cross-Border Healthcare

Taking into account the *Kohll* and *Decker* cases of the CJEU in 1998 and subsequent case law, especially *Elchinov*, it has become clear that a person insured in one Member State is, in principle, entitled to purchase health services in another EU Member State with partial coverage by his or her insurer, on the basis of Article 56 TFEU on the freedom to provide services, and prior authorization, as a restriction, must be interpreted restrictively. Cases have reached a level, both in number and importance, where the EU legislator proposed to regulate the issue in secondary legislation in order to guarantee legal certainty. In 2006, health services were left out of Directive 2006/123/EC on services in the internal market,[32] but with the proviso that they would be covered by a separate directive: this occurred in 2011, with Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (2011/24/EU Directive).[33]

Thus, the abovementioned case law on Article 56 TFEU is implemented by the 2011/24/EU Directive, with particular regard to the prior authorization of treatments intended to be received in another Member State and the reimbursement of the cost of such treatments. The primary aim of the 2011/24/EU Directive is to facilitate access to cross-border healthcare by clarifying patients' rights to care, in line with the case law of the CJEU.[34] Among its broader objectives, the 2011/24/EU Directive lists the operation of a high quality healthcare system, with general, universal, equitable and equal access, which are the fundamental principles for healthcare systems in Europe.[35] Thus, the 2011/24/EU Directive calls for the main features of a healthcare system based on solidarity as an objective, but also, as its title suggests, its provisions facilitate the enforcement of cross-border patients' rights, on the understanding that this implicitly refers to the enforcement of individual patients' rights.

3.1. Prior Authorization under the 2011/24/EU Directive

The general principle laid down by the 2011/24/EU Directive is that the cost of any treatment provided by a healthcare provider registered in another Member State must be reimbursed according to the same tariffs and conditions as those applicable in the State where the person concerned is insured. Member States have a certain degree of flexibility with regard to the reimbursement of cross-border healthcare costs. Reimbursement may in some cases be subject to prior authorization, however, this restriction must, on the one hand, be subject to the condition that there are overriding reasons of general interest (mostly planning requirements and financial reasons), and, on the other hand, the national provision introduced must

32 For more information, *see* Éva Lukács Gellérné & Laura Gyeney, 'Élesedő kontúrok – gyakorlati kihívások a határon átnyúló egészségügyi ellátás területén', *Pázmány Law Working Papers*, 2014/15.

33 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.

34 For more information, *see* Berki 2018.

35 For more information, *see* Danielle Da Costa & Leite Borges, 'European Health Systems and the Internal Market: Reshaping Ideology?', *Health Care Analysis*, Vol. 19, 2011, pp. 365-387.

be proportionate and necessary in relation to the objective to be achieved.[36] Moreover, the list of healthcare services subject to prior authorization should be made available in a transparent way in the national systems, the list should be easily accessible, and the eligibility criteria should be made public in advance.

Article 8 of the 2011/24/EU Directive implements the case law of the CJEU in the field of prior authorization. The key provision is Article 8(2), which sets out in summary form the cases of prior authorization.[37] The Directive also specifies in Article 8(5) that prior authorization may not be refused when the healthcare cannot be provided in the state of affiliation within a time limit which is medically justifiable, based on an objective medical assessment of the patient's medical condition, the history and probable course of the patient's illness, the degree of the patient's pain and/or the nature of the patient's disability at the time when the request for authorization was made or renewed.

Two main conclusions follow from the adoption of the Directive. *(i)* First, Member States cannot make reimbursement of the costs of cross-border healthcare subject to prior authorization beyond what is contained in the exhaustive list of Article 8(2) read together with Article 8(5).[38] Most importantly, there is an obligation for Member States to verify compliance with these restrictive conditions, and the burden of proof in this respect lies on the Member States. *(ii)* Second, when comparing the case law and the provisions of the Directive, it is notable that the provisions of the Directive do not fully and textually cover what has been laid down by the CJEU regarding prior authorization in *Elchinov*. The scope of lawful prior authorization has not been adjusted to the judgment which confirmed that there was no proper justification for maintaining the prior authorization system where the person concerned could not wait for the decision or was prevented from submitting a request based on his/her health status.[39] As it will be pinpointed later on, this hiatus of implementing the first Elchinov doctrine added to the difficulties appearing in *WO*.

4. Hungarian Aspects of Implementation

Member States were obliged to transpose the 2011/24/EU Directive until 25 October 2013, after which the Commission initiated a total of 26 infringement procedures against Member States for late or incomplete notification of

36 2011/24/EU Directive, Recitals (40)-(41).

37 "2. Healthcare that may be subject to prior authorization shall be limited to healthcare which: (a) is made subject to planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources and: *(i)* involves overnight hospital accommodation of the patient in question for at least one night; or *(ii)* requires use of highly specialized and cost-intensive medical infrastructure or medical equipment;".

38 2011/24/EU Directive, Article 7(8).

39 *Case C-173/09, Elchinov*, para. 46.

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transposition measures.[40] The main Hungarian implementing legislation is, on the one hand, Act LXXXIII of 1997 on the Services of the Compulsory Health Insurance System (Health Insurance Act), and, on the other hand, Government Decree No. 340/2013 of 25 September 2013 on medical treatment abroad (Government Decree). The Health Insurance Act declares the substantive rights of beneficiaries. Subsection s) of Section 5/B of the Health Insurance Act defines the term 'Union patient'[41] and 'cross-border healthcare'[42] in accordance with the 2011/24/EU Directive. The Act declares that Hungarian insured persons may receive healthcare in another EU Member State or from a provider established there (or *vice versa*, that Union patients can come to Hungary under the 2011/24/EU Directive, but this is not the central issue of this article).

