LEGAL OPINION IN THE CASE OF LYSIANE PAKTER

I. Introduction and context

1. Mr Philippe Pakter and Ms Delphine Beulné have asked me to write a legal opinion in support of their case before the Tribunal Judiciaire de Lyon, in which they challenge the refusal of L'Assurance Maladie to provide prior authorisation for their daughter, Lysiane, to receive medical treatment for Pierre Robin Sequence at the Tübingen University Hospital in Germany in May 2017.

2. I am very happy to write this opinion, because Lysiane's case raises important and complicated questions about the interaction between the EU rules on free movement of patients on the one hand, and patients with rare diseases on the other hand. It is important to receive clarification from the Court of Justice of the EU ("CJEU") on how the Social Security Regulation[1] and the Cross-Border Healthcare Directive[2] should be interpreted in cases brought by patients with rare diseases. This question has not yet been addressed in the case law of the CJEU.

3. Furthermore, in its recent case law, the CJEU has started to develop the relationship between the EU rules on free movement of patients and the Charter of Fundamental Rights ("the Charter"). Lysiane's case raises important questions about the effect of the Charter on the interpretation of the Social Security Regulation and the Cross-Border Healthcare Directive when public authorities or health insurers are dealing with requests for prior authorisation of cross-border medical treatment submitted by patients with rare diseases.

4. I am Associate Professor in EU Law and Deputy Dean (Education) at Durham Law School in the United Kingdom. I am a non-practising barrister (Gray's Inn) and qualified as a barrister in criminal law and medical professional discipline. From 2017 to 2020, I co-directed the Durham European Law Institute, which is one of the leading research centres in EU Law in the United Kingdom.

[1] Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems.
[2] 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.

5. One of my main areas of research is the interaction between EU law and medical law. From 2016, I have published several articles on free movement of patients and free movement of doctors in leading EU law journals. The focus of these publications has been on (1) the interaction between free movement of patients and the quality of healthcare provided in the EU Member States; (2) the interaction between free movement of patients and medical ethics; and (3) the interaction between free movement of patients and the Charter of Fundamental Rights. I have attached my list of publications.

6. In March 2023, I was approached by Mr Philippe Pakter to discuss a number of my publications in the field of free movement of patients. Since then, I have been in regular contact with Mr Pakter to discuss the progress of Lysiane's case. I have received access to Mr Pakter's documents in the case, and I have provided input in the drafting process of the request for a preliminary reference submitted by Lysiane's parents.

7. The aim of this legal opinion is to provide an analysis of the CJEU's case law on free movement of patients in support of the request for a preliminary reference in Lysiane's case. I will develop my analysis in three steps.

8. First, it will be shown that the CJEU has not yet addressed and clarified the obligations of public authorities and health insurers in dealing with requests for prior authorisation of cross-border treatment submitted by patients with rare diseases. Patients with rare diseases are a vulnerable group of patients who are significantly more likely to require cross-border healthcare than patients with more regular illnesses or diseases.

9. As a result, they require additional protection in the consideration of their requests for prior authorisation of cross-border medical treatment under the Social Security Regulation and/or the Cross-Border Healthcare Directive. The obligations imposed on public authorities or health insurers who are assessing requests for prior authorisation submitted by patients with rare diseases should be defined more precisely by the CJEU.

10. Second, this position is reinforced by the CJEU's recent focus on the role of the Charter in free movement of patients cases. The CJEU has held that the interpretation and application of the provisions of the Social Security Regulation and the Cross-Border Healthcare Directive should be compatible with the rights protected by the Charter. This

includes the right not to be discriminated against on the ground of disability, which is protected by Article 21 of the Charter.

11. It will be argued that, to avoid discrimination on the ground of disability, more onerous and more precise obligations should be imposed on public authorities or health insurers when they are dealing with requests for prior authorisation submitted by patients with rare diseases.

