Order for Reference

Order referring questions to the Court of Justice of the European Union for a Preliminary Ruling under Article 267 of the Treaty on the Functioning of the European Union, regarding the interpretation of Article 20 of EU Regulation (EC) No 883/2004, Articles 9 and 13 of the Directive 2011/24/EU, and Articles 20 and 21(1) of the Charter of Fundamental Rights of the European Union, considering that a decision on the questions is necessary to enable the referring Tribunal to give judgment in the present case.

Submitted by:
Le Tribunal Judiciaire de Lyon, Pôle Social, Contentieux Général, 67 rue Servient - CS 73816, 69433 Lyon CEDEX 03, France.
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Concerning case:
N° RG 19/00047, N° Portalis DB2H-W-B7D-TQUU (CG)

Plaintiffs
Lysiane Pakter and Ms. Delphine Beulné (mother), represented by Mr. Claude Lienhard, SCP Lienhard & Petitot, 21, rue des Francs-Bourgeois, 67000 Strasbourg, France.
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Defendant
La Caisse Primaire d'Assurance Maladie (CPAM) du Rhône, represented by Ms. Emmanuelle Lafoux, Directrice Générale, 69907 Lyon CEDEX 20, France.
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Contents

I. Subject Matter of The Dispute: Claim, and Defense

1. The plaintiff, Lysiane Elodie Pakter, is six years of age. She is represented by legal counsel, Mr. Claude Lienhard. On 2 May 2017, Lysiane's parents submitted to L'Assurance Maladie, France's national healthcare fund, an application, under Regulation 883/2004, requesting prior authorisation, an S2 document, for Lysiane to receive, in Germany, a highly specialized, medically proven, safe treatment for her rare disease, Pierre Robin Sequence, at an officially recognized Center of Expertise for Pierre Robin Sequence, the Tübingen University Hospital. L'Assurance Maladie refused to grant Lysiane the S2. Lysiane's family claims that France's refusal to grant Lysiane an S2 was legally unfounded; L'Assurance Maladie claims that the refusal was lawful.

II. Facts

2. Lysiane was born on 29 March 2017 in Croix-Rousse Hospital in Lyon, France. Lysiane suffered a dangerous and difficult birth. Emergency resuscitation efforts included manual ventilation assistance, which failed. In her 29th minute of life Lysiane was intubated and connected to a mechanical breathing machine. After six days in the Neonatal Resuscitation Unit, Lysiane was transferred to the Intensive Care Unit. She remained in the Intensive Care Unit, immobilized in her hospital bed, attached to a breathing machine, a feeding machine, and various tubes and monitors. She was diagnosed with a life-threatening rare disease called Pierre Robin Sequence. Pierre Robin Sequence is a rare condition where babies are born with a small lower jaw, have difficulties breathing (airway obstruction) and often have a cleft of the palate (an opening in the roof of the mouth). The breathing problems start either at birth or shortly after birth and are often also associated with feeding difficulties and problems with gaining weight. Babies born with Pierre Robin Sequence suffer from significant morbidity and significant mortality. They face a high risk, over 50%, of suffering from additional, associated conditions, as is the case with Lysiane. These associated conditions can have serious physical, intellectual, and neurological consequences, which can further complicate treatment.

3. For patients like Lysiane who suffer from a complex rare disease, it is vitally important to receive treatment at a Center of Expertise which specializes in treating patients with that rare disease. Croix-Rousse Hospital was not a Pierre Robin Sequence Center of Expertise. Her parents, after thorough research of their own, managed to locate a registered Center of Expertise, in Tübingen, Germany, by using the EU's Orphanet Rare Disease Database, as mentioned in Article 13(a) ("Rare diseases") of the Directive 2011/24/EU.

4. The type of treatment Lysiane needed was an oral medical device called a palatal plate. This type of treatment is offered in France; it is included in the French national healthcare system's basket of benefits. However, according to France's top expert on Pierre Robin Sequence, Dr. Véronique Abadie, the Coordinator of France's main Pierre Robin Sequence Orphanet Center of Expertise at Necker Hospital in Paris, the palatal plates offered in France do not resolve the baby's breathing difficulties. Dr. Abadie informed Lysiane's parents that Lysiane could obtain a palatal plate in France, from a certain French physician named Dr. Isabelle James, but that these French palatal plates have no effect on breathing – *"elles n'ont pas d'effet sur la ventilation"*[1]. Thus, if a Pierre Robin Sequence baby like Lysiane were to receive the French palatal plate, she would still need to remain attached to the mechanical breathing machine. In Germany, Pierre Robin Sequence experts at the Pierre Robin Sequence Center of Expertise at the Tübingen University Hospital have developed an advanced version of the palatal plate. The Tübingen palatal plate has been scientifically proven, in a series of internationally peer reviewed medical studies, using evidence-based medicine and objective criteria, including pre-treatment and post-treatment polysomnography, to safely resolve the baby's breathing difficulties, and to improve feeding and weight gain. Breathing difficulties, and feeding difficulties, are the two most serious problems facing babies with this rare disease; the Tübingen palatal plate addresses both problems. The French palatal plates have no effect on breathing.

[1] Exhibit 1, 28 April 2017, email from Dr. Véronique Abadie to Lysiane's family

5. Under the EU's social security coordination rules, patients like Lysiane, who wish to receive medical care in another EU country and receive reimbursement from their national healthcare fund, have to obtain an "S2" document. Lysiane's alleged right to receive cross-border treatment is based on EU Regulation (EC) No 883/2004 on the coordination of social security systems, EU Regulation (EC) No 987/2009 laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems, the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, and on the case-law of the Court. France, as member of the EU, has transposed the provisions of the Regulation and the Directive into its national legal system.

6. Concerning rare diseases in particular, the official French government website administered by Le Centre des liaisons européennes et internationales de sécurité sociale (CLEISS), states that "Patients affected or suspected of being affected by a rare disease have the right to access healthcare in another State of the European Union or the European Economic Area (Iceland, Liechtenstein and Norway) and to be reimbursed within the framework of Regulations (EC) No. 883/04 and No. 987/09, even if the diagnosis and/or treatment in question is not available in their State of affiliation". This text on the CLEISS website mirrors the text of Article 13(b) ("Rare diseases") of the Directive 2011/24/EU. At the time of submitting this request for a Preliminary Ruling, this same message can be found on the same page of this French government website[2].