Section 27(6) of the Health Insurance Act lays down the basic principles for reimbursement of the costs of treatment received by insured persons in another Member State, namely that the health insurance fund will reimburse the actual cost of the treatment, duly justified by credible evidence, in an amount not exceeding the cost of the same publicly funded treatment provided in Hungary.

According to Section 3(1) of the Government Decree, an insured person can, as a main rule, receive health care in another Member State on the basis of the 2011/24/EU Directive without prior authorization, except in cases which are listed in Annex 1 of the Government Decree, which are subject to a prior authorization issued by NEAK (*Nemzeti Egészségbiztosítási Alapkezelő*, National Health Insurance Fund of Hungary) prior to the treatment abroad. According to Section 13(1), the authorization can only be refused if the treatment can be provided in Hungary by a publicly funded healthcare provider within a medically justifiable time frame. An application for authorization may be submitted by the patient, his/her legal representative or his/her treating physician. Reimbursement is conditional not only on the proper submission of the application for authorization, but also on the actual issuance of the authorization by NEAK prior to the treatment abroad.

The key provision is Annex 1 that lists the treatments subject to authorization, the original version of which was amended in 2017, right after the start of the national procedures in *WO*.[43] The 2013 version of Annex 1 listed the following care as subject to authorization, by referring to the annexes of Decree No. 9/1993 of 2 April 1993 of the Minister of Welfare:[44] all in-patient specialized care and related disposable equipment and implants, active substances, which are subject to itemized settlement; one-day surgery and cure treatments; high-value surgical procedures and interventions that are not common nationwide, excluding organ transplantation-related care, finally, high-value outpatient care, as well as diagnostic and therapeutic procedures (*e.g.* CT, MR). The version that entered into

40 Willy Palm, 'The Cross-Border Care Directive: Implementation Status', *Eurohealth*, Vol. 22, Issue 1, 2016, p. 21.

41 Health Insurance Act, Section 5/B(r).

42 Id. Section 5/B(s).

43 Established by Section 35 and Annex 11 of Government Decree No. 464/2016. (XII. 23.), entered into force on 1 January 2017.

44 Decree No. 9/1993. (IV. 2.) of the Minister of Welfare on certain aspects of the social security financing of specialized health care.

force on 1 January 2017 removed several treatments that were previously subject to authorization from Annex 1, most importantly some less specialized services, which fall within the scope of one-day surgery. In the 2017 version only those one-day surgeries remained in Annex 1 which are *(i)* subject to overnight hospital accommodation in the target Member State and *(ii)* which are highly specialized.[45]

With the amendment of 2017, the Hungarian legislation has made it possible to avoid the need for an authorization for the receipt of such treatment abroad which is considered one-day surgery under Hungarian law, since it is not subject to overnight hospital accommodation. However, the legislation has limited the exemption from authorization to cases where the procedure in question is carried out as a one-day surgery also abroad. If it is linked to a hospital accommodation there, then the actual treatment no longer qualifies as a 'one-day' surgery under Hungarian law, and the patient loses the benefit of the exemption from authorization. This Hungarian rule is a good example of how it is not enough to take into account the legislation of one Member State when enforcing cross-border patients' rights, but, where appropriate, it is also necessary to be familiar with the legislation of the other Member State concerned.

5. The WO Case before the CJEU

The CJEU declared in *Elchinov* that there must be a mechanism in national law for a substantive review of the application for authorization submitted by the patient, as to whether the conditions for authorization are met, even if the patient was unable to submit the application for authorization or if he/she had submitted the application but could not wait for a decision because of his/her state of health. *Elchinov* was decided when the 2011/24/EU Directive had not yet been adopted, and the Directive has not incorporated the mentioned legal notion contained therein into Article 8(2). Consequently, it was an open issue how the CJEU was going to handle a case similar to *Elchinov* after the adoption of the 2011/24/EU Directive.

WO[46] was the first case in which issues on prior authorization had to be decided by the CJEU in the light of the 2011/24/EU Directive. Additionally, *WO* is also of interest in relation to another EU legislation from the realm of social security coordination – Regulation 883/2004[47] – which also contains rules on prior authorization, the case law of which however is rather limited. The CJEU has only had three opportunities to adjudicate on prior authorization under the Regulation

45 "The one-day care listed in Annex 9 to the Decree if it is provided in the context of in-patient specialized care in the EU Member State where the care is provided. The following day-care services are in any case subject to authorization because of their high value: gamma-ray brain surgery (special intracranial surgery over and under the age of 18), electrophysiological examination of the heart, angioplastica arteriae subclaviae PTA, angioplastica extremitatis inferioris PTA, angioplastica aa. pelveos PTA, pacemaker and defibrillator implantation, other alternative LASER operations on the prostate."

46 Judgment of 23 September 2020, *Case C-777/18, WO*, ECLI:EU:C:2020:745.

47 Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems.

