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Legal opinion in the case of Lysiane Pakter v. CPAM du Rhône (n° RG 19/00047)

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1. Mr. Philippe Pakter and Ms. Delphine Beulné, parents of the child Lysiane Pakter, born on 29 March 2017 in Lyon and suffering from the rare disease "Pierre Robin Sequence," have asked me in my capacity as Professor of Public Law at the University of Paris-Est Créteil to support their request, made to the Lyon Judicial Court (Social Division), for a preliminary ruling from the Court of Justice of the European Union, in the context of their dispute with the Caisse Primaire d'Assurance Maladie of the Rhône (hereinafter CPAM), due to the latter's refusal to authorize coverage of healthcare for Lysiane in another Member State of the European Union (in this case Germany), under Art. R 160-2 of the Social Security Code.

2. The case presented by the applicants is part of the complex issue of patient mobility in European Union law, which is based on the dual foundation of the so-called "patient mobility" Directive (Directive 2011/24/EU of 9 March 2011 on the application of patients' rights in cross-border healthcare, which aims to guarantee patient mobility and the freedom to provide healthcare services) and the so-called social security coordination rules (Regulation 883/2004 of 29 April 2004 on the coordination of social security systems). Having myself worked on and published about these texts[1], and being particularly sensitive to the situation of their daughter Lysiane, who suffers from serious disability requiring highly specialized care due to the orphan disease nature of Pierre Robin Syndrome, I am providing below an independent legal opinion inviting the Lyon Judicial Court to stay the proceedings and refer a question to the Court of Justice of the European Union for a preliminary ruling, in the context of the dispute arising out of CPAM's refusal to authorize coverage of healthcare for Lysiane in Germany following CPAM's letter of refusal dated 18 May 2017.

3. It should be recalled at the outset that the opportunity to refer a matter to the Court of Justice of the European Union by way of a preliminary reference, on the basis of Article 267 of the Treaty on the Functioning of the European Union, falls within the exclusive jurisdiction of the national court – in this case the Lyon Judicial Court. It is settled case-law that "the national court alone has jurisdiction to find and assess the facts in the case before it and to interpret and apply national law. Similarly, it is solely for the national court, ***before which the dispute has been brought and which must assume responsibility for the forthcoming judicial decision,***

[1] Cf. Quels droits pour les patients en mobilité ? À propos de la directive sur les droits des patients en matière de soins transfrontaliers, *Revue Française des Affaires Sociales*, 2012.

to determine, in the light of the particular circumstances of the case, both the need for and the relevance of the questions which it submits to the Court. Consequently, where the questions submitted concern the interpretation of European Union law, the Court is in principle bound to give a ruling" (Court of Justice of the European Union, 26 May 2011, *Stichting Natuur*, Case C-166/09, paragraph 47).

4. While it is true that the national court is not required to refer the matter to the Court where such decisions are subject to appeal – which is the case here – it should also be borne in mind that in the event that the case goes back to the court of last resort (a highly probable scenario in this case, given the seriousness of Lysiane's condition), the applicant's situation would be one in which the judge would have no choice but to make a preliminary reference. Courts of last resort are **"required"** to refer a matter to the Court of Justice for a preliminary ruling (Article 267 of the Treaty on the Functioning of the European Union); this referral requirement is waived when the question raised is irrelevant, or when the EU law provision in question has already been interpreted by the Court, or when the correct interpretation of EU law is so obvious as to leave no scope for any reasonable doubt (see, for example, Court of Justice of the European Union, 6 October 2021, *Consorzio Italian Management and Catania Multiservizi*, C-561/19). In view of the sensitivity of the facts of this case, it seems to me necessary that the Lyon Judicial Court assess and anticipate the need for a preliminary ruling, which will almost inevitably be required if the case goes back to the Court of Cassation. If at the end of the chain no preliminary reference is initiated, the State could be held liable for "judicial failure", in view of the seriousness of the facts.

5. Indeed, in light of the circumstances of this case, there can be no doubt that there is no self-evident, no certain, and even less, no clear-cut solution which can be applied to enable "the correct interpretation of EU law". To support this observation it is essential to emphasize here that to our knowledge, the Court of Justice of the European Union has not yet had to consider the interpretation of Article 20(2) of Regulation 883/2004 concerning the system of prior authorization for planned healthcare in another EU Member State, in the delicate context of a patient suffering from an orphan disease, identified as such by the Orphanet network referred to in Directive 2011/24 (Art. 12, European Reference Networks). Similarly, the reasoning behind a refusal of authorization – which is at issue here – has never been examined by the Court of Justice in the context of such a disease. In view of these facts, and in light of the case-law mentioned in paragraph 4 above, there is neither clarity nor certainty in the present case; on the contrary, the circumstances of the applicant, and the "paucity" of reasons given by CPAM for refusing authorization for cross-border healthcare, fully correspond to a case in which a major doubt can be raised as to compliance with EU law.