7. On 2 May 2017, Lysiane's parents submitted an application for an "S2" document to France's L'Assurance Maladie, the French national healthcare fund, in order for Lysiane to receive a highly specialized rare disease treatment at the Orphanet Pierre Robin Sequence Center of Expertise in Tübingen, Germany[3]. Their application included hard copy color printouts of 4 internationally peer reviewed medical studies which scientifically demonstrated, using evidence-based medicine and objective criteria, the safety of this German rare disease treatment, and its proven efficacy in resolving the breathing difficulties of babies with Pierre Robin Sequence. These 4 studies in turn cited previous studies, dating back over a decade. Their application also included a letter providing further details about the highly specialized treatment, and how Lysiane in particular would benefit from it. The letter was issued by Professor Dr. Christian Poets, an internationally renowned Pierre Robin Sequence expert, and Coordinator of the Center of Expertise for Pierre Robin Sequence at the Tübingen University Hospital.

8. On 18 May 2017, L'Assurance Maladie rejected Lysiane's S2 application[4]. To justify the refusal, L'Assurance Maladie stated only the following: "I inform you that the medical evaluation department has determined: that the same treatment or equally effective treatment can be obtained in France without undue delay". The French treatment in question was not identified. No evidence was provided to support this statement that the unidentified French treatment was equally effective.

9. The refusal letter included the text of the French Social Security Code's Article R332-4 (version en vigueur du 27 avril 2005 au 24 mai 2014, Création Décret n°2005-386 du 19 avril 2005 - art. 3 JORF 27 avril 2005 et rectificatif JORF 18 juin 2005). However at the time of the refusal, Article R332-4 was already out of date by three years, and reflected French national law before France had transposed the Directive 2011/24/EU on the

[2] CLEISS website, rare diseases, https://www.cleiss.fr/particuliers/venir/soins/ue/maladies-rares.html
[3] Exhibit 2, the S2 application submitted by Lysiane's family
[4] Exhibit 3, 18 May 2017, S2 refusal letter from L'Assurance Maladie

application of patients' rights in cross-border healthcare. This suggests that L'Assurance Maladie, when refusing Lysiane's S2, did not consider the provisions or the requirements of the Directive 2011/24/EU, which codified many years of important decisions of this Court.

10. Because the German treatment was time-sensitive, Lysiane's family took out a bank loan, paid for the German treatment themselves, transferred Lysiane to the Tübingen University Hospital's Pierre Robin Sequence Center of Expertise, and then lodged an appeal against L'Assurance Maladie's refusal after the German treatment was underway.

11. As the peer-reviewed articles and the experts at Tübingen Hospital predicted, when Lysiane received the German treatment, she was liberated from the breathing machine, and safely discharged from the hospital after 19 days[5]. Before this, in France, Lysiane had spent 5 weeks in the Intensive Care Unit connected to a breathing machine, with no release date in sight.

12. On 20 July 2017 Lysiane's family registered a complaint, No. 2569/17/DE, with the European Commission's SOLVIT Network, an official EU body which assists EU citizens in disputes involving EU law; the EU's SOLVIT Network concluded that France's refusal to grant Lysiane an S2 violated Regulation 883/2004[6]. As required by SOLVIT, Lysiane's family continued pursuing domestic remedies in France.

13. On 23 June 2017, the parents filed their appeal against L'Assurance Maladie's decision. The appeal began with a so-called Expertise Médicale procedure. Their appeal argued that based on the international medical studies and the expert opinion included in Lysiane's S2 application, the German palatal plate was more effective for their daughter Lysiane, because it cured her breathing difficulties, unlike the French palatal plate, and also, it liberated her from the breathing machine.

14. In the Expertise Médicale procedure, a decision is delivered after a hearing by a committee of three experts. The medical expert appointed by the French authorities to chair the committee of experts was Dr. Isabelle James, the very same physician who produced the French palatal plates, and who therefore had a conflict of interest.

15. In the Expertise Médicale hearing, Lysiane's family was not requesting prior authorisation; they were contesting the refusal which had been issued by L'Assurance Maladie earlier in the year, on 18 May 2017. Therefore Lysiane's medical records, from birth, up to May 2017, were a key evidentiary component of the October 2017 Expertise Médicale hearing, because these medical records demonstrated Lysiane's medical condition in May 2017, when Lysiane's family submitted Lysiane's S2 application. The convocation letter which called upon Lysiane's family to attend the Expertise Médicale hearing specifically instructed Lysiane's family to bring Lysiane's medical records to the hearing: "certificats, radiographies, résultats d'analyses, etc". Lysiane's family sent a letter by certified mail, #1E00167889272, to Croix-Rousse Hospital on 8 August 2017 requesting Lysiane's medical records. According to French law, Croix-Rousse was required to provide the medical records within 8 days. They did not. On 11 September 2017, Lysiane's family sent a second letter to the hospital, again by certified mail, #1E00168671883, requesting

[5] Exhibit 4, 26 June 2017, letter from Tübingen University Hospital, discharging Lysiane without a breathing machine
[6] Exhibit 5, 2 August 2017, letter from EU SOLVIT, agreeing that Lysiane was entitled to receive an S2

Lysiane's medical records, and reminding the hospital of the 8-day legal time limit under French law.

16. Lysiane's medical records arrived on 20 October 2017, after 72 days, in spite of the 8-day limit defined by French law. As a result of these missing medical records, the Expertise Médicale hearing which was scheduled for 13 October 2017 had to be postponed. Subsequently, the French authorities would state that an Expertise Médicale hearing actually took place on 13 October 2017, and that Lysiane's family did not show up at the hearing.

17. Both Lysiane's family, and the lawyer representing Lysiane, sent several letters to Dr. Isabelle James requesting a hearing date that would permit them to study the medical records and prepare. However on 6 February 2018, L'Assurance Maladie informed Lysiane's family that the Expertise Médicale was complete; the Expertise Médicale rejected Lysiane's appeal[7].