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(including *WO*),[48] albeit this provision builds on the wealth of cases decided under Article 22(1)(c) of Regulation 1408/71, and consequently, the relatively well-defined scope of application of the respective provision.[49]

According to the facts of the case, a Hungarian insured person, who was blind in one eye and had been diagnosed with glaucoma in the other eye, had glaucoma surgery in Germany, but did not obtain prior authorization.[50] After the surgery, on his return home, he submitted an application for reimbursement to the Vas County Government Office *(Vas Megyei Kormányhivatal)*, which was rejected by the government office and then on appeal by the Government Office of the Capital City Budapest (*Budapest Főváros Kormányhivatala*, BFKH). The authorities rejected the application on the formal ground that there was no prior authorization and that, in the absence of such authorization, no reimbursement could be granted, citing EU law and, in particular, Section 3(1) and Section 13(1) of the Government Decree cited above. According to the Government Decree, reimbursement was only possible if the patient had prior authorization from NEAK before the surgery. However, the patient claimed that he had gone abroad for a medical consultation and was operated on the following day because of abnormal medical results, and therefore did not have time to apply for an authorization (*i.e.*, he was prevented from doing so and even if he had submitted an application, he would not have had time to wait for the decision). Consequently, based on *Elchinov*, he was entitled to submit the request after the intervention has been carried out and the Hungarian authorities were obliged to examine and decide his application in the merits ex post facto.

The CJEU dealt at great length, in a whole separate point, with the applicability of Article 56 TFEU and Article 8(1) of 2011/24/EU Directive on prior authorization.[51] On the one hand, the CJEU made clear that the Hungarian system, by completely excluding reimbursement in the absence of prior authorization, "[…] contains a disproportionate restriction of the freedom to provide services enshrined in Article 56 TFEU and fails to have regard to Article 8(1) of Directive 2011/24".[52] Thus, in the case of a patient who is unable to await the decision of the competent authority or who is prevented from submitting an application, the requirement of prior authorization for eye surgery cannot be justified under the Directive.[53] The CJEU, on the other hand, considered both the first medical consultation and the subsequent surgery[54] as planned and, because of their planned nature, ruled that the need for authorization could be accepted as a general rule. The first condition for this is that the treatment in question must be included in the list of care subject to prior authorization. The second condition is that the treatment must meet the

48 Judgment of 18 September 2019, *Case C-222/18, VIPA*, ECLI:EU:C:2019:751; Judgment of 5 June 2014, *Case C-255/13, I*, ECLI:EU:C:2014:1291]

49 Santa Slokenberga, 'Case C-243/19, *A v Veselibas ministrija*, Judgment of the Court (Second Chamber) of 29 October 2020, EU:C:2020:872', *European Journal of Health Law*, Vol. 28, Issue 3, 2021, p. 300.

50 *Case C-777/18, WO*, para. 24.

51 Id. paras. 56-84.

52 Id. paras. 75, and 85.

53 Para. 83 of the judgment refers verbatim to para. 46 of *Elchinov*, cited above.

54 Id. paras. 45, and 55.

requirements that *(i)* no treatment of equivalent efficacy was available in Hungary within a medically justifiable time frame, taking into account the patient's condition at the time of the intervention, and *(ii)* the patient was prevented from submitting the application, or from waiting for the decision. The CJEU pointed out that twenty days had elapsed between the patient's contact with the German doctor and the surgery taking place in Germany,[55] which should be taken as the basis for deciding the second question. The CJEU, however, essentially answers its own question on prevention: "[…] even if WO had not been prevented from applying for prior authorization, he could not have waited for the decision of the competent institution on that application."[56] Thus, according to the CJEU, the patient has fulfilled condition *(ii)* in one way or another, the only question to be examined is whether he could have been treated within a medically appropriate time frame.

The CJEU therefore confirmed that the authority dealing with the application for reimbursement could not have rejected the application for reimbursement on the ground that no prior application for authorization had been submitted, and the application for reimbursement must have been examined on its merits and substance. Starting with whether the person concerned was prevented from acting and continuing with whether or not authorization was required for the receipt of the treatment in question and, if authorization was required, whether the conditions for such authorization were met.

Upon the examination of the Directive, the CJEU gave a twofold answer to the question posed, which is essentially the question of whether the Hungarian legislation in the specific case is contrary to Article 56 TFEU, Article 8(1) of 2011/24/EU Directive and the principles of proportionality and necessity. The CJEU examined separately the first medical consultation sought by the patient in Germany and the subsequent eye operation itself, which was carried out the following day. It clearly ruled that the former did not require prior authorization under the Directive, as it was not covered by Annex 1 of Government Decree No. 340/2013 of 25 September 2013 effective at the time of the case, and therefore its costs should be reimbursed. In the case of the second treatment, *i.e.*, the eye surgery, it also relies on the fact that the patient was prevented from applying for prior authorization and that the application should therefore be examined on its merits. It is for the Hungarian court to determine whether the treatment falls within the scope of the Directive as a case for authorization. Here, the CJEU envisaged a two-step examination, firstly, whether the eye surgery is included in the list of care subject to authorization (Annex 1 to the Government Decree) in accordance with the wording of the Directive. In other words, whether it is a treatment requiring an overnight hospital accommodation or a treatment requiring high costs. If it is not, then, under the Directive, the patient is entitled to reimbursement up to the domestic cost, without any further investigation. If, on the other hand, the eye surgery qualifies as a treatment requiring overnight hospital accommodation or high costs, reimbursement cannot be refused even then, but then it must be examined whether the prior authorization system was

55 Id. para. 52.
56 Id. para. 54.

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proportionate. In this context, it makes clear that it is not proportionate to exclude subsequent authorization altogether, including where the patient is prevented from applying for prior authorization or is unable to wait for the authorization. Based on the 2011/24/EU Directive, the CJEU essentially states that WO was entitled to reimbursement.

