REPORT FOR THE HEARING

in Case E-9/23

APPLICATION to the Court pursuant to the second paragraph of Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice in the case between

the EFTA Surveillance Authority

and

the Kingdom of Norway,

seeking a declaration that, in relation to certain national rules and practices governing access to in-patient treatment in other EEA States, the Kingdom of Norway has breached Article 36 of the Agreement on the European Economic Area, Article 20(2) of Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems and/or Article 3 of the Agreement on the European Economic Area, as well as the principle of legal certainty.

I Introduction

1. The application results from the EFTA Surveillance Authority ("ESA") deciding to conduct an own-initiative investigation of the Norwegian rules for in-patient treatment received abroad. The Norwegian rules have undergone changes since the investigation started in 2009, and the current application addresses, in particular, the rules at the deadlines for compliance following ESA's two reasoned opinions, namely, 20 January 2018 ("the First Compliance Deadline") and 22 December 2022 ("the Second Compliance Deadline").

2. ESA asserts that, by maintaining in force national requirements which are contrary to, or do not reflect, the right under EEA law for in-patient treatment in other EEA States and having a procedural system which fails to apply EEA law for in-patient treatment in other EEA States, Norway has failed to fulfil its obligations under Articles 3 and 36 of the Agreement on the European Economic Area ("EEA Agreement" or "EEA"), Article 20(2) of Regulation (EC) No 883/2004 ("Regulation 883/2004" or "the Regulation"), as well as the principle of legal certainty.

3. ESA's application is based on three pleas:

(1) Article 36 EEA and Article 20(2) of Regulation 883/2004 confer on patients the right to seek treatment abroad where the same or equally-effective treatment cannot be provided in the home State within a time limit which is medically justifiable, taking into account the patient's current state of health and the probable course of their illness. By maintaining in force national provisions which are in conflict with, or do not correctly reflect this right, and/or by failing correctly to apply Article 36 EEA and/or Article 20(2) of Regulation 883/2004 in practice, Norway has acted in breach of Article 36 EEA and/or Article 20(2) of Regulation 883/2004:

(i) At the First Compliance Deadline, the fourth paragraph of Section 2-1b of the Patients' Rights Act ("PRA") and Section 6 of the Prioritisation Regulation ("PR") restricted the ability of patients to seek treatment abroad when the medically-justifiable deadline for treatment could not be met. Patients could not travel freely abroad on expiry of the deadline but were required to contact the Norwegian Health Economics Administration ("Helfo").

(ii) At the Second Compliance Deadline, the fourth paragraph of Section 2-1b PRA and Section 6 PR did not provide any right for patients to seek treatment abroad when the deadline cannot be met: any such right was removed by the Norwegian legislature with effect from 1 March 2020. Prior to this date, the provisions were problematic as set out in point (i) above.

(iii) At the First Compliance Deadline, the fifth paragraph of Section 2-1b PRA and the fourth paragraph of Section 3 PR were framed and/or applied in such a way that the existence of waiting lists (lack of capacity) was not taken into consideration and thus whether treatment could be given within a medically-justifiable deadline was not considered correctly or at all.

(iv) At the Second Compliance Deadline, letter (a) of the second paragraph of Section 2-4a PRA and Section 3 PR (which replaced the provisions mentioned immediately above) required the patient to document that the treatment abroad is more effective than the national treatment (a higher threshold than the same or equally-effective), and failed to include any deadline within which treatment must be given.

(2) At the Second Compliance Deadline and at least since the First Compliance Deadline, Norway has failed to secure patient rights to equally-effective treatment in time, in breach of Article 36 EEA and/or Article 20(2) of Regulation 883/2004, by:

(i) maintaining PRA/PR jurisdictional and procedural rules which prevent and/or discourage the PRA/PR complaint and appeal bodies from correctly applying the rights to equally-effective treatment in time,

(ii) maintaining an administrative and decisional practice of the PRA/PR complaint and appeal bodies which fails correctly to apply or secure the right to equally-effective treatment in time, in breach also of Article 3 EEA.

(3) At the Second Compliance Deadline and at least since the First Compliance Deadline, the unclear and/or conflicting national rules and practice and the national PRA/PR complaint and appeals procedure and practice breach the principle of legal certainty and undermine the effectiveness of Article 36 EEA and Article 20(2) of the Regulation, in breach of those provisions and/or of Article 3 EEA.

4. Norway opposes the action.

II Legal background

EEA law

5. Article 3 EEA reads:

> *The Contracting Parties shall take all appropriate measures, whether general or particular, to ensure fulfilment of the obligations arising out of this Agreement.*
>
> *They shall abstain from any measure which could jeopardize the attainment of the objectives of this Agreement.*
>
> *Moreover, they shall facilitate cooperation within the framework of this Agreement.*

6. Article 36 EEA reads:

> *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.*
>
> *2. Annexes IX to XI contain specific provisions on the freedom to provide services.*

7. Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems (OJ 2004 L 166, p. 1, as corrected by OJ 2004 L 200, p. 1; Norwegian EEA Supplement 2015 No 76, p. 40) was incorporated into the EEA Agreement at point 1 of Annex VI (Social security) by Decision No 76/2011 of the EEA Joint Committee of 1 July 2011 (OJ 2011 L 262, p. 33; Norwegian EEA Supplement 2011 No 54, p. 46). Constitutional requirements were indicated by Iceland and Liechtenstein. The requirements were fulfilled by 31 May 2012 and the decision entered into force on 1 June 2012.

8. Article 20(1) and (2) of Regulation 883/2004, entitled "Travel with the purpose of receiving benefits in kind – authorisation to receive appropriate treatment outside the Member State of residence", reads:

> *1. Unless otherwise provided for by this Regulation, an insured person travelling to another Member State with the purpose of receiving benefits in kind during the stay shall seek authorisation from the competent institution.*
>
> *2. An insured person who is authorised by the competent institution to go to another Member State with the purpose of receiving the treatment appropriate to his/her condition shall receive the benefits in kind provided, on behalf of the competent institution, by the institution of the place of stay, in accordance with the provisions of the legislation it applies, as though he/she were insured under the said legislation. The authorisation shall be accorded where the treatment in question is among the benefits provided for by the legislation in the Member State where the person concerned resides and where he/she cannot be given such treatment within a time limit which is medically justifiable, taking into account his/her current state of health and the probable course of his/her illness.*

9. Regulation (EC) No 987/2009 of the European Parliament and of the Council of 16 September 2009 laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems ("Regulation 987/2009") (OJ 2009 L 284, p. 1; Norwegian EEA Supplement 2015 No 76, p. 89) was incorporated into the EEA Agreement at point 2 of Annex VI (Social security) by Decision No 76/2011 of the EEA Joint Committee of 1 July 2011 (OJ 2011 L 262, p. 33; Norwegian EEA Supplement 2011 No 54, p. 46). Constitutional requirements were indicated by Iceland and Liechtenstein. The requirements were fulfilled by 31 May 2012 and the decision entered into force on 1 June 2012.

10. Article 22(1), entitled "General implementing provisions", reads:

> *The competent authorities or institutions shall ensure that any necessary information is made available to insured persons regarding the procedures*

and conditions for the granting of benefits in kind where such benefits are received in the territory of a Member State other than that of the competent institution.

National law[1]

11. The EEA Agreement is implemented into Norwegian law by virtue of Section 1 of the Norwegian EEA Act:

The provisions in the main part of the Agreement on the European Economic Area shall apply as Norwegian law, with the amendments resulting from the protocol on adjustment of the agreement of 17 March 1993, of the EEA enlargement agreement of 14 October 2003, of the EEA enlargement agreement for Bulgaria and Romania in 2007 and of the EEA enlargement agreement for Croatia of 2014. The same applies to Articles 1 to 3 of the Agreement's Protocol 25 on competition in coal and steel production.

12. Regulations 883/2004 and 987/2009 have been made part of Norwegian law by Section 1-3a of the Norwegian National Insurance Act of 28 February 1997 No 19 (*folketrygdloven*) (the "NIA"). Section 1-3a NIA is entitled "Implementation of the social security coordination regulation and the implementing regulation" and reads:

Annex VI No 1 to the EEA Agreement (Regulation (EC) No 883/2004 on the coordination of social security schemes, as amended by Regulation (EC) No 988/2009, Regulation (EU) No 1244/2010, Regulation (EU) No 465/2012, Regulation (EU) No 1224/2012, Regulation (EU) No 517/2013, Regulation (EU) No 1372/2013, Regulation (EU) No 1368/2014 and Regulation (EU) 2017/492) (the social security regulation) applies as [Norwegian] law with the adaptations that follow from Annex VI, Protocol 1 and the agreement in general.

Annex VI No 2 to the EEA Agreement (Regulation (EC) No 987/2009 laying down detailed rules for the implementation of Regulation (EC) No 883/2004 on the coordination of social security schemes, as amended by Regulation (EU) No 1244/2010, Regulation (EU) No 465/2012, Regulation (EU) No 1224/2012, Regulation (EU) No 1372/2013, Regulation (EU) No 1368/2014 and Regulation (EU) 2017/492) (the implementing regulation) applies as [Norwegian] law with the adaptations that follow from Annex VI, Protocol 1 and the agreement in general.

[1] Translations of national provisions are unofficial and mainly based on those contained in the documents of the case.

> *The provisions given in or pursuant to this Act shall be waived to the extent necessary to comply with obligations arising from the regulations mentioned in the first and second paragraphs.*

13. The right to in-patient treatment is governed by the Patients' Rights Act of 2 July 1999 No 63 (*Lov om pasient- og brukerrettigheter / Pasient- og brukerrettighetsloven*) ("PRA").

14. At the First Compliance Deadline, the second paragraph of Section 2-1b PRA, entitled "Right to necessary healthcare from the specialist healthcare services", read:

> *The patient is entitled to receive necessary healthcare from the specialist health service. The specialist health service shall, within the assessment period, cf. the Patients' Rights Act s. 2-2 first paragraph, set a deadline within which the patient shall at the latest receive the necessary healthcare. The deadline shall be set in accordance with what professional responsibility would require. …*

15. At the Second Compliance Deadline, the second paragraph of Section 2-1b PRA read:

> *The patient is entitled to receive necessary healthcare from the specialist health service. The specialist health service shall, within the assessment period pursuant to s. 2-2 first paragraph, set a deadline within which the patient shall at the latest receive the necessary healthcare. The deadline shall be set in accordance with what professional responsibility would require. …The right to necessary healthcare applies to the services that the specialist health service is responsible for providing and financing, cf. the Specialist Health Services Act ss. 2-1a and 4-4.*

16. At the First Compliance Deadline, the fourth paragraph of Section 2-1b PRA read:

> *If the regional health authority has not ensured that a patient with the right to necessary healthcare from the specialist health service receives the necessary healthcare within the deadline set in accordance with the second paragraph, the patient has the right to necessary healthcare without delay, if necessary from a private service provider or a service provider outside the realm.*

17. At the Second Compliance Deadline, the fourth paragraph of Section 2-1b PRA read:

> *If the regional health authority has not ensured that a patient with the right to necessary healthcare from the specialist health service receives the necessary healthcare within the deadline set in accordance with the second paragraph, the patient has the right to necessary healthcare without delay, if necessary from a private service provider.*

18. At the First Compliance Deadline, the fifth paragraph of Section 2-1b PRA read:

> *If the regional health authority cannot provide healthcare to a patient who is entitled to necessary healthcare because there is no adequate treatment offer in the realm, the patient has the right to necessary healthcare from a service provider outside the realm within the deadline established pursuant to the second paragraph.*

19. At the Second Compliance deadline, Section 2-4a PRA, entitled "Healthcare abroad", read:

> *A patient has the right to have expenses for healthcare received in another EEA State fully or partially covered*
>
> *a) pursuant to the National Insurance Act s. 5-24a with regulations that implement the Patients' Rights Directive into Norwegian law. This applies when the healthcare in question corresponds to healthcare that the patient would have been offered in the public health and care service in Norway.*
>
> *b) pursuant to Council Regulations (EC) Nos. 883/2004 and 987/2009, which, among other things, give the right to be reimbursed for necessary healthcare during temporary stays and for planned healthcare in other EEA States if the healthcare is not provided within a reasonable time in Norway.*
>
> *A patient has the right to have expenses for healthcare received abroad fully or partially covered*
>
> *a) if the patient is entitled to necessary healthcare from the specialist health service according to s. 2-1b and there is no offer in the realm or the healthcare abroad is documented to be more effective than the healthcare offered by the public sector in Norway.*
>
> *b) pursuant to the National Insurance Act s. 5-24 and provisions issued pursuant to it, which, among other things, give the right to receive benefits*

for health services for members of the National Insurance Scheme who stay abroad over time.

Expenditure on healthcare that has been decided not to be introduced in Norway is not covered, cf. the Specialist Health Services Act s. 4-4. However, this does not apply to healthcare during temporary stays pursuant to the first paragraph, letter b.

