REPORT FOR THE HEARING
in Joined Cases E-11/07 and E-1/08

REQUESTS to the Court under Article 34 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice by Borgarting lagmannsrett (Borgarting Court of Appeal) and Oslo tingrett (Oslo District Court), Norway, in cases pending before them between

Olga Rindal (Case E-11/07);

Therese Slinning, represented by legal guardian Olav Slinning (Case E-1/08)

and

The Norwegian State, represented by the Board of Exemptions and Appeals for Treatment Abroad (Case E-11/07 and Case E-1/08);

concerning the interpretation of the rules on the free movement of services in the European Economic Area, in particular the interpretation of Articles 36 and 37 of the EEA Agreement, and of Article 22 of Council Regulation (EEC) No 1408/71 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community, as adapted to the EEA Agreement by Protocol 1 thereto.[1]

I Introduction

1. By a letter dated 14 December 2007, registered at the Court on 19 December 2007 as Case E-11/07, Borgarting lagmannsrett made a request for an Advisory Opinion in a case pending before it between Olga Rindal and the Norwegian State, represented by the Board of Exemptions and Appeals for Treatment Abroad.

2. By a letter dated 16 January 2008, registered at the Court on 21 January 2008 as Case E-1/08, Oslo tingrett made a request for an Advisory Opinion in a case pending before it between Therese Slinning and the Norwegian State, represented by the Board of Exemptions and Appeals for Treatment Abroad. As of 9 April 2008, the name of the Board is "the Board of Appeals for Treatment Abroad". The Board will hereinafter be referred to as "the Board of Appeals".

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[1] OJ 1971 L 149, p. 2.

3. By a decision of 18 February 2008, the Court, pursuant to Article 39 of the Rules of Procedure and after having received observations from the parties, joined the two cases for the purposes of the written and oral procedures.

4. The Appellant, and respectively the Plaintiff, in both cases claim from the Norwegian State reimbursement of expenses for medical treatment in another EEA State.

II Legal background

EEA law

5. Article 36(1) of the Agreement on the European Economic Area (hereinafter "the EEA Agreement" or "EEA") reads as follows:

> *1. Within the framework of the provisions of this Agreement, there shall be no restrictions on freedom to provide services within the territory of the Contracting Parties in respect of nationals of EC Member States and EFTA States who are established in an EC Member State or an EFTA State other than that of the person for whom the services are intended.*

6. Article 37 EEA reads as follows:

> *Services shall be considered to be 'services' within the meaning of this Agreement where they are normally provided for remuneration, in so far as they are not governed by the provisions relating to freedom of movement for goods, capital and persons.*
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> *'Services' shall in particular include :*
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> *(a) activities of an industrial character;*
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> *(b) activities of a commercial character;*
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> *(c) activities of craftsmen;*
>
> *(d) activities of the professions.*
>
> *Without prejudice to the provisions of Chapter 2, the person providing a service may, in order to do so, temporarily pursue his activity in the State where the service is provided, under the same conditions as are imposed by that State on its own nationals.*

7. 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 (hereinafter "Regulation 1408/71") is referred to at point 1 of Annex VI to the EEA Agreement. The Regulation is adapted to the EEA Agreement by way of Protocol 1 thereto and the adaptations contained in Annex VI.

8. Article 22, paragraphs 1 and 2 of Regulation 1408/71 read as follows:

> *1. An employed or self-employed person who satisfies the conditions of the legislation of the competent State for entitlement to benefits, taking account where appropriate of the provisions of Article 18, and:*
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> *(a) (…)*
>
> *(b) (…)*
>
> *(c) who is authorised by the competent institution to go to the territory of another Member State to receive there the treatment appropriate to his condition,*
>
> *shall be entitled:*
>
> *(i) to benefits in kind provided on behalf of the competent institution by the institution of the place of stay or residence in accordance with the legislation which it administers, as though he were insured with it; the length of the period during which benefits are provided shall be governed however by the legislation of the competent State;*
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> *(ii) to cash benefits provided by the competent institution in accordance with the legislation which it administers. However, by agreement between the competent institution and the institution of the place of stay or residence, such benefits may be provided by the latter institution on behalf of the former, in accordance with the legislation of the competent State.*
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> *2. (…)*
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> *The authorisation required under paragraph 1 (c) may not be refused where the treatment in question is among the benefits provided for by the legislation of the Member State on whose territory the person concerned resided and where he cannot be given such treatment within the time normally necessary for obtaining the treatment in question in the Member State of residence taking account of his current state of health and the probable course of the disease.*

National law

9. In Norway, the conditions for coverage of expenses for medical treatment abroad are regulated by Section 2–1 of Act of 2 July 1999 No 63 on the Rights of Patients (hereinafter the "Patients' Rights Act"), and by Regulation of 1 December 2000 No 1208 on Prioritisation of Health Services and the Right to Health Care from the Specialist Health Service, on the Right to Treatment Abroad and a Board of Exemptions and Appeals, as amended by

Regulation of 7 July 2004 No 1121 (hereinafter the "Prioritisation Regulation")[2].

10. The main requirement for the right to treatment in Norway and abroad is the same: the patient must be entitled to "necessary health care". The conditions for entitlement to necessary health care are based on the connection between the seriousness of the patient's medical condition, the possibility of improving it through health care and the cost effectiveness of the health care. The second, fourth and fifth paragraph of Section 2–1 of the Patients' Rights Act read as follows:

> *Section 2-1. The right to necessary health care*
>
> *(…)*
>
> *The patient is entitled to receive necessary health care from the specialist health service. This right only applies if the patient can be expected to get the anticipated benefit from the health care, and the costs are reasonable in relation to the effect of the measure. The specialist health service shall, based on medical considerations, set a time limit within which a person with such a right shall receive necessary health care.*
>
> *(…)*
>
> *If the regional health undertaking has not ensured that a patient who is entitled to necessary health care from the specialist health service receives such care within the time limit fixed pursuant to the second paragraph, the patient has the right to receive necessary health care without delay, if necessary from a private service provider or service provider outside the Realm.*
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> *If the regional health undertaking cannot provide health care to a patient who is entitled to necessary health care, because there are no adequate medical services in the Realm, the patient has the right to receive necessary health care from a service provider outside the Realm within the time limit fixed pursuant to the second paragraph.*
>
> *(…)*

11. The more precise conditions for entitlement to health care follow from Section 2, first paragraph of the Prioritisation Regulation:

> *The patient is entitled to necessary health care from the specialist health service pursuant to Section 2–1, second paragraph of the Patients' Rights Act, when:*

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[2] The amendments by the 2004 Regulation, as well as some amendments to the Patients' Rights Act which took effect in 2004, apply only to the facts of Case E-1/08, but the relevant provisions for Case E-11/07 are identical in substance according to Borgarting lagmannsrett and the parties. Only the amended provisions applying to Case E-1/08 are reproduced for the purpose of this Report for the Hearing.

> *1. the patient will have a certain deterioration of prognosis in regard to life expectancy or a not insignificant decrease in quality of life if the health care is postponed and*
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> *2. the patient can be expected to get the anticipated benefit from the health care, with the exception mentioned in Section 3 second paragraph, and*
>
> *3. the expected costs are reasonable in relation to the effect of the measure.*

12. The second condition concerning anticipated benefit is clarified in Section 2, third paragraph of the Prioritisation Regulation:

> *By anticipated benefit of the health care, it is meant that there is sufficient documentation*[3] *that active medical treatment can improve the patient's life expectancy or quality of life for a certain duration, that the [patient's] state of health can worsen without treatment or that possibilities for treatment would be lost by postponement of the treatment.*

According to the Government bill, this is to be understood in the way that entitlement to necessary health care does not include experimental or test treatment. Beyond the right to necessary health care, Section 3, second paragraph of the Prioritisation Regulation states that "individual patients with rare diseases" may, in special cases, get coverage for experimental or test treatment abroad. "Experimental treatment" is defined as "undocumented treatment which is not part of a controlled study, and where effects, risks and adverse effects are unknown or incompletely elucidated". "Test treatment" is defined as "treatment which is being tested as part of a scientific study, but where the requirements of fully adequate documentation, as compared to recognised treatment, have not yet been fulfilled". The third paragraph of Section 3 defines "rare diseases" as diseases/conditions which occur so rarely, and/or are so exceptional, that no national medical competence has been developed.

13. Section 3, first paragraph of the Prioritisation Regulation (*Health care abroad due to lack of medical competence in Norway*) reads as follows:

> *A patient who is entitled to necessary health care, but who cannot get health care because the treatment cannot be provided properly in Norway according to accepted methods, is entitled to health care abroad, cf. Section 2–1, fifth paragraph of the Patients' Rights Act. It is a precondition that the health care can be provided properly by the service provider abroad according to accepted methods and that the patient's condition and the specific treatment fulfil the requirements in Section 2.*

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[3] The original term in Norwegian is "god dokumentasjon". In the Defendant's view, this term implies that there always has to be a certain level of documentation. The Defendant has therefore suggested that a more appropriate translation would be "well documented".

14. The legislature's justification for why treatment should be carried out primarily in Norway is expressed *inter alia* in Ot.prp. No 53 (1996–97) p. 10:

> *In the consultation paper, the Ministry based itself on the premise that the overriding goal of Norwegian health policy is that the country to the highest possible degree shall be self-sufficient with health services, including hospital treatment. The starting point must therefore be that the population in Norway is to rely on domestic offers of treatment, both regarding medical competence, treatment capacity and prioritisation.*

15. Regarding patients who have an immediate entitlement to treatment abroad according to the fifth paragraph of Section 2–1, the Government bill explains that this rule will apply when there is a lack of medical competence in Norway. The following is stated in Ot.prp. No 63 (2002–2003) p. 61:

> *The patient will not be entitled to necessary health care abroad if a recognised treatment exists in Norway, even if a possibly more advanced treatment has been developed abroad.*

16. In accordance with Section 2–4 of the Patients' Rights Act, a patient who is entitled to necessary health care domestically may choose the institution which will administer his treatment. It is a precondition that the institution chosen is owned by one of the public regional health undertakings or has entered into an agreement with one of them, and is thus insofar a part of the Norwegian public health service. The institution may refuse patients from other regions in order to give priority to local patients. The following is stated in Ot.prp. No 12 (1998–99) p. 48:

> *It is an objective to ensure increased co-determination for the patients, improved service, and to unite the values of equality with increased freedom of choice, at the same time as the control over the total health budgets and the objective of geographical distribution of the health services are maintained.*

According to the written observations of the Defendant, relatively few patients wish to receive treatment in non-local hospitals, whereas the vast majority of patients prefers their local hospital or a hospital in their health region.

III Facts and procedure

Facts and Procedure in Case E-11/07

17. The Plaintiff in Case E-11/07, Olga Rindal, was diagnosed with whiplash after having suffered a severe automobile accident in 1987. Starting in 1989, severe back pain also began to afflict her. As of 1 April 1999, she has been drawing a 100% disability pension. In spite of different forms of treatment, including surgery in May 1999, her back pain did not go away. In 2000, the final specialist report on her condition concluded that further surgical

treatment was not indicated, given the high risk which theoretically possible surgery would entail for this patient. Therefore, no further surgery was offered to Ms. Rindal. Instead, she continued to receive treatment which she already had received without satisfying results over time.