6. The WO Case before the Hungarian Courts and Authorities – Procedural Aspects

In July 2023, the Hungarian proceeding is ongoing, but it is well possible to make a few comments.

The case started with the rejection of a request for reimbursement of the costs of healthcare by the Vas County Government Office in Szombathely.[57] The Vas County Government Office was competent on the basis of the place of residence of the plaintiff. Furthermore, the jurisdiction over the subject-matter of the case that time was based on Section 5 of Government Decree No. 386/2016. (XII. 2.) on health insurance authorities, pursuant to which, as part of its health insurance duties, the government office performs the tasks arising from paragraphs (1), (2), (5), (7) and (11) of Section 27 of the Health Insurance Act. The common denominator of the enumerated paragraphs in the Act is that they are all related to reimbursements of medical costs abroad which are not subject to prior authorization. Reimbursement related to prior authorization falls exclusively within the competence of NEAK. NEAK possesses national jurisdiction, pursuant to Section 7 of Government Decree No. 386/2016. (XII. 2.) on health insurance authorities, which implements Sections 27(3) and 27(6) of the Health Insurance Act. In sum, NEAK is centrally responsible for receiving and processing prior authorization requests while regional government offices are responsible for post-medical reimbursement of treatments abroad that are not subject to prior authorization. Henceforth the dividing line of competence is whether reimbursement is subject to prior authorization or not. The first administrative procedure started before the county government office because the patient based its claim on the legal basis of reimbursement without prior authorization. The BFKH upheld the decision on refusal. During the first administrative procedure no one contested the competence of the county government office.

The court case started before the Administrative and Labor Court in Szombathely. This court requested the preliminary decision of the CJEU. However, between 2018 and 2020 the court system has been changed in Hungary.[58] Administrative and labor courts were merged into civil courts, and as a result the Győr Regional Court became competent to continue the proceedings following the decision of the CJEU. In administrative cases pending on 31 December 2017, the provisions of Act III of 1952 on the Code of Civil Procedure (former CCP) applies.

57 *See Case C-777/18, WO*, Summary of the request for a preliminary ruling pursuant to Article 98(1) of the Rules of Procedure of the Court of Justice.

58 Act CXXVII of 2019 on the amendment of certain laws related to the creation of single-level district office procedures, entered into force on 1 March 2020.

According to Section 339(1) of the former CCP, the annulment of the administrative act and the order for a new trial is the general rule.[59] This may be derogated from only in the cases listed in points (a) to (p) of Section 339(2) of the former CCP or if another Act provides for an exception [pursuant to Section 339(2)(q)].[60] Therefore, the reformatory power of courts regarding administrative authorities' acts can only be applied in a narrow range of cases, and explicitly cannot be applied in cases concerning health insurance, because the Health Insurance Act did not (and does not) allow reformatory power as a *lex specialis*.[61] The *WO* case started in 2017 on the basis of the former CCP, with no reformatory powers granted to the courts at that time.

On 1 January 2018, Act I of 2017 on the Code of Administrative Litigation (new CAL) entered into force, which made the reformatory power of courts a main rule, with certain exceptions.[62] With effect from 1 April 2020, the rules on reformatory power have been clarified.[63] Accordingly, the court can change the administrative act if *(i)* the administrative act was carried out in several-instance proceedings,[64] or *(ii)* if the procedure was single instance, but reversal is expressly permitted by law,[65] and (as a general cumulative condition) if the nature of the case allows it, the factual situation is sufficiently clear and the available information enables the dispute to be finally settled. On the other hand, the court shall make a mandatory change to the administrative act ('reformatory sanction' or '*lex Torubarov*'[66]), if, in the repeated procedure the administrative authority – on the basis of the same legal or factual situation – has acted contrary to the prior judgment of the court, meaning that the administrative authority fails to follow

59 In the meantime, Act III of 1952 has been repealed, so the term 'former Code of Civil Procedure (CCP)' is used, and Act III of 1952 has been replaced by Act CXXX of 2016 on Civil Procedure (new Code of Civil Procedure) as of 1 January 2018.

60 "With effect from 15 September 2015, the Hungarian legal environment changed, which, breaking with decades of practice, explicitly excluded the possibility of a court to overturn the decision of the asylum authority." *See* Árpád Szép, 'A bíróság reformatórius jogköre a menekültügyi eljárásokban – gondolatok egy előzetes döntéshozatali eljárás kapcsán', *Iustum Aequum Salutare*, Vol. 14, Issue 4, 2018, p. 114.

61 Chapter IX does not contain a statutory authorization for the revising court to change the administrative decision.

62 Explanatory memorandum to Parliamentary Bill T/12243 (that time Article 91 in the Bill, now Article 90 in the Act): "The Code of Procedure puts the reformatory power on a new footing. It is no longer an exceptional option, the granting of which is decided by a separate law or enumeration, but a general alternative for decision."

63 Act CXXVII of 2019 amending certain Acts in connection with the establishment of single-level district administrative procedures, Article 222. *See also* Gergely Barabás *et al.* (eds), *Kommentár a Közigazgatási Perrendtartáshoz*, Wolters Kluwer, Budapest, 2018, Article 90. Krisztina Rozsnyai, 'Anfängliche Schwierigkeiten bei der Anwendung der ungarischen Verwaltungsprozessordnung', *Jahrbuch für Ostrecht*, Band 61, 2020, p. 200.