The Ministry may issue regulations with further provisions on the types of healthcare that are covered by the expenditure coverage, conditions for having the expenses covered and the calculation of the expenditure coverage.

20. At both Compliance Deadlines, the first paragraph of Section 7-2 PRA, entitled "Complaint", read:

A patient or user or their representative who believes that the provisions in Chapters 2, 3 and 4, as well as ss. 5-1, 6-2 and 6-3, have been breached may complain to the County Governor. The complaint is sent to the body that made the individual decision or decision.

21. At the First Compliance Deadline, the second paragraph of Section 7-2 PRA read, in extract:

A patient or a representative for the patient who believes that the provision in s. 2-1b fifth paragraph has not been complied with may complain to an appellate body appointed by the Ministry. …

22. At the Second Compliance Deadline, the second paragraph of Section 7-2 PRA read, in extract:

A patient or a representative for the patient who believes that the provision in s. 2-4a second paragraph, subparagraph a, has not been complied with may complain to an appellate body appointed by the Ministry. …

23. The requirements laid down in the Patients' Rights Act are specified in the Prioritisation Regulation of 1 December 2000 No 1208 (*Prioriteringsforskriften*) ("PR").

24. At the First Compliance Deadline, the first paragraph of Section 3 PR, entitled "Healthcare abroad due to lack of competence in Norway", read:

> *A patient who is entitled to necessary healthcare, but who cannot receive healthcare because the treatment cannot be performed properly in Norway according to accepted methods, is entitled to healthcare abroad, cf. the Patients' Rights Act s. 2-1b fifth paragraph. It is a prerequisite [for this provision to apply] that the healthcare can be performed properly by the service provider abroad according to accepted methods and that the patient's condition and the treatment in question satisfy the requirements of s. 2. The assessment of the patient's benefit from the treatment shall be individual and based on international medical science.*

25. At the Second Compliance Deadline, the first paragraph of Section 3 PR read:

> *A patient who is entitled to necessary healthcare, but who cannot receive healthcare because there is no offer in the realm or healthcare abroad is documented to be more effective than the healthcare offered by the public sector in Norway, is entitled to healthcare abroad, cf. the Patients' Rights Act s. 2-4a second paragraph subparagraph a. It is a prerequisite that the healthcare can be performed properly by the service provider abroad according to accepted methods and that the patient's condition and the treatment in question satisfy the requirements of s. 2. The assessment of the patient's benefit from the treatment shall be individual and based on international medical science.*

26. At the Both Compliance Deadline, the fourth paragraph of Section 3 PR read:

> *Insufficient capacity in specialist health services does not render patients eligible for treatment abroad under this provision. Right to treatment does not include shipment/sending of laboratory samples for analysis with a foreign service provider if it is not part of treatment abroad.*

27. At both Compliance Deadlines, the first and second paragraphs of Section 6 PR, entitled "Breach of deadline", read:

> *The regional health authority in the patient's region of residence shall ensure that patients who are entitled to necessary healthcare pursuant to s. 2 [PR], or are entitled to healthcare abroad pursuant to s. 3 [PR], are offered healthcare from the specialist health service within the deadline stipulated pursuant to s. 4 or s. 4a [PR].*

If the specialist health service cannot give the patient a time to start the assessment or treatment before the deadline for necessary healthcare must be given at the latest, or the time must later be changed so that the deadline cannot be met, or if the deadline is exceeded, the specialist health service must contact Helfo immediately, cf. the Patients' Rights Act s. 2-1b fourth paragraph. If the deadline is exceeded, the patient can also contact Helfo.

28. At the First Compliance Deadline, the third paragraph of Section 6 PR read:

Helfo shall without delay ensure that the patient is offered treatment from a public service provider or, if necessary, from a private service provider in the realm or, if necessary, abroad. The patient is not free to choose a service provider.

29. At the Second Compliance Deadline, the third paragraph of Section 6 PR reads:

Helfo shall without delay ensure that the patient is offered treatment from a public service provider or, if necessary, from a private service provider in the realm. The patient is not free to choose a service provider.

30. At the First Compliance Deadline, the fourth paragraph of Section 6 PR read:

Irrespective of whether there is a breach of the deadline, the patient can apply for reimbursement of expenses for health services received in another EEA State in accordance with the regulation on benefits for health services received in another EEA State [the Norwegian reimbursement regulation]. *The patient may also be entitled to reimbursement of expenses for health services in other EEA States in accordance with the conditions in Council Regulation (EC) No 883/2004. An application for reimbursement in accordance with the regulation on benefits for health services received in another EEA State or prior approval pursuant to Council Regulation (EC) No 883/2004 is processed by Helfo.*

31. At the Second Compliance Deadline, the fourth paragraph of Section 6 PR read:

Irrespective of whether there is a breach of the deadline, the patient can apply for reimbursement of expenses for health services received in another EEA Sate in accordance with the regulation on benefits for health services received in another EEA State, cf. the National Insurance Act s. 5-24a. The patient may

also have the right to have expenses covered for health services in other EEA States pursuant to the conditions of Council Regulation (EC) No 883/2004 Article 20, cf. the National Insurance Act s. 1-3a. Decisions pursuant to Council Regulation (EC) No 883/2004 Article 20 and the regulation on benefits for health services received in another EEA country are made by Helfo, cf. the National Insurance Act s. 21-11a.

32. At the First Compliance Deadline, Section 7 PR, entitled "Right to Complaint", read:

A patient who disagrees with the assessment made pursuant to ss. 2, 2a, 3, 4, or 4a [PR] or who believes that no such assessments have been made, may complain to the County Governor, cf. the Patients' Rights Act s. 7-2. If the assessment the specialist health service makes concerns whether the patient has a right to treatment abroad, cf. s. 3, he may complain to the appellate body which is mentioned in s. 9 [PR].

33. At the Second Compliance Deadline, Section 7 PR read:

A patient who disagrees with the assessment made pursuant to ss. 2, 2a, 4 or 4a [PR], or who believes that such assessments have not been made, may complain to the County Governor, cf. the Patients' Rights Act s. 7-2 PRA.

Decisions made pursuant to s. 3 PR may be appealed to the appellate body appointed pursuant to s. 9 [PR].

*Decisions pursuant to Council Regulation (EC) No 883/2004 Article 20 or the regulation No 1466 of 22 November 2010 on benefits for health services received in another EEA State may be appealed to the Office for Health Service Appeals (*Helseklage*), cf. the National Insurance Act s. 21-11a.*

34. At both Compliance Deadlines, the first paragraph of Section 8 PR, entitled "The Appellate Body's Competence", read:

The Appellate Body decides on appeals against decisions pursuant to s. 3 [PR], cf. the Patients' Rights Act s. 7-2 second paragraph.

III Pre-litigation procedure

35. In 2009, after receiving complaints about the Norwegian system for in-patient treatment and the ability to receive such treatment abroad, ESA decided to conduct an own-initiative assessment of the relevant Norwegian rules. Between 2009 and 2013 ESA and the Norwegian Government engaged in detailed discussions about the issues raised in the complaints and the related rules.

36. On 14 May 2014, ESA issued a letter of formal notice to the Norwegian Government concluding that, by maintaining in force certain provisions of national law which affected the rights of patients to receive in-patient treatment abroad, or to be reimbursed for such treatment, Norway had failed to meet its obligations under Article 20 of Regulation 883/2004 and/or Article 36 EEA.

37. In its reply of 15 August 2014, the Norwegian Government did not accept that ESA's concerns were well-founded. Nevertheless, the Government explained that legislative amendments had been proposed which would address some of the reimbursement-related issues raised by ESA. It indicated that it was also considering providing additional information and clarifications in relation to rights to healthcare abroad, enhancing legal certainty.

38. On 3 February 2016, ESA issued a supplementary letter of formal notice. Despite the adoption of legislation extending the Norwegian reimbursement scheme to in-patient treatment abroad, ESA considered that the rest of its concerns had not been addressed. Further to the incorporation of the Patients' Rights Directive, Directive 2011/24/EU, into the EEA Agreement, ESA concluded that the relevant Norwegian law was also, or alternatively, in breach of various articles of the Directive.

39. The Norwegian Government replied to the supplementary letter of formal notice by letter of 3 May 2016.

40. ESA delivered a reasoned opinion to Norway on 20 September 2017 as ESA did not consider Norway's reply wholly satisfactory. ESA considered that no legislative amendments made to the relevant provisions since the supplementary letter of formal notice had addressed its concerns.

41. In its answer to the reasoned opinion, the Norwegian Government maintained, by letter dated 19 January 2018, that, at that the First Compliance Deadline, there was no breach of EEA law. The Government explained how, with effect from 1 January 2018, several amendments had been made to the relevant provisions to remove any doubt as to how they were intended to operate, or to clarify their operation. By letter dated 11 April 2018, Norway also informed ESA of further assessments, planned changes in the legislative framework, and practical improvements planned to ensure an easily accessible system.

42. ESA considered the legislative amendments to be unsatisfactory and, on 18 December 2019, decided to refer the matter to the EFTA Court.

43. In the course of preparing its application to the Court, ESA sent a request for information to the Norwegian Government on 7 May 2021 after having received and assessed additional information from an individual complainant. In light of the reply to the request for information and having examined further legislative changes which the Norwegian Government introduced after the expiry of the First Compliance Deadline, the Authority decided to issue a second supplementary letter of formal notice on 18 May 2022.

44. On 8 July 2022, Norway replied to the second supplementary letter of formal notice.

45. On 22 October 2022, ESA issued a supplementary reasoned opinion. One of ESA's concerns was that the manner in which Regulation 883/2004 had been incorporated into Norwegian law meant that provisions of the Regulation would not prevail over conflicting provisions of national law: in this case, the Patient's Rights Act. ESA considered this to be in breach of Articles 3 and 7 and Protocol 35 EEA.

46. On 20 December 2022, the Norwegian Government replied to the supplementary reasoned opinion maintaining its position that, at the Second Compliance Deadline, Norwegian law complied with EEA law. By amendments which had entered into force on 25 November 2022, Norway amended the manner in which Regulation 883/2004 was incorporated into Norwegian law.

47. ESA thereafter considered that the matter of incorporation and priority of Regulation 883/2004 had been sufficiently resolved. On 26 July 2023, ESA decided to refer the remaining matters to the EFTA Court. In ESA's view, the other issues raised by the reasoned opinion and the supplementary reasoned opinion remain to be resolved. ESA considers that Norway still fails to ensure patients' rights to access in-patient treatment in other EEA States, in breach of its EEA law obligations.

IV Procedure and forms of order sought by the parties

48. On 26 July 2023, ESA lodged an application pursuant to the second paragraph of Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice ("SCA") seeking a declaration that Norway has failed to fulfil its obligations under Articles 3 and 36 EEA, Article 20(2) of Regulation 883/2004, as well as the principle of legal certainty ("the Application").

49. ESA requests the Court to declare that:

> *1. By maintaining in force legislation, such as ss. 2-1b(4) PRA and 6 PR, which unjustifiably restricts or does not include the right to seek in-patient treatment in another EEA State when a medically-justifiable deadline for providing treatment cannot be met, the Kingdom of Norway has failed to fulfil its obligations under Article 20(2) of Regulation 883/2004 and/or Article 36 EEA;*

2. *By maintaining in force legislation, such as ss. 2-1b(5) and 3(4) PR and ss.2-4a(2)a PRA and 3 PR, which failed or fails correctly to reflect the rights of patients to seek treatment in another EEA State where the same or equally-effective treatment cannot be provided in the home State within a time limit which is medically justifiable, the Kingdom of Norway has failed to fulfil its obligations under Article 20(2) of Regulation 883/2004 and/or Article 36 EEA;*

3. *By maintaining in force an appeals and procedural structure under provisions such as Section 7-2 PRA and Sections 7 and 8 PR which prevents and/or discourages the PRA/PR complaint/appeal bodies from correctly applying and securing the rights of patients to seek treatment in another EEA State where the same or equally-effective treatment cannot be provided in the home State within a time limit which is medically justifiable, and/or by maintaining an administrative practice in which such rights are not secured, the Kingdom of Norway has failed to fulfil its obligations under Article 20(2) of Regulation 883/2004 and/or Article 36 EEA, in breach also of Article 3 EEA;*

4. *By maintaining in force and applying the above unclear and/or conflicting national rules and practice in relation to patients' rights to seek treatment in another EEA State, the Kingdom of Norway has breached the principle of legal certainty and undermined the effectiveness of Article 36 EEA and Article 20(2) of Regulation 883/2004, in breach of those provisions, and/or of Article 3 EEA.*

50. On 9 October 2023, Norway submitted its Defence, pursuant to Article 107 of the Rules of Procedure ("the Defence"). Norway requests the Court to:

(i) *Dismiss the Application of the EFTA Surveillance Authority as unfounded.*

(ii) *Order the EFTA Surveillance Authority to pay the costs of the proceedings.*

51. On 13 November 2023, ESA submitted its reply ("the Reply"). On 15 December 2023, Norway submitted its rejoinder ("the Rejoinder").