18. In March 2001, Ms. Rindal was referred by her attending physician to the private clinic of Dr. Montazem in Germany, where she received surgical treatment in July and September 2001. The operations consisted of the fixation of the neck and the stabilisation of the lower back through the use of titanium plates. Ms. Rindal feels that both operations have improved her state of health.

19. On 28 August 2002, the Board of Appeals upheld a decision by the National Insurance Administration to reject her application for coverage of the expenses for the operations, concerning a sum of NOK 316 814 in total. The decisive argument in the Board of Appeals' decision was that medical competence existed in Norway to examine and treat this type of neck and back injuries, and therefore the conditions for coverage of treatment abroad were not found to be fulfilled.

20. Ms. Rindal filed a lawsuit in the Oslo tingrett and submitted, *inter alia*, that the decision was contrary to EEA law. In its judgment from 17 February 2006, that court ruled in favour of the Norwegian State. It agreed with the findings made by the Board of Appeal and stated *inter alia* that while immobilization of the neck was an operation which was also performed to a relatively large degree in Norway, it was not performed on the basis of Ms. Rindal's indications. Oslo tingrett also rejected Ms. Rindal's submission that the decision was contrary to EEA law. With regard to the neck operation, it stated, in particular, that there was scant documentation and that the method could not be considered to be the norm in international medical circles applied in relation to the indications which Ms. Rindal had. With regard to the back operation, Oslo tingrett found that Ms. Rindal was not entitled to a new operation in Norway at the relevant point of time, and that therefore there was no entitlement to coverage of expenses related to the operation abroad.

21. Ms. Rindal appealed the judgment of Oslo tingrett to Borgarting lagmannsrett. On 19 February 2007, Borgarting lagmannsrett decided to request an Advisory Opinion from the Court. By letter of 14 December 2007, it referred the following questions:

> **1. Is it compatible with Articles 36 and 37 of the EEA Agreement and Article 22 of Council Regulation (EEC) No 1408/71 to refuse coverage of expenses for treatment abroad which according to international medicine must be considered experimental or test treatment, when there is no entitlement to such treatment in the home State?**

2. Is it of significance for the answer to Question No 1 that the method of treatment itself is internationally recognised and documented, but where this only applies to other medical indications than those which the patient in question has?

3. Is it compatible with Articles 36 and 37 of the EEA Agreement to refuse coverage of expenses for hospital treatment abroad if the patient in the home State can receive an offer of adequate medical treatment assessed according to accepted international methods within a medically justifiable time limit?

Is it of significance for the answer to Question No 3 whether coverage of such expenses may be refused even if the treatment abroad is considered as possibly more advanced than the treatment in the home State?

4. Is it of significance for the answers to the questions above whether

a) the home State as a matter of fact does not offer the treatment received abroad?

b) the patient as a matter of fact has not been offered the treatment in question in the home State even if the treatment is offered there?

c) the patient has been assessed in the home State, but has not been given the offer of further surgical treatment because the patient is not considered to get documented benefit from the treatment?

d) the treatment given abroad actually resulted in an improvement of the specific patient's state of health?

Facts and Procedure in Case E-1/08

22. The Plaintiff in Case 1/08, Ms. Therese Slinning, sustained a serious brain injury in a traffic accident in March 2002. Early on, it was presumed that she would not survive, and therefore in the beginning it was not considered appropriate to offer her rehabilitation at a specialised hospital. She was admitted to the hospital "Diakonhjemmet" in order to receive end-of-life care with dignity.

23. From September 2002 to May 2004, Ms. Slinning lived mostly in a nursing home mainly equipped for elderly people. In October 2003, she stayed for four weeks as an in-patient in Sunnaas hospital, which is Norway's largest specialised hospital in the field of rehabilitation and physical medicine. This stay was mostly for the purpose of assessment of Ms. Slinning's further treatment arrangements. In May 2004, she moved to Stigenga Living and

Rehabilitation Centre. The parties before the national court hold different views on the character and scope of treatment Ms. Slinning has received in Norway, especially whether she has received proper rehabilitation treatment.

24. From 15 March 2005 to 9 May 2005, Ms. Slinning underwent treatment at Hammel Neurocenter in Denmark, for which she paid DKK 390 000. At the time of the treatment, the rehabilitation arrangement at Hammel was not on offer in Norway.

25. Ms. Slinning's application for coverage of her expenses at Hammel Neurocenter from December 2004 was rejected by the Office for Hospital Treatment at Ullevål University Hospital by decision of 15 March 2005. On appeal, the rejection was upheld by the Board of Appeals on 28 September 2005. The Board of Appeals based its decision on two sets of grounds. Firstly, it stated that there was adequate available treatment for Ms. Slinning in Norway, even though the treatment offered at Hammel Neurocenter was more comprehensive and intensive than that offered at Sunnaas Hospital. The Board found that the treatment available in Norway ought, as a main rule, to be utilised even if a possibly more advanced treatment had been developed abroad. Secondly, the Board of Appeals considered the treatment at Hammel to be experimental/test treatment, and that it could not be said to be scientifically documented. According to the assessment of the Board of Appeals, the right to treatment abroad did not encompass experimental/test treatment.

26. In the application procedure, Dr. Berstad at Sunnaas Hospital, Dr. Solgaard at Ullevål University Hospital and the Directorate for Health and Social Affairs assessed the treatment at Hammel Neurocenter as experimental/test treatment, and not scientifically documented. Furthermore, both experts stated that there is competence for the rehabilitation of head injuries in Norway. Nevertheless, Dr. Berstad found the treatment at Hammel Neurocenter to be better than what was available in Norway, and considered it as serious and adequate treatment which is internationally recognized. Dr. Solgaard considered the treatment at Hammel as being not the same as the one in Norway, and recommended that Slinning be treated there. According to the written observations of the Government of Denmark, all patients in Denmark have a right to be referred to this rehabilitation service, provided that they meet the indication criteria. However, it also follows from the observations of the Government of Denmark that the conditions for access to treatment in Denmark are somewhat different from those in Norway; in particular, insofar that patients in Denmark may, under certain circumstances, also receive experimental or test treatment. In the course of 2006–2007, efforts were made to establish several elements of the Danish treatment as test treatment in Norway.

27. Ms. Slinning filed a lawsuit against the State represented by the Board of Appeals, pleading *inter alia* that the decision adopted was contrary to EEA law. On 30 April 2007, Oslo tingrett decided to request an Advisory Opinion

from the Court. By letter of 16 January 2008, it referred the following questions:

> **1. Is it compatible with Articles 36 and 37 of the EEA Agreement and Article 22 of Council Regulation (EEC) No 1408/71 to refuse coverage of expenses for treatment abroad which according to international medicine must be considered experimental or test treatment, when there is no entitlement to such treatment in the home State?**
>
> **2. Is it of significance for the answer to Question No 1 that the method of treatment in question must be considered to be implemented in the home State or the home State is considering its implementation in the future?**
>
> **3. Is it compatible with Articles 36 and 37 of the EEA Agreement to refuse coverage of expenses for hospital treatment abroad if the patient in the home State can receive an offer of adequate medical treatment assessed according to accepted international methods within a medically justifiable time limit?**
>
> **Is it of significance for the answer to this question that**
>
> **a) coverage of such expenses may be refused even if the treatment abroad is considered as possibly more advanced than the treatment in the home State?**
>
> **b) the patient, having decided to receive treatment abroad rather than an adequate treatment in the home State, does not get coverage for the costs of treatment abroad to the same extent as the treatment offered in the home State would have cost?**
>
> **4. Is it of significance for the answers to the questions above whether**
>
> **a) the patient as a matter of fact has not been offered a treatment in question in the home State which can be considered adequate treatment?**
>
> **b) the treatment given abroad actually led to an improvement of the specific patient's state of health?**

IV Written Observations

28. Pursuant to Article 20 of the Court's Statute and Article 97 of the Rules of Procedure, written observations have been received from:

- the Plaintiff in Case E-1/08, represented by Jan Gunnar Ness and Katrine Hellum Øren, advocates, Oslo;
- the Respondent in Case E-11/07 and Defendant in Case E-1/08, represented by Ketil Bøe Moen, advocate, Office of the Attorney General (Civil Affairs), acting as Agent;
- the Government of Denmark, represented by Jonas Bering Liisberg, Head of Department, and Bolette Weis Fogh, Deputy Head of Department, Ministry of Foreign Affairs, acting as Agents;
- the Government of Iceland, represented by Sesselja Sigurðardóttir, First Secretary and Legal Officer, Ministry for Foreign Affairs, acting as Agent;
- the Government of the Netherlands, represented by Corinna Wissels, Head of the European Law Division, and Caroline ten Dam, European Law Division, Legal Affairs Department, Ministry of Foreign Affairs, acting as Agents;
- the Government of Poland, represented by Mikolaj Dowgielewicz, Secretary of State, Secretary of the Committee for European Integration, acting as Agent;
- the Government of the United Kingdom, represented by Zoë Bryanston-Cross, European Litigation, Treasury Solicitors, acting as Agent, and Jason Coppel, Barrister;
- the EFTA Surveillance Authority, represented by Ólafur Jóhannes Einarsson, Senior Officer, and Lorna Young, Officer, Department of Legal & Executive Affairs, acting as Agents; and
- the Commission of the European Communities, represented by Viktor Kreuschitz, its Legal Adviser, and Nicola Yerrell, member of its Legal Service, acting as Agents.

The Plaintiff in Case E-1/08

29. The Plaintiff submits that the Board of Appeal's refusal of her claim on the basis that there was sufficient medical competence to treat her condition in Norway, even if a possibly more advanced treatment may have been developed abroad, violates Articles 36 and 37 of the EEA Agreement and Article 22 of Regulation 1408/71. It is further submitted that it is also contrary to those provisions of EEA law to base the refusal on the argument that the treatment at Hammel is experimental/test treatment, when the home State at a political, as well as at a practical level, has implemented that very treatment.

30. The Plaintiff argues that restrictions on the free movement of health services may only be applied if two criteria are fulfilled, namely that the restrictions are based on objective criteria and that they are proportionate to their objective. Although the Plaintiff acknowledges that EEA States are under

no obligation to expand their coverage of health services so that other types of health services than those covered in the patient's home State will be covered abroad, it is submitted that the criteria restricting the health coverage must be objective and independent of the origin of the service in such a way that indirect discrimination of foreign service providers is avoided.[4] The Plaintiff contends that the justifications put forward by the Defendant, especially the risk of weakening competence and experience in the national health system, must be rejected. She points out that in the present case, there was rather a lack of capacity that caused the patient to wait for more than three years, and that the Defendant has not demonstrated that, in relation to head trauma patients, the need of protecting public health services is an objective and overriding reason that justifies the restrictions present.

31. Addressing the first and the second question, the Plaintiff contends that the conditions for entitlement to benefits abroad according to Article 22 of Regulation 1408/71 are fulfilled if the national court should establish that the Plaintiff was entitled to necessary health care from the specialist health service, as she did not receive adequate treatment for three years following the traffic accident.