64 Code of Administrative Litigation, Section 90(1)(a).

65 Id. Section 90(1)(b).

66 *Torubarov* was decided by the CJEU on 29 July 2019 on the basis of a preliminary ruling of the Administrative and Labor Court of Pécs, Hungary, submitted on 22 September 2017. Judgment of 29 July 2019, *Case C-556/17, Torubarov*, ECLI:EU:C:2019:626.

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the guidelines given by the court, covering all essential aspects of remedying the infringement found, in accordance with Section 86(4) of the new CAL.[67]

The above mentioned reformatory sanction (mandatory change of the administrative act) is called *'lex Torubarov'* because the introduced measure is a consequence of the *Torubarov* case, and "also means that the reformatory sanction cannot be excluded even by law".[68] As a result, courts have been given a strong mandate to overturn an infringing administrative act in a repeated trial, whereas only annulment on grounds of invalidity was available in this case under the former CCP (Section 339). It is interesting that the CJEU decided *Torubarov* in light of the provisions of the former CCP, declaring its provisions regarding the repeated procedure unlawful from the point of view of EU law, but – since that law has been repealed in the meantime – the legal principle could only be incorporated into the new CAL that replaced it.

Already at that time, it was difficult to foresee what would happen in cases that were still ongoing under the former CCP which contains the old and unchanged – not EU conform – rules, especially in the repeated procedure which was the subject-matter of *Torubarov*. The transitional provisions of the new CAL [Section 157(1)] made it clear that the new CAL shall only apply to proceedings initiated by an application filed on or after 1 January 2018, and the former CCP shall apply to earlier cases.

The above-mentioned legislative changes affecting the CAL in 2018 and 2020, namely the reformatory power in the case of several-instance proceedings [Section 90(1)(a) of the new CAL], and secondly the reformatory sanction [Section 90(2)(b) of the new CAL] have not been (could not have been) included in the former CCP, because it has previously been repealed. However, several proceedings – such as the trial leading to the *WO* case – started and continued on the basis of the former CCP under which courts had only jurisdiction for annulment and this jurisdiction have not been (could not have been) supplemented with reformatory powers.

Consequently, the judge in the *WO* case did not become entitled to reverse the decision of the county government office and the BFKH, because the reformatory power in several-instance administrative proceedings of the new CAL did not apply on the basis of the former CCP. The judgment of the Regional Court could not have contained anything other than a repeal in accordance with the cassation power and instructions for the defendant for the repeated procedure.[69] The Regional Court also refers to the leitmotiv of the former CCP, that the court does not deprive the administrative authority of its freedom of decision, because the plaintiff has the right to have the conditions laid down in the judgment of the CJEU "first examined by the authority and then, if the plaintiff does not agree with the decision of the

67 Code of Administrative Procedure, Section 90(2)(b).

68 In *Torubarov*, the CJEU ruled that if a Hungarian court – in the absence of the power to vary – does not have the right to grant refugee status to an asylum seeker under Hungarian law, and the authority fails to do so, despite the court's instructions, then, in order to ensure an effective remedy, the court will be entitled to grant refugee status as a 'sanction' even if it would otherwise not have the power to vary. *See* Explanation to Section 90 of the Code of Administrative Litigation.

69 BH.2022.166, Reasoning [16].

authority, to initiate judicial review in this context".[70] The court stated that in the repeated procedure the defendant shall examine whether the plaintiff was prevented from submitting an application or was unable to wait for the authorization in light of his state of health, moreover, whether the treatment could have been provided in Hungary within a medically justifiable time frame.[71]

The defendant county government office submitted a claim for revision to the *Kúria* (the Supreme Court of Hungary) against the decision of the Regional Court.[72] It stated that it had no jurisdiction to examine the issues in the repeated administrative procedure, because the trial was about planned treatments that require prior authorization and cases regarding prior authorization fell within the competence of NEAK. The *Kúria* agreed to this notion, annulled the decisions of the government office and the BFKH and the judgment of the Győr Regional Court, and ordered a repeated procedure to be carried out by the competent institutions, be it the original defendant or the NEAK.[73]

Since the *Kúria* annulled the administrative decisions of 2016 and 2017 and ordered a new procedure, the administrative procedure was repeated in 2021 and 2022. This was again a two-tier procedure, but this time with NEAK acting as the first instance and the National Directorate General for Hospitals (*Országos Kórházi Főigazgatóság*, OKF) acting as the second-instance authority.[74] NEAK and OKF again rejected the claim for reimbursement. NEAK has entrusted a forensic medical expert to address the questions of the court. Based on this medical assessment, NEAK declared that the medical procedure sought and received abroad could have been provided for in Hungary within a reasonable time frame, meaning that the treatment abroad was not necessary, implying that prior authorization would have been refused if submitted in time. Furthermore, it is also stated that there was no indication that the person was prevented from submitting the application for prior authorization, consequently, examining the request now, the authorities arrived at the same conclusion.

However, the decision of the authorities has not named the specific Hungarian institution which could have carried out the same medical procedure. According to the plaintiff, this is because it was not and still is not possible, hence no Hungarian institution could have carried out the special medical procedure invented and applied by the German professor himself. The plaintiff referred to the second Elchinov doctrine, which stated that the lack of a specific medical procedure in the state of affiliation obliges the competent institution to grant the prior authorization in relation to healthcare which is among the care to which the insured person is entitled in the Member State of affiliation.[75] The plaintiff stated that treatment of glaucoma in general terms is among the Hungarian care – this has been confirmed by NEAK as well – but the specific procedure itself is not, thereby the plaintiff is *per se* entitled to authorization (he would have been entitled to it if submitting the

70 10.K.701.624/2020/17. (judgment of first instance), Reasoning [15].
71 Kúria Kfv.VII.37.402/2021/6, Reasoning [7]-[17].
72 Id.
73 BH.2022.166, Reasoning [45].
74 Pursuant to Section 14/a(2).
75 Also reaffirmed in Article 7(1) of the Directive.