52. On 11 December 2023, the European Commission ("the Commission") submitted written observations pursuant to Article 20 of the Statute ("Written Observations").

V Written procedure before the Court

53. Pleadings have been received from:

- the applicant, ESA, represented by Claire Simpson, Erlend Møinichen Leonhardsen, Marte Brathovde, and Ewa Gromnicka, acting as Agents;

- the defendant, Norway, represented by Lotte Tvedt, Simen Hammersvik, Andreas Runde, and Marie Munthe-Kaas, acting as Agents.

54. Pursuant to Article 20 of the Statute, written observations have been received from:

- the Commission, represented by Bernd-Roland Killmann, Freya van Schaik, and Nicola Yerrell, acting as Agents.

VI Summary of pleas in law and arguments submitted

Parallel schemes for in-patient treatment abroad

55. The parties agree that there are three different schemes for in-patient treatment abroad in the Norwegian legal system:

(i) The first scheme will be referred to as "the Regulation 883/2004 Scheme" or "the National Insurance Act Scheme" and identifies the first paragraph of Section 1-3a NIA, which directly incorporates Regulation 883/2004 and Regulation 987/2009 into Norwegian law.

(ii) The second type of scheme will be referred to as the "PRA Schemes" or the "Supplementary Schemes". This reference identifies two further schemes: the fourth paragraph of Section 2-1b PRA ("the Breach of Deadline Scheme") and the fifth paragraph of Section 2-1b/letter (a) of the second paragraph of Section 2-4a PRA ("the No Adequate Treatment Scheme").

(iii) The third scheme will be referred to as "the Reimbursement Scheme", identifying the Norwegian reimbursement regulation No 1466 of 22 November 2010 implementing Directive 2011/24/EU and case law related to Article 36 EEA. The Reimbursement Scheme does not form part of the current proceedings. The Regulation 883/2004 Scheme and the Reimbursement Scheme are referred to together as "the EEA Schemes".

56. The parties agree that it is settled case law that Article 20(2) of Regulation 883/2004 requires patients to be permitted to travel abroad for in-patient treatment where two conditions are satisfied: First, the treatment in question is among the benefits provided for by the legislation of the competent State, i.e. Norway ("the First Condition"); and second, (i) the same or equally-effective treatment compared with the

treatment abroad (ii) cannot be provided in the State of residence within a time limit which is medically justifiable ("the Second Condition").[2]

57. The present proceedings concern the question of whether the rules and practice for receiving in-patient treatment abroad in accordance with the fourth paragraph of Section 2-1b PRA and the fifth paragraph of Section 2-1b/letter (a) of the second paragraph of Section 2-4a PRA constitute a breach of EEA law.

58. In its Application, ESA submits that the Regulation does not prohibit the existence of parallel systems and a number of EEA States provide for such systems in national legislation or in bilateral agreements.[3] However, ESA submits that all national healthcare routes which lead to in-patient treatment abroad must comply with EEA law. Even if an additional scheme goes beyond the rights under the Regulation, it must still be subjected to an assessment under Article 36 EEA.[4] ESA submits that the Norwegian PRA Schemes are conducted and operated in a way that hinders the effective enforcement of patients' EEA rights.

59. In its Defence, the Norwegian Government disputes that all national healthcare routes which lead to in-patient treatment abroad must comply with the Second Condition of Article 20(2) of Regulation 883/2004, as this would require harmonisation of national legislation and not merely minimum requirements. The Regulation provides guidance on coordination, not harmonisation, of the EEA States' social security systems.[5] Norway argues that it is free to provide supplementary schemes for in-patient treatment abroad, and that patients are secured the right to equally-efficient treatment in time through the National Insurance Act Scheme and the Reimbursement Scheme. Norway does not deny that all national law must comply with Article 36 EEA, but denies that the supplementary provisions in the fourth paragraph of Section 2-1b PRA and letter (a) of the second paragraph of Section 2-4a PRA violate Article 36 EEA.

60. In its Written Observations, the Commission focuses its observations on the framework for analysing whether the Norwegian system regarding in-patient hospital treatment in other EEA States complies with the requirements of Article 20(2) of Regulation 883/2004. The Commission observes that EEA law does not as such preclude the possibility for EEA countries to apply supplementary – or even alternative – schemes for in-patient treatment abroad. The Commission states that Norway is in principle free to organise its own healthcare system as it sees fit, subject however to the key condition that the system as a whole ensures that EEA law is complied with.[6] A patient must be

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[2] Reference is made to the judgments in *Watts*, C-372/04, EU:C:2006:325, paragraphs 46-47, and *Vanbraekel and Others*, C-368/98, EU:C:2001:400.

[3] Reference is made to the report prepared for the European Commission, *"Cross-border healthcare in the EU under social security coordination - Reference year 2020"*, submitted as Annex A.20 to the Application, p. 68.

[4] Reference is made to the judgment in *Vanbraekel*, cited above.

[5] Reference is made to Recital 4 of Regulation 883/2004 and Case E-8/20 *Criminal Proceedings Against N*, judgment of 5 May 2021, paragraphs 71-72.

[6] Reference is made to Joined Cases E-11/07 and E-1/08 *Rindal and Slinning* [2008] EFTA Ct. Rep. 320, paragraph 43, and to the judgments in *Smits and Peerbooms*, C-157/99, EU:C:2001:404, paragraphs 44-46; *Watts*, cited above, paragraph 92; and *Elchinov*, C-173/09, EU:C:2010:581.

able to benefit from the rights deriving from EEA law regardless of how this result is formally achieved under the national system.

61. The Commission observes that the existence in the national healthcare system of "parallel" schemes for in-patient treatment in other EEA States will only comply with EEA law if (i) the "additional" schemes supplement the schemes incorporating EEA law, and (ii) the (basic) scheme *itself* complies with EEA law. Further, the overall system must be designed in such a way as to ensure that a patient may at any time "revert" to the basic scheme, which must then be applied without delay in order to ensure that the rights granted under EEA law are not rendered ineffective.

First plea – the fourth paragraph of Section 2-1b PRA (Breach of Deadline Scheme) and compliance with EEA law

62. In its Application, ESA submits that the law and practice under the fourth paragraph of Section 2-1b PRA, supplemented by Section 6 PR, does not ensure the right to equally-effective treatment in time in breach of Article 20(2) of Regulation 883/2004 and Article 36 EEA.

63. ESA submits that the Breach of Deadline Scheme is problematic for two reasons. First, at both Compliance Deadlines, until the deadline for necessary healthcare is exceeded, even when it is clear in advance that the deadline will be exceeded, the patient is required to wait for the health services to take action via Helfo. Second, while the patient can approach Helfo directly once the deadline has been exceeded, the patient is prohibited or discouraged from directly going abroad because (i) the second paragraph of Section 6 PR requires the patient to contact Helfo and (ii) the third paragraph of Section 6 PR states that the patient cannot freely choose the service provider. ESA claims that it has observed this practice in decisions from the Appellate Body for Treatment Abroad ("*klagenemnda for behandling i utlandet*").[7] Such a requirement restricts the ability of the patient to seek treatment abroad in circumstances where the patient has a freestanding right to such treatment. According to ESA, Norway has not advanced any objective justification for this restriction.

64. According to ESA, the existence of a legislative cross-reference in the fourth paragraph of Section 6 PR to the possibility of seeking reimbursement under Regulation 883/2004 and the Norwegian reimbursement regulation does not cure the breach. ESA submits that the fourth paragraph of Section 2-1b PRA and Section 6 PR must, in themselves, comply with and not undermine EEA law. Moreover, the reference to reimbursement in the fourth paragraph of Section 6 PR at the First Compliance Deadline did not make it clear that in cases where the medically justifiable deadline will not be met, prior authorisation *must* be granted to the patient.

65. ESA submits that the removal of the reference to treatment abroad in the fourth paragraph of Section 2-1b PRA and the third paragraph of Section 6 PR following the

[7] Reference is made to the decisions from the Appellate Body for Treatment Abroad UKN-2012-108 p. 175 and UKN-2010-11 p. 128 in Annex A.21 to the Application.

First Compliance Deadline and before the Second Compliance Deadline means that patients no longer have a right to seek treatment abroad in conflict with EEA law.

66. In its Defence, the Norwegian Government asserts that a patient who is referred to the specialist healthcare service must receive information about whether they are entitled to necessary healthcare from that service and be given a deadline for when they at the latest are to receive the healthcare, cf. Section 2-2 PRA. It follows from the second paragraph of Section 2-1b PRA that the deadline must be set so that healthcare can be started and completed in a medically justified time, and so that the patient's condition does not worsen, or examination or treatment options are not lost along the way. Norway submits that a breach of the deadline set in accordance with the second paragraph of Section 2-1b PRA does not necessarily entail that the patient does not receive necessary healthcare within a medically justifiable time limit. The deadline is to be set such that, if necessary, Helfo can find an alternative provider who can provide the healthcare within a medically justifiable time limit.[8] Whether a patient receives necessary healthcare within a reasonable time, depends on an overall assessment of the patient's condition, state of health, when they actually receive necessary healthcare, etc.[9]

67. In relation to Regulation 883/2004, Norway submits that the Regulation is, in its entirety, as such, implemented in Norwegian law. Patients who fulfil the criteria set out in Article 20(2) of the Regulation are entitled to authorisation or reimbursement in accordance with the Regulation if they decide to apply for it and have not been accorded cost assumption for the same healthcare under another scheme. Norway submits that there is nothing in the Supplementary Schemes under the PRA and PR that restricts this right. The provisions in the PRA and PR partly provide different support and partially cover situations different to those envisaged in Article 20(2) of Regulation 883/2004.

68. In relation to the Breach of Deadline Scheme provided for in the fourth paragraph of Section 2-1b PRA, Norway submits that there is no conflict with Article 20(2) of Regulation 883/2004. This is because, first, the fourth paragraph of Section 2-1b PRA is meant to ensure that the specialist healthcare service's obligation to provide necessary healthcare within the deadline is fulfilled. If healthcare abroad under the fourth paragraph of Section 2-1b PRA is accessed before the deadline is breached, the patient will not fulfil the Second Condition of Article 20(2) of the Regulation. Second, a patient who fulfils the criteria of both the fourth paragraph of Section 2-1b PRA and Article 20(2) of the Regulation is free to choose under which schemes they want coverage.

69. Norway submits further that the fourth paragraph of Section 2-1b PRA is more favourable to patients than Article 20(2) of Regulation 883/2004 in three aspects: (i) the provision entails cost assumptions in excess of what is covered under Article 20(2) of the Regulation and where the healthcare is delivered in Norway (it covers expenses for treatment, catering, travel and accommodation and travel and accommodation for a companion if necessary); (ii) the provision provides the patient with an alternative

[8] Reference is made to Norwegian preparatory works concerning amendments to the Patients' Rights Act, Prop. 118 L (2012–2013), p. 41.
[9] Reference is made to Norwegian preparatory works concerning amendments to the Patients' Rights Act, Prop. 118 L (2012–2013), p. 53.

through Helfo so that they do not have to find a healthcare provider abroad themselves; and (iii) the provision covers private healthcare providers.

70. With regard to the legislative amendment removing the reference to treatment abroad in the fourth paragraph of Section 2-1b PRA and Section 6 PR, Norway cannot see that this is contrary to Regulation 883/2004 given that patients still have their rights under the Regulation. In addition, Norway notes that the competitions related to the framework agreements entered into by Helfo to provide the treatment in accordance with the provision remain open to service providers from other EEA States.

71. Further, Norway submits that ESA has taken an incorrect approach to assessing whether the PRA Schemes for in-patient treatment abroad conflict with Article 36 EEA. Norway argues that it must be assessed whether the Supplementary Schemes under the PRA constitute a restriction, and if so, whether those restrictions may be justified. Norway emphasises that the Court and the European Court of Justice ("ECJ") have defined "restriction" of the freedom to provide services in a limited way, holding that there is only a restriction if it is "more difficult" to provide services between EEA States than within the State.[10] The right to treatment abroad depends, inter alia, on the entitlement to treatment domestically: the concept of restriction is inextricably linked to the criteria for the right to healthcare set forth in the State in question.

72. In relation to the Breach of Deadline Scheme provided for in the fourth paragraph of Section 2-1b PRA, Norway submits that it does not constitute a restriction because the conditions set forth in the provision apply equally to domestic treatment and treatment abroad. The provision only applies when the deadline is, or is expected to be, breached, and the need to consult Helfo applies regardless of whether the treatment is performed by a national (private) service provider or a service provider abroad.