32. Furthermore, it is submitted that the requirement under Norwegian law that the health care can be provided properly by the service provider abroad according to accepted methods is open to a number of interpretations which could include discrimination of foreign service providers, and must be interpreted as what is recognised in international medical science. It is submitted that according to the case law of the ECJ, the EEA States must, when applying this requirement, 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 EEA State in which the treatment is provided.[5] In that regard, the Plaintiff points out that the treatment received in Hammel is covered by the public insurance in Denmark; that it is implemented in Norway; and that Norwegian medical practitioners recognize and support it. The Plaintiff is further of the opinion that the differences between the methods used in Sunnaas Hospital and the methods used in Hammel are quantitative rather than qualitative.

33. The Plaintiff submits that the refusal based on the consideration that the treatment given in Denmark was experimental makes the provision of services between EEA States more difficult than the provision of services purely within the home State. In the alternative, the Plaintiff argues that even if the treatment

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4 Reference is made to Case C-385/99 *Müller-Fauré and van Riet* [2003] ECR I-4509; and Case C-372/04 *Yvonne Watts* v *Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-4325.

5 Reference is made to Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraphs 61, 92, 94, 97 and 98.

is to be considered experimental or test treatment, to reject coverage for this reason alone does entail preferential treatment for domestic health undertakings when the same treatment is actually provided in the home State.

34. With regard to the third question, it is submitted that the condition in Section 2-1, fifth paragraph of the Patient's Rights Act, and the rejection of the Plaintiff's claims based thereupon, constitute a restriction on the free movement of services and entail discrimination between services provided in Norway and those provided in other EEA States. The Plaintiff argues, *inter alia*, that a restriction according to which a patient does not have the right to necessary health care abroad if adequate medical services exist in the home State goes beyond the accepted restrictions listed in Article 22 of Regulation 1408/71. Furthermore, and also with regard to Question 3a), it is argued that to reject a claim on the grounds that the treatment abroad does not offer much greater prospects of success constitutes a prohibited restriction on the free movement of services.[6] The Plaintiff concludes that a provision which entails that, as a main rule, use shall be made of treatment offered in the home State even if a possibly more advanced treatment has been developed abroad is precluded by the Articles 36 and 37 EEA.

35. The Plaintiff submits that the Defendant has not demonstrated the existence of overriding reasons of public interest. It is argued that the Defendant has neither shown that overcapacity in Norwegian rehabilitation hospitals is a problem, nor that a large number of head trauma patients would seek to obtain treatment in other EEA States and thereby jeopardise the public health services.[7]

36. With regard to Question 3b), it is submitted that the Plaintiff's expenses should be covered in full since the treatment would be covered under national law if given to patients in Norway. It is argued that pursuant to Article 22(2), second subparagraph, of Regulation 1408/71, patients have the right to conditions for reimbursement of costs for treatment in another EEA State that are as favourable as those in the home State.[8] In the alternative, it is submitted that the Plaintiff may claim coverage of the expenses for the treatment in Hammel up to the maximum of what a comparable stay at Sunnaas Hospital in Norway would have cost.

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6 Reference is made to Case C-8/02 *Ludwig Leichtle* v *Bundesanstalt für Arbeit* [2004] ECR I-2641.

7 Reference is made to Case C-372/04 *Yvonne Watts* v *Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-4325; Case C-158/96 *Raymond Kohll* v *Union des caisses de maladie* [1998] ECR I-1931, at paragraphs 6–8, 41 and 51–53; and Case C-385/99 *Müller-Fauré and van Riet* [2003] ECR I-4509, at paragraph 95.

8 Reference is made to Case C-372/04 *Yvonne Watts* v *Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-4325, at paragraph 135.

37. Regarding Question 4a), the Plaintiff submits that authorisation to assume costs of hospital care in another EEA State may be refused on the ground that such action is not necessary for the injured person's health care only if treatment which is the same or equally effective for the patient can be obtained in the home State without undue delay.[9] It is argued that Ms. Slinning did not at any time receive adequate, nor similar or equal treatment in Norway during more than three years following her accident, and that therefore, according to Articles 36 and 37 EEA and Article 22 of Regulation 1408/71, authorisation to cover expenses for treatment abroad could not be refused.

38. As to Question 4b), the Plaintiff submits that the fact that the rehabilitation treatment at Hammel Neurocenter actually led to an improvement in Ms. Slinning's state of health entails that the Board of Appeals' assessment of the treatment as experimental is contrary to EEA law. It is pointed out that according to the ECJ, authorised opinions of specialists shall be given weight when considering whether a treatment is recognized internationally or not, and that in this case, the specialists have stated that her condition has improved as a result of the treatment at Hammel Neurocenter.[10]

39. The Plaintiff in Case E-1/08 suggests answering the questions as follows:

> *1. It is not compatible with Articles 36 and 37 of the EEA Agreement and Article 22 of Council Regulation (EEC) No 1408/71 to refuse coverage of expenses for treatment abroad which the home State deems experimental or test treatment, when the medical profession considers the treatment to be internationally recognised.*
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> *2. It is not compatible with Articles 36 and 37 of the EEA Agreement and Article 22 of Council Regulation (EEC) No 1408/71 to refuse coverage of expenses for treatment abroad which the home State deems experimental or test treatment, when the home State has implemented or is considering implementing it.*
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> *3. It is not compatible with Articles 36 and 37 of the EEA Agreement and Article 22 of Council Regulation (EEC) No 1408/71 to refuse coverage of expenses for treatment abroad on the grounds that the treatment can be provided properly in Norway according to accepted methods.*

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9 Reference is made to Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraphs 103 and 108; Case C-372/04 *Yvonne Watts* v *Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-4325, at paragraph 57; and Case C-385/99 *Müller-Fauré and van Riet* [2003] ECR I-4509.

10 Reference is made to Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraph 98.

a) It is not compatible with Articles 36 and 37 of the EEA Agreement and Article 22 of Council Regulation (EEC) No 1408/71 to refuse coverage of expenses for treatment abroad because the treatment can be provided properly in Norway according to accepted methods, when treatment available abroad is considered to be more advanced than the treatment in the home State.

b) It is not compatible with Articles 36 and 37 of the EEA Agreement and Article 22 of Council Regulation (EEC) No 1408/71 to refuse coverage of expenses for treatment abroad in full, given that a person has the right to receive that treatment under national law.

4. a) It is not compatible with Articles 36 and 37 of the EEA Agreement and Article 22 of Council Regulation (EEC) No 1408/71 to refuse coverage of expenses for treatment abroad because the treatment can be provided properly in Norway according to accepted methods, when the patient in question has not in fact been offered adequate treatment within a medically justifiable time limit in the home State.

4. b) It is not compatible with Articles 36 and 37 of the EEA Agreement and Article 22 of Council Regulation (EEC) No 1408/71 to refuse coverage of expenses for treatment abroad because the treatment can be provided properly in Norway according to accepted methods, when the treatment abroad in fact led to improvement of the patient in question's health.

The Defendant

40. The Defendant submits that, although the principle of free movement of services is applicable to national regulations concerning conditions for coverage of expenses for hospital treatment, the special characteristics of the health care sector, and of hospital services in particular, must be taken into account. Having regard to Article 152 EC, it points to the national autonomy for questions of public health. The differences between the health sectors of the EEA States, as regarding their organisation, the level of public regulation as well as the level of health services offered to the population, must be respected.[11] The Defendant also points to the social and economic importance of the health sector, and to the complex and often controversial priority

[11] Reference is made to Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraph 87. As to the existing differences, the Defendant refers to a summary made by the Commission, Commission summary paper of 3 November 2006 on Common principles of care, from the Mapping Exercise of the High level Group on Health Care Services 2006, pages 35–37. It is however noted that all EEA States on which information was available to the Defendant seem to base their regulation on the condition that they may limit coverage of expenses abroad to patients entitled to treatment at home.

assessments which have to be undertaken, including difficult medical, financial and ethical considerations.[12]

41. In its assessment of the case law on whether a restriction of the freedom to provide services exists, the Defendant points out that a restriction will only exist if it is more difficult to provide services between EEA States than within the EEA State in question.[13] It is concluded that the rejection of reimbursement does not constitute a restriction of services if the desired form of treatment is not offered at all in the home State, or not offered to the particular patient. The Defendant argues that the patient is free to travel abroad and to receive the services, and that without entitlement domestically, the expenses must be covered by the patient irrespective of whether the treatment is performed at home or abroad.

42. This conclusion is found to be supported by the case law of the ECJ, according to which it is for the Member States to determine the conditions for entitlement to benefits from their national social security scheme.[14] It is argued that if the EEA States are not required to extend the number of services paid for, it follows that they cannot be obliged to reimburse costs for services received abroad which are not recoverable at home.[15]

43. The Defendant contends that *de facto*, the ECJ has concentrated its assessments on discriminatory conditions for coverage of expenses of hospital treatment abroad, an approach which the Defendant finds appropriate in regard to the specifics of the health sector. In this, it sees parallels to the case law concerning the export of goods.[16] In regard to the Plaintiff's argument in Case E-1/08 that the ECJ in *Smits and Peerbooms* assessed the suitability and necessity of the restriction even though the treatment in question was not

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12 Reference is made to the Council Conclusions on Common values and principles in EU Health Systems, OJ 2006 C 146/1; and to the Report of the European Parliament of 10 May 2007 on the impact and consequences of the exclusion of health services from the Directive on services in the internal market, A6-0173/2007, at pages 13 and 18.

13 Reference is made to Case C-372/04 *Yvonne Watts* v *Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-4325, at paragraph 94; and Case C-8/02 *Ludwig Leichtle* v *Bundesanstalt für Arbeit* [2004] ECR I-2641, at paragraphs 37 *et seq*.

14 Reference is made to Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraphs 45 and 85; Case C-385/99 *Müller-Fauré and van Riet* [2003] ECR I-4509 at paragraph 100; and Case C-372/04 *Yvonne Watts* v *Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-4325, at paragraph 92.

15 Reference is made to Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraphs 86–87; and Case 238/82 *Duphar BV and Others* v *The Netherlands State* [1984] ECR 523, at paragraphs 17 and 20–21. This is also found to be in line with recent political statements of the Commission; reference is made to the Proposal for a Directive of the European Parliament and of the Council on services on the Internal market, COM(2004) 2 final, at Article 23 and the Preamble, recitals 51–57; and the Commission working document "Consultation regarding Community action on health services", SEC(2006) 1195/4, at page 4.

16 Reference is made to Case C-412/97 *ED Srl.* v *Italo Fenocchio* [1999] ECR I-3845, at paragraph 10.

offered in the Netherlands, the Defendant submits that this must be understood on the basis of the prior authorisation scheme which was only applicable to treatment abroad, and thus discriminatory.