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application for authorization in 2016 and he would be entitled now in the subsequent examination), and he again sought judicial review against these administrative acts.

Since in the repeated proceedings the plaintiff filed the application after 1 January 2018, it complied with the provisions of Section 157(1) of the CAL, and thereby the court proceedings were transferred under the scope of the CAL. This obviously gives grounds to judicial review on the merits. The court can either apply the provisions of Section 90(1)(a) as an option or the mandatory provisions of Section 90(2)(b) if it considers that the administrative body has acted contrary to the court's instructions. Either way, the administrative act may be reversed if the conditions for reversal are met. It is important to note that *Torubarov* is of paramount importance in *WO*, because the reformatory power cannot be taken away from the Hungarian courts on this ground, at least as far as the repeated trial is concerned, so there can be no complete return to the cassation system of the former CCP.

At the moment, the repeated trial is ongoing at the Győr Regional Court, the purpose of which is to determine whether or not the plaintiff is ultimately entitled to reimbursement of the costs incurred by the medical treatment abroad.

7. Challenges in the Implementation of the WO Judgment

The Regional Court is in the position in the repeated procedure to amend the decisions of the administrative authorities and establish on its own whether WO is entitled to reimbursement. The Regional Court will presumably try to establish whether the patient was prevented from applying for authorization or was unable to wait for the decision, moreover whether the care could or could not have been provided within a reasonable time frame in Hungary without worsening the patient's condition. The Regional Court has to decide whether it would adjudicate the matter on the basis of 2011/24/EU Directive or the EU legislative instrument on social security coordination, Regulation 883/2004.

7.1. Decision Based on Regulation 883/2004.

If adjudicating on the basis of the Regulation (which is superior in hierarchy to the Directive in this regard[76]), the starting point is that the treatments against glaucoma are enumerated among the Hungarian healthcare benefits. This is not contested by any of the parties. Based on Regulation 883/2004, full reimbursement will be due if the Regional Court declares that, based on medical proof, the specific medical procedure itself (the intervention of the German professor) could not have been provided for in Hungary, and prior or subsequent authorization must have been given on that single basis. This would mean the complete application of the

76 Pursuant to Article 8(3) of the Directive: "With regard to requests for prior authorization made by an insured person with a view to receiving cross-border healthcare, the Member State of affiliation shall ascertain whether the conditions laid down in Regulation (EC) No 883/2004 have been met. Where those conditions are met, the prior authorization shall be granted pursuant to that Regulation unless the patient requests otherwise."

second Elchinov doctrine and would render the examination of the first Elchinov doctrine (that of urgency and inability) obsolete. This would result in full reimbursement of the costs and, based on the hierarchy of the Regulation over the Directive, this would render the examination of the case on the basis of the Directive also obsolete.

7.2. Decision Based on the Directive

If adjudicating on the basis of the Directive, based on the judgment of the CJEU, the costs of the medical examination based on internal tariffs in Germany must be reimbursed in any event, because – irrespective whether it was planned or unplanned – it is not subject to prior authorization.

The Regional Court will have the discretion to address the eye surgery itself. First, it needs to decide whether it was legitimate that the eye surgery, as a one-day treatment, was included in Annex 1 of the 2013 version of the Government Decree as an intervention subject to prior authorization. In other words, whether it was legitimate to classify the one-day surgery as one which requires an authorization. The new version of the Government Decree, which entered into force on 1 January 2017, clearly states that such one-day eye surgeries are not covered by prior authorization. Thus, since 2017, these types of treatments do not require prior authorization, and the Hungarian legislation has changed precisely to this effect.

Excluding eye surgery from the treatments requiring prior authorization was entirely appropriate. This is not and should not have been qualified as healthcare that requires the use of "highly specialized and expensive medical infrastructure or medical equipment" in accordance with Article 8(2) of the 2011/24/EU Directive. An analysis was performed in 2014[77] according to which such medical infrastructure is highly specialized and expensive medical infrastructure which *(i)* is expensive to buy and maintain, relative to the per capita health expenditure in the country; or which *(ii)* is relatively rarely used for interventions, because the device is very difficult to use, and few specialists are able to operate it. This is certainly the case for certain devices used for cancer screening in France:

> "[…] positron emission tomography, used in the detection and treatment of cancer, […] represents costs of hundreds of thousands, even millions, of euro, in both its purchase and in its installation and use".[78]

But this also includes scintillation cameras with or without a positron emission coincidence detector, emission tomographs, positron cameras, magnetic resonance imaging equipment or spectrometers (MRI) for clinical use, medical scanners, high-pressure chambers and cyclotrons for medical use.

77 Matthijs Versteegh *et al.*, *Literature-based approach to defining the concept of healthcare which requires "highly specialised and costintensive medical infrastructure or medical equipment"*, Final Report, prepared for DG Sante, Luxembourg, 2014.

78 Judgment of 5 October 2010, *Case C-512/08, Commission v France*, ECLI:EU:C:2010:579, para. 39.

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In principle, the Regional Court could conclude with a high degree of certainty that it was not legitimate to make the eye surgery subject to prior authorization even in November 2016, that requirement was neither proportionate nor necessary in light of EU law, and thereby the Regional Court could award the patient the domestic costs of the eye surgery without further medical evidence. This would mean the application of the proportionality and necessity doctrine based on Article 56 TFEU, and would render the examination of the first Elchinov doctrine (that of urgency and inability) obsolete.