18. On 3 April 2018, Lysiane's parents appealed to the Commission de Recours Amiable. They claimed that the decision of the Expertise Médicale lacked a proper assessment of the case because no hearing of the parents took place, the Expert Committee was not impartial, key evidence which was necessary to prepare for the hearing was not delivered for 72 days, one week after the 13 October 2017 hearing, when according to French law it should have been delivered in 8 days, and the Expert Committee's decision lacked any reasoning[8]. They also included formal letters of support from the European Organisation for Rare Diseases (EURORDIS), which state that the refusal was legally unfounded; from the European Patients' Forum, which characterized Lysiane's case as a "shocking situation", "an unfounded denial of patient's rights that violates both EU and French law"; and from a Member of European Parliament, Françoise Grossetête, who called it an "unacceptable situation", and "contrary to the laws in force". Ms. Grossetête, a lawyer trained in both French and EU law, is a recognized expert on planned cross-border healthcare in Europe; she had served as the Special Rapporteur for the EU's 2011 Patients' Rights Directive.

19. On 9 November 2018, the Commission de Recours Amiable rejected the appeal[9]. The complaints raised by the Applicant's parents were not addressed. None of the three above decisions of the administrative bodies addressed the question of whether the highly specialized rare disease treatment offered in Germany is more effective in the plaintiff's case than the treatment offered in France. No assessment was provided; no explanation was given. The authorities did not identify any available French treatment, nor did they provide any evidence or present any arguments as to how it was equally effective as the German treatment. The question of the right of a rare disease patient to access cross-border healthcare under EU law was not addressed by any of these decision-making bodies at any stage of this preliminary administrative procedure.

20. On 4 January 2019 Lysiane's family filed a lawsuit against L'Assurance Maladie in the Tribunal Judiciaire de Lyon, the first instance court in Lyon, France[10].

[7] Exhibit 6, 6 February 2018, letter from L'Assurance Maladie indicating that Lysiane's family lost the Expertise Médicale
[8] Exhibit 7, 3 April 2018, letter from Mr. Claude Lienhard to the CRA, appealing the Expertise Médicale
[9] Exhibit 8, 9 November 2018, letter from the CRA, rejecting the appeal
[10] Exhibit 9, 4 January 2019, Lysiane's family files a lawsuit in the Tribunal Judiciaire de Lyon

21. On 20 March 2023, after a delay of 4 years, 2 months, and 16 days, the first case hearing was held in the Tribunal Judiciaire de Lyon. This delay is the subject of a separate lawsuit which is currently being heard by the European Court of Human Rights.

22. At the first case hearing in the Tribunal Judiciaire de Lyon on 20 March 2023, Lysiane's lawyer, Mr. Claude Lienhard, submitted arguments to the court on behalf of Lysiane[11]. L'Assurance Maladie indicated to the court that L'Assurance Maladie needed time to respond to the arguments submitted on behalf of Lysiane. The court scheduled the second case hearing for 25 September 2023, half a year later. L'Assurance Maladie informed Lysiane's lawyer, Mr. Claude Lienhard, that L'Assurance Maladie would provide their written response by late July/early August[12]. L'Assurance Maladie actually delivered their response on 25 September 2023, at 8h51 in the morning, by email, nine minutes before the second case hearing began[13].

III. National Law

23. In the letter refusing to grant Lysiane an S2, L'Assurance Maladie included the text of the French Social Security Code's Article R332-4 (version en vigueur du 27 avril 2005 au 24 mai 2014, Création Décret n°2005-386 du 19 avril 2005 - art. 3 JORF 27 avril 2005 et rectificatif JORF 18 juin 2005)[14]. However at the time of the refusal, Article R332-4 was already out of date by three years, and reflected French national law before France had transposed the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare. R332-4:
https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000006749300/2005-04-27/

24. This suggests that L'Assurance Maladie, when refusing Lysiane's S2, did not consider the provisions or the requirements of the Directive 2011/24/EU, which codified many years of important decisions of this Court.

25. French law, in the version actually applicable to the main proceedings, was R160-2 of the Code de la sécurité sociale, which provided:

Article R160-2
Version en vigueur du 06 mai 2017 au 01 janvier 2019, Modifié par Décret n°2017-736 du 3 mai 2017 - art. 1
https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000034623135/2017-05-06/

I.-Les caisses d'assurance maladie ne peuvent procéder que sur autorisation préalable au remboursement des frais de soins dispensés aux personnes bénéficiaires de la prise en charge des frais de santé au titre des articles L. 160-1 et L 160-2 et aux personnes qui leur sont rattachées au sens des règlements européens dans un autre Etat membre de l'Union européenne ou partie à l'accord sur l'Espace économique européen ou en Suisse, dans le cadre d'un déplacement aux fins de recevoir un traitement adapté, lorsque ces soins :

1° Impliquent le séjour du patient concerné dans un établissement de soins pour au moins une nuit ; ou

[11] Exhibit 10, 20 March 2023, arguments submitted by Mr. Claude Lienhard on behalf of Lysiane, in the Tribunal Judiciaire de Lyon
[12] Exhibit 11, 28 March 2023, email from L'Assurance Maladie to Mr. Claude Lienhard, promising a response in July/August 2023
[13] Exhibit 12, 25 September 2023, 8h51, arguments submitted by L'Assurance Maladie on the morning of the second case hearing
[14] Exhibit 3, 18 May 2017, S2 refusal letter from L'Assurance Maladie

2° Nécessitent le recours aux infrastructures ou aux équipements médicaux hautement spécialisés et coûteux, qui figurent sur une liste établie par arrêté des ministres chargés de la sécurité sociale et de la santé.

II.-L'autorisation mentionnée au I ne peut être refusée lorsque les conditions suivantes sont réunies :

1° La prise en charge des soins envisagés est prévue par la réglementation française ;

2° Ces soins sont appropriés à l'état de santé du patient ;

3° Un traitement identique ou présentant le même degré d'efficacité ne peut pas être obtenu en France dans un délai acceptable sur le plan médical, compte tenu de l'état de santé actuel du patient et de l'évolution probable de son affection.

L'assuré social adresse la demande d'autorisation à sa caisse de rattachement. La décision est prise par le contrôle médical. Elle doit être notifiée dans un délai compatible avec le degré d'urgence et de disponibilité des soins envisagés et au plus tard deux semaines après la réception de la demande de l'intéressé ou, le cas échéant, de la demande de l'institution de l'Etat de résidence. En l'absence de réponse à l'expiration de ce dernier délai, l'autorisation est réputée accordée.