44. Furthermore, the Defendant points out several objectives of public interest which may legitimise a restriction in the free movement of hospital services and which also constitute, in its view, the underpinnings of the Norwegian legislation. In particular, the Defendant submits that the need for extensive planning and regulation within the health sector, the aim to maintain a balanced medical and hospital service open to all, the objective of maintenance of sufficient treatment capacity and competence in the national territory, as well as financial considerations, i.e. to avoid seriously undermining the financial balance of a social security system, constitute legitimate objectives of public health.[17]

45. With regard to the requirement that a restriction of the freedom to provide services must be necessary in order to achieve objectives of public interest, the Defendant submits that the Court should make a cautious approach, having regard to the specific characteristics of the health sector and to the wide discretion of the EEA States in this respect.[18] At least, this must apply to cases concerning hospital treatment. Accordingly, it should be for the national court, being in a better position to undertake the assessment of necessity, to make the concrete appraisal with regard to this question and to accept grounds of protection of public health unless it is "apparent" that less restrictive means exist.[19] Respectively, the Defendant points out that the ECJ has held in its rulings concerning matters involving political, economic and social choices, and in which the legislature is called on to undertake complex assessments, that a measure is not necessary only if it is "manifestly inappropriate" in relation to the objective pursued by the competent authority.[20] It submits that in the health care cases, the ECJ's caution led to limiting the assessment of necessity to a procedural test, namely whether the criteria for a refusal, in addition to being non-discriminatory, are objective and known in

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17 Reference is made to Case C-372/04 *Yvonne Watts* v *Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-4325, at paragraphs 103–105 and 108; and the Preamble of the Proposal for a Directive of the European Parliament and of the Council on services on the Internal market, COM(2004) 2 final, at recital 55.

18 Reference is made to Case C-322/01 *Deutscher Apothekerverband eV* v *0800 DocMorris NV and Jacques Waterval* [2003] ECR I-14887, at paragraph 103; Case C-429/02 *Bacardi France SAS* v *Télévision française 1 SA and Others* [2004] ECR I-6613, at paragraph 31; Case C-262/02 *Commission* v *France* [2004] ECR-6569, at paragraph 24; and Joined Cases 266 and 267/87 *The Queen* v *Royal Pharmaceutical Society of Great Britain and Others* [1989] ECR 1295, at paragraph 21.

19 Reference is made to Case E-4/04 *Pedicel AS* v *Sosial- og helsedirektoratet (Directorate for Health and Social Affairs)* [2005] EFTA Court Report 1, at paragraphs 57 and 61.

20 Reference is made to Case C-157/96 *The Queen* v *National Farmers' Union and Others* [1998] ECR I-2211, at paragraph 61; Case C-491/01 *The Queen* v *British American Tobacco and Others* [2002] ECR I-11453, at paragraph 123; and Case C-210/03 *Swedish Match* v *Secretary of State for Health* [2004] ECR I-11893, at paragraph 48.

advance, and whether there are procedural requirements ensuring the legal certainty of the parties involved.[21]

46. Based on these considerations, the Defendant suggests answering the first question in both cases in the affirmative. It submits that, given that there is no entitlement to the treatment in the home State, refusal of coverage of the treatment abroad does not constitute a restriction on the freedom to provide services under Article 36 EEA, and that, due to the same reason, Article 22 of Regulation 1408/71 is not applicable. The Defendant points out that the question is based on the premise that there is no entitlement to experimental or test treatment in the home State.

47. In the alternative, it is argued that such a restriction would be justified in order to achieve the public interest objectives accepted by the ECJ, in particular the aim to maintain sufficient treatment capacity and competence in all parts of the country. It is submitted that the ECJ already held similar limitations in *Smits and Peerbooms* to be suitable and necessary to achieve such public interest aims. Even though the Defendant considers the Court not to be invited by the national courts to assess the compatibility of the Norwegian legislation with EEA law, it points out that the exclusion of experimental and test treatment from the definition of "necessary health care" through Section 2–1, third paragraph, of the Prioritisation Regulation is based on non-discriminatory, objective criteria which are known in advance, and that there is a procedural system of administrative and judicial review securing legal certainty. It is recalled that the assessment of a treatment as "sufficiently tried and tested" is undertaken with regard to international medicine, as required by the ECJ in *Smits and Peerbooms*. The Defendant contends that mere "recognition" by international medicine neither implies a right to treatment according to Norwegian legislation, nor does it fulfil the criteria set out in *Smits and Peerbooms*.[22]

48. The Defendant submits that the circumstances addressed in the second question in both cases are irrelevant to the answer to the first question, and suggests answering these two questions accordingly.

49. With regard to Case E-11/07, it is argued that whereas spinal fusion surgery in the neck is a recognised method for treatment of certain types of injuries like fractures in the neck, there is no scientific documentation showing that such an invasive measure should be undertaken for whiplash injuries. It is submitted that it is not the treatment as such which has to be considered in order to assess whether a method is internationally recognised and documented, but the application of this method of treatment on the relevant category of

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21 Reference is made to Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraphs 90 and 97.

22 Reference is made to Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraphs 92–98.

patients, i.e. the patients with the same medical indications as those of the patient in question.

50. With regard to Case E-1/08, the Defendant finds that it makes no difference whether a method of treatment is implemented in the home State, or is being considered to be implemented, as long as it still constitutes experimental or test treatment. Firstly, the Defendant contends that there is nothing in the *Smits and Peerbooms* case indicating that the ECJ's acceptance of refusal of treatments not sufficiently tested in international science is limited to treatments not offered in the home State. Secondly, it argues that to deduce an obligation to cover such treatment abroad from the fact that it is offered in the home State when there are accessible resources and, for instance, a need for research and development in the field, would entail a risk that expenses for treatments, which eventually may never be recognised in international medicine, would have to be covered. That would further entail a risk for necessary research and testing never being initiated due to ethical and financial concerns that the state must cover corresponding non-recognised treatment in all EEA States. With regard to the question of whether it is of significance that a treatment is being considered for use in the home State in the future, the Defendant further argues that to make the entitlement to coverage of expenses for hospital treatment abroad dependent on possible future developments would entail an expansion of the treatments covered by the national health system, contrary to the national discretion and the case law of the ECJ.

51. Assessing the first paragraph of the third question in both requests for advisory opinion, the Defendant submits that it is compatible with Articles 36 and 37 EEA to refuse coverage of expenses for hospital treatment abroad if the patient is offered adequate medical treatment assessed according to accepted international methods in the home State within a medically justifiable time limit. First of all, it argues that if the specific form of treatment is not available in the home State, there is no obligation to cover this treatment abroad, as this would amount to forcing the home State to expand the medical services covered by its national system. The Defendant contends that this is the situation in Case E-11/07 and also in Case E-1/08, as the Defendant considers that the form of treatment provided at Hammel Neurocenter was not available at the time in Norway. The Defendant considers this to be the case even today despite several aspects of the Danish treatment now being offered as test treatment in Norway.

52. With regard to the Plaintiff's claim to the contrary in Case E-1/08, that this treatment was indeed offered in Norway, the Defendant concedes that in such a case, a rule requiring a patient to make use of the medical competence of the home State if the treatment is offered within a medically justifiable time, could be considered a restriction on the free movement of services. However, the Defendant submits that such a restriction would not be directly discriminatory, as it would not be based on the nationality of the service provider. It is argued that the indirect discrimination which would – under

these circumstances – be inherent in this rule would be justified by legitimate objectives of public interest, i.e. to maintain and develop a balanced health service open to all parts of the population with sufficient medical competence and experience. The Defendant points out that the settlement pattern in Norway is characterised by areas which are, in a European context, sparsely populated, and by great distances, and that *inter alia* for this reason the specialist health service is geographically spread out. Therefore, it is important to utilise the source of patients and to be able to plan carefully in order to maintain sufficient medical competence and experience.[23]

53. Even though, as argued by the Plaintiff in Case E-1/08, lack of capacity may be a concern for some groups of patients, this would not, according to the Defendant, invalidate the public policy goals stated in the preceding paragraph, as long as adequate treatment is offered within a medically justifiable time. It is pointed out that patients have a right to necessary health care abroad under the Norwegian rules if no relevant treatment can be offered within such a time, and that the assessment of the time limit is made individually for each patient and based on an objective medical assessment in the light of all factors characterising the patient's medical condition. It is submitted that this rule is objective and non-discriminatory, and its application subject to judicial review, and therefore, that the restriction is necessary in achieving the desired level of protection of these objectives.[24]

54. The Defendant rejects the argument of the Plaintiff that it has failed to provide documentation substantiating that the coverage of expenses for treatment abroad prior to the set time limit would have negative consequences. It is submitted that one must base oneself on the reasonable assumption that some priority to the national health service is indeed necessary in order to achieve important objectives, and that the ECJ has done so in its comparable cases. Otherwise, planning and predictability in the sector would be illusory.

55. In its assessment of the second paragraph of question 3 in Case E-11/07, respectively of question No 3, second paragraph, litra a) in Case E-1/08, the Defendant submits that it is of no significance to the answer to question No 3 whether the treatment abroad is considered as possibly more advanced than the treatment at home.

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[23] Reference is made to Case C-372/04 *Yvonne Watts* v *Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-4325, at paragraphs 90 and 102 *et seq*; Case E-3/05 *EFTA Surveillance Authority* v *Norway* [2006] EFTA Court Report 104, at paragraph 59; Case 182/83 *Robert Fearon & Company Limited* v *Irish Land Commission* [1984] ECR 3677, at paragraph 10; Case C-237/94 *John O'Flynn* v *Adjudication Officer* [1996] ECR I-2617, at paragraphs 18–20; and Case C-452/01 *Margarethe Ospelt and Schlössle Weissenberg Familienstiftung* [2003] ECR I-9743, at paragraph 37.

[24] Reference is made to Case C-372/04 *Yvonne Watts* v *Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-4325, at paragraphs 68 and 120.

56. First of all, it is pointed out that if the standard for a particular treatment is far better abroad than in the home State, it may be that the medical service in the home State will not be regarded as adequate, i.e. that the patient would not receive treatment according to an internationally accepted method. In such circumstances, Norwegian legislation would entail a claim to receive the more advanced treatment abroad and, consequently, not restrict the free movement of services. Accordingly, a restriction exists only if the treatment in Norway is indeed adequate. It is submitted that this restriction is justified by the objectives of public interest as described above, at paragraph 52.

57. The Defendant submits that the ECJ has made it clear that it is for the EEA States to determine the conditions for entitlement to benefits from their national social security scheme. This applies to treatment at home and abroad, and is irrespective of whether the medical treatment in question is awarded in other states.[25] The Defendant argues that the requirements that the restriction must be non-discriminatory, objective and subject to judicial control are fulfilled. The assessment of whether a treatment is "adequate" is made on the basis of international standards, and it is subject to administrative and judicial review. The Defendant submits that the requirement at issue must be accepted, as had been the Dutch condition in the *Smits and Peerbooms* case that treatment must be regarded as "normal", as long as it was applied in relation to international medical science. Under these circumstances, it was objective and non-discriminatory, and thus justified in view of the need to maintain an adequate, balanced and permanent supply of hospital care on the national territory, and to ensure the financial stability of the sickness insurance system.[26]

58. The argument of the Appellant in Case E-11/07 and the Plaintiff in Case E-1/08 that the refusal of coverage of expenses abroad is only compatible with EEA law as long as the treatment in the home State is equally effective as the one the patient seeks abroad is rejected. This would lead to a situation where all EEA citizens would be entitled to the best hospital services within the entire EEA, even though the treatment does not exist in the home State. This would be contrary to the basic rule that patients must be entitled to treatment in the home State before access to treatment abroad can be required. It is argued that such an understanding would put at risk the home State's right to make necessary priorities and to predict and plan for the need of medical services in its population, and thereby to realise the goal of a balanced and high-quality national health service in the whole country with sufficient medical competence and experience. Also, this would endanger the financial stability of

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25 Reference is made to Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraphs 45 and 85; Case C-385/99 *Müller-Fauré and van Riet* [2003] ECR I-4509 at paragraph 100; and Case C-372/04 *Yvonne Watts* v *Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-4325, at paragraph 92.