73. In the subsidiary event that there is a restriction, Norway submits that the restriction is justified. Contrary to the approach taken by ESA, Norway submits that the assessment of justification is not solely determined by the criteria of ensuring equally-effective treatment in time – as these requirements are only minimum requirements that must be fulfilled through some means of national legislation. Norway highlights that EEA law itself provides in Regulation 883/2004 and Directive 2011/24/EU for different approaches to the coverage of costs in cross-border healthcare, and that ESA's interpretation would entail full harmonisation.

74. Norway submits that the relevant approach instead follows from the ECJ's case law.[11] The case law assesses whether additional national schemes for healthcare abroad entailing a restriction are justified by overriding reasons in the public interest, do not exceed what is objectively necessary for that purpose, and that the same result cannot be achieved by less restrictive rules. Furthermore, the national provisions must be based on objective, non-discriminatory criteria that are known in advance, in such a way as to

[10] Reference is made to *Rindal and Slinning*, cited above, paragraph 44, and to the judgments in *Vanbraekel*, cited above, paragraph 44, and *Watts*, cited above, paragraph 94.
[11] Reference is made to the judgments in *WO*, C-777/18, EU:C:2020:745, paragraph 62; *Elchinov*, cited above, paragraph 44; and *Vanbraekel*, cited above.

circumscribe the exercise of the national authorities' discretion, so that it is not used arbitrarily.

75. According to Norway, the ECJ has recognised in particular four objectives that may justify restrictions on healthcare services under Article 36 EEA: (i) preventing the possible risk of seriously undermining the financial balance of a social security system; (ii) maintaining a balanced medical and hospital service open to all; (iii) maintaining treatment capacity or medical competence on national territory; and (iv) making it possible to create a plan seeking, first, to ensure that there is sufficient and permanent access to a balanced range of high-quality hospital treatment in the Member State concerned and, second, to ensure cost control and to prevent, as far as possible, any wastage of financial, technical and human resources.[12] On the question of whether the restrictions are necessary to achieve these aims, Norway argues that the EEA States must have a wide discretion when implementing the means appropriate to ensure the objectives related to public health.

76. Norway submits that the potential restrictions under the fourth paragraph of Section 2-1b PRA of having to wait until the deadline is breached before contacting Helfo or being prohibited or discouraged from directly going abroad since the provision requires Helfo to organise the healthcare are justified. This is because, first, the provision maintains the allocation of responsibilities to the regional healthcare authorities ("the RHAs") to provide necessary healthcare within an acceptable time and not to the patient. Norway argues that the RHA is best placed to assess whether the deadline will be breached such that Helfo must be contacted, and Helfo is better suited to finding a service provider than the patient themselves. Leaving the responsibility to the patient to contact Helfo, to find a relevant service provider, to organise the treatment and travel, and to pay initially for the treatment is not adequate to ensure that the State's responsibility towards the patient is met.

77. Second, the allocation of responsibility is closely linked to the control of costs and to prevent waste of financial, technical, and human resources. Norway argues that there would be a risk of seriously undermining the financial balance of the social security system if patients were allowed to seek treatment abroad under the scheme without the involvement of Helfo. Further, Norway considers the restrictions necessary to secure overall health protection, emphasising that the State is free to design and organise its healthcare system.

78. Third, patients may seek healthcare in other EEA States in accordance with Regulation 883/2004 and Directive 2011/24/EU and organise this themselves.

79. With regard to the removal of the reference to service providers outside of the realm from the fourth paragraph of Section 2-1b PRA at the Second Compliance Deadline, Norway submits that the restriction is of a minor nature since patients still can receive treatment in EEA States through other schemes, and service providers in other EEA States can take part in competitions for framework agreements with Helfo. Norway

[12] Reference is made to the judgment in *WO*, cited above, paragraph 59.

submits that since the healthcare in question is available in Norway, Norway is entitled to prioritise healthcare delivered domestically. This is justified with a view to maintaining treatment capacity and medical competence in Norway, and to making it possible to plan for balanced healthcare and cost control. Norway submits further that, in any event, no applications have been filed under this particular scheme since 2013.

80. In its Reply, ESA disputes Norway's claim that guaranteeing the right to equally-effective treatment in time in all of its legislative schemes would wrongly "fully harmonise EEA law on this point". According to ESA, this claim misses the point, as the right to equally-effective treatment in time is a minimum requirement: Norway has the right to provide additional benefits for patients as long as these minimum requirements are respected.

81. In relation to the Breach of Deadline Scheme under the fourth paragraph of Section 2-1b PRA and Section 6 PR, ESA considers Norway to agree that the right to equally-effective treatment in time applies to this situation. Where this right is engaged, it follows, according to ESA, that authorisation to receive treatment abroad cannot be refused. Thus, it considers Norway to wrongly persist in the view that the scheme need not itself guarantee such rights or comply with EEA law. According to ESA, it is not enough that patients are free to choose the alternative Regulation 883/2004 Scheme, as this is not an easy task. Further, ESA does not consider Norway to have provided in the Defence any new arguments as to why the Breach of Deadline Scheme is more favourable to the patient.

82. On the question of whether the Breach of Deadline Scheme constitutes a restriction, ESA replies that the restriction is the fact that the scheme limits the rights of patients to receive treatment in other EEA States unless certain additional conditions are met. Such conditions do not apply to the receipt of in-patient treatment in Norway, where the only requirement is that the right to necessary healthcare in the second paragraph of Section 2-1b PRA is met. For the purposes of assessing a restriction under the fourth paragraph of Section 2-1b PRA, ESA submits that the relevant comparator is not private service providers under the scheme, but the normal domestic system. Normally, patients have free choice of treatment between public and private institutions in Norway. However, under the fourth paragraph of Section 2-1b PRA, Helfo always finds a service provider and the patient cannot decide on the service providers. Therefore, ESA concludes that there is a difference in treatment and a restriction and that Norway cannot rely on the case law it cites.

83. ESA emphasises that it is the State which bears the burden of proving that the restriction may be justified. ESA argues that Norway has not shown that the objectives recognised in previous case law apply to the present case. ESA submits that Norway has only provided generic references to abstract justifications and has not submitted evidence. Norway has not shown that the risks of seriously undermining the financial balance are real and material and that the restrictions are necessary and proportionate. ESA wonders, in particular, how Norway can maintain its position given that there have been no applications under the fourth paragraph of Section 2-1b PRA scheme since 2013 and, at the same time, 6814 patients have been permitted to go abroad under the

Directive and Regulation 883/2004 routes. If the risk was real that in the absence of the restriction the additional scheme might undermine the financial balance, ESA would expect to see calculations of this.

84. In relation to the removal of the reference to treatment abroad after the First Compliance Deadline, ESA submits that unjustified restrictions are precluded, however minor. Further, Norway's assertion that the prioritisation of domestic treatment is required to ensure cost control and medical competence in Norway fails, on ESA's submission, to meet the evidential requirements for objective justification and hence must be rejected.

85. In its Rejoinder, Norway reiterates its position that the Breach of Deadline Scheme under the fourth paragraph of Section 2-1b PRA is not subject to the temporal requirements set out in Article 20(2) of Regulation 883/2004 when this is guaranteed in other provisions in national law. It avers that the Breach of Deadline Scheme provides better financial support and broader coverage than the EEA Schemes. Norway submits further that, as demonstrated by case law, reimbursement is not required by Regulation 883/2004 in relation to coverage that is "more beneficial" and, hence, rights going beyond what Article 20(2) of Regulation 883/2004 requires are not covered by that provision.[13] Therefore, in Norway's view, it would not make sense and would lead towards full harmonisation if additional schemes had to be provided within the temporal requirements of Article 20(2) of the Regulation. Finally, any practical difficulties do not substantiate the alleged *legislative* conflict between the Breach of Deadline Scheme under the fourth paragraph of Section 2-1b PRA and Article 20(2) of Regulation 883/2004.

86. In relation to Article 36 EEA, Norway rejects ESA's approach to assessing whether a restriction exists. Norway maintains that the relevant comparison to be made, in determining whether the Breach of Deadline Scheme makes it more difficult to receive healthcare on a cross-border basis than within the State, is to examine what conditions apply when patients receive healthcare under the same scheme, and thus gain the same coverage, domestically. Because the conditions apply equally to treatment received from service providers inside and outside the realm, there is no restriction. Norway submits that if the scheme under the fourth paragraph of Section 2-1b PRA were to be compared with the normal domestic system, it is the level of cost assumption granted under that scheme and the normal domestic system that must be compared. The fact that the disputed scheme provides better financial support than the normal domestic system excludes the possibility of there being a restriction. For completeness, Norway avers that it is not correct, as asserted by ESA, that patients need to fulfil additional conditions to receive treatment abroad in comparison with domestic treatment, as the the Norwegian reimbursement regulation allows patients to freely travel abroad to receive in-patient treatment before the national time limit is, or is expected to be, breached and to be reimbursed accordingly.

[13] Reference is made to the judgments in *Vanbraekel*, cited above, paragraph 37, and *Watts*, cited above, paragraph 138.

87. Should the Breach of Deadline Scheme be considered a restriction, Norway rejects ESA's view that to be justified it must comply with the temporal requirement in Article 20(2) of Regulation 883/2004. Rather, Norway submits that EEA States are not under any requirement to provide the full cost coverage that the Breach of Deadline Scheme entails, even in situations where the same or equally effective treatment cannot be obtained domestically without due delay.[14]

88. Hence, Norway maintains that the relevant test is whether the potential restrictions are justified by overriding reasons in the public interest. It avers that the potential restrictions are justified by the need to ensure cost control, rapid and adequate treatment for the patient, and to ensure the purpose of the scheme itself, i.e. to remedy breach of national deadlines. Norway argues that the intention of the legislature, to be gathered from the political debates preceding the adoption of a law or from the statement of the grounds on which it was adopted, may be an indication of the aim of that law, although not conclusive.[15] In this connection, Norway refers to excerpts from the national preparatory works showing that the purpose of having Helfo as an organiser of the scheme was to ensure both cost control and rapid and adequate treatment for the patients.[16]

89. In response to ESA's remark wondering how Norway can maintain that allowing patients to freely access healthcare abroad under the Breach of Deadline Scheme would result in financial risk while admitting that there have been no applications under the scheme since 2013 and, at the same time, permitting 6814 patients to go abroad under the other EEA schemes, Norway makes two points. First, Norway clarifies that the Breach of Deadline Scheme is frequently used domestically although under the scheme no patients have received healthcare abroad. Further, the fact that no patients have received healthcare abroad under the scheme since 2013 does not indicate that it would not seriously undermine the financial balance if the conditions were different. Second, Norway highlights the difference in cost coverage, which is the whole reason for the different treatment under these schemes. The increased cost coverage under the Breach of Deadline Scheme necessitates a more restrictive approach to ensure that the scheme is only used in the situations that it is meant to regulate.

90. In its Written Observations, the Commission briefly comments on the Breach of Deadline Scheme noting that Norway and ESA disagree on whether the scheme is more or less advantageous to patients than Article 20(2) of Regulation 883/2004.

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[14] Reference is made to the judgment in *Watts*, cited above, paragraph 140.

[15] Reference is made to Case E-1/06 *ESA* v *Norway* [2007] EFTA Ct. Rep. 8, paragraph 33, and to the judgment in *Finalarte and Others*, C-49/98, C-50/98, C-52/98 to C-54/98 and C-68/98 to C-71/98, EU:C:2001:564, paragraph 40.

[16] Reference is made to Norwegian preparatory works concerning amendments to the Patients' Rights Act, Ot.prp. no 63 (2002–2003).

First plea – the fifth paragraph of Section 2-1b/letter (a) of the second paragraph of Section 2-4a PRA and Section 3 PR (No Adequate Treatment Scheme) and compliance with EEA law

91. In its Application, ESA submits that the fifth paragraph of Section 2-1b PRA at the First Compliance Deadline and letter (a) of the second paragraph of Section 2-4a PRA at the Second Compliance Deadline, with the corresponding Section 3 PR, are not in compliance with the requirements of EEA law.

92. First, at the First Compliance Deadline, the No Adequate Treatment Scheme gave patients a right to treatment abroad where there was "no adequate medical service in the realm". At the Second Compliance Deadline, the criteria to be satisfied were the existence of "no offer" in Norway or that the healthcare abroad is documented to be "more effective" than the healthcare offered by the public sector in Norway. According to ESA, however, the test under EEA law involves an assessment of whether national treatment which is *the same or equally effective* as that sought abroad can be provided in time. Thus, ESA submits that there is a failure to correctly reflect the EEA right at both Compliance Deadlines.