Les décisions de refus sont dûment motivées et susceptibles de recours dans les conditions de droit commun devant le tribunal des affaires de sécurité sociale compétent.
…

IV. European Union Legislation

26. Article 20 of Regulation 883/2004 provides:

Article 20
Travel with the purpose of receiving benefits in kind - Authorisation to receive appropriate treatment outside the Member State of residence

1. Unless otherwise provided for by this Regulation, an insured person travelling to another Member State with the purpose of receiving benefits in kind during the stay shall seek authorisation from the competent institution.

2. An insured person who is authorised by the competent institution to go to another Member State with the purpose of receiving the treatment appropriate to his condition shall receive the benefits in kind provided, on behalf of the competent institution, by the institution of the place of stay, in accordance with the provisions of the legislation it applies, as though he were insured under the said legislation. The authorisation shall be accorded where the treatment in question is among the benefits provided for by the legislation in the Member State where the person concerned resides and where he cannot be given such treatment within a time-limit which is medically justifiable, taking into account his current state of health and the probable course of his illness.

27. Article 9(4) of the Directive 2011/24/EU provides:

Article 9(4): Administrative procedures regarding cross-border healthcare

Member States shall ensure that individual decisions regarding the use of cross-border healthcare and reimbursement of costs of healthcare incurred in another Member State are properly reasoned and subject, on a case-by-case basis, to review and are capable of being challenged in judicial proceedings, which include provision for interim measures.

28. Article 13 of the Directive 2011/24/EU provides:

Article 13: Rare diseases

The Commission shall support Member States in cooperating in the development of diagnosis and treatment capacity in particular by aiming to:

(a) make health professionals aware of the tools available to them at Union level to assist them in the correct diagnosis of rare diseases, in particular the Orphanet database, and the European reference networks;

(b) make patients, health professionals and those bodies responsible for the funding of healthcare aware of the possibilities offered by Regulation (EC) No 883/2004 for referral of patients with rare diseases to other Member States even for diagnosis and treatments which are not available in the Member State of affiliation.

29. Articles 20 and 21(1) of the Charter of Fundamental Rights of the European Union provide:

Article 20: Equality before the law

Everyone is equal before the law.

Article 21: Non-discrimination

1. Any discrimination based on any ground such as sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation shall be prohibited.

V. Arguments of the Parties, and Reasons that Prompted the Order for Reference

30. The dispute raises three questions which must be resolved to enable the referring Tribunal to give judgment in the present case. The Court's existing case-law on planned cross-border healthcare in Europe does not appear to provide the necessary guidance in relation to a new set of facts: insured persons belonging to a particularly vulnerable patient group, those suffering from a rare disease.

31. **First question: differential treatment of an S2 application to access a rare disease treatment in Europe,**

32. The special challenges which rare disease patients face on the level of grave medical symptoms, and difficulties accessing care, were acknowledged in Recital 55 of the Directive 2011/24/EU:

33. *"Rare diseases are those that meet a prevalence threshold of not more than five affected persons per 10 000, in line with Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products, and they are all serious, chronic and often life threatening. Some patients affected by rare diseases face difficulties in their quest for a diagnosis and treatment to improve their quality of life and to increase their life expectancy, difficulties which were also recognised by the Council Recommendation of 8 June 2009 on an action in the field of rare diseases."*

    Recital 55 of the Directive 2011/24/EU

34. As reported in The Lancet, there are over 6,000 rare diseases that we know of today; 95% of them have no approved treatment or cure. Half of these rare diseases strike children; 30% of these children will die before they are five years old[15].

35. For approximately 5% of rare diseases, there are effective treatments or cures. These highly specialized rare disease treatments are often only available in certain geographically limited locations, at an officially designated Orphanet Center of Expertise, which focuses on treating patients with that particular rare disease. When one of these safe and effective rare disease treatments is not available in the EU Member State where the patient lives, Regulation 883/2004 allows that patient to access it where it is available, elsewhere in the European Union. Article 13(b) ("Rare diseases") of the Directive 2011/24/EU explicitly refers to this right under Regulation 883/2004, in the specific context of patients suffering from a rare disease.

36. Regulation 883/2004 can make a profound difference for a rare disease patient, by allowing them to access a highly specialized rare disease treatment which is not available where that patient lives, but which is available elsewhere in Europe.

37. EU-funded research conducted by the European Organization for Rare Diseases (EURORDIS) reports that "24% of the rare disease sample declare that during the past 12 months they did not get the medical treatment they needed because the treatment was not available in their country… The difference with the general population is striking… The gap between the general population and rare disease patients was reported as even deeper in some countries"[16]. If the rare disease treatment is not available locally, and if the rare disease patient faces obstacles when trying to access it abroad, the result is "Unequal Care for European Rare Disease Patients", the title of this official report published by the EU's major, mainstream rare disease patient organization, EURORDIS.

38. The European Parliament's Committee on the Environment, Public Health and Food Safety has carried out multiple studies on cross-border healthcare in Europe. In a 2010 report, the Parliamentary Committee documented the challenges patients faced when trying to obtain

[15] The Lancet Diabetes Endocrinology. "Spotlight on Rare Diseases." *Lancet Diabetes Endocrinol*., 2019 Feb, vol. 7,2, p. 75.
[16] EURORDIS, Access to Treatment: Unequal Care for European Rare Disease Patients; a Rare Barometer Survey, February 2017.

prior authorisation; the Committee emphasized that "the case law [of the European Court of Justice] concerned not the authorisation procedure in itself, but the manner in which it has been abused to deny patients the right to travel to receive healthcare or to hinder the use of that right"[17].

39. Nine years later the same Parliamentary Committee carried out further research and determined that the challenges remained; in their 2019 report the Parliamentary Committee observed that "in a considerable number of Member States, the obstacles that patients encounter when dealing with health systems remain significant… in some Member States insurance companies have discriminated arbitrarily or created unjustified obstacles to the free movement of patients and services" and "expresses disappointment that a significant number of Member States have not effectively implemented the requirements for guaranteeing patients' rights"[18]. These obstacles affect all patients seeking access to planned cross-border healthcare, but they have a disproportionate impact on an already vulnerable patient group: patients suffering from a rare disease, who are trying access to a highly specialized treatment which is not available where they live.