26 Reference is made to Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraph 97.

the social security and health systems of less developed countries within the EEA.

59. The Defendant acknowledges that there may be limits to the home State's discretion in choosing the level of treatment that must be regarded as acceptable.[27] However, the Defendant submits that more extensive restrictions must be regarded as necessary within the hospital-based specialist health services than for example with regard to spa cures as in the *Leichtle*-case, due to a greater and better substantiated need for planning and to ensure sufficient medical competence for the benefit of the whole population. It is also argued that the condition assessed in the *Leichtle*-case requiring "greatly increased prospects of success" for the treatment abroad implies a greater difference between the quality of the treatment abroad and the treatment in the home State as compared to the provisions applicable to the present cases. In order to be adequate, the treatment cannot depart significantly from the standards in other states.

60. With regard to question No 3, second paragraph litra b) in Case E-1/08, the Defendant acknowledges that under the condition that costs for treatment abroad are only covered to the same extent as the treatment offered in the home State would have cost, the financial balance of a social security system would not be seriously undermined. However, it submits that the primary objective of the Norwegian legislation is to offer high quality hospital services to all parts of the population. Reaching this objective will be more difficult if patients are treated abroad, independently of whether the costs of such treatment are covered up to the costs of the potential domestic treatment. Accordingly, the Defendant considers this to be irrelevant to the answer to question No 3.

61. Assessing the significance of the different aspects referred to in the fourth question of both Case E-11/07 and Case E-1/08, the Defendant submits with regard to questions 4a), 4b) and 4c) in Case E-11/07 and question 4a) in Case E-1/08 that the home State is not obliged to expand its offer of health services by covering a treatment performed abroad which is either not covered domestically in general or to which, even if the method of treatment is offered as such, the patient in question is not entitled to according to the conditions of the home State. It is added that Article 22 of Regulation 1408/71 does not apply if the conditions for treatment at home are not fulfilled. Such a condition might be that it must be anticipated that the patient gets documented benefits from the treatment. It is only if the treatment to which a patient is entitled to domestically could not be provided within a medically justifiable time that this treatment shall be offered abroad. The Defendant submits that even in this case, the home State may be allowed to lay down further requirements in relation to treatment abroad, including the requirement that the treatment is provided properly and according to accepted methods.

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[27] Reference is made to Case C-8/02 *Ludwig Leichtle* v *Bundesanstalt für Arbeit* [2004] ECR I-2641, at paragraphs 41 *et seq*.

62. Lastly, the Defendant considers it to be without significance whether the treatment abroad actually resulted in an improvement of the specific patient's state of health. It is argued that such an effect does not change the character of a treatment as test or experimental treatment, that the considerations which justify requiring patients to receive treatment primarily in the home State are not affected by the outcome of a specific treatment, and that it would be unreasonable to base the decision about the coverage of costs on the often random outcome of a specific treatment. With regard to the latter point, it is added that some positive or negative effects may be visible only after several years. It is concluded that such a decision must be based on the well documented long term effects for the entire category of patients, and not on the short term effects for one patient alone.

63. Based on the above, the Defendant suggests answering the questions as follows:

> *l. It is compatible with Articles 36 and 37 of the EEA Agreement and Article 22 of Council Regulation (EEC) No 1408/71 to refuse coverage of expenses for hospital treatment abroad which according to international medicine must be considered experimental or test treatment, when there is no entitlement to such treatment in the home State.*
>
> *2a). The treatment is considered experimental or test treatment even if the method of treatment itself is internationally recognised and documented, provided that this does not apply to patients with the same medical indications which the patient in question has.*
>
> *2b). It is without significance for the answer to Question No l that the method of treatment in question must be considered to be implemented in the home State or the home State is considering its implementation in the future, unless the patient is entitled to that treatment under the rules of the home State, but the home State fails to offer adequate treatment within a medically justifiable time limit.*
>
> *3. It is compatible with Articles 36 and 37 of the EEA Agreement to refuse coverage of expenses for hospital treatment abroad if the patient, in the home State and within a medically justifiable time limit, can receive adequate medical treatment assessed according to accepted international methods. This applies also where coverage may be refused even if the treatment offered abroad is considered possibly more advanced than the treatment in the home State, and where the patient, upon treatment abroad does not receive coverage for the expenses which correspond to what the treatment offered in the home State would have cost.*

4a). If the patient in question has not received adequate treatment within a medically justifiable time limit, then hospital treatment offered in other EEA States shall be covered provided that such treatment is also offered in the home State and the patient is entitled to that treatment under the rules of the home State. Further requirements may be laid down in relation to treatment abroad, including a condition that the treatment must be provided properly according to accepted methods.

4b). The rest of the circumstances which are mentioned in Question No 4 in Case E-11/07 and in Case E-1/08 are without significance to the answers to the other questions.

The Government of Denmark

64. The Government of Denmark submits that it is for the EEA Member States to decide what medical services they offer to their citizens, that EEA law cannot require an EEA State to extend the list of medical services it offers, and accordingly, that the fact that a medical treatment is covered by the systems of other countries is irrelevant. The Government of Denmark finds that this principle is well established with regard to medically recognised treatment, and argues that this must thus apply even more to other treatments, including experimental and test treatments.[28] It is pointed out that experimental treatment entails an increased uncertainty as to whether or not the treatment has any effect at all and, if so, whether it may harm the patient or whether the positive effects outweigh any harmful effects. Furthermore, referral to experimental treatment may also involve opting out of a medically recognised treatment which might otherwise have provided some benefit to the patient.

65. Furthermore, the Government of Denmark submits that patients have no right to obtain authorisation for a service abroad, even if the conditions for such authorisation are otherwise met, when this service is not offered in the country where the patient is covered by a sickness insurance system. This must apply to experimental and test treatment even more, given its special characteristics and the fact that such treatment is typically not internationally standardised.[29]

66. Finally, it is submitted that even if a certain test or experimental treatment is actually offered in the home State, patients have a right to this treatment abroad only if it is required, cannot be obtained in the home State without undue delay and actually is covered by the home State's insurance scheme.[30] With regard to the last condition, it is pointed out that the fact that a

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28 Reference is made to Case C-158/96 *Raymond Kohll* v *Union des caisses de maladie* [1998] ECR I-1931, at paragraphs 16–18; Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraph 87; and Case C-372/04 *Yvonne Watts* v *Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-4325.

29 Reference is made to Case C-385/99 *Müller-Fauré and van Riet* [2003] ECR I-4509, at paragraph 98.

30 Reference is made to Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473.

state offers an experimental or test treatment does not in itself entail that all citizens with similar needs obtain a right to such treatment, as such treatment may be undertaken only in relation to a limited number of patients, and may be stopped at any time due to medical, budgetary or other reasons. To ignore these particularities would lead to much reluctance regarding the introduction of new experimental treatments, and thus have enormous consequences for research and development.

67. The Government of Denmark suggests answering the first question in both cases as follows:

> *It is consistent with Articles 36 and 37 of the EEA Agreement and Council Regulation (EEC) no 1408/71 Article 22 to refuse coverage of costs for treatment abroad which according to international medical assessment must be considered as experimental treatment or test treatment when there is no right to such treatment in the home country.*

The Government of Iceland

68. At the outset, the Government of Iceland observes that medical services fall within the scope of Articles 36 and 37 EEA, and that the free movement of services also implies the rights of the recipients of services to travel and move freely within the EEA to receive the services they choose.[31] It is also stated that according to settled case law, Community law does not detract from the power of the Member States to organise their social security systems. Thus, in the absence of harmonisation in this sphere of law, it is the internal legislation of each EEA State that shall determine the conditions concerning the right or duty to be insured with a social security system and the conditions for entitlement to benefits. However, when exercising that power, the States must comply with the fundamental principles of the EEA Agreement.[32]

69. It is noted that limiting a patient's choice of medical treatment to domestic options, when they are available, or requiring an authorisation for the treatment in advance can be considered to constitute a barrier to the freedom to provide services, which may however be justified by overriding considerations with regard to the protection of public health. Those considerations may include the risk of seriously undermining the financial balance of a social security system, the objective of maintaining a balanced medical and hospital service open to all and situations where the maintenance of treatment capacity or medical competence on national territory is essential for the public health, and even the survival, of the population.[33] However, a system of prior authorisation based on these considerations must also satisfy the requirement of proportionality. Furthermore, it cannot legitimise discretionary decisions and must be based on objective, non-discriminatory criteria which are known in

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31 Reference is made to Joined Cases 286/82 and 26/83 *Graziana Luisi and Giuseppe Carbone* v *Ministero del Tesoro* [1984] ECR 377, at paragraph 10; Case C-158/96 *Raymond Kohll* v *Union des caisses de maladie* [1998] ECR I-1931; Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473; and Case C-372/04 *Yvonne Watts* v *Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-4325.

32 Reference is made to Case 238/82 *Duphar BV and Others* v *The Netherlands State* [1984] ECR 523, at paragraph 16; Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraphs 45–46; Case 110/79 *Una Coonan* v *Insurance Officer* [1980] ECR 1445, at paragraph 12; and Joined Cases C-4/95 and C-5/95 *Fritz Stöber and José Manuel Piosa Pereira* v *Bundesanstalt für Arbeit* [1997] ECR I-511, at paragraph 36.

33 Reference is made to Case C-158/96 *Raymond Kohll* v *Union des caisses de maladie* [1998] ECR I-1931, at paragraphs 41 and 51–52; Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraphs 72–74 and 80–81; and Case C-372/04 *Yvonne Watts* v *Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-4325, at paragraphs 103–105 and 112–113.

advance. Also, the system must be based on an easily accessible procedural system which deals with applications within a reasonable time.[34]

70. Turning to the first and second questions, the Government of Iceland submits that it follows from the power of the EEA States to decide on the conditions for eligibility for coverage of expenses that EEA States are not precluded from making coverage of expenses dependent on the fact that treatment must be regarded as normal or recognised in the professional circles concerned. It is pointed out that such a requirement is based on the aim of the treatment resulting in benefit for the patient. Referring to *Smits and Peerbooms*, the Government of Iceland argues that it is compatible with EEA law to refuse coverage for treatment abroad which according to international medicine must be considered experimental or test treatment, where there is no entitlement to such treatment in the home State.[35]

71. It is noted that if there would be an entitlement to an experimental treatment in the home State, so that it would be eligible for cost participation of the State, it would not be justifiable to reject such an application for cost coverage in another EEA State on that ground alone. Therefore, it may be of significance that the method of treatment must be considered to be implemented and recognised so that there is entitlement to the treatment in the home State at the time of the application for treatment abroad. However, the Government of Iceland considers it to be of no significance what future changes might happen in the home State. Furthermore, it is submitted that it is of no significance for the compatibility of the refusal of experimental or test treatment with EEA law that the method of treatment itself is internationally recognised with regard to other medical indications than those which the patient in question has. In that regard, it is argued that it is the likely benefit to that specific medical condition which is of concern to the State.