12. Third, and finally, I will summarise the legal analysis and identify the core issues which the CJEU should be invited to address in the request for a preliminary reference. I will focus on the substantive and procedural obligations imposed on public authorities and health insurers in comparing the effectiveness of medical treatments in different EU Member States.

II. The interaction between the Social Security Regulation, the Cross-Border Healthcare Directive, and prior authorisation requests submitted by patients with rare diseases

13. The right for patients to receive medical treatment in another Member State from the one in which they are insured, and to be reimbursed for the cross-border treatment by their home health insurer or healthcare system, is one of the key patient rights granted by EU law. This right was originally developed under the predecessor of the Social Security Regulation.[3] From the late 1990s, the CJEU started to develop an additional and supplementary right to reimbursement of cross-border healthcare on the basis of Article 56 TFEU (the right to freely receive services in another Member State).[4]

14. In 2011, the EU adopted the Cross-Border Healthcare Directive ("the Directive"), which codified the CJEU's case law and (in most cases) replaced the right to reimbursement of cross-border healthcare under Article 56 TFEU.[5] In practice, today, the two main "routes"

[3] Council Regulation (EEC) No 1408/71 of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community.
[4] See Case C-158/96, *Kohll v Union des caisses de maladies*, ECLI:EU:C:1998:171 and Case C-120/95, *Decker v Caisse de maladie des employés privés*, ECLI:EU:C:1998:167.
[5] See S. de la Rosa, 'The Directive on Cross-Border Healthcare, or the Art of Codifying Complex Case Law' (2012) 49 *CML Rev* 15.

for reimbursement of cross-border healthcare are the Social Security Regulation and the Cross-Border Healthcare Directive.

15. From the 2000s, the EU has recognised the important potential of cross-border healthcare for patients with rare diseases. Because the number of patients with rare diseases is very low, the level of expertise available to diagnose and treat these patients is likely to be widely divergent in different EU Member States. Moreover, the expertise is likely to be centralised in a limited number of EU Member States (or sometimes in only one EU Member State).

16. The need to address and protect the position of patients with rare diseases was recognised by a Council Recommendation in June 2009.[6] Moreover, the Cross-Border Healthcare Directive includes two provisions which explicitly address the position of patients with rare diseases.

17. Article 12 of the Directive provides that the Commission shall support healthcare providers and centres of expertise in the development of European Reference Networks, in particular to support patients with rare diseases.[7] These networks shall focus on sharing and developing knowledge, expertise, and research on rare diseases.

18. Furthermore, Article 13 focusses specifically on rare diseases. It provides that the Commission shall support Member States in cooperating in the development of diagnosis and treatment capacity for patients with rare diseases.[8] Article 13(b) refers specifically to making patients, health professionals and funding bodies aware of the possibility of applying for prior authorisation of cross-border medical treatment under the Social Security Regulation.

19. The Directive does not make a direct link between Articles 12-13 and the specific provisions on how public authorities and health insurers should assess requests for prior authorisation for cross-border treatment (Articles 7-9 of the Directive). At the same time, Articles 12-13 provide important context to these provisions, and they can be relied on to define in a more precise way the obligations imposed on public authorities and health

[6] Council Recommendation of 8 June 2009 on an action in the field of rare diseases (2009/C - 151/02).
[7] Article 12(1) of the Cross-Border Healthcare Directive.
[8] Article 13(a) and 13(b) of the Cross-Border Healthcare Directive.

insurers in dealing with requests for prior authorisation of cross-border healthcare submitted by patients with rare diseases.

20. None of the cases on free movement of patients that have reached the CJEU since the late 1990s were brought by patients with rare diseases.[9] Although the case law has covered questions about experimental medical treatments,[10] and new or technologically more advanced medical treatments,[11] the CJEU has never had to address or define the obligations of public authorities and health insurers in the specific context of requests for prior authorisation submitted by patients with rare diseases.

21. This lack of case law at the EU level could be explained by the fact that, in practice, Member States usually adopt a flexible approach to requests for prior authorisation submitted by patients with rare diseases.