40. In cases before the Court in which prior authorisation was refused, EU Member States have long argued that cross-border healthcare creates the risk of "seriously undermining a social security system's financial balance" (*Veselības*, C-243/19, ECLI:EU:C:2020:872, para 47; *Elchinov*, C-173/09, ECLI:EU:C:2010:581, para 42; *Smits and Peerbooms*, C-157/99, ECLI:EU:C:2001:404, para 72). However, the European Commission's official figures, based on data provided directly by EU Member States, indicate that the budgetary impact of planned cross-border healthcare under Regulation 883/2004, as a proportion of total national healthcare spending across Europe, is very low. In the year 2015, planned cross-border healthcare amounted to 0.05% of total healthcare spending across Europe[19]; in 2016, 0.03%[20]; in 2017, 0.03%[21]; in 2018, 0.02%[22]; in 2019, 0.02%[23]. In 2020, in the midst of the COVID-19 pandemic, the European Commission reports that planned cross-border healthcare decreased even further, to approximately 0.01%[24]. Setting aside the year 2020, and focusing instead on the preceding five years, the official EU figures indicate that the overall budgetary impact of planned cross-border healthcare, as a proportion of total national healthcare spending across Europe, is not only very low, but even before COVID-19 it was getting even lower, dropping down to 0.02%.

[17] European Parliament, Report A7-0307/2010, Recommendation for a second reading on the Council position at first reading with a view to the adoption of a directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare, November 2010.
[18] European Parliament, Resolution of 12 February 2019 on the implementation of the Cross-Border Healthcare Directive, 2018/2108(INI).
[19] European Commission, Coordination of social security systems at a glance, 2016 Statistical Report, Frederic De Wispelaere & Jozef Pacolet, Directorate-General for Employment, Social Affairs and Inclusion, Directorate D, Unit D/2, Social security coordination, Brussels, December 2016, p. 25
[20] European Commission, Coordination of social security systems at a glance, 2017 Statistical Report, Frederic De Wispelaere & Jozef Pacolet, Directorate-General for Employment, Social Affairs and Inclusion, Directorate D, Unit D/2, Social security coordination, Brussels, December 2017, p. 21.
[21] European Commission, Coordination of social security systems at a glance, 2018 Statistical Report, Frederic De Wispelaere, Lynn De Smedt & Jozef Pacolet, Directorate-General for Employment, Social Affairs and Inclusion, Directorate D, Unit D/2, Social security coordination, Brussels, December 2018, p. 16.
[22] European Commission, Coordination of social security systems at a glance, 2019 Statistical Report, Frederic De Wispelaere, Lynn De Smedt & Jozef Pacolet, Directorate-General for Employment, Social Affairs and Inclusion, Directorate D, Unit D/2, Social security coordination, Brussels, December 2019, p. 15.
[23] European Commission, Coordination of social security systems at a glance, 2020 Statistical Report, Frederic De Wispelaere, Lynn De Smedt & Jozef Pacolet, Directorate-General for Employment, Social Affairs and Inclusion, Directorate D, Unit D/2, Social security coordination, Brussels, November 2020, p. 17.
[24] European Commission, Coordination of social security systems at a glance, 2021 Statistical Report, Frederic De Wispelaere, Lynn De Smedt & Jozef Pacolet, Directorate-General for Employment, Social Affairs and Inclusion, Directorate D, Unit D/2, Social security coordination, Brussels, December 2021, p. 21.

41. Lysiane's parents emphasize that 0.02%, this two hundredths of one percent figure, is an aggregate figure; it represents the total cost of all planned cross-border healthcare under Regulation 883/2004, for all patients, not just for rare disease patients. Lysiane's parents also emphasize that in 2017, the year when L'Assurance Maladie refused to grant Lysiane an S2 to access the Tübingen palatal plate rare disease treatment in Germany, France's planned cross-border healthcare costs under Regulation 883/2004 were exactly in line with the EU average.

42. Thus: rare disease patients have a particularly strong need for planned cross-border healthcare, in order to access highly specialized treatments which are not available where they live – and the total cost associated with planned cross-border healthcare for rare disease patients amounts to an extremely small portion of total national healthcare spending in Europe.

43. The 2021 UN Resolution, "Addressing the challenges of persons living with a rare disease"[25], calls upon nations to eliminate gaps in coverage for rare disease patients. The UN 2030 Agenda's Sustainable Development Goals specifically identify rare disease patients as a vulnerable patient group, which merits special assistance. "The 2030 Agenda places emphasis on equality, and the commitments to leave no one behind, and to reach first those who are furthest behind, are founded on the human rights principles of equality and non-discrimination, and of prioritizing the vulnerable and marginalized in society... States should ensure, in particular, that the legal and policy framework addresses discrimination in access to health care and services, ensures effective access to medicines, therapies and technologies for all persons without discrimination, and protects the rights of persons living with rare diseases… and other vulnerable groups, including through the use of special measures where appropriate"[26].

44. In its case-law on planned cross-border healthcare in Europe, the Court has itself applied the principle of equal treatment and non-discrimination from the Charter of Fundamental Rights of the European Union (*Veselības*, C-243/19, ECLI:EU:C:2020:872). According to the principle of equal treatment, "comparable situations must not be treated differently", and on the other side of the coin, "different situations must not be treated in the same way" (*Veselības*, C-243/19, ECLI:EU:C:2020:872, para 37). This leads to the first question which the referring Tribunal submits to the Court.

45. Lysiane's parents argue that based on exclusively medical criteria – the fact that rare disease patients face grave health problems, have very limited treatment options, and are often very young and vulnerable children – a rare disease patient's S2 application should not be processed in the same way as an S2 application for dental care or eyeglasses or other routine healthcare services. They claim that based on the Charter's principle of equal treatment and non-discrimination, which is enshrined in Article 20 and 21(1), a Member State should consider a broader range of scientific evidence, and provide a more extensive justification, and meet a higher threshold of necessity and proportionality, when refusing to grant an S2 to a rare disease patient seeking access to a safe and effective treatment which is only available in another Member State of the European Union. In their 25

[25] United Nations, Addressing the challenges of persons living with a rare disease and their families, Resolution adopted by the General Assembly, Seventy-sixth session, 16 December 2021, document A/RES/76/132.
[26] United Nations, Report on universal health coverage and human rights; United Nations High Commissioner for Human Rights, submitted to 2019 session of the Economic and Social Council, 15 May 2019, E/2019/52.