72. Addressing the third question, the Government of Iceland notes that a national rule which requires a patient to make use of available medical competence in the home State can be considered a restriction of the free movement of services. It is submitted, however, that the requirement can be justified by the need to maintain and further develop a balanced health service with sufficient medical competence and experience.

73. The Government of Iceland points out that in order to maintain medical competence within a State, its doctors need, in addition to education and training, to have patients to treat. It is argued that all patients choosing to seek treatment abroad decrease the possibilities of medical training for the doctors in

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[34] Reference is made to Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraphs 82 and 90; and Case C-372/04 *Yvonne Watts* v *Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-4325, at paragraphs 115–116.

[35] Reference is made to Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraph 97.

the home State. Having regard to the case law of the ECJ, it is submitted that it is compatible with the Articles 36 and 37 EEA to refuse coverage of expenses for hospital treatment abroad if the patient can receive the same or equally effective medical treatment within a medically justifiable time limit in the home State.[36] In the view of the Government of Iceland, this must also apply if the coverage of costs for treatment abroad is requested only to the same extent as what the costs for the treatment in the home State would have been.

74. With regard to the situation that the treatment abroad is possibly more advanced than the treatment available in the home State, the Government of Iceland submits that the main issue would be whether the treatment at home can be considered equally effective.[37] It is pointed out that this can hardly be the case if it is documented that the treatment abroad generally leads to better results for the health of patients who are in comparable situations as the patient concerned. It is added that such a comparison needs to be done at a case-by-case basis, taking into account all available information on the case concerned. However, it is also recalled that it follows from the autonomy of the EEA States to organize their social security system that it must first be assessed whether the treatment concerned is considered to be covered by the system of the home State, and that EEA law cannot force a State to expand the medical services covered by its system.[38] Accordingly, it is submitted that it may be of significance for the EEA compatibility of refusing coverage whether the treatment in the home State can be considered equally effective as the treatment abroad, if the patient, having decided to rather receive treatment abroad, does not get coverage for the costs of the treatment abroad to the same extend as he would have for the treatment offered in the home State.

75. The Government of Iceland considers the fourth question in both cases to concern mainly the factual situations in the cases at hand, and has therefore not submitted observations with regard to these questions.

76. The Government of Iceland suggests answering the questions as follows:

> *1. It is compatible with Articles 36 and 37 of the EEA Agreement and Article 22 of Council Regulation (EC) No 1408/71 to refuse coverage of expenses for treatment abroad which according to international medicine must be considered experimental or test*

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36 Reference is made to Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraphs 103–105.

37 Reference is made to Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraphs 103–104.

38 Reference is made to Case 238/82 *Duphar BV and Others* v *The Netherlands State* [1984] ECR 523, at paragraph 17; and Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraphs 86–87.

treatment, when there is no entitlement to such treatment in the home State;

2. E-11/07: It is of no significance for the answer to question No 1 that the method of treatment itself is internationally recognised and documented, but that only applies to other medical indications than those which the patient in question has;

E-1/08: It may be of significance for the answer to Question No 1 that the method of treatment in question must be considered to be implemented and recognized so that there is an entitlement to the treatment in the home State at the time of application for treatment abroad;

3. It is compatible with Articles 36 and 37 of the EEA Agreement to refuse coverage of expenses for hospital treatment aborad if the patient in the home State can receive equally effective medical treatment assessed according to accepted international methods within a medically justifiable time limit;

1. It may be of significance for the answer to this question whether coverage of such expenses may be refused even if the treatment abroad is proven to be more advanced so that the treatment in the home State cannot be considered equally effective.

2. E-1/08: It is of no significance for the answer to this question that the patient, having decided to receive treatment abroad rather than an adequate treatment in the home State, does not get coverage for the costs of treatment abroad to the same extent as the treatment offered in the home State would have cost.

The Government of the Netherlands

77. The Government of the Netherlands makes no suggestions as to the answers the Court should give to the referring courts, but elaborates on certain aspects which it considers the Court should take into account when giving its Advisory Opinion.

78. Having regard to the case law of the ECJ, the Government of the Netherlands submits that Community law does not detract from the power of the Member States to organise their social security systems.[39] In the absence of

[39] Reference is made to Case 238/82 *Duphar and Others* v *The Netherlands State* [1984] ECR 523, at paragraph 16; Case C-70/95 *Sodemare and Others* v *Regione Lombardia* [1997] ECR I-3395, at paragraph 27; Case C-158/96 *Raymond Kohll* v *Union des caisses de maladie* [1998] ECR I-1931, at paragraph 17; and Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraph 44.

harmonisation at Community level, it is therefore for the legislation of each Member State to determine the conditions for entitlement to benefits.[40] Nevertheless, the Member States must comply with Community law when exercising that power.[41]

79. In that regard, the Government of the Netherlands considers it settled case law that Article 49 EC precludes the application of any national rule which has the effect of making the provision of services between Member States more difficult than the provision of services within a single Member State.[42] When national rules have this effect, it is necessary to determine whether these rules can be justified in the light of overriding reasons; and if this is the case, to make sure that they do not exceed what is objectively necessary for that purpose and that the same result cannot be achieved by less restrictive rules.[43]

80. For the Government of the Netherlands, it follows that EEA law cannot in principle have the effect of requiring an EEA State to extend the list of medical services paid by its social insurance system, and that it is irrelevant in that regard whether or not a particular type of medical treatment is covered by the sickness insurance system of other EEA States.[44] To the Government of the Netherlands, the decisive point is that the basket of benefits must be drawn up on the basis of objective, non-discriminatory and verifiable criteria. It considers that a condition for a treatment to be "sufficiently tried and tested by international medical science" satisfies these requirements.[45]

81. In order to elucidate its position, the Government explains the concept of "evidence based medicine". The importance of scientific studies in the application of this concept is highlighted, as are the relatively insignificant weight of expert opinions. Also, it is pointed out that even if all EEA States

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40 Reference is made to Joined Cases C-4/95 and C-5/95 *Fritz Stöber and José Manuel Piosa Pereira* v *Bundesanstalt für Arbeit* [1997] ECR I-511, at paragraph 36; Case C-158/96 *Raymond Kohll* v *Union des caisses de maladie* [1998] ECR I-1931, at paragraph 18; and Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraph 45.

41 Reference is made to Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraph 46.

42 Reference is made to Case C-381/93 *Commission* v *France* [1994] ECR I-5145, at paragraph 17; Case C-158/96 *Raymond Kohll* v *Union des caisses de maladie* [1998] ECR I-1931, at paragraph 33; and Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraph 61.

43 Reference is made to Case 205/84 *Commission* v *Germany* [1986] ECR 3755, at paragraphs 27 and 29; Case C-180/89 *Commission* v *Italy* [1991] ECR I-709, at paragraphs 17–18; Case C-106/91 *Claus Ramrath* v *Ministre de la Justice* [1992] ECR I-3351, at paragraphs 30–31; and Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraph 75.

44 Reference is made to Case 238/82 *Duphar and Others* v *The Netherlands State* [1984] ECR 523, at paragraphs 17 and 20-22; and Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraphs 86, 87 and 89.

45 Reference is made to Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraph 94.

used the same methodology, differences could still persist due to different standards of proof required for reimbursing the costs of a treatment, be it on the general level or with regard to specific treatments for particular afflictions of patients.

82. The Government of the Netherlands submits that evidence based medicine provides objective, non-discriminatory and verifiable criteria, and that an EEA State is allowed to apply such criteria in order to decide on the reimbursement of costs for a treatment abroad, even if an adequate treatment cannot be provided to the patient in the home State. An EEA State may thus demand that a specific treatment abroad would be an included benefit according to such criteria in the patient's country if the treatment were available there. For this reason, it is found to be irrelevant whether a treatment in an individual case actually resulted in an improvement in the specific patient's state of health.

The Government of Poland

83. The Government of Poland points out that although the elimination of protectionist measures in the field of medical services is an essential part of the principle of free movement of services, it also needs to be kept in mind that Article 152(5) EC lays down that Community action in the field of public health fully respects the responsibility of the Member States for the organisation and delivery of health services and medical care. Furthermore, Articles 36 and 37 EEA should be interpreted in light of Article 22(2) of Regulation 1408/71.

84. With regard to Regulation 1408/71, it is pointed out that Article 22 was amended by Regulation No 2793/81 subsequent to the rulings of the ECJ in the *Pierik* cases, out of the fear of the Member States that a large number of patients would want to benefit from the possibilities for treatment abroad which these judgments entailed.[46] It is argued that it follows from the wording of the provision that Member States may refuse to cover the costs of services obtained abroad if these services are not among those to which a given person is entitled to under the public health insurance system of his country.

85. The Government of Poland submits that the same result follows from Article 49 EC. It is argued that no obligation of a Member State to extend the catalogue of medical services covered by its public health insurance system can be inferred from Community law, and that it is insignificant whether a given service is financed from public resources in another Member State. It is pointed out that the ECJ consistently has recognised this principle and the importance of promoting the financial stability of health insurance systems, as long as the

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[46] Reference is made to Case 117/77 *Bestuur van het Algemeen Ziekenfonds Drenthe-Platteland* v *G. Pierik* [1978] ECR 825, at paragraph 22; and Case 182/78 *Bestuur van het Algemeen Ziekenfonds Drenthe-Platteland* v *G. Pierik* [1979] ECR 1977, at paragraph 16.

list of services excluded is based on unbiased criteria, i.e. without differentiation depending on the origin of services.[47] The Government of Poland concludes that the first question should be answered in the positive.

86. With regard to the second question in Case E-11/07, it is argued that a method of treatment is always connected to specific medical indications. Referring to the answer to the first question, the Government of Poland considers it to be in line with EEA law to refuse coverage of treatment abroad if coverage of the treatment is generally refused on the ground that it is considered experimental with regard to the medical indication of the patient. Correspondingly, it is submitted with regard to the second question in Case E-1/08 that it is insignificant whether the introduction of a service is considered by the EEA State or whether there may be reasons to introduce it. It is argued that what matters is whether a service is objectively within the scope of covered treatments, and that deviating from this principle would result in a failure to respect the exclusive competences of the EEA States to determine the benefits within their public health insurance system.

87. To the Government of Poland, this competence is also decisive for the answer to the third question from the referring courts. It is submitted that even if the ECJ has stated that refusal to accept treatment abroad is acceptable if an identical or equally effective treatment is offered to the patient in due time, the general precondition for the right to coverage of treatment abroad is still that the desired health care belongs to the group of services which are, according to the national legislation of the patient's home State, funded by the sickness insurance system of the home State. Thus, it is considered irrelevant whether the treatment abroad is possibly more advanced than the treatment offered in the home State.[48] The Government of Poland concludes that the State is not obliged to reimburse costs for treatment abroad if it provides the patient appropriate treatment according to commonly recognised methods within a medically justified time limit, even if the therapy offered abroad is considered more advanced.