22. However, this approach is currently not sufficiently "anchored" in the case law of the CJEU. For that reason, patients with rare diseases are inherently more vulnerable when their requests for prior authorisation are being assessed than patients with more regular illnesses or diseases.

23. Against this background, it is necessary that the CJEU explicitly addresses the obligations imposed on public authorities and health insurers in dealing with requests for prior authorisation submitted by patients with rare diseases. Some indications for the foundations of such an approach can be found in the case law – in particular, in its judgments in *Peerbooms*[12] and *Elchinov*.[13]

24. Under the Social Security Regulation, Article 56 TFEU and the Cross-Border Healthcare Directive, Member States can refuse to provide prior authorisation for cross-border healthcare if "the same or equally effective medical treatment" is available in the home Member State.[14]

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[9] See B. van Leeuwen, 'The Patient in Free Movement Law: Medical History, Diagnosis, and Prognosis' (2019) 21 *Cambridge Yearbook of European Legal Studies* 162.
[10] Case C-157/99, *Geraets-Smits and Peerbooms*, ECLI:EU:C:2001:404.
[11] Case C-56/01, *Inizan v Caisse primaire d'assurance maladie des Hauts-de-Seine*, ECLI:EU:C:2003:578 and Case C-173/09, *Elchinov*, ECLI:EU:C:2010:581.
[12] *Peerbooms*, supra n 10.
[13] *Elchinov*, supra n 11.
[14] *Peerbooms*, supra n 10, paras 103-104.

25. One of the fundamental starting points for patients with rare diseases is that international scientific evidence should be taken into account in the comparative assessment of the effectiveness of the proposed treatment in the other Member State and the alternative treatment in the home Member State.

26. In *Peerbooms*, the CJEU held that, in considering what constituted "normal treatment" in the context of a request for prior authorisation of cross-border medical treatment, Member States had to adopt an international perspective on the medical scientific research which was available.[15] It was not possible for a Member State to adopt an exclusively national perspective on this assessment – the scientific research had to be *international* scientific evidence. As a result, a strong connection was made between cross-border healthcare and evidence-based medicine.[16]

27. In *Peerbooms*, the assessment conducted by the health insurer focussed on the question whether the cross-border treatment which Mr Peerbooms wanted to receive was *covered* by his home health insurance.[17] As such, the obligation to take international scientific evidence into account was relevant to the analysis of the coverage of his health insurance policy – not to the question of the *effectiveness* of the medical treatment.

28. Nevertheless, because the obligation to rely on international scientific evidence was based on the principle of non-discrimination on the ground of nationality protected by Article 56 TFEU, there is no reason why this obligation to take international scientific evidence into account should not also apply to the assessment of whether the same or equally effective medical treatment is available in the patient's home Member State.

29. As a result, in Lysiane's case, the CJEU should be invited to extend the obligation to take international scientific evidence into account to the assessment of the effectiveness of the proposed cross-border treatment and the comparison of the proposed treatment and the treatment available in the patient's home Member State.

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[15] *Peerbooms*, supra n 10, paras 93-98.
[16] See B. van Leeuwen, 'The Doctor, the Patient, and EU Law: The Impact of Free Movement Law on Quality Standards in the Healthcare Sector' (2016) 41 *EL Rev* 638, 642-643.
[17] *Peerbooms*, supra n 10, paras 83-87.

30. For patients with rare diseases, the focus on international scientific evidence does not only require that public authorities and health insurers think carefully about *which scientific evidence* is taken into account in the assessment – it also requires that they think carefully about *which medical professionals* provide input in this assessment.

31. To be able to analyse the relative effectiveness of treatment options in different Member States, a strong case can be made that this assessment should include an obligation to consult healthcare professionals in the proposed country of treatment, if these doctors work in a recognised centre of expertise specialised in the patient's rare disease and if they are able to provide a highly specialised rare disease treatment (supported by international scientific evidence) which is not available in the patient's home Member State. This obligation is based directly on the obligation laid down by the CJEU in *Peerbooms* to take international scientific evidence into account in the assessment of requests for prior authorisation.