93. Second, ESA submits that it is settled case-law that a State can only prioritise its own treatment offer under Regulation 883/2004 and/or Article 36 EEA if the offer is available *within a time-limit which is medically justifiable*.[17] ESA contends that the No Adequate Treatment Scheme is framed in such a way, however, that it fails to ensure that this time-limit is taken into account and/or complied with because long waiting times were considered irrelevant and/or outside the scope of the provision. The fourth paragraph of Section 3 PR explicitly excludes insufficient capacity in the specialist health services as a reason for treatment abroad under the scheme. ESA contends that a refusal to grant authorisation solely on the ground that there are waiting lists breaches Regulation 883/2004 and/or Article 36 EEA.[18]

94. According to ESA, it is no defence that, in practice, patients in the circumstances of long waiting lists could have recourse to authorisation or reimbursement under Regulation 883/2004 or the Norwegian reimbursement regulation. First, ESA submits that the No Adequate Treatment Scheme must in itself comply with EEA law. Otherwise, a State could immunise itself from scrutiny under EEA law in respect of a large part of its legislation simply by pointing to the fact that at least some of its law correctly reflects the relevant EEA law rights. ESA considers Norway's characterisation of Article 20 of the Regulation as "other legal grounds for publicly paid treatment abroad" as revealing what, in ESA's view, is the misunderstanding at the heart of Norway's approach to EEA treatment abroad:[19] the comment fails to recognise that the

[17] Reference is made to the judgments in *Smits and Peerbooms*, cited above, paragraph 107, and *Watts*, cited above, paragraphs 63-79.
[18] Reference is made to the judgments in *Müller-Fauré*, C-385/99, EU:C:2003:270, paragraph 92, and *Smits and Peerbooms*, cited above, paragraph 63.
[19] Reference is made to Norway's reply to the Request for Information submitted as Annex A.13 to the Application, pp.13 and 14.

provisions of the PRA and PR must also be in compliance with Article 20(2) of the Regulation and must not undermine the rights conferred therein.

95. Second, ESA submits that even if it is sufficient to have alternative EEA compliance routes, there was nothing in the PRA or PR provisions at the First Compliance Deadline that made this clear. There was no link between the schemes, creating an issue of transparency and legal certainty. Further, patients who were refused authorisation to travel abroad were not redirected to the specific Regulation 883/2004 route. At the Second Compliance Deadline, an overview of the various schemes for covering healthcare abroad was included in Section 2-4a PRA for informational purposes and reflected in Section 3 PR. In ESA's view, however, the main problem persists despite these amendments: the scheme is still not consistent with the conditions of EEA law requiring treatment abroad when equally-effective treatment domestically cannot be provided in time.

96. Third, ESA submits that the problem goes beyond the wording of the provisions, because practice from the Office for Medical Treatment Abroad and the Appellate Body for Treatment Abroad shows that patients who find themselves in the No Adequate Treatment Scheme end up in a position where their EEA rights to healthcare within a medically justifiable time-limit are not respected and effectively secured. ESA points, for instance, to 26 decisions of the Offices for Medical Treatment Abroad in 2019, all of which apply a test which considers long waiting times as irrelevant to the right of patients to go abroad, and which further do not apply any medically justifiable time-limit.[20] Consistent practice by the Appellate Body for Treatment Abroad did not apply any medically justifiable time-limit and disregarded the relevance of long waiting times for the right to go abroad.[21] Also at the Second Compliance Deadline, following changes to the scheme, ESA contends that the Offices for Medical Treatment Abroad and the Appellate Body for Treatment Abroad require patients to document that the treatment abroad is (i) more effective than domestic treatment,[22] and (ii) refuse to consider the

[20] Reference is made to Annex A.22 to the Application: OSLO-2019-1-R, p. 5, OSLO-2019-1-HN-R, p. 8, OSLO-2019-2-R, p. 10, OSLO-2019-2-HN-R, p. OSLO-2019-3-R, p. 13, OSLO-2019-3-HN-R, p. 15, OSLO-2019-4-R, p. 17, OSLO-2019-4-HNR, p. 18-19, OSLO-2019-5-R, p. 22, OSLO-2019-5-HN-R, p. 24, OSLO-2019-6-R, p. 26, OSLO-2019-7-R, p. 29, OSLO-2019-8-R, p. 31, OSLO-2019-9-R, p. 33, OSLO-2019-10-R, p. 36, OSLO-2019-11-R, p. 38, OSLO- 2019-12-R, p. 40, OSLO-2019-13-R, p. 42, OSLO-2019-15-R, p. 44, OSLO-2019-16-R, p. 46, OSLO-2019- 17-R, p. 48, OSLO-2019-18-R, p. 50, OSLO-2019-21-R, p. 54, OSLO-2019-22-R, p. 56, OSLO-2019-23-R, p. 58, OSLO-2019-24-R, p. 60 and OSLO-2019-25-R, p. 62.

[21] Reference is made to Annex A.21 to the Application: UKN-2005-26, p. 12, UKN-2007-18, p. 58, UKN-2008-2, pp. 70-71, UKN-2008-29, p. 74 (Switzerland), UKN-2009-53, p. 90, UKN-2009-95, pp. 99-100, UKN-2010-21, pp. 110-111, UKN-2010-103, pp. 126-127, UKN-2010-111, p. 130, UKN-2011-38, p. 139 (the US), UKN-2012-63, p. 170 (the US), UKN-2012-108, p. 176, UKN-2013-110, pp. 184-185, UKN-2014-53, pp. 190-191 (the US) and UKN-2021-1194, pp. 248-249.

[22] Reference is made to decisions from the Offices for Medical Treatment Abroad in Annex A.22 to the Application: OSLO-2022-2-R, p. 63-64, OSLO-2022-2H-R, p. 65-66, OSLO-2022-3-R, p. 67, OSLO-2022-3-HN-R, p. 69, OSLO-2022-4-R, p. 71-72, OSLO-2022-4H-R, p. 73-74, OSLO-2022-6-R, p. 77, OSLO-2022-6B-R, p. 78-79, OSLO-2022-7-R, p. 80-81, OSLO-2022-8-R, p. 82-83, OSLO-2022-9-R, p. 84-85, OSLO-2022-10-R, p. 86-87, OSLO-2022-11-R, p. 88-89, OSLO-2022-12-R, p. 90-91, OSLO-2022-13-R, p. 93-94, OSLO-2022-14-R, p. 96-97, OSLO-2022-15-R, p. 98-99, OSLO-2022-16-R, p. 100-101, OSLO-2022-17-R, p. 102, OSLO-2022-18-R, p. 104-105, OSLO-2022-19-R, p. 106-107, OSLO-2022-20-R, p. 108-109, OSLO-2022-22-R, p. 111-112 OSLO-2022-23-R, p. 114-115, OSLO-2022-24-R, p. 117-118, OSLO-2023-25-R, p. 120-121, OSLO-2023-26-R, p. 123-124, OSLO-2023-27-R, p. 126-127, OSLO-2023-28-R, p. 128-129, OSLO-2023-29-R, p.

timing element or consider that long waiting lists and/or lack of capacity are not relevant.[23] Thus, at both Compliance Deadlines, ESA concludes that the practice was not in compliance with the conditions of EEA law.

97. In its Defence, the Norwegian Government primarily submits that the No Adequate Treatment Scheme under the fifth paragraph of Section 2-1b/letter (a) of the second paragraph of Section 2-4a PRA does not cover the same situation as Article 20(2) of Regulation 883/2004. Article 20(2) of the Regulation covers the situation where the treatment abroad is "among the benefits provided for by the legislation in the [EEA] State where the person concerned resides". Norway claims that it is not specified in the provision, any other parts of the Regulation, or in case law, how "provided for by the legislation" is to be interpreted, and submits that it must be understood to only cover treatment that is actually available in Norway.[24]

98. Norway submits that the *wording* of Article 20(2) of the Regulation suggests that the provision only applies to treatment that is available in the patient's state of residence. Norway submits that this is also supported by the *context* of the provision – the timing element would be without practical impact if the treatment was not available or offered in the public health system. According to Norway, the *purpose* and *objective* also best aligned with this interpretation, as the right under Article 20(2) of the Regulation is intrinsically linked to the national public healthcare services that are offered in the patient's state of residence. Norway submits that this interpretation ensures that it is for each EEA State to decide what healthcare services are to be covered under its social security system, irrespective of whether the service is carried out domestically or abroad. Norway adds that its interpretation is supported by Recital 34 to Directive 2011/24/EU.

99. Alternatively, Norway submits that even if the treatment referred to in letter (a) of the second paragraph of Section 2-4a PRA fulfils the First Condition of Article 20(2) of Regulation 883/2004, the national provision does not in any circumstances conflict with the Regulation. Norway stresses that the national provision does not preclude

131-132, OSLO-2023-30-R, p. 134-135, OSLO-2023-31-R, p. 137-138, BERGEN-2022-1-R, p. 157-158, BERGEN-2022-2-R, p. 160, BERGEN-2022-3-R, p. 162-163, BERGEN-2022-4-R, p. 165-166, BERGEN-2022-5-R, p. 168-169, BERGEN-2022-7-R, p. 171-172, BERGEN-2022-9-R, p. 176-177, BERGEN-2022-10-R, p. 179, BERGEN-2022-11-R, p.182-183, BERGEN-2022-12-R, p. 184, BERGEN-2022-13-R, p. 187 and BERGEN-2023-1-R, p. 190. Reference is made to decisions from the Appellate Body for Treatment Abroad in Annex A.21 to the Application: UKN-2020-4720, p. 232, UKN- 2020-9761, p. 244, UKN-2021-2248, pp. 252-253, UKN-2021-5490-1, p. 260, UKN-2021-6562, p. 263, UKN-2021-6559, p. 267, UKN-2021-8834, p. 280, UKN-2021-10307, pp. 284-385, UKN-2022-542, p. 294, UKN-2022-813, pp. 300-301, UKN-2022-543, pp. 297-298, UKN-2021-11716, pp. 284-285 and UKN-2021-11858, p. 292.

[23] Reference is made to decisions from the Offices for Medical Treatment Abroad in Annex A.22 to the Application: OSLO-2022-10-R, p.86, OSLO-2022-15-R, p. 98, OSLO, 2022-23-R, p. 115, BERGEN-2022-7-R, p. 172, BERGEN-2022-8-R, p. 174 (United Kingdom), BERGEN-2022-9-R, p. 176, as well as OSLO-2022-2-R, p. 63, OSLO-2022-3-R, p. 67 and OSLO-2022-4-R, p. 71. Reference is made to decisions from the Appellate Body for Treatment Abroad in Annex A.21: UKN-2022-542, pp. 294-295 and UKN-2022-1202, p. 305 (United Kingdom), as well as UKN-2021-8790, p. 276, UKN-2021-6713, pp. 271-272, UKN-2021-4648, p. 255, UKN-2021-1194, p. 248, UKN-2020-5914, p. 236, UKN-2020-6443, p. 240, UKN-2020-1625, p. 229 and UKN-2020-1615, p. 225.

[24] Reference is made to the judgment in *Elchinov*, cited above, paragraph 62.

patients from choosing to request and receive authorisation under Article 20(2) of the Regulation where the conditions for this are fulfilled.

100. On the question of whether the No Adequate Treatment Scheme is contrary to Article 36 EEA, Norway submits that the scheme does not constitute a restriction that makes it more difficult for patients to receive in-patient treatment in other EEA States compared to Norway. In the case of the first alternative for treatment under the scheme ("no offer"), the healthcare in question does not exist in Norway and there is therefore no sufficient basis for comparison and consequently no restriction. Norway submits that this applies equally to the situation where there is no "adequate" or "effective" service offer in the realm, referring to the difference between the wordings at the First and Second Compliance Deadlines. In the case of the second alternative for treatment under the scheme, where the treatment abroad is more effective, Norway contends that, as a matter of Norwegian law, a patient is not entitled to the assumption of costs for any domestic treatment that is more effective than what is offered and considered adequate by the specialist healthcare service in Norway.

101. In Norway's view, the conclusion that the scheme does not constitute a restriction is supported by *Rindal and Slinning*.[25] Although that case concerned a different matter, the Court accepted that where the same treatment is not offered or paid for whether in Norway or abroad this does not constitute a restriction. Norway submits that this applies also in the current case where the Norwegian legislator has gone further and provided for treatment abroad, which cannot be seen as a restriction on the free movement of services.

102. Should the Court find, however, that the No Adequate Treatment Scheme constitutes a restriction, Norway submits that the restriction is justified. According to Norway, the restriction would result from the fact that the provision is limited to providing access to in-patient treatment in other EEA States where there is no adequate service offer/no service offer in the realm, or the service offer abroad is more effective than the offer available in Norway. Norway emphasises that where an adequate service offer does exist in Norway, or there is no more effective service offer abroad, the situation falls outside the scheme in question. Instead, it falls within the situation identified by the Court in *Rindal and Slinning*, namely, "if the home State offers the same or equally effective treatment, and provides it within a medically justifiable time limit, the home State may justify prioritising its own offer of treatment".[26]

103. For the sake of completeness, Norway adds that the No Adequate Treatment Scheme provides highly specialised and resource-intensive healthcare, covers private service providers, and includes full coverage of necessary travel and accommodation expenses. Norway submits that there would be a risk of seriously undermining the financial balance of the social security system if an EEA State were not allowed to limit its obligation to cover such extensive costs. Norway argues that it would have major financial implications if States which choose to provide additional offers to patients who

[25] Reference is made to *Rindal and Slinning*, cited above, paragraphs 46–57.
[26] Reference is made to *Rindal and Slinning*, cited above, paragraph 83.

otherwise would have no (adequate) service offer, or a less effective service offer than that available abroad were obliged to extend the level of coverage of costs also to the situation where the patient may obtain an adequate service offer domestically. Should the Court rule in favour of the latter, Norway submits that it would have little choice but to consider a repeal of the scheme in question.