September 2023 submission to the court, L'Assurance Maladie does not address EU law, or respond to these arguments. Thus the first question is:

46. ***Do Articles 20 and 21(1) of the Charter of Fundamental Rights of the European Union require that Member States adopt a presumption in favor of granting prior authorisation under Article 20(2) of Regulation 883/2004 in the case of a patient suffering from a rare disease who is seeking access to a highly specialized rare disease treatment which is offered at an Orphanet Center of Expertise in another EU Member State, but which is not available in the EU Member State where that patient lives?***

47. **<u>Second question: the minimum requirements of a refusal to issue an S2 to a rare disease patient,</u>**

48. Article 9(4) ("Administrative procedures regarding cross-border healthcare") of the Directive 2011/24/EU states that "Member States shall ensure that individual decisions regarding the use of cross-border healthcare and reimbursement of costs of healthcare incurred in another Member State are properly reasoned and subject, on a case-by-case basis, to review and are capable of being challenged in judicial proceedings, which include provision for interim measures".

49. The Court has consistently decided that refusals to grant prior authorisation must be properly reasoned (*Inizan*, C-56/01, ECLI:EU:C:2003:578, para 49; *Watts*, C-372/04, ECLI:EU:C:2006:325, para 117); this circumscribes the exercise of the national authorities' discretion, and helps to ensure that such discretion is not used arbitrarily.

50. Concerning France in particular, in *European Commission v. French Republic,* C-512/08, ECLI:EU:C:2010:579, the Court considered an excerpt from French government circular DSS/DACI/2005/235 of 19 May 2005, in which the French administration stated that:

> *"Reasons must, of course, be given for refusals. When prior authorisation is refused, the [Court of Justice] does not permit the decision not to inform the insured person specifically of the reasons why he is not allowed to obtain treatment in another Member State. Thus, the mere statement, without further details, that there exists treatment which could be provided in good time in France, cannot be considered sufficient having regard to the [Court of Justice's] requirements. If, therefore, the applicant is told that treatment having equivalent effect can be provided in France, the refusal must include the facts supporting that assertion."*
>
> *European Commission v. French Republic*, C-512/08, ECLI:EU:C:2010:579, para 5.

51. In the letter refusing to grant Lysiane an S2, L'Assurance Maladie stated only the following: "I inform you that the medical evaluation department has determined: that the same treatment or equally effective treatment can be obtained in France without undue delay". L'Assurance Maladie did not identify France's equally effective treatment. Also, L'Assurance Maladie did not provide any evidence to support the assertion that France's unidentified treatment is equally effective.

52. More than 6 years after Lysiane's S2 was refused, France's equally effective treatment remains unidentified. Also, L'Assurance Maladie has at no stage in the appeal process

provided any evidence to support the assertion that France's treatment, which remains unidentified, is equally effective.

53. Lysiane's family argues that based on the case-law of the Court, France's prior authorisation system must be "easily accessible and capable of ensuring that a request for authorisation will be dealt with objectively and impartially" (*Watts*, C-372/04, ECLI:EU:C:2006:325, para 116; *Smits and Peerbooms*, C-157/99, ECLI:EU:C:2001:404, para 90; *Müller-Fauré and van Riet*, C-385/99, ECLI:EU:C:2003:270, para 85). They argue that Lysiane's S2 refusal letter omits basic factual elements which are necessary to meet minimum standards of accessibility, objectivity, impartiality, transparency, and legal certainty. Lysiane's parents further argue that based on the text of French government circular DSS/DACI/2005/235 of 19 May 2005 (*European Commission v. French Republic*, C-512/08, ECLI:EU:C:2010:579, para 5), which reflects the French administration's own understanding of the Court's minimum requirements, Lysiane's S2 refusal "cannot be considered sufficient".

54. Lysiane's family further argues that since rare disease patients face grave health problems, have very limited treatment options, and are often very young and vulnerable children, a refusal to grant a rare disease patient an S2 to access a highly specialized treatment offered at an Orphanet Center of Expertise should provide more extensive and more detailed reasoning than a refusal to grant an S2 to access routine healthcare services for common medical conditions. They argue that this more onerous obligation to provide reasons when refusing a rare disease patient's S2 application flows from Articles 20 and 21(1) of the Charter of Fundamental Rights of the European Union. As the Court stated in *Veselības*, "different situations must not be treated in the same way" (*Veselības*, C-243/19, ECLI:EU:C:2020:872, para 37). The reason for refusing to grant an otherwise healthy patient an S2 to obtain a routine dental cleaning abroad is self-evident, because the same or equally effective treatment is certainly available locally. On the other hand, refusing to grant a rare disease patient an S2 to access a highly specialized treatment at an Orphanet Center of Expertise, which can dramatically improve her health and her quality of life, naturally calls for a more extensive and more detailed set of reasoning.

55. In their 25 September 2023 submission to the court, L'Assurance Maladie does not address EU law. They do make reference to French law, Article R160-2, the legislation which was actually applicable at the time of the refusal. L'Assurance Maladie agrees that according to Article R160-2, "Les décisions de refus sont dûment motivées". L'Assurance Maladie argues however that the 18 May 2017 letter from L'Assurance Maladie refusing to grant Lysiane an S2 was "perfectly reasoned" ("*parfaitement motivée*")[27].

56. The referring Tribunal requests clarity from the Court as to the minimum requirements of a refusal under Article 20(2) of Regulation 883/2004, read in conjunction with Articles 20 and 21(1) of the Charter of Fundamental Rights of the European Union, in the special context of a rare disease patient seeking access to a highly specialized treatment which is only offered at an Orphanet Center of Expertise in another EU Member State. Thus the second question is:

57. *Where a competent institution refuses to grant a rare disease patient an S2 to access a highly specialized treatment at an Orphanet Center of Expertise in another EU Member*

[27] Exhibit 12, 25 September 2023, 8h51, arguments submitted by L'Assurance Maladie on the morning of the second case hearing

State, on the basis that the Member State of affiliation offers a local treatment which is the same or equally effective, is it compatible with Article 20(2) of Regulation 883/2004 in conjunction with Articles 20 and 21(1) of the Charter of Fundamental Rights of the European Union for the Member State of affiliation to provide no reason as to how the unidentified local treatment is the same or equally effective as the treatment which the rare disease patient seeks to access abroad?