88. Addressing question 3b) in Case E-1/08, the Government of Poland contends that the question referring to the equivalent amount of costs for treatment in the home State is only theoretical. In that regard, the Government of Poland argues that no treatment analogous to that received in Denmark was provided in Norway. It is nonetheless noted that the obligation of an EEA State to cover costs for treatment abroad is in principle limited to the amount

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47 Reference is made to Case 238/82 *Duphar BV and Others* v *The Netherlands State* [1984] ECR 523, at paragraph 16; Case C-158/96 *Raymond Kohll* v *Union des caisses de maladie* [1998] ECR I-1931; Case C-120/95 *Nicolas Decker* v *Caisse de maladie des employés privés* [1998] ECR I-1831; Case C-385/99 *Müller-Fauré and van Riet* [2003] ECR I-4509; and Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraphs 87–97.

48 Reference is made to Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraphs 87 and 103; and Case C-372/04 *Yvonne Watts* v *Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-4325, at paragraphs 61–62.

equivalent to costs of such treatment which are reimbursable in accordance with the national principles of the home State, when that obligation is derived from the freedom to provide services. It is added that patients are entitled to full reimbursement only if the treatment abroad has been obtained on the basis of an authorisation issued according to Article 22(1)(c) of Regulation 1408/71.[49]

89. Finally, the Government of Poland submits that it is acceptable to refuse coverage of treatment abroad which is within the scope of services covered by the national sickness insurance if the competent institution provides the possibility of an identical or equally effective treatment without undue delay. It is argued that otherwise, free movement of patients would not only lead to increased payments, but also disrupt hospital care organisation.[50]

90. The Government of Poland suggests answering the questions as follows:

> *1. Neither Articles 36 and 37 of the EEA Agreement nor Article 22 of Regulation (EEC) 1408/71 are against refusals by a competent authority of a Member State to cover costs of treatment obtained in another Member State owing the fact that within the common health insurance system of the former State there is no entitlement to such services due to its experimental nature.*
>
> *2. That a given therapeutic method as such is recognised by the international medical circles, however with regard to other medical indications than those of the interested person, is of no relevance to resolution of the first question.*
>
> *Whether the therapeutic method applied should be considered as recommended for application in the relevant State or whether the State has been considering future introduction of this method is of no relevance to resolving the first question.*
>
> *3. Refusal to cover the costs of hospital treatment obtained in another Member State if the patient can be offered appropriate treatment, concordant with the commonly recognised standards, within a period under the maximum period acceptable in medical terms, in the State*

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49 Reference is made to Case C-158/96 *Raymond Kohll* v *Union des caisses de maladie* [1998] ECR I-1931; Case C-120/95 *Nicolas Decker* v *Caisse de maladie des employés privés* [1998] ECR I-1831; Case C-385/99 *Müller-Fauré and van Riet* [2003] ECR I-4509; Case C-368/98 *Abdon Vanbraekel and Others* v *Alliance nationale des mutualités chrétiennes* [2001] ECR I-5363; and Case C-372/04 *Yvonne Watts* v *Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-4325.

50 Reference is made to Case C-385/99 *Müller-Fauré and van Riet* [2003] ECR I-4509, at paragraphs 79–82; and Case C-372/04 *Yvonne Watts* v *Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-4325, at paragraphs 110–113.

where they are covered with health insurance system, is compliant with Articles 36 and 37 of the EEA Agreement.

The fact that the method of adequate treatment applied in another Member State may be considered more advanced is of no relevance to the resolution of the basic issue expressed in question three.

The Government of the United Kingdom

91. On the assumption that the treatments received in both cases were indeed experimental/test treatment, the Government of the United Kingdom, addressing the first question, points out that both the Plaintiff and the Appellant did not satisfy the conditions of the Norwegian legislation for entitlement to benefits, and accordingly, that they did not satisfy the conditions of Article 22(1) of Regulation 1408/71 for entitlement to benefits. Furthermore, it is submitted that the refusal of an authorisation to go to the territory of another EEA State for treatment is not precluded by Article 22(2), as experimental and test treatment are not among the benefits provided for by the legislation of Norway.

92. The Government of the United Kingdom considers this to be a strong indication that the claimants cannot rely on Articles 36 and 37 EEA either. It is argued that whilst the fact that a national measure is consistent with a provision of secondary legislation cannot have the effect of removing it from the scope of a Treaty provision, the ECJ has considered Article 22 of Regulation 1408/71 alongside Article 49 EC in a series of cases, without identifying any substantive differences between their requirements, save in respect of the bases of calculation of the reimbursement which must be provided.[51]

93. Moreover, reference is made to a number of principles developed by the ECJ with regard to reimbursement for medical treatment abroad; i.e. that Article 49 EC precludes only the application of national rules which have the effect of making the provision of services between Member States more difficult than the provision of services purely within a Member State, that Article 49 EC cannot require a Member State to extend the list of medical services paid for by its social security system, and that Community law does not detract from the power of the Member States to organise their social security and health care systems. Whilst such power must be exercised in accordance with the general principles of Community law, there remains a broad discretion to determine the basic parameters of a social security and health care system.[52] It is submitted that these principles must lead to the

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51 Reference is made to Case C-372/04 *Yvonne Watts* v *Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-4325, at paragraphs 47 and 124–143.

52 Reference is made to Case C-372/04 *Yvonne Watts* v *Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-4325, at paragraph 94; Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraphs 45, 83–87 and 91–98; and Case C-385/99 *Müller-Fauré and van Riet* [2003] ECR I-4509, at paragraphs 98 and 106.

conclusion that the general exclusion of test and experimental treatment from cost coverage does not constitute a restriction pursuant to Articles 36 and 37 EEA, given that this exclusion is non-discriminatory and applies to treatment abroad in the same way as to treatment at home.

94. Furthermore, the Government of the United Kingdom contends that even if a restriction were to be recognised, it could be justified by the objectives to avoid the danger of undermining the financial balance of the social security system, to provide a balanced medical and hospital service and to maintain treatment capacity and medical competence on national territory.[53]

95. Accordingly, it is submitted that the first question should be answered in the affirmative. It is further submitted that the question of whether treatments are indeed to be regarded as test or experimental treatment is a matter for the national authorities and courts, and that they are required to reach their conclusion with reference to the circumstances of the particular patient and the particular point in time at which the treatment is sought. In that regard, the Government of the United Kingdom considers the aspects highlighted in the second questions and in question 4b) in Case E-11/07, respectively question 4d) in Case E-1/08, to be of no significance.

96. The third question is addressed on the assumption that the treatment in question is not experimental or test treatment but is, in principle, available under the domestic health care system. The Government of the United Kingdom submits that a presumption in favour of domestic treatment constitutes an obstacle to the free movement of services which may, however, be justified according to the criteria in the case law of the ECJ. It is argued that delay in receiving treatment is no issue here, and that the grounds of justification accepted by the ECJ relating to the financial balance of the social security system, the maintenance of a balanced medical and hospital system open to all and the maintenance of treatment capacity and medical competence on national territory are of general application.[54] It is added that the latter policy aim would be jeopardised even if reimbursement would be granted only up to the level of payment which would have been available for treatment within the domestic system.

97. Finally, with regard to the issues raised by question 4, the Government of the United Kingdom further submits that national authorities are entitled to rely on domestic medical opinion, provided that it takes into account international medical standards, notwithstanding that the patient is able to find some medical practitioner elsewhere in the EEA who offers a different view. It is argued that relying on domestic expertise is a matter of fairness to national

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53 Reference is made to Case C-372/04 *Yvonne Watts* v *Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-4325, at paragraphs 103–105.

54 Reference is made to Case C-372/04 *Yvonne Watts* v *Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-4325, at paragraphs 103–122.

taxpayers, that is has practical advantages as to the availability of medical records, and that otherwise patients would be encouraged to search the EEA for a doctor who is prepared to endorse medical treatment which their doctors at home had decided to be unsuitable or inappropriate for them.

98. The Government of the United Kingdom suggests answering the questions as follows:

> *1. Norway is not required to provide funding for patients to receive experimental or test treatment, which is not available within its domestic health care system, in another Member State.*
>
> *2. For those treatments which are available, Norway is entitled to operate a presumption whereby they should be carried out within the domestic health care system, provided that can be done within a period which is medically justifiable.*
>
> *3. Norway is not required to provide funding for medical treatment received in another Member State for a particular patient where that treatment has been deemed by medical practitioners within the domestic health care system to be unsuitable or inappropriate for the patient.*

The EFTA Surveillance Authority

99. As a preliminary observation, the EFTA Surveillance Authority (hereinafter "ESA") notes that whereas the right to reimbursement according to Article 22 of Regulation 1408/71 is determined in relation to the costs of the place of treatment, entitlement to reimbursement of costs based on Article 36 EEA is granted only within the limits of the cover provided for by the sickness insurance of the home State.[55] Also, ESA points out that although Article 22 is based on a system of preliminary authorisation, the lack of authorisation is without prejudice to the right to reimbursement according to Article 22 if the authorisation sought by the Plaintiffs has been wrongfully refused.[56] Nevertheless, the right to reimbursement under Article 22 is subject to the conditions that the treatment must be included in the home State's social security system, that the insured person satisfies the conditions of the legislation of the home State for entitlement to benefits, and that the patient cannot be given such treatment within the time normally necessary for obtaining the treatment in that State, taking account of his current state of health and the probable course of the disease.

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55 Reference is made to Case C-368/98 *Abdon Vanbraekel and Others* v *Alliance nationale des mutualités chrétiennes* [2001] ECR I-5363, at paragraph 33; and Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraph 98.

56 Reference is made to Case C-368/98 *Abdon Vanbraekel and Others* v *Alliance nationale des mutualités chrétiennes* [2001] ECR I-5363, at paragraph 34.

100. With regard to Article 36 EEA, ESA observes that medical activities can fall within the scope of Article 37 EEA, and that any national rule which has the effect of making the provision of services between EEA States more difficult than the provision of services purely within an EEA State constitutes a restriction on the free movement of services.[57] ESA considers the fact that the Norwegian system precludes patients which are entitled to receive treatment from other providers than the national health service from choosing a hospital on their own, but obliges them to contact a public body which will procure the necessary services on behalf of the patient, to constitute a restriction on the freedom to provide services under Article 36 EEA, comparable to a prior authorisation requirement.[58]

101. ESA considers it to be appropriate to assess the first and the third questions in both cases together. It thereby bases itself on the understanding that the questions concern treatment which is experimental, and that such treatment is not covered under the Norwegian legislation.

102. As a starting point, ESA notes that EEA law does not detract from the power of the State to organise its social security system as it seems fit. In the absence of harmonisation, it is for the legislation of each EEA State to determine which kind of treatment shall be paid for by the social security system of that State. EEA law cannot in principle have the effect of requiring a State to extend the list of medical services paid for by its social security system.[59] ESA concludes that an EEA State is free to refuse to cover experimental treatment as part of its social security system, and that EEA law will not require it to reimburse costs for such treatment simply because it is received abroad.

103. Nevertheless, ESA suggests that the conditions under which treatment may be procured under the applicable Norwegian provisions should be assessed in order to determine whether they can be justified in accordance with the case law on restrictions on the fundamental freedoms.[60] ESA considers the elements which contribute to creating a restriction on the freedom to provide services to be the following: the construction of the system in a way which equates it to a system of prior authorisation; the condition that the treatment and its benefits

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57 Reference is made to Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraph 57; Case E-1/03 *EFTA Surveillance Authority* v *Iceland* [2003] EFTA Court Report 143, at paragraph 28; and Case C-372/04 *Yvonne Watts* v *Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-4325, at paragraph 94.