104. Furthermore, Norway submits that a removal of the criteria provided for in letter (a) of the second paragraph of Section 2-4a PRA would affect the flow of patients traveling abroad, as it would give patients who have an adequate offer in the country a right to travel abroad on better financial terms than domestically. This would have an impact on the possibility to create a plan seeking, first, to ensure that there is sufficient and permanent access to a balanced range of high-quality in-patient treatment in Norway and, second, to ensure cost control and to prevent, as far as possible, any wastage of financial, technical, and human resources.

105. Norway submits that the potential restriction is suitable and necessary. Regarding the latter, Norway emphasises how the State must enjoy a wide margin of appreciation when determining which types of healthcare patients should have access to and on what terms, especially when the healthcare in question does not exist, or exists only in a less effective manner, domestically. In addition, Norway finds it difficult to see how less restrictive measures could achieve the same effects as the criteria in the No Adequate Treatment Scheme: the provision is limited to exactly that group that the State has found it appropriate to provide with an additional scheme and extending it to cover patients who have an adequate offer in the realm would undermine the entire purpose behind the scheme.

106. In its Reply, ESA engages first with what it considers to be two fundamental errors in Norway's argument. The first error is that Norway confuses the criterion of *entitlement to treatment* under national legislation with the question of whether or not the treatment is *in practice available* in Norway, and therefore misapplies the First Condition of Article 20(2) of Regulation 883/2004 or Article 36 EEA. ESA emphasises that, according to settled case law and the wording of Article 20(2), the condition will be met where the treatment in question is "among the benefits provided for by the legislation in the State where the person concerned resides". Thus, ESA concludes that States are required to authorise treatment in other EEA States where the patient is entitled to the same or equally-effective treatment domestically.

107. ESA further substantiates its argument by pointing to how it is a requirement in the Norwegian specialist healthcare system that the patient is first found to have a right to necessary healthcare under the second paragraph of Section 2-1b PRA and Section 2 PR. ESA submits that a consequence of how Norway has decided to designed its system is that once it is determined that the patient has the right to "necessary healthcare", the First Condition of Article 20(2) of Regulation 883/2004 is always met. If the Second Condition is also met, i.e. the necessary healthcare cannot be provided in Norway "in time", this "necessary healthcare" will have to be authorised in another EEA State.

108. ESA submits that case law and a proper interpretation of EEA law does not support Norway's claim that even if a patient is entitled to healthcare domestically, if such healthcare is not in practice available domestically, Article 20(2) of Regulation 883/2004 and Article 36 EEA does not apply. ESA submits that the right to equally-effective treatment in time is a "minimum guarantee": if treatment to which a patient is entitled domestically is not available within a medically justifiable time limit, they are entitled to go to another EEA State to receive the same or equally-effective treatment. ESA argues that Norway's position would enable States to evade the operation of EEA law simply by saying that even though the patient is entitled to certain treatment nationally it is not available. If Norway's position were correct, there would be, in ESA's submission, no reason for Article 20(2) of the Regulation to exist. However, ESA submits that the case law concerning the provision's interpretation has found that it is precisely in this situation that patients must be entitled to treatment abroad: where treatment is not available domestically, States can no longer prioritise their own national treatment.[27]

109. ESA also submits that the wording of the No Adequate Treatment Scheme at the First Compliance Deadline supports its understanding. The wording of the then fifth paragraph of Section 2-1b PRA clearly conferred a right to the same (or equivalent) treatment abroad as that to which the patient was entitled at home.

110. The second fundamental error that ESA claims Norway to have made is that Norway wrongly equates the need to ensure the right to equally-effective treatment in time with a right to treatment to which patients are not entitled. ESA argues that only the first is an EEA law requirement and that it never has claimed that the latter is: there is no requirement to treatment abroad to which the patients are not entitled domestically.[28] ESA's position means that the right to equally-effective treatment in time is engaged in respect of particular treatment to which a patient is entitled domestically. Norway must ensure that, in granting any more beneficial rights, the minimum right to equally-effective treatment is respected.

111. ESA then summarises why the No Adequate Treatment Scheme breaches Article 20(2) of Regulation 883/2004 and Article 36 EEA. ESA submits that this is because neither lack of capacity nor long waiting times is considered relevant or confers a right to treatment under the scheme. The right to equally-effective treatment in time is therefore not secured. ESA further dismisses the arguments put forward by Norway in defence of the scheme. First, the argument that treatment under the scheme does not engage EEA law is rejected because, in ESA's view, it does concern treatment provided for in Norwegian legislation. Second, the argument that patients can have recourse in any event to other schemes in order to exercise their EEA law rights is considered inadequate; rather there is an obligation on national authorities themselves to apply EEA law correctly. Third, the argument that the requirement for the treatment to be more

[27] Reference is made to the judgments in *WO*, cited above, paragraphs 43-44, and *Elchinov*, cited above, paragraph 62.
[28] Reference is made to *Rindal and Slinning*, cited above, and Recital 34 of Directive 2011/24/EU.

effective takes the scheme outside of EEA law is rejected; rather Norway is wrongly applying a higher threshold than the EEA law requirements.

112. Lastly, ESA rejects the submission that Norway has justified the restriction. ESA submits that a State may only prioritise its own treatment when such treatment can be given in time; after that, this justification no longer exists. Further, ESA submits that Norway has not provided any evidence for its claims in relation to the risk of seriously undermining the financial balance of the social security system, and to cost control and wastage.

113. In its Rejoinder, Norway addresses the alleged fundamental error of confusing the criterion of entitlement to treatment under national legislation with the question of whether or not the treatment is in practice available in Norway. Norway makes three clarifications. First, the second paragraph of Section 2-1b PRA on the right to necessary healthcare does not give the patient the right to receive a specific type of healthcare. On the contrary, Norway submits that the right is limited to the services provided for by the specialist health services, which follows from Sections 2-1a and 4-4 of the Specialist Health Services Act.[29] The specialist health service assesses, and decides, what kind of healthcare should be provided in each individual case based on a specific and individual assessment of the individual patient's needs. The right to "necessary healthcare" is interpreted as providing legal requirements for healthcare with a reasonable minimum standard. In the range between the minimum standard and the best available healthcare, it is for the RHAs to assess, based on available resources, which healthcare should be available to the patient from the public specialist health service. Hence, Norway submits that the RHAs' specification of healthcare also constitutes the framework for patients' right to necessary healthcare in accordance with the second paragraph of Section 2-1b PRA. Second, Norway submits that the healthcare covered by the No Adequate Treatment Scheme is not merely "not physically available", but rather is healthcare that is not provided for by the public specialist health service in Norway. Third, Norway argues that it follows that specialist healthcare service cannot logically be obliged to offer a treatment that is not provided for in Norway, and the patient, correspondingly, may not demand such treatment from the public specialist healthcare service. Norway submits that this is exactly why the No Adequate Treatment Scheme exists: to enable patients to receive such treatment from service providers abroad at the Government's expense.

114. Following these three clarifications, Norway submits that it does not follow from Section 2-1b PRA whether the treatment is among the benefits provided for by national legislation. Instead, the crucial question is whether the "benefits" that must be provided for by the home State's legislation according to Article 20(2) of Regulation 883/2004 refers to benefits provided for in the home State, or if it also refers to benefits provided in another Member State at the home State's expense.

115. Norway submits that the *wording* supports both interpretations. However, when the two conditions of Article 20(2) of the Regulation are read in *context* with Article

[29] Reference is made to Annex 2 to the Rejoinder.

20(1) of the Regulation, the First Condition must refer to treatments that are provided in the Member State in which the patient resides. The reference to benefits in kind, which must be provided in another Member State, presupposes that the treatment is available in the Member State of residence. The words "where" and "cannot be given treatment" presupposes the same. Norway submits that also a *teleological* interpretation of the purpose of Article 20(2) of the Regulation presupposes that such treatment is otherwise provided in the State of residence. Norway further submits that the *history* of the provision sheds light on this. In the original version of Article 22 of Regulation 1408/71, Member States were obliged to grant authorisation to treatment abroad if the treatment in question "cannot be provided for the person concerned within the territory of the Member State in which he resides," which supports ESA's interpretation. However, Norway submits that the provision was changed to increase the discretionary power of the Member States in granting authorisation to treatment abroad. The new wording was intended to avoid the potential abuse of a patient wishing to go to another Member State for the sole aim of receiving medical treatment there that is not provided for by the legislation of the Member State in which the patient is insured.[30] Norway submits that the history strongly indicates that the change was introduced in order to give Member States the ability to deny authorisation for treatment abroad which is not provided for domestically. Finally, Norway submits that also *case law* supports the view that it is treatment that the home State itself can provide that is covered by the provision.[31]

116. Irrespective of these arguments on the scope of Article 20(2) of the Regulation, Norway argues that the existence of a supplementary scheme does not impede or restrict patients' right to seek treatment abroad under the EEA Schemes, thus ruling out the possibility of conflict of norms.

117. Norway then moves on to assess whether the No Adequate Treatment Scheme violates Article 36 EEA. Norway disputes the view that the additional condition under the scheme constitutes a restriction because, according to Norway, there is no normal domestic system to compare the conditions with. According to Norway, a restriction only exists if it has the effect of making the provision of services more difficult between EEA States than within an EEA State. Hence, Norway submits that this cannot be the case when services within Norway completely fall outside of the scheme.

118. In the alternative, Norway submits that the restriction is objectively justified. The purpose of the No Adequate Treatment Scheme is to remedy the situation that no treatment is provided in Norway or that a more effective treatment exists abroad because the public specialist health services do not offer the treatment in question domestically. National law ensures full cost coverage and the RHAs will assist in organising the journey, which ensures rapid and adequate cost control. The criteria under the scheme only include those who either have no adequate treatment offer in Norway, or those who have a more effective offer abroad. Norway submits that the criteria are exact and well-defined to prevent other patients receiving the increased coverage that this scheme provides, as they are not in need of such coverage since they can receive treatment

[30] Reference is made to the Commission's proposal COM(80) 580 final, on which Council Regulation (EEC) No 2793/81 was based.
[31] Reference is made to *Rindal and Slinning*, cited above, paragraph 83.

through the "normal" system, either domestically or abroad. Hence, Norway submits that the criteria are both suitable and necessary.

119. In its Written Observations, the Commission comments on Norway's suggestion that if a certain healthcare treatment is not in practice available in Norway, Article 20(2) of Regulation 883/2004 cannot apply. The Commission argues that this is a misunderstanding of the proper operation of Article 20(2) of the Regulation. The national scheme is free to list the benefits provided in a fixed, exhaustive list, or to state more generally the categories or types of treatments or treatment methods covered.[32] However, the Commission emphasises that question of whether there is *entitlement* to a certain treatment under Article 20(2) of the Regulation must be distinguished from the issue of whether that particular treatment is *available* in Norway. The Commission refers to *Elchinov*, which, on the Commission's submission, clearly states that the mere fact that a treatment is not (actually) provided in the Member State of residence does not mean that it is not included among the benefits provided for by the legislation of that State.[33]

Second plea – the complaints and appeal procedure and compliance with EEA law

120. In its Application, ESA emphasises that the Second Condition of Article 20(2) of Regulation 883/2004 and Article 36 EEA require an assessment of whether (i) equally-effective treatment (ii) can be provided in time. Whereas ESA's first plea related to the failure of the PRA Schemes to correctly reflect this two-pronged test in law and practice, the second plea concerns the procedural rules governing the competence of the complaint and appeals bodies relating to the PRA Schemes. ESA submits that the rules discourage or prevent these bodies from making an overall assessment of whether treatment was both equally effective and could be provided in time.

121. ESA submits that, at the Second Compliance Deadline, the first and second paragraphs of Section 7-2 PRA split the competence between the County Governor, which had competence to hear complaints about the national time limit under the fourth paragraph of Section 2-1b PRA, and the Appellate Body for Treatment Abroad, which had competence to hear complaints about the availability or effectiveness of treatment in Norway under letter (a) of the second paragraph of Section 2-4a. Consequently, ESA submits that neither complaint body was permitted under the PRA to consider both criteria included in the Second Condition of EEA law. ESA substantiates this submission by first highlighting the formal division of competence in the provisions of the first and second paragraphs of Section 7-2 PRA and Sections 7 and 8 PR, and then highlighting how this division is maintained in practice by the complaint and appellate bodies.