58. **Third question: prioritizing a less effective, local treatment for a rare disease.**

59. The type of rare disease treatment which Lysiane's parents sought with their S2 application was an oral medical device called a palatal plate. This type of treatment is offered in France; it is included in the French national healthcare system's basket of benefits. However, according to France's top expert on Pierre Robin Sequence, Dr. Véronique Abadie, the Coordinator of France's main Pierre Robin Sequence Orphanet Center of Expertise at Necker Hospital in Paris, the palatal plates offered in France do not resolve the breathing difficulties of babies suffering from this rare disease; she stated that the French palatal plates "have no effect on breathing"[28]. Thus if Lysiane were to receive the French palatal plate, she would still need to remain attached to a mechanical breathing machine, because the French palatal plates have no effect on breathing.

60. Dr. Véronique Abadie's conclusion, as France's top expert on this rare disease, mirrored the findings of established international scientific research which had compared the advanced palatal plates proposed in Tübingen Germany, to conventional palatal plates[29]. This internationally peer reviewed medical study, which relied on evidence-based medicine, and objective criteria – polysomnography exams before and after treatment – had scientifically demonstrated that the advanced palatal plates administered in Tübingen significantly reduced upper airway obstruction in babies with Pierre Robin Sequence, while the conventional palatal plates – the kind which were available in France – did not reduce upper airway obstruction at all.

61. When it comes to protecting the life and health of individuals, the European Court of Human Rights places a special emphasis on children (see notably *Vavřička and Others v. the Czech Republic* [GC], no. 47621/13, judgment of 8 April 2021, para 282), and obliges states to "to place the best interests of the child, and also those of children as a group, at the center of all decisions affecting their health and development" (para 288). Lysiane's parents argue that their child Lysiane was in need of urgent medical care for a serious condition. She was diagnosed right after birth with a life-threatening rare disease. For babies like Lysiane who suffer from a complex rare disease, it is vitally important to receive treatment as soon as possible at an Orphanet Center of Expertise which specializes in treating patients with that rare disease. Absent treatment that would resolve her breathing difficulties, Lysiane would have remained immobilized in the hospital bed, attached to a mechanical breathing machine, for a considerable amount of time, during a sensitive period of the baby's life which is crucial for her long-term development. Immobilization always has dire consequences, but especially so for a baby.

[28] Exhibit 1, 28 April 2017, email from Dr. Véronique Abadie to Lysiane's family
[29] Exhibit 13, 27 February 2007, medical study, Buchenau et al. "A randomized clinical trial of a new orthodontic appliance to improve upper airway obstruction in infants with Pierre Robin sequence." *The Journal of pediatrics* vol. 151,2 (2007): 145-9.

62. France's routine of attaching Lysiane to a mechanical breathing machine also forced her mother and her father to accept the hospital's Intensive Care Unit as their second home. Lysiane's parents argue that while the French authorities did not forcibly attach Lysiane to the mechanical breathing machine, they were the ones who could help her getting released from it, by facilitating access to a highly specialized treatment at an Orphanet Center of Expertise in Germany, which would relieve both Lysiane and her parents from a prolonged existence in this dire state.

63. Lysiane's parents argue that since France covers the palatal plate treatment for babies suffering from the rare disease, Pierre Robin Sequence, L'Assurance Maladie was obliged to grant Lysiane an S2 to obtain this type of treatment in Germany, where a more advanced, more effective version of this treatment was available. They argue that by refusing to grant Lysiane an S2, L'Assurance Maladie was, directly or indirectly, prioritizing the less effective palatal plates offered in France. They argue that such discrimination based on the nationality of the service provider – German, versus French – violates the most basic principles on which the EU is based. It also condemned Lysiane to remain attached to a mechanical breathing machine, a condition of dramatically reduced mobility, and extended hospitalization, without any scheduled date of release. This made normal life for the baby, and professional activities for the parents, impossible.

64. Lysiane's parents refer to Article 20(2) of Regulation 883/2004, which states that "The authorisation shall be accorded where the treatment in question is among the benefits provided for by the legislation in the Member State where the person concerned resides and where he cannot be given such treatment within a time-limit which is medically justifiable, taking into account his current state of health and the probable course of his illness." They also refer to the consistent case-law of the Court, which has decided 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" (*Veselības*, C-243/19, ECLI:EU:C:2020:872, para 28; *Elchinov*, C-173/09, ECLI:EU:C:2010:581, para 65; *Watts*, C-372/04, ECLI:EU:C:2006:325, para 61; *Inizan,* C-56/01, ECLI:EU:C:2003:578, paras 45 and 60; *Smits and Peerbooms*, C-157/99, ECLI:EU:C:2001:404, para 103). The palatal plate treatment is covered by L'Assurance Maladie, and the palatal plate treatment offered in France is not "the same or equally effective", since it does not resolve the baby's breathing difficulties. Therefore, according to Lysiane's parents, L'Assurance Maladie should have granted Lysiane an S2.

65. Lysiane's parents state that their position mirrors that of Advocate General Cruz Villalón, in the Opinion he delivered in the *Elchinov* case: "If a Member State wishes to be at the cutting edge of medical treatment (which naturally requires time), European Union law allows its citizens to receive in another Member State treatment which the former State wishes to make available to them domestically, although not at present in a position to do so. Further, where a State provides for a particular treatment in its national legislation, an attempt to prevent the receipt of that treatment in another Member State is not only contrary to the rules governing the internal market but also contributes to the fragmentation of the healthcare sector, which requires cooperation and the sharing of professional resources, expertise and skills" (*Elchinov*, C-173/09, Opinion of Mr Advocate General Cruz Villalón, ECLI:EU:C:2010:336, para 72). Lysiane's parents argue that "cooperation and the sharing of professional resources, expertise and skills" is especially important in the area of complex rare diseases, because no country alone has the knowledge and capacity to treat every single rare disease.

66. In 2019, Stanford University began offering the Tübingen palatal plate to American babies. Harvard University soon followed. In 2022 and 2023 two teams of French clinicians, the first team from Nantes, and the second team from Paris, traveled to Germany and underwent medical training at the Tübingen University Hospital, so that they could return to France and eventually administer this highly specialized rare disease treatment, the Tübingen palatal plate, to French babies. Lysiane's parents welcome these developments, but they argue that until such time that the Tübingen palatal plate is offered in Nantes, or is offered in Paris, L'Assurance Maladie cannot prevent French babies with this rare disease from accessing this highly specialized treatment where it is available, in Germany, and prioritize France's own less effective version of this treatment.