58 Reference is made to Case C-372/04 *Yvonne Watts* v *Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-4325, at paragraph 98.

59 Reference is made to Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraph 87; and Case 238/82 *Duphar BV and Others* v *The Netherlands State* [1984] ECR 523, at paragraph 17.

60 Reference is made to Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraph 75.

be sufficiently documented; and the condition that the treatment, which is expected to benefit the patient, cannot be properly provided in Norway.

104. ESA submits that the requirement for prior authorisation as such is acceptable if the two conditions for the authorisation comply with the requirements of necessity and proportionality.[61]

105. With regard to the first condition that the treatment must be sufficiently documented, it is pointed out that it applies irrespective of where the treatment is provided. If interpreted on the basis of what is sufficiently tried and tested by international medical science, ESA therefore considers this condition to satisfy the requirements of case law that a restriction be based on objective and non-discriminatory criteria which are known in advance.[62]

106. In the opinion of ESA, it is also compatible with Article 36 EEA to refuse coverage of treatment abroad where the patient has been offered adequate treatment in his home State within a medically acceptable time limit. It is noted that the ECJ stated in *Smits and Peerbooms*, at paragraph 103, that treatment abroad may only be refused if "the same or equally effective treatment" can be obtained without undue delay in the home State. However, it is argued that since the question of the standard of treatment was not an issue in the reasoning of the ECJ, this statement cannot be read as an exception to the general principle that it is up to each EEA State to decide on the benefits to be included in its social security system. Giving a right under EEA law to treatment abroad which is not available in the home State would have the effect of requiring the home State to extend the list of medical services paid for by its social insurance system. Furthermore, this would endanger the planning of the social security system, which the ECJ has also held to be a legitimate consideration. With regard to the argument concerning extension of the list of covered treatments, it is added that this would hold true irrespective of whether treatment of an illness is already covered by the social security system or not. Holding that the rights created by Article 36 EEA could be more extensive than what a patient would be entitled to in the home State would presuppose that an independent right to state funding of medical treatment could be derived from the EEA Agreement, an understanding which ESA does not share.[63]

107. In that regard, ESA also rejects the idea of a right to at least the money that would have been spent in the home State. Such a right would allow patients to sidestep the prior authorisation requirement. This would render

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61 Reference is made to Case C-385/99 *Müller-Fauré and van Riet* [2003] ECR I-4509, at paragraphs 81–83.

62 Reference is made to Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraphs 90 and 94–98.

63 Reference is made to Case C-372/04 *Yvonne Watts* v *Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-4325, at paragraphs 57–78 and 145; and Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraphs 87, 103 and 106.

meaningless the case law of the ECJ allowing a State to retain a certain element of control by imposing such a requirement and planning of hospital services would serve no purpose. Only if the treatment is provided within the system do the resources remain there, being utilised to pay medical professionals working there as a part of planned capacity.[64]

108. ESA concludes that it falls to the national judge in each case to assess whether the Norwegian legislation results in a right to the treatment in question. Only if this is the case does Article 22 of Regulation 1408/71 require that authorisation may not be refused where the patient cannot be given the treatment within a medically justified time.

109. In its assessment of the second questions, ESA considers that the question of whether a particular treatment, which is in itself internationally recognised and documented, could be applied based on different medical indications than those to which it is habitually applied, is first and foremost a medical issue. In any event, it is argued that EEA law does not confer a right to receive funding for services procured in another EEA State which are not funded at home. Similarly, how a treatment is perceived or whether it is implemented in Norway cannot be accorded any special significance when it comes to evaluating whether it is in fact internationally recognised, the latter being a matter of fact which is for the referring court to assess.

110. Addressing the fourth questions, ESA submits that the factors listed cannot have any relevance insofar as taking them into account would lead to a right to treatment even if no such right exists under the national law.

111. The EFTA Surveillance Authority suggests answering the questions as follows:

> *Article 36 EEA and Article 22 of Regulation 1408/71 do not preclude a State from refusing to cover experimental treatment in another EEA State where there is not entitlement to such treatment under the national system.*
>
> *Article 36 EEA and Article 33 of Regulation 1408/71 do not preclude a State from refusing to cover hospital treatment in another EEA State where adequate treatment, assessed according to accepted international standards, is available within a medically justifiable time limit in the home State, even if the treatment in the host State is considered to be more advanced. Moreover, if the patient decides to receive the more advanced treatment abroad instead of the adequate treatment on offer in the home State, the said provisions do not grant the patient a right to*

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64 Reference is made to Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraph 81; and Case C-372/04 *Yvonne Watts* v *Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-4325, at paragraph 112.

have reimbursed at least the expenses that would have been incurred had the patient accepted the adequate treatment on offer in that State.

It is of no significance for the answers above that:

- *the treatment is internationally recognised and documented for other medical conditions that that displayed by the patient in question;*

- *the treatment must be considered to be implemented in the home State or the home State is considering its implementation in the future;*

- *the home State as a matter of fact does not offer the treatment received abroad;*

- *the patient as a matter of fact has not been offered the treatment in question in the home State even if the treatment is offered there;*

- *the patient has been assessed in the home State, but has not been given the offer of further surgical treatment because the patient is not considered to get documented benefit from the treatment;*

- *the treatment given in the host State actually resulted in an improvement of the specific patient's state of health; or*

- *as a matter of fact, the patient has not been offered adequate treatment in the home State.*

The Commission of the European Communities

112. The Commission of the European Communities (hereinafter "the Commission") observes that the ECJ has held that certain barriers to the exercise of the free provision of services in the sphere of hospital treatment may be justified by overriding considerations. These considerations include the possible risk of seriously undermining a social security system's financial balance and the public health objective of maintaining a balanced medical and hospital service essential for the population. It is thus not in principle incompatible with EEA law for an EEA State to exclude certain products or types of medical or hospital treatment from reimbursement under its social security scheme, and EEA law cannot have the effect of requiring an EEA State to extend the list of medical services paid for by its social security system, as long as the criteria used for determining the treatments covered by the national

system are objective, non-discriminatory and known in advance, thereby avoiding any arbitrary exercise of discretion.[65]

113. The Commission considers that the exclusion of experimental and test treatment from "necessary health care" under Norwegian law satisfies these criteria. It points out that there is no entitlement to the coverage of costs of such treatment regardless of whether it is offered in Norway or another EEA State. However, it is added that in order to ensure compliance with EEA law, "experimental treatment" must not be interpreted as including treatments which are sufficiently tried and tested by international medical science. Whether this is so must be assessed by the national authorities in each individual case, based on an individual examination of the nature of the particular treatment in relation to the patient's specific condition, and taking into consideration all the relevant 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 EEA State in which the treatment is provided. To the Commission, these criteria also provide the solution to question 4b) in Case E-11/07.[66]

114. With regard to question 3, the Commission considers the rule that treatment abroad should not be authorised if a patient receives an offer of adequate medical treatment at home within a medically justifiable time limit to be broadly similar in result to that examined by the ECJ in *Smits and Peerbooms* and *Müller-Fauré*, where the Dutch legislation provided for coverage of costs for the treatment only where such treatment was "necessary". It is submitted that it follows from this case law that in order to be in compliance with Article 36 EEA, such a rule must be interpreted in the way that an authorisation to go abroad may be refused only if there is a treatment in the home State which is the same or equally effective and can be obtained without undue delay. It is added that the ECJ considered that a "necessity" requirement interpreted in this way could be justified as allowing an adequate, balanced and permanent supply of high-quality hospital treatment to be maintained at national level, and the financial stability of the sickness insurance system to be assured.[67]

115. The Commission more specifically submits that in order to determine whether an equally effective treatment is available, the national authorities are

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65 Reference is made to Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraphs 72–74, 86–87, 90 and 106; and Case C-372/04 *Yvonne Watts* v *Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-4325, at paragraphs 115–116.

66 Reference is made to Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraphs 94–98; Case C-385/99 *Müller-Fauré and van Riet* [2003] ECR I-4509, at paragraph 90; and Case C-56/01 *Patricia Inizan* v *Caisse primaire d'assurance maladie des Hauts-de-Seine* [2003] ECR I-12403, at paragraph 46.

67 Reference is made to Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraph 103; and Case C-385/99 *Müller-Fauré and van Riet* [2003] ECR I-4509, at paragraphs 89–91.

required to have regard to all circumstances of each specific case and to take due account of the individual patient's current medical condition and medical history and the degree of pain and the nature of any disability suffered which might make it impossible or extremely difficult for him to carry out a professional activity. This individual assessment must be based on objective and non-discriminatory criteria by reference to accepted international methods, the procedural system must be easily accessible and refusals must be capable of being challenged in judicial or quasi-judicial proceedings. The Commission considers that insofar the treatment abroad is not experimental, these considerations provide also the answer to question 4c) in Case E-11/07. With regard to question 4b) in Case E-11/07, the Commission is however of the opinion that it is not an indication in itself for there being no equivalent treatment available if a certain treatment is not used for a certain condition.[68]

116. The Commission understands question 3b) in Case E-1/08 as asking whether the costs of a treatment abroad should be refunded if the decision of the authorities refusing coverage of the costs of treatment were subsequently found to be unlawful, for example because equally effective treatment for the patient did not exist in Norway. The Commission considers the answer to this question to be that the person concerned is entitled to reimbursement for costs directly by the competent institution, for the same amount which would have been covered if the initial authorisation would have been issued.[69]

117. Finally, if the conditions for entitlement to an authorisation for treatment abroad have not been met, the Commission considers it to be without significance whether the treatment abroad subsequently resulted in an improvement of the patient's state of health.

118. The Commission of the European Communities suggests answering the questions as follows:

> *1. Articles 36 and 37 of the EEA Agreement do not preclude a provision to the effect that coverage of costs for hospital treatment abroad will be refused in relation to experimental treatment. In this context, "experimental treatment" must be understood as referring to treatment which is not sufficiently tried and tested by international medical science.*
>
> *2. In the case of hospital treatment which is not experimental, Articles 36 and 37 of the EEA Agreement preclude a refusal to cover costs for*

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68 Reference is made to Case C-385/99 *Müller-Fauré and van Riet* [2003] ECR I-4509, at paragraph 90; Case C-372/04 *Yvonne Watts* v *Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-4325, at paragraph 119; Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, at paragraph 90; and Case C-56/01 *Patricia Inizan* v *Caisse primaire d'assurance maladie des Hauts-de-Seine* [2003] ECR I-12403, at paragraph 48.

69 Reference is made to Case C-368/98 *Abdon Vanbraekel and Others* v *Alliance nationale des mutualités chrétiennes* [2001] ECR I-5363, at paragraph 53.

treatment abroad, unless an equally effective treatment can be obtained without undue delay in the home State. The evaluation of whether equally effective treatment is available must be based on the circumstances of each individual case by reference to accepted international methods.

3. Where it is subsequently established that a request for authorisation for treatment abroad was unlawfully refused, the person concerned is entitled to reimbursement from the home Member State.

Carl Baudenbacher
Judge-Rapporteur