32. The CJEU's reasoning in *Peerbooms* could be linked to the case of *Elchinov*. In *Elchinov*, the CJEU held that the fact that a treatment is not available in the patient's home Member State does not automatically determine whether the treatment is covered by the patient's home healthcare system or health insurance.[18] The question of the potential coverage of a treatment should be kept separate from the question of its availability. If the treatment can be held to be covered by the home Member State, the fact that it cannot be provided in the home Member State, and that it is much more advanced than the treatments available in the home Member State, does not prevent the patient from having a right to reimbursement under the Social Security Regulation.

33. Again, in *Elchinov*, the CJEU focussed on the question of the coverage of the home healthcare system. There was no doubt that the treatment in the other Member State was more effective – the question was whether it could be held to be covered by the home healthcare system.[19] In effect, the CJEU imposed something similar to a "duty of consistent interpretation"[20] on public authorities or health insurers to adopt a generous interpretation of the entitlements of patients under their home healthcare system or health insurance

[18] *Elchinov*, supra n 11, paras 56-62.
[19] *Elchinov*, supra n 11, paras 63-67.
[20] See B. van Leeuwen, 'The Doctor, the Patient, and EU Law: The Impact of Free Movement Law on Quality Standards in the Healthcare Sector' (2016) 41 *EL Rev* 638, 645-646.

policy if the wording of the policy or the relevant legislation makes it possible to adopt such a broad interpretation. In these cases, national healthcare systems or health insurance policies can be held to cover treatments which are not in fact available under the national healthcare system.

34. Similarly to *Peerbooms*, the CJEU's analysis in *Elchinov* focussed on the question of what was covered by the patient's home healthcare system. Again, it can be argued that the "duty of consistent interpretation" approach should be extended to the assessment of whether the same or equally effective medical treatment is available in the patient's home Member State. This is particularly important for patients with rare diseases.

35. Based on *Elchinov*, it could be argued that public authorities and health insurers are under an obligation to find that, for patients with a rare disease for whom the doctors in the Member State of the proposed treatment are able to provide a highly specialised rare disease treatment (based on international scientific evidence), which is not available in the patient's home Member State, the proposed cross-border treatment is more effective than what can be provided in the home Member State.

36. Overall, based on the CJEU's analysis in *Peerbooms* and *Elchinov*, it is important that the CJEU is invited to lay down more precise guidelines on how the principles laid down in these judgments apply to patients with rare diseases when a public authority or health insurer in the home Member States is required to make a comparison between the effectiveness of the medical treatment in the home Member State and the effectiveness of the medical treatment in the proposed Member State of treatment.

37. This substantive assessment should be linked to the procedural requirements for dealing with requests for prior authorisation submitted by patients with rare diseases.

38. In *Peerbooms*, the CJEU laid down the procedural requirements with which public authorities and health insurers must comply in assessing requests for prior authorisation.[21] These obligations were confirmed and extended in the Cross-Border Healthcare Directive.[22] In particular, Article 9(4) of the Directive provides that decisions on requests

[21] *Peerbooms*, supra n 10, para 90.
[22] Article 9 of the Cross-Border Healthcare Directive.

for cross-border healthcare are "properly reasoned". Furthermore, under Article 9(3), the specific medical condition and the urgency and individual circumstances of the patient must be taken into account.

39. On the basis of the documents I have seen, it is clear that the response provided by L'Assurance Maladie to the request for prior authorisation submitted by Lysiane's parents did not comply with the conditions laid down in Article 9 of the Directive. No explanation was provided by L'Assurance Maladie as to why or how equally effective medical treatment could be provided to Lysiane in France. From this perspective, L'Assurance Maladie could simply be found to be in breach of the obligation to provide a properly reasoned response to Lysiane's parents.