6. Among the many arguments put forward by the parents, it seems to us that a very serious doubt is raised by the reasoning which CPAM provided when refusing to grant prior authorization. It should be recalled here that the case-law of the Court, which interprets the Directive 2011/24 and Regulation 883/2004 in a joint and cross-cutting manner, consistently emphasises that "the authorisation required cannot be refused if the ***same or equally effective treatment*** cannot be given in good time in the Member State of residence of the person concerned" (see, most recently, Court of Justice of the European Union, 29 October 2020, *A v. Veselības ministrija*, Case C-243/19, paragraph 28). And European Union case-law consistently states that:

> *"In order to assess whether such a treatment exists, the Court has stated that the competent institution is required* ***to have regard to all the circumstances of each***

> ***specific case, taking due account not only of the patient's medical condition at the time when authorisation is sought and, where appropriate, the degree of pain or the nature of the patient's disability, but also of his or her medical history*** (see, to that effect, judgments of 16 May 2006, *Watts*, C-372/04, EU:C:2006:325, paragraph 62; of 5 October 2010, *Elchinov*, C-173/09, EU:C:2010:581, paragraph 66; and of 9 October 2014, *Petru*, C-268/13, EU:C:2014:2271, paragraph 32)."

7. Relying on this well-settled case-law, which is based on procedural guarantees that are owed to patients, the Court stated in *A v. Veselības ministrija* (*supra*) that:

> *"It follows from that case-law that* ***the examination of all the circumstances of each specific case which must be taken into consideration in the light of Article 20(2) of Regulation No 883/2004****, in order to determine whether the same or equally effective treatment can be given in the insured person's Member State of residence, constitutes an objective medical assessment."*

8. In light of these considerations, it seems to us that a double misunderstanding of European Union law is potentially found in the situation of the child, Lysiane.

First of all the reasoning provided in CPAM's refusal letter dated 18 May 2017 merely repeats in a boilerplate manner the text of Art. R. 332-4 of the Social Security Code, stating, without any further explanation, and without any consideration of the patient's condition, that the same or equally effective treatment can be provided in France without undue delay. In our view such a justification totally contradicts the requirements set forth in the case-law of the Court of Justice of the European Union, which emphasizes that a prior authorization regime "cannot legitimise discretionary decisions taken by the national authorities" (*Watts*, paragraph 115), and that the reasoning must demonstrate "an objective medical assessment of the patient's medical condition, the history and probable course of his illness, the degree of pain he is in and/or the nature of his disability" (*Watts,* paragraph 119). In our opinion these factors alone are sufficient for the Lyon Judicial Court to uphold the appeal lodged by Lysiane and her parents, and to overturn CPAM's refusal to grant prior authorization.

9. Furthermore the serious disability from which Lysiane suffers warrants, in our opinion, special consideration, and more extensive reasoning. Based on the above-mentioned case-law, disability unquestionably constitutes an important factor in the evaluation, in particular by integrating the network of orphan diseases (Orphanet, to which the 2011 Directive refers). This special consideration must also be taken into account in light of the requirements of Article 21 of the Charter of Fundamental Rights of the European Union, which prohibits any discrimination based in particular (...) on disability.

10. In our view, the applicability of the Charter and the principle of non-discrimination to the case at hand increases the risk of a violation of European Union law and further supports the need for a preliminary reference to the Court of Justice of the European Union (or the finding, made directly by the judge, that CPAM's refusal was unlawful). Indeed, the principle of non-discrimination *"requires that comparable situations must not be treated differently and that different situations must not be treated in the same way unless such treatment is objectively justified. A difference in treatment is justified if it is based on an objective and reasonable criterion, that is, whether the difference relates to a legally permitted aim pursued by the legislation in question, and it is proportionate to the aim pursued by the treatment"* (a consistent principle, invoked in particular in *A v. Veselības ministrija, op. cit.,* paragraph 37).

Even if (which we strongly doubt) CPAM's reasoning was sufficiently clear in light of the requirements laid down by the case-law, there is nevertheless little doubt that by application of Article 21 of the Charter, the applicant, given her serious disability, is in a different situation from other patients, since the disability is congenital and could jeopardise the child's chances of survival at birth.

11. The gravity of the patient's disability constitutes in our view an objective and reasonable criterion which justifies more extensive reasoning and much stronger procedural safeguards when assessing a request for prior authorization for planned healthcare in another EU Member State on the basis of Article 20(2) of Regulation 883/2004.

12. In light of the foregoing, and taking due account of existing case-law, we consider that a very serious doubt is raised in the present case as to whether the procedure which CPAM followed when refusing prior authorisation (especially in terms of the reasoning given for the refusal) complies with the requirements of Regulation 883/2004. This doubt is all the more pronounced given that Article 21 of the Charter of Fundamental Rights justifies special attention and even differential treatment, based on the applicant's serious disability.

In our opinion these considerations justify the Lyon Judicial Court referring the arguments alleging infringement of European Union law to the Court of Justice of the European Union, in the form of a preliminary reference for interpretation.

Paris, 3 March 2025,

Professor Stéphane de la Rosa