[32] Reference is made to the judgments in *Smits and Peerbooms*, cited above, paragraph 87, and *Elchinov*, cited above, paragraphs 56-62.
[33] Reference is made to the judgment in *Elchinov*, cited above, paragraph 62.

122. In examining the administrative practice, ESA asserts that in 35 decisions from the Offices for Medical Treatment Abroad[34] and in 25 decisions from the Appellate Body for Treatment Abroad,[35] these bodies did not consider themselves to have the competence to assess the timing element of the fourth paragraph of Section 2-1b PRA and only considered themselves competent to assess the adequacy/effectiveness of treatment under the fifth paragraph of Section 2-1b/letter (a) of the second paragraph of Section 2-4a PRA. Further, in the other cases these bodies do not explicitly state that they are not competent to assess the timing element of the fourth paragraph of Section 2-1b PRA, but, according to ESA, there is no indication that they apply the timing condition or consider themselves competent to do so. ESA asserts that, in at least one case, the patient therefore resorted to bringing parallel complaint proceedings before the Appellate Body for Treatment Abroad and Helfo to secure their EEA rights.[36] ESA submits that the split legal tests and split legal competence meant that the PRA Schemes were necessarily ineffective in securing for patients the right to equally effective treatment in time. Despite the fact that the Offices for Medical Treatment Abroad and the Appellate Body for Treatment Abroad were entitled to apply Article 36 EEA, ESA asserts that (a) none of the decisions from the Offices for Medical Treatment Abroad applied EEA law; and (b) none of the decisions from the Appellate Body for Treatment Abroad applied Article 20 of Regulation 883/2004, while only four decisions from the Appellate Body considered Article 36 EEA but did not grant rights on that basis.[37]

123. ESA submits that the split competence prevented or at least discouraged each such body from making the two-pronged assessment required under the Second Condition, in breach of Article 36 EEA and Article 20(2) of Regulation 883/2004. The split competence also makes it excessively difficult for patients to enforce their rights under EEA law. ESA submits that a significant number of patients find themselves in the PRA Schemes each year, and once there, the relevant provisions do not reflect their EEA rights.[38] As a result of the bodies not taking steps, as appropriate, to secure the

[34] Reference is made to Annex A.22 to the Application: OSLO-2019-1-R, p. 5, OSLO-2019-1-HN-R, p. 8, OSLO-2019-2-R, p. 10, OSLO-2019-2-HN-R, p. OSLO-2019-3-R, p. 13, OSLO-2019-3-HN-R, p. 15, OSLO-2019-4-R, p. 17, OSLO-2019-4-HNR, p. 18-19, OSLO-2019-5-R, p. 22, OSLO-2019-5-HN-R, p. 24, OSLO-2019-6-R, p. 26, OSLO-2019-7-R, p. 29, OSLO-2019-8-R, p. 31, OSLO-2019-9-R, p. 33, OSLO-2019-10-R, p. 36, OSLO-2019-11-R, p. 38, OSLO2019-12-R, p. 40, OSLO-2019-13-R, p. 42, OSLO-2019-15-R, p. 44, OSLO-2019-16-R, p. 46, OSLO-2019-17-R, p. 48, OSLO-2019-18-R, p. 50 OSLO-2019-21-R, p. 54, OSLO-2019-22-R, p. 56, OSLO-2019-23-R, p. 58, OSLO-2019-24-R, p. 60 and OSLO-2019-25-R, p. 62, OSLO-2022-10-R, p.86, OSLO-2022-15-R, p. 98, OSLO, 2022-23-R, p. 115, BERGEN-2022-7-R, p. 172, BERGEN-2022-8-R, p. 174 (United Kingdom), and BERGEN-2022-9-R, p. 176, OSLO-2022-2-R, p. 63, OSLO-2022-3-R, p. 67 and OSLO-2022-4-R, p. 71.

[35] Reference is made to Annex A.21 to the Application: UKN-2005-26, p. 12, UKN-2007-18, p. 58, UKN-2008-2, pp. 70-71, UKN-2008-29, p. 74 (Switzerland), UKN-2009-53, p. 90, UKN-2009-95, p. 99-100, UKN-2010-21, pp. 110-111, UKN-2010-103, pp. 126-127, UKN-2010-111, p. 130, UKN-2011-38, p. 139 (the US), UKN-2012-63, p. 170 (the US), UKN-2012-108, p. 176, UKN-2013-110, pp. 184-185, UKN-2014-53, pp. 190-191 (the US) and UKN-2021-1194, pp. 248-249, OSLO-2022-2-R, p. 63, OSLO-2022-3-R, p. 67 and OSLO-2022-4-R, p. 71 (United Kingdom), UKN-2021-8790, p. 276, UKN-2021-6713, pp. 271-272, UKN-2021-4648, p. 255, UKN-2021-1194, p. 248, UKN-2020-5914, p. 236, UKN-2020-6443, p. 240, UKN-2020-1625, p. 229 and UKN-2020-1615, p. 225.

[36] Reference is made to Annex A.21 to the Application: UKN-2019-6144 pp. 217-220.

[37] Reference is made to Annex A.21 to the Application: UKN-2010-54, pp. 116-121, UKN-2011-97, pp. 155-159, UKN-2017-8826, pp. 193-195 and pp. 196-197 (decision made twice).

[38] Reference is made to overviews of the number of patients utilising each of the Schemes set out in Annex A.1 to the Application.

interpretation of national law in conformity with EEA law or, in the case of conflict, to disapply national law, ESA further argues that such bodies and therefore Norway have failed to ensure the full effectiveness of EEA law, in breach also of the principle of sincere cooperation in Article 3 EEA.

124. ESA then makes six points in response to Norway's statement, in its reply to the supplementary reasoned opinion, that the fact that the County Governor and Appellate Body for Treatment Abroad do not apply Regulation 883/2004 does not in itself give a basis for a claim that their decisions are contrary to EEA law because the PRA Schemes on which these bodies adjudicate are supplementary to the rights under Regulation 883/2004 and Directive 2011/24/EU. First, ESA submits that even if patients can easily access the specific EEA routes, the PRA Schemes must also apply the correct legal tests. Case law requires that "refusals to grant authorisation must be capable of being challenged in judicial or quasi-judicial proceedings", and ESA argues that requiring a patient to commence a new set of "EEA specific" administrative/complaint proceedings, rather than being able to rely directly and immediately on their EEA law rights before the current PRA complaint/appeal body, fails to effectively meet this requirement.[39]

125. Second, ESA asserts that patients who are denied authorisation (of their original application or following a complaint) under the PRA Schemes are not by default directed to the specific EEA Schemes, even though they are seeking authorisation or reimbursement for treatment in another EEA State. ESA claims that (i) many are simply denied treatment abroad;[40] (ii) others are instead directed to the County Governor and the "timing provision" of the fourth paragraph of Section 2-1b PRA;[41] (iii) a third category of patients is referred explicitly to Helfo and the "Directive route";[42] and (iv) there is no mention of the "Regulation 883/2004 route".

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[39] Reference is made to *Rindal and Slinning*, cited above, paragraph 48, and to the judgments in *Smits and Peerbooms*, cited above, paragraph 90, and *Watts*, cited above, paragraphs 115–116.

[40] Reference is made to decisions from the Offices for Medical Treatment Abroad in Annex A.22 to the Application: OSLO-2019-1-HN-R, OSLO-2019-2-R, OSLO-2019-5-R, OSLO-2019-7-R, OSLO-2019-8-R, OSLO-2019-23-R, OSLO-2022-2-R, OSLO-2022-6B-R, TRONDHEIM-2019-9-R, BERGEN-2019-1-R, BERGEN-2019-3-R, BERGEN-2019-4-R, BERGEN-2019-7-R, BERGEN-2019-8-R, BERGEN-2019-10-R, BERGEN-2022-5-R, BERGEN-2022-11-R, and BERGEN-2022-13-R. reference is made to decisions from the Appellate Body for Treatment Abroad in Annex A.21 to the Application: UKN-2005-24, UKN-2005-27, UKN-2005-45, UKN-2005-37, UKN-2005-46, UKN-2005-73, UKN-2005-105, UKN-2006-50, UKN-2006-86, UKN-2006-89, UKN-2006-111, UKN-2007-77, UKN-2007-86, UKN-2007-109, UKN-2008-77, UKN-2008-115, UKN-2009-3, UKN-2009-33, UKN-2009-35, UKN-2009-67, UKN-2009-80, UKN-2009-112, UKN-2010-33, UKN-2010-9, UKN-2010-85, UKN-2011-31, UKN-2011-63, UKN-2011-64, UKN-2011-90, UKN-2012-35, UKN-2012-61, UKN-2012-89, UKN-2012-121, UKN-2018-7704, UKN-2018-7706, UKN-2018-7770, UKN-2019-2771, UKN-2019-4619, UKN-2019-3151, UKN-2019-8665, UKN-2020-1625, UKN-2020-5914, UKN-2021-10307 and UKN-2022-543, especially highlighting UKN-2012-61.

[41] Reference is made to decisions from the Appellate Body for Treatment Abroad in Annex A.21 to the Application: UKN-2012-108, p. 176 and UKN-2013-110, p. 179. Reference is made to decisions from before 2012 made by the Norwegian Board of Health Supervision ("*Helsetilsynet*") in Annex A.21 to the Application: UKN-2008-2, p. 71; UKN-2009-53, p. 91; UKN-2009-95, pp. 99-100; UKN-2010-21, p. 111; UKN-2010-103, pp. 125-127; and UKN-2010-111, pp. 128-131.

[42] Reference is made to decisions from the Offices for Medical Treatment Abroad in Annex A.22 to the Application: OSLO-2019-18-R (Switzerland), p. 50, OSLO-2019-19-R, p. 52, TRONDHEIM-2019-2-R, p. 195, TRONDHEIM-2019-5-R, p. 199 and BERGEN-2019-2-R, pp. 143-144. Reference is made to decisions from the Appellate Body for Treatment Abroad in Annex A.21 to the Application: UKN-2011-58, pp. 140-143, and UKN-2011-97, pp. 155-158.

126. Third, ESA disagrees with Norway's assessment that the supplementary PRA Schemes are "better" for the patient in the typical scenario. ESA cites, by way of example, the circumstance that (i) under the fourth paragraph of Section 2-1b PRA there is no right to go abroad even when the time limit has expired; and (ii) under letter (a) of the second paragraph of Section 2-4a PRA waiting times and time limits will be ignored while patients must establish that the treatment is more effective.

127. Fourth, ESA submits that the drafting error at the Second Compliance Deadline in the first paragraph of Section 7-2 PRA, according to which complaints regarding the first paragraph of Section 2-4a PRA (the Regulation 883/2004 Scheme) were to go to the County Governor although, in practice, they were made to the Office for Health Service Appeals ("*Helseklage*"), demonstrates the difficulties patients face in attempting to navigate complex sets of legal provisions in order to find an EEA-compliant route abroad, and to effectively enforce their rights on appeal if they consider that their rights are being infringed.

128. Fifth, ESA submits that practice under the Regulation 883/2004 Scheme by the complaint body (Helfo) and appeals body (National Insurance Court) is not compliant with EEA law. Firstly, ESA asserts that in the period of ESA's examination, the National Insurance Court has not been consistent on whether it has jurisdiction to apply EEA law at all. ESA submits that both the Regulation[43] and Article 36 EEA[44] were applied by the National Insurance Court until its judgment TRR-2014-2387, in which it denied such jurisdiction. This was reversed in TRR-2016-301 for the Regulation but the judgment did not mention Article 36 EEA. Article 36 EEA was first applied again by the National Insurance Court in TRR-2020-2665. ESA submits that over a period of eight years the National Insurance Court seems to have failed completely to apply Article 36 EEA in any and all cases concerning in-patient treatment in other EEA States.

129. Secondly, ESA submits, without prejudice to whether the substantive conditions were, or were not, met by the individual patient in any given case, that both Helfo and the National Insurance Court typically only assessed whether a specific type of treatment is available in Norway and, in that way, failed to apply altogether the equally-effective treatment requirement of the Second Condition of Article 20(2) of Regulation 883/2004 and Article 36 EEA. Such bodies rarely, if ever, applied the Regulation and Article 36 EEA in a manner prescribed by the European Courts, including the equally-effective treatment element and the timing element. ESA illustrates its argument by contrasting TRR-2020-2665,[45] which ESA considers to set out the relevant test in compliance with

[43] Reference is made to cases from the National Insurance Court in Annex A.28 to the Application: TRR-2012-268, TRR-2012-1439, TRR-2012-1883, TRR-2012-2553, TRR-2013-514, TRR-2013-761, TRR-2013-2486 and TRR-2014-621.