40. Nevertheless, because of the complicated nature of prior authorisation requests submitted by patients with rare diseases, the CJEU should be encouraged to lay down more precise guidelines on the obligations with which public authorities and health insurers have to comply when they respond to requests for prior authorisation submitted by patients with rare diseases.

41. The principle of proportionality, on which Article 9 of the Directive is based, requires that a more onerous obligation is imposed on public authorities and health insurers when they are responding to a request for prior authorisation submitted by a patient with a rare disease. In these cases, more extensive and more detailed reasons should be provided as to why and how the same or equally effective medical treatment can be provided in the home Member State.

42. Because patients with rare diseases are a vulnerable group of patients, the CJEU should be invited to define the obligations of public authorities and health insurers when they are assessing requests for prior authorisation submitted by patients with rare diseases in a more precise way. This is closely to linked to the analysis of the role of the Charter of Fundamental Rights below.

III. The role of the Charter of Fundamental Rights in cases brought by patients with rare diseases

43. There is a close link between the right of patients to receive reimbursement of cross-border medical treatment and the fundamental rights protected by the Charter. Article 35 of the Charter provides a right to access preventive healthcare and medical treatment under the conditions established by national laws and practices. Moreover, it provides that the EU shall ensure a high level of human health protection in the definition and implementation of Union policies.

44. Although Article 35 – primarily because of its second sentence – has so far only been interpreted as a principle (rather than a right which can be directly enforced by individuals before national courts), it also includes a right for individual patients to access preventive healthcare and medical treatment. In line with the limited competences of the EU in the field of medical care,[23] this right is restricted by "the conditions established by national laws and practices".

45. Article 35 is not the only Charter provision which could potentially be relied on by patients who are seeking access to or reimbursement of cross-border medical treatment. Other rights include the right to human dignity (Article 1), the right to respect for private and family life (Article 7), and the right not to be discriminated against on various grounds in Article 21.

46. Article 21 of the Charter was relied on by the CJEU in the recent case of *A v Veselības Ministrija*[24] to develop the connections between the Charter on the one hand, and the Social Security Regulation and the Cross-Border Healthcare Directive on the other hand. In *A*, the CJEU held that a Member State's refusal to provide prior authorisation in a situation where the patient wanted to access cross-border medical treatment for religious reasons could constitute indirect discrimination under Article 21 of the Charter.[25] This discrimination could be justified by the Member State, but it had to provide a ground of justification and establish that the restriction was proportionate.

47. The CJEU subsequently interpreted the provisions of the Social Security Regulation and the Cross-Border Healthcare Directive from the perspective of the justification of the

[23] Article 168(7) TFEU.
[24] Case C-243/19, *A v Veselības Ministrija*, ECLI:EU:C:2020:872.
[25] *A v Veselības Ministrija*, above n 24, paras 35-43.

interference with Article 21 of the Charter.[26] Because the Charter constitutes primary EU law, with the same status as the Treaty provisions, the interpretation of the Social Security Regulation and the Cross-Border Healthcare Directive had to be compatible with the requirements of the Charter.

48. The case of *A* should be distinguished from Lysiane's case in the sense that the motive for seeking cross-border healthcare was based exclusively on religious reasons. There was no doubt that equally effective medical treatment could be provided in the patient's home Member State.[27] However, the patient was seeking a certain type of treatment in another Member State which was consistent with their religious beliefs and convictions. As a result, the case of *A* was important to the relationship between patient choice (or patient autonomy) and the patient's medical assessment made by doctors.

49. Despite these differences in factual background, the way in which the CJEU developed a framework of assessment based on Article 21 of the Charter in *A* can be applied to Lysiane's case. It is important that the CJEU develops the relationship between the Charter and the rules on free movement of patients. From this perspective, Lysiane's case provides an important opportunity to develop the approach laid down in *A* to other grounds of non-discrimination, such as the right not to be discriminated against on the ground of disability.[28]

50. If the CJEU's approach in *A* was applied to Lysiane's case, the starting point would be to assess whether L'Assurance Maladie's refusal to provide prior authorisation could be regarded as discrimination on the ground of disability under Article 21 of the Charter. The refusal did not constitute direct discrimination on the ground of disability, because L'Assurance Maladie did not make a direct or open distinction between patients with a disability and patients without a disability.