The CJEU has already decided this issue by stating that "[...] even if WO had not been prevented from applying for prior authorization, he could not have waited for the decision of the competent institution on that application".[79] Thus, according to the CJEU, the patient has fulfilled the condition of urgency and inability, irrespective of what the national medical forensic experts would state.

8. Horizontal Assessment

Since 1986, the CJEU has reduced Member States' room for maneuver on certain aspects of their social security systems, as they now has to consider allocating money to reimburse the costs of treatment received in other Member States by their own insured persons.[80] The CJEU did not consider this to be a matter of national sovereignty and competence, although it is in fact a matter of Member States having to pay, without any discretionary power, for the use of medical services outside their jurisdiction.

8.1. Erosion of 'Prior' Authorization

Undoubtedly, the CJEU has also allowed Member States to make exceptions, *i.e.*, it has accepted to limit the reimbursement of costs in certain cases. 'Prior authorization' has become the tool for this. In *Watts*, the CJEU considered it legitimate that prior authorization is required for hospital treatment in another Member State, as well as for non-hospital care requiring the use of highly specialized and expensive medical infrastructure or medical equipment.[81]

The implementation of the case law of the CJEU at the level of secondary legislation has been achieved by 2011/24/EU Directive, Article 8 of which implements the concepts relating to prior authorization. The possibility of prior authorization is however limited. In *Elchinov*, decided before the adoption of the Directive, the CJEU ruled that not only prior authorization can give entitlement to a patient to reimbursement but also an *ex post facto* examination of facts if the patient was unable to submit an application or was unable to await the decision. Albeit the CJEU introduced this doctrine, it has not been endorsed by 2011/24/EU Directive. Article 8(2) of the Directive that deals with prior authorization does not contain this concept.

79 *Case C-777/18, WO*, para. 54.

80 Tomislav Sokol, 'Rindal and Elchinov, A(n) (Impending) Revolution in EU Law on Patient Mobility?', *Croatian Yearbook of European Law & Policy*, Vol. 6, Issue 1, 2010, pp. 167-208.

81 *Case C-372/04, Watts*, paras. 109-110.

The first case in which the CJEU had to decide on prior authorization in the light of the Directive was the Hungarian case of *WO*. In *WO*, the CJEU ruled in accordance with its former case law that a national rule which in any event excludes reimbursement of planned medical treatment received in another Member State in the absence of prior authorization, even though the other legal conditions are satisfied, cannot be justified by an overriding reason relating to the public interest, does not satisfy the requirement of proportionality and is clearly an unjustified restriction on the freedom to provide services.[82] The CJEU has unquestionably allowed subsequent applications for reimbursement even in the absence of prior authorization having been applied for and granted. The authority must examine the merits of any application for reimbursement.

From a holistic point of view, the 2011/24/EU Directive already took a stand on the solidarity-individualist approach, reinforcing the latter. The CJEU has gone one step further. Even in lack of an express provision in the 2011/24/EU Directive, it fully endorsed the individualist line in *WO* by substantially weakening the 'prior' condition for obtaining an authorization. The CJEU overstepped the formal condition of prior authorization. Indeed, the CJEU has adopted an EU content, which, on the basis of *WO*, seems to be a rather broad interpretation and exemption for patients from the requirement of prior authorization.

Above all, the CJEU has weakened the exercise of the national authority's gatekeeping function. In the absence of a prior application, the national authority – the burden bearer of the insured, the body responsible for the reimbursement of costs – is not aware that expenses will be incurred, or at least that there is a possibility of expenses. This may well have a negative impact on the planning objectives previously agreed by the CJEU. The CJEU has previously confirmed that, for both hospital and non-hospital treatments, planning is an appropriate – necessary and reasonable – justification for authorization.[83] In *WO*, the national authority cited the need for planning as a reason for requiring the submission of an authorization, arguing that the possibility of subsequent authorization would weaken the system both financially and in terms of human resources.[84] The CJEU, however, using the doctrine of prevention and inability, overruled the argument based on the need for planning, which may be due to the fact that it perceives prevention and inability a rather specific case.

Last but not least, the European Commission, as part of its monitoring role, draws up periodic reports on the functioning of the 2011/24/EU Directive, the first of which was published in 2015.[85] The 2015 report identified the fact that the majority of Member States continue to maintain comprehensive prior authorization systems as a key challenge for implementation.[86] The Commission's second report

82 *Case C-777/18, WO*, para. 48.

83 *Case C-372/04, Watts*, paras. 109-110.

84 *Case C-777/18, WO*, para. 77.

85 Commission Report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, COM(2015) 421 final, 24 September 2015.

86 Id. pp. 3-6.

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in 2018 also identified the area of prior authorization as a potential problem.[87] The Commission

> "identified four priority areas for the compliance assessment which had the greatest potential to act as barriers to patients if left unaddressed: systems of reimbursement, use of prior authorization, administrative requirements and charging of incoming patients".[88]

The Commission has published the third periodic review on the functioning of the 2011/24/EU Directive in May 2022.[89] The 2022 Report reaffirmed prior authorization as a problematic area, it confirmed the extensive use of prior authorization in 75% of Member States still 10 years after the adoption of the Directive.