67. The Court's decision in *Smits and Peerbooms* (C-157/99, ECLI:EU:C:2001:404) provides guidance on evaluating the effectiveness and scientific basis of one medical treatment in relation to another. The effectiveness of a medical treatment must be evaluated based on whether it has been "sufficiently tried and tested by international medical science" (para 94), and this evaluation "must take into consideration all the relevant available information, including, in particular, existing scientific literature and studies, the authorised opinions of specialists and the fact that the proposed treatment is covered or not covered by the sickness insurance system of the Member State in which the treatment is provided" (para 98).

68. According to Lysiane's parents, the four internationally peer reviewed medical studies which were included in Lysiane's S2 application demonstrated using evidence-based medicine that the highly specialized Tübingen palatal plate sought by Lysiane's parents had successfully treated hundreds of babies suffering from the rare disease, Pierre Robin Sequence, over a period spanning more than 15 years; it was endorsed by one of the world's most renowned experts on Pierre Robin Sequence, Dr. Christian Poets; and it was covered by the sickness insurance system in Germany, where the treatment is provided. Lysiane's parents argue that these factors supported a finding of scientific validity and effectiveness using the Court's criteria as presented in *Smits and Peerbooms*.

69. However, Lysiane's parents argue that rare disease patients face special challenges in terms of the gravity of their symptoms, their limited treatment options, and the fact that rare diseases disproportionately strike young children. These special challenges call for enhanced vigilance and increased scrutiny when evaluating and comparing treatments. They point out that the majority of rare diseases are complex conditions with a genetic basis; for exceedingly few rare diseases patients does medical science currently offer a full and complete cure. The best scenario which many rare disease patients and their families can hope for is a treatment which safely relieves symptoms, or which halts the progression of a degenerative disease, or which meaningfully improves the patient's quality of life, which is vitally important for both the rare disease patient and the family. Lysiane's parents argue that the Charter's principle of equal treatment and non-discrimination obliges EU Member States to take these factors into account when comparing the effectiveness of a highly specialised rare disease treatment which is only available abroad, at an Orphanet Center of Expertise, vis-à-vis the conventional treatment, if any, which local doctors are able to offer at home.

70. In the 25 September 2023 arguments which L'Assurance Maladie submitted to the court in Lysiane's case, L'Assurance Maladie did not address any aspect of EU law, or make reference to any of the Court's case-law as cited by Lysiane's family.

71. While the Court's decisions in *Elchinov* and *Smits and Peerbooms* and related cases provide the referring Tribunal with guidance as to the interpretation of Article 20(2) of Regulation 883/2004, Lysiane's case involves a new set of facts: the patient concerned is a patient diagnosed with a rare disease, seeking access to a highly specialised rare disease treatment which is not available in her Member State of affiliation. Thus the third question concerning the manner in which EU law is to be interpreted and applied is:

72. Must Article 20(2) of Regulation 883/2004 in conjunction with Articles 20 and 21(1) of the Charter of Fundamental Rights of the European Union be interpreted as meaning that where a rare disease patient seeks access to a type of treatment which is included among the benefits provided for by the Member State of affiliation, that the competent institution is precluded from prioritizing its own less effective version of that treatment, by refusing to grant an S2 to access a more effective version offered at an Orphanet Center of Expertise in another EU Member State?

VI. Questions Referred to the Court of Justice of the European Union

73. Do Articles 20 and 21(1) of the Charter of Fundamental Rights of the European Union require that Member States adopt a presumption in favor of granting prior authorisation under Article 20(2) of Regulation 883/2004 in the case of a patient suffering from a rare disease who is seeking access to a highly specialized rare disease treatment which is offered at an Orphanet Center of Expertise in another EU Member State, but which is not available in the EU Member State where that patient lives?

74. Where a competent institution refuses to grant a rare disease patient an S2 to access a highly specialized treatment at an Orphanet Center of Expertise in another EU Member State, on the basis that the Member State of affiliation offers a local treatment which is the same or equally effective, is it compatible with Article 20(2) of Regulation 883/2004 in conjunction with Articles 20 and 21(1) of the Charter of Fundamental Rights of the European Union for the Member State of affiliation to provide no reason as to how the unidentified local treatment is the same or equally effective as the treatment which the rare disease patient seeks to access abroad?

75. Must Article 20(2) of Regulation 883/2004 in conjunction with Articles 20 and 21(1) of the Charter of Fundamental Rights of the European Union be interpreted as meaning that where a rare disease patient seeks access to a type of treatment which is included among the benefits provided for by the Member State of affiliation, that the competent institution is precluded from prioritizing its own less effective version of that treatment, by refusing to grant an S2 to access a more effective version offered at an Orphanet Center of Expertise in another EU Member State?

List of Exhibits

Exhibit 1, 28 April 2017, email from Dr. Véronique Abadie to Lysiane's family

Exhibit 2, the S2 application submitted by Lysiane's family

Exhibit 3, 18 May 2017, S2 refusal letter from L'Assurance Maladie

Exhibit 4, 26 June 2017, letter from Tübingen University Hospital, discharging Lysiane without a breathing machine

Exhibit 5, 2 August 2017, letter from EU SOLVIT, agreeing that Lysiane was entitled to receive an S2

Exhibit 6, 6 February 2018, letter from L'Assurance Maladie indicating that Lysiane's family lost the Expertise Médicale

Exhibit 7, 3 April 2018, letter from Mr. Claude Lienhard to the CRA, appealing the Expertise Médicale

Exhibit 8, 9 November 2018, letter from the CRA, rejecting the appeal

Exhibit 9, 4 January 2019, Lysiane's family files a lawsuit in the Tribunal Judiciaire de Lyon

Exhibit 10, 20 March 2023, arguments submitted by Mr. Claude Lienhard on behalf of Lysiane, in the Tribunal Judiciaire de Lyon

Exhibit 11, 28 March 2023, email from L'Assurance Maladie to Mr. Claude Lienhard, promising a response in July/August 2023

Exhibit 12, 25 September 2023, 8h51, arguments submitted by L'Assurance Maladie on the morning of the second case hearing

Exhibit 13, 27 February 2007, medical study, Buchenau et al. "A randomized clinical trial of a new orthodontic appliance to improve upper airway obstruction in infants with Pierre Robin sequence." The Journal of pediatrics vol. 151,2 (2007): 145-9.