51. Nevertheless, a strong case can be made that the way in which L'Assurance Maladie rejected Lysiane's request for prior authorisation constituted indirect discrimination on the ground of disability. As has been explained above, patients with rare diseases are inherently

[26] *A v Veselības Ministrija*, above n 24, paras 45-56.
[27] *A v Veselības Ministrija*, above n 24, paras 28-32.
[28] See B. van Leeuwen, 'Patient Choice, Medical Ethics and Free Movement of Patients: The 'Emancipation' of the Cross-Border Healthcare Directive' (2023) 48 *EL Rev* 662.

more vulnerable as a patient group, because of the lack of expertise available to diagnose and treat their diseases, and the centralisation of the treatment and research expertise in certain Member States (or just in one Member State).

52. From this perspective, Article 21 of the Charter requires that, to avoid indirect discrimination on the ground of disability, public authorities and health insurers are under an obligation to provide additional protection – and to take additional steps – in the assessment of a request for prior authorisation submitted by patients with rare diseases.

53. In particular, a public authority or health insurer will have to take more care in making the comparative assessment of the relative effectiveness of the cross-border treatment and the treatment available in the home Member State for patients with rare diseases than for patients with a more regular illness or disease.

54. If a Member State fails to take international scientific evidence into account in the assessment of the request for prior authorisation, this causes a particular disadvantage to patients with rare diseases, because, for this patient group (as confirmed by Articles 12-13 of the Cross-Border Healthcare Directive), it is particularly important that an international scientific perspective is taken on their case. This is the direct result of the lack of expertise in dealing with certain rare diseases in some Member States, and the fact that the treatment and research expertise for rare diseases has often been centralised in a limited number of Member States.

55. It could even be argued that, in the case of patients with rare diseases, Article 21 of the Charter creates a presumption that prior authorisation will be granted in cases where a patient with a rare disease is seeking cross-border treatment in a centre of expertise in another Member State when no such centre of expertise is available in the patient's home Member State or when the doctors in the proposed Member State of treatment provide a highly specialised rare disease treatment (supported by international scientific evidence) which is not available in the patient's home Member State.

56. This presumption would impose a burden of proof on the public authority or health insurer to justify why, in the individual circumstances of the patient's case, it can still be held that the same or equally effective medical treatment is available in the patient's home Member State.

57. Similarly, if a public authority or health insurer fails to provide detailed reasons for its refusal to provide prior authorisation, this has a particularly negative impact on patients with a rare disease, because it is particularly important to them to understand on what basis it has been concluded that the same or equally effective medical treatment can be provided in the home Member State.

58. Therefore, a failure to provide detailed reasons in the case of a patient with a rare disease does not only constitute a breach of Article 9(4) of the Cross-Border Healthcare Directive – it also constitutes indirect discrimination on the ground of disability under Article 21 of the Charter.

59. For both examples of indirect discrimination, L'Assurance Maladie would be required to provide a ground of justification, and it would be required to show that the restriction of Article 21 of the Charter was proportionate. It is difficult to identify potential grounds of justification that would be available to L'Assurance Maladie in the case of Lysiane.

60. One final observation should be made about the potential role of the Charter. Article 47 of the Charter protects the right to an effective judicial remedy. As such, it provides an additional layer of protection to patients whose request for prior authorisation of cross-border medical treatment has been refused.