These challenges coupled with the legal concepts of urgency and inability in *Elchinov* and *WO* might form a good basis for supplementing the existing legal framework, *in concreto* Article 8 of the Directive, aimed at narrowing (if not watering) down the legal scope of authorization prior to the treatment abroad. The approximation of laws in the area would help to avoid unforeseeable and ambiguous legal situations and unjust outcomes for patients legitimately seeking care abroad.

8.2. Implications for Hungarian Law

The CJEU noted in *WO* that, according to the referring court, there is no provision in the Hungarian system governing the subsequent submission of an application for authorization. Moreover, there is no possibility of examining the conditions laid down for authorization, even if the insured person was prevented from submitting an application for authorization for reasons connected with his/her state of health or the need to seek treatment urgently or he/she was unable to await the decision of the competent institution.

Indeed, there are no explicit rules in the Government Decree for these types of cases. It is worrying that at present hardly any Hungarian patient could effectively make use of the legal notions of *WO*. From a technical point of view, there are no provisions whatsoever under Hungarian law for patients who would seek authorization and reimbursement after the treatment based on urgency or on being unable to submit an application.

Partially this might be due to the fact, that the 2011/24/EU Directive does not contain the doctrine of urgency and inability in Article 8(2) as an exemption for the patient from obtaining prior authorization. The main implementing Hungarian laws (Health Insurance Act and Government Decree) were deemed to be technically in conformity with the Directive so far. Obviously, CJEU judgments are *erga omnes* mandatory for Member States,[90] but the way prior authorization procedures are

87 Commission Report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, COM(2018) 651 final, 21 September 2018.

88 Id. p. 2.

89 Commission Report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, COM(2022) 210 final, 22 May 2022.

90 Katalin Gombos, *Európai jog – az Európai Unió közjoga*, Wolters Kluwer, Budapest, 2021, p. 5.

implemented differs greatly across Member States,[91] and under these circumstances the Hungarian legislator has not yet felt inclined to pass a specific legislation.

Having said that, it is important to clarify that the CJEU does not oblige Member States to grant reimbursements in each and every case when the application for authorization and reimbursement was belated. The obligation refers to the examination of the conditions subsequent to the treatment abroad and to pass a decision in light of that examination. The decision can be passed in favor of the patient or can also be a refusal of the authorization and the reimbursement. What is important is the existence of the *ex post facto* mechanism, and the establishment of a procedure that is able to effectively handle a subsequent assessment of the medical criteria. The medical decision on prior authorization is now the responsibility of the Medical Research Council (*Egészségügyi Tudományos Tanács*, ETT).[92] Presumably, in a professional sense, the ETT or a similar independent evaluation body would be required to act for subsequent authorization.

As it was to be seen in the Hungarian follow-up of *WO*, the lack of a proper procedure deprives both the patient and the competent authority of the chance to receive an objective description of the patients' medical conditions and the possibility of available national treatment options within an acceptable time frame. Lack of appropriate procedures and the related passage of time (in *WO* exactly 7 years) could threaten both the patient and the state with an unjust result at the end. The Hungarian administrative authorities refused in both instance the authorization and the reimbursement in the repeated administrative procedure. They carried out a new examination, and the basis for the decision was that, according to a medical report, the patient could have been treated in Hungary back in 2016. It is clear that in the present case the passage of time exerted an adverse effect on the patient.

Not only legislators and administrative authorities are addressees of EU law, but courts are also obliged and at the same time empowered to set aside national laws that are infringing EU law. Now, it is for the Hungarian court to become the enforcer of the judgment of the CJEU in *WO*. Hungarian civil procedure law has gone through a series of changes lately, starting with zero judicial review to the limited reformatory powers currently in place. As a result of the provisions introduced after *Torubarov*, the present version of the new CAL empowers the court to alter the administrative act in the repeated procedure. In theory, the court can implement the CJEU decision in *WO* and grant the patient the claimed reimbursement. The court – in lack of medical documents – has already appointed a forensic medical expert who is entrusted with exploring in 2023 the factual and medical situation at the end of 2016. This is the risk that was mentioned above, because the envisaged task is extremely difficult if not impossible. There is unlikely to be an expert in Hungary who could reassure these factual and medical questions now. It is even possible that the ETT itself would not be able to carry out such an

91 European Commission, Study on Enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU, Publications Office of the European Union, Luxembourg, 2022, p. 5.

92 Government Decree 340/2013. (IX. 25.), Section 14/A.

examination, as it is challenging to get information now whether the treatment could or could not have been performed anywhere in Hungary back in 2016.

However, as I concluded before, on the basis of the 2011/24/EU Directive the court does not even need medical proof for deciding in favor of the patient, because it can state that the requirement of prior authorization for eye surgery was neither proportionate nor necessary in light of EU law (Article 56 TFEU) in 2016, and thereby the court could award the patient the domestic costs of the eye surgery.

Finally, there is an approach that patients who assert their cross-border patient rights before a national court can be seen as kind of explorers for the national health insurance system.[93] In fact, the case law they generate may also improve the situation of those who would not have been able to travel abroad for treatment, and in fact, mobile patients may contribute to solidarity within the national system of the Member State where they are insured. *WO* might represent another step further along this path, through which the eligibility of cross-border care recipients has been extended. It remains a question to be answered in the future whether this will really strengthen solidarity within the national healthcare systems.

93 Barend van Leeuwen, 'The Patient in Free Movement Law: Medical History, Diagnosis, and Prognosis', *Cambridge Yearbook of European Legal Studies*, Vol. 21, 2019, p. 164: "Through the exercise of their free movement rights, moving patients acted as explorers for their national healthcare systems."