61. In the last decade, Article 47 has become one of the – if not the – most powerful Charter rights, which has been regularly relied on by the CJEU.[29] One of the strands of the CJEU's case law on Article 47 has focussed on the obligation to give reasons for decisions, and the link between the obligation to give reasons and the ability of individuals to challenge decisions in administrative or legal proceedings.[30]

62. In Lysiane's case, the lack of reasons provided by L'Assurance Maladie for its refusal of the request for prior authorisation could also be challenged under Article 47 of the Charter. Article 9 of the Directive gives specific expression to the right to an effective remedy in the context of requests for prior authorisation of cross-border healthcare.

[29] See E. Frantziou, 'The Binding Charter Ten Years On: More Than a Mere Entreaty?' (2019) 38 *Yearbook of European Law* 73.
[30] For a recent example, see Case C-715/20, *X (Absence de motifs de résiliation)*, ECLI:EU:C:2024:139.

63. In effect, Article 47 of the Charter could be relied on in combination with Article 21 of the Charter to argue that, in cases of patients with rare diseases, public authorities and health insurers are under an obligation to provide detailed and specific reasons for decisions to refuse a request for prior authorisation. The lack of reasons provided by L'Assurance Maladie made it impossible for Lysiane's parents to understand on what basis their request had been rejected, and to decide how they could effectively challenge the rejection before the French courts.

64. From this perspective, the CJEU should be encouraged to integrate Article 47 of the Charter in its assessment of what the precise obligations of public authorities and health insurers are when they are dealing with a request for prior authorisation submitted by a patient with a rare disease under the Social Security Regulation and/or the Cross-Border Healthcare Directive.

IV. The necessity and importance of a preliminary reference in Lysiane's case

65. There are two main reasons why it is necessary and important that Lysiane's case is referred to the CJEU under Article 267 TFEU.

66. First, Lysiane's case raises specific and complicated questions about the obligations imposed on public authorities and health insurers in the context of requests for prior authorisation of cross-border treatment submitted by patients with rare diseases under the Social Security Regulation and the Cross-Border Healthcare Directive. These questions have not been addressed by the CJEU, and the CJEU should be invited to lay down more detailed guidelines on the substantive and procedural requirements for assessing requests for prior authorisation submitted by patients with rare diseases.

67. Second, Lysiane's case provides an important example of the vulnerable position of patients with rare diseases when they submit requests for prior authorisation of cross-border healthcare under the Social Security Regulation and/or Cross-Border Healthcare Directive. There is a clear public interest, reinforced by Article 21 of the Charter, to invite the CJEU to provide more precise guidelines on the substantive and procedural requirements for assessing requests for prior authorisation submitted by patients with rare

diseases. Ultimately, this would improve the protection of a group of patients who are particularly vulnerable, and who require additional protection in comparison with patients with more regular illnesses or diseases.

68. In formulating the questions for the preliminary reference, my advice would be to focus on the following aspects of Lysiane's case:

    (i) What are the precise substantive and procedural obligations that public authorities and health insurers must comply with in assessing requests for prior authorisation submitted by patients with rare diseases under the Social Security Regulation and/or the Cross-Border Healthcare Directive?

    (ii) To what extent do these obligations require public authorities and health insurers to take international scientific evidence into account in making the assessment of the relative effectiveness of the proposed cross-border treatment and the treatment in the home Member State?

    (iii) To what extent are public authorities and health insurers under an obligation to consult healthcare professionals in the proposed Member State of treatment, if these doctors work in a recognised centre of expertise with expertise in the specific rare disease of the patient and if they are able to provide a highly specialised rare disease treatment (supported by international scientific evidence) which is not available in the patient's home Member State?

    (iv) To what extent do Articles 21 and 47 of the Charter impose more onerous obligations on public authorities and health insurers when they assess requests for prior authorisation of cross-border healthcare submitted by patients with rare diseases in comparison with requests submitted by patients with more regular illnesses or diseases?

69. I strongly support the draft order for a preliminary reference prepared by Lysiane's parents, and the way in which the questions for a preliminary reference have been formulated in this document.

70. To conclude, I very much hope that the court will make a preliminary reference to the CJEU under Article 267 TFEU to receive answers to these important and complicated questions.

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