[44] Reference is made to cases from the National Insurance Court in Annex A.28 to the Application: TRR-2012-1439 and TRR-2014-247.

[45] Reference is made to Annex A.28 to the Application, p. 165.

EEA law, with the formulation of the test in TRR-2017-653[46] and 37 decisions from Helfo.[47]

130. Sixth, ESA argues that its analysis of the decisions from the Appellate Body for Treatment Abroad reveals how the proper application of EEA law does not happen.

131. In its Defence, the Norwegian Government understands ESA's second plea to be limited to the procedural rules in Section 7-2 PRA and Sections 7 and 8 PR and the administrative practice of the bodies administering the Supplementary Schemes set out in the fourth and fifth paragraphs of Section 2-1b and letter (a) of the second paragraph of Section 2-4a PRA. Given its view that the Supplementary Schemes do not need to reflect the equally-effective treatment in time criteria, Norway contends that there is no breach of Article 20(2) of the Regulation or of Articles 36 and 3 EEA by reason of the fact that the procedural rules prevent the bodies from applying these criteria or that in practice these criteria are not applied.

132. Because Norway finds that ESA's second plea also seems to challenge the procedural rules and administrative practice related to the right to receive treatment abroad under Article 20(2) of Regulation 883/2004, Norway contends that the procedural rules and administrative practice under all routes to healthcare abroad are consistent with EEA law.

133. Norway starts with the submission that EEA law does not deprive EEA States of the competence to organise their social security system. In addition, Norway submits that the main part of the EEA Agreement does not set out general requirements for the organisation of the national administration, nor for its case handling.[48] Norway acknowledges that this principle of procedural and organisational autonomy for the EEA States does not imply that the EEA States are completely free to organise their administrative systems. Pursuant to the duty of loyalty set out in Article 3 EEA, the principles of equivalence and effectiveness have been developed through case law.[49] This includes an obligation to ensure compliance with the right to an effective remedy in accordance with the principle of effective judicial protection,[50] entailing the opportunity for individuals to enforce the rights conferred upon them by EEA law before the national courts.[51] However, Norway submits that EEA law does not give rise to a requirement for a right of appeal within the national administrative system as such – the

[46] Reference is made to Annex A.28 to the Application, p. 121.
[47] Reference is made to decisions from Helfo in Annex A.29 to the Application: 20/105941-15 (HELFO-4) p. 7, 20/112229-3 (HELFO-5) p. 9, 20/127067-3 (HELFO-6) p. 11, 20/130989-3 (HELFO-7) p. 13, 20/217238-3 (HELFO-11) p. 20, 20/275805-3 (HELFO-12) p. 22, 20/352331-5 (HELFO-13) p. 24, 20/363635-3 (HELFO-14) p. 26, 20/367805-5 (HELFO-15) p. 28, 20/501097-5 (HELFO-16) p. 30, 20/501102-3 (HELFO-17) p. 32, 21/5454-5 (HELFO-18) p. 34, 21/47511-2 (HELFO-19) p. 36, 21/26659-7 (HELFO-20) p. 38, 21/108633-6 (HELFO-21) p. 40, 21/162098-4 (HELFO-23) p. 44, 21/206311-4 (HELFO-24) p. 46, 21/325101-3 (HELFO-25) p. 48, 19/497549-22 (HELFO-33) p. 65, 20/105941-3 (HELFO-35) p. 70, 20/403353-3 (HELFO-36) p. 72.
[48] Reference is made to Case E-1/04 *Fokus Bank* [2004] EFTA Ct. Rep. 11, paragraph 41.
[49] Reference is made to the judgments in *Sopropé*, C-349/07, EU:C:2008:746, paragraph 38, and *SC C.F. SRL*, C-430/19, EU:C:2020:429, paragraph 34.
[50] Reference is made to *Rindal and Slinning*, cited above, paragraph 48, and Joined Cases E-11/19 and E-12/19 *Adpublisher AG* v *J & K*, judgment of 10 December 2020, paragraphs 49-50.
[51] Reference is made to the judgment in *Johnston*, C-222/84, EU:C:1986:206, paragraphs 17-18.

decisive factor is whether decisions may be challenged in judicial (or quasi-judicial) proceedings.

134. On the question of whether the Norwegian procedural rules governing the complaint and appeal structure in relation to healthcare abroad is in accordance with EEA law, Norway submits some preliminary remarks. Norway submits that the EEA Schemes and the Supplementary Schemes have important differences that makes it reasonable and beneficial for patients to divide the administration of the schemes between different bodies. First, while the schemes administered by Helfo safeguard patients' rights to reimbursement or the assumption of costs in relation to healthcare abroad that is equivalent to healthcare offered in Norway, the Offices for Medical Treatment Abroad handle cases which concern treatment that is not offered in the specialist healthcare service in Norway. The latter schemes require that the administrative body possesses sufficient medical competence to be able to assess whether the treatments in question fulfil the criteria set out in Section 2-1b PRA and, in particular, Sections 2, 2a, and 3 PR. Second, Norway submits that the EEA Schemes are merely "benefit" schemes where the administrative body reimburses or settles the costs for treatment for which the patient themselves is responsible. Under the Supplementary Schemes, however, Norway contends that the administrative bodies also take responsibility for, among other things, agreements with foreign hospitals on financial settlement, planning and booking of travel and accommodation, follow-up during the treatment, invoice processing, travel bills and medical coding.

135. In relation to the EEA Schemes, Norway argues that the procedural system is in accordance with EEA law.

136. Norway argues that the right to treatment abroad under the EEA Schemes is easily accessible for the patient and it is neither impossible nor excessively difficult to exercise this right.[52] Norway highlights that, pursuant to the second paragraph of Section 21-11a NIA and Section 10 of the Norwegian reimbursement regulation, patients may apply directly to Helfo for authorisation or reimbursement pursuant to Article 20(2) of Regulation 883/2004 and the Norwegian reimbursement regulation. Helfo has both the competence and obligation to assess these applications under the criteria set out in these provisions. Norway submits that the fact that patients may alternatively apply to the Supplementary Schemes does not deprive the EEA Schemes of their accessibility, and there is no hierarchy between the schemes. An overview of all the schemes is available to patients in Section 2-4a PRA and it is thoroughly explained to patients and healthcare providers on helsenorge.no.[53] Further, Norway submits that the bodies administering the Supplementary Schemes were encouraged to redirect patients to the EEA Schemes upon rejection under the Supplementary Schemes,[54] and in most cases, patients were redirected to the EEA Schemes.[55] According to Norway, the low numbers of applications received under Article 20(2) of Regulation 883/2004 is not an indication that this scheme is considered unavailable by patients, as there could be many

[52] Reference is made to *Rindal and Slinning*, cited above, paragraph 48.
[53] Reference is made to screenshots from helsenorge.no in Annex 4 to the Defence.
[54] Reference is made to Annex 5 to the Defence and Annex A.24 to the Application.
[55] Reference is made to Annex A.22 to the Application, pp. 5 and 8.

explanations for this. Norway particularly highlights the variables that favour the schemes under the Norwegian reimbursement regulation and the Supplementary Schemes at the expense of Article 20(2) of Regulation 883/2004.

137. Turning to ESA's submission that the procedural structure makes it impossible or excessively difficult to challenge refusals for authorisation in judicial or quasi-judicial proceedings, Norway asserts that a rejection from Helfo can be appealed to the Office for Health Service Appeals pursuant to the second paragraph of Section 21-11a NIA, and that a rejection from the Office for Health Service Appeals may be brought before the National Insurance Court. Norway submits that the National Insurance Court has always had competence to (i) deal with appeals in cases relating to Article 20(2) of Regulation 883/2004, and (ii) to apply Article 36 EEA in general.

138. The National Insurance Court's competence to apply Article 36 EEA in general follows from the fact that Article 36 EEA is incorporated into Norwegian law as such, with priority over conflicting national legislation. The fact that the National Insurance Court has allegedly not applied this provision in the judgments ESA has examined may have many explanations and, in Norway's submission, does not prove that the National Insurance Court has not considered itself competent to apply this provision.

139. The National Insurance Court has handled cases relating to Article 20(2) of Regulation 883/2004 and its predecessor since the 1990s. Norway is aware of case TRR-2014-2387, with a dissenting opinion from its leader, in which the National Insurance Court stated that it did not have such competence. Norway emphasises, however, that the judgment was appealed to the Parliamentary Ombud for Scrutiny of the Public Administration ("*Sivilombudet*"), who came to a different conclusion. In addition, Norway emphasises that shortly after this the National Insurance Court (sitting with five members) reached the conclusion that it did have this competence.[56] Norway therefore concludes that there is no doubt that the National Insurance Court, at both Compliance Deadlines, and historically, has had the competence to handle appeals under Article 20 of Regulation 883/2004.

140. In relation to the Supplementary Schemes, Norway submits that the EEA requirements of accessibility, effectiveness, and a right to an effective legal remedy do not apply to these schemes because the right to receive healthcare in other EEA States under these schemes constitutes an additional right to treatment abroad that is not implementing EEA law.

141. Nevertheless, Norway contends that the EEA requirements of having an accessible appeal structure, where rejections may be brought before the national courts, are also fulfilled in relation to the Supplementary Schemes. Decisions under the No Adequate Treatment Scheme are made by the Office for Medical Treatment Abroad in the health region where the patient is resident and may be appealed to the Appellate Body for Treatment Abroad. The latter's decisions may be challenged before the ordinary courts. Under the Breach of Deadline Scheme, Helfo has been appointed with

[56] Reference is made to the judgment in TRR-2016-301 in Annex A.28 to the Application, p. 76.

the task of assisting the RHAs in finding an alternative service provider to provide necessary healthcare in accordance with the third paragraph of Section 6 PR. If the patient has not received an offer of necessary healthcare within a medically justifiable time, the patient can complain to the County Governor. The latter's decision may be challenged before the ordinary courts.

142. On the question of whether the administrative practices in relation to treatment abroad are in accordance with EEA law, Norway first comments on the EEA Schemes.

143. Norway contends that ESA has not established sufficient proof of an administrative practice of a consistent and general nature in breach of Article 20(2) of Regulation 883/2004 and/or Article 36 EEA. Norway submits that it is for ESA to substantiate its claim that Norwegian administrative practice is not compliant with EEA law.[57] In its Application, ESA refers to a number of decisions and judgments from Helfo and the National Insurance Court which, according to ESA, do not apply EEA law in a correct way because they typically only assess whether a specific type of treatment is available in Norway and do not consider the equally-effective treatment criterion of the Second Condition included in Article 20(2) of Regulation 883/2004. Norway submits, however, that ESA seems to overlook the fact that when the treatment is not available in Norway, the First Condition is not met – and when the First Condition is not met it is neither compulsory nor necessary to assess the criteria of the Second Condition. Norway asserts that the decisions referred to by ESA generally relate to situations where the First Condition is not met.[58] Although Norway cannot categorically rule out the possibility that there may be examples of decisions from Helfo and/or the National Insurance Court that apply the criteria under Regulation 883/2004 in an incorrect way, Norway emphasises that isolated examples of EEA breaches in practice are not sufficient to establish an administrative practice in breach of EEA law.[59]

144. In relation to the PRA Schemes, Norway argues that the bodies administering these schemes do not need to apply the equally-effective treatment in time criteria under the Second Condition. Hence, it is not in breach of EEA law that the split competence between the Appellate Body and the County Governor under the first and second paragraphs of Section 7-2 PRA prevents these bodies from applying both these criteria, and that the bodies do not apply these criteria in practice. Norway emphasises that the bodies administering the PRA Schemes usually redirect patients to the EEA Schemes when relevant.

145. In its Reply, ESA notes Norway's contention that EEA law does not apply to the PRA Schemes and submits that Norway does not engage with, and offers no other defence to, ESA's arguments about the procedural rules and decisional practice in relation to the PRA Schemes. ESA contends that Norway rather proceeds on the basis

[57] Reference is made to the judgment in *Commission* v *Hellenic Republic*, C-156/04, EU:C:2007:316, paragraph 50.

[58] Reference is made to decisions in Annex A.29 to the Application: 21/108633-6 (HELFO-21), p. 40, 19/50214-3 (HELFO-27), p. 52, and 19/388959-4 (HELFO-31), p. 61. Norway also refers to cases where the First Condition is not fulfilled due to lack of documentation: 19/585086-4 (HELFO-3), p. 5, 20/105941-15 (HELFO-04), p. 7, and 20/403353-3 (HELFO-36), p. 72.

[59] Reference is made to the judgment in *Commission* v *Hellenic Republic*, cited above, paragraph 51.

that ESA's description is correct but considers this not to matter because (i) the complaint bodies do not need to apply EEA law and (ii) the patient is always free to apply for authorisation or reimbursement under the EEA Schemes.

146. ESA contends that the complaint bodies are organs of the State and required to apply EEA law[60] and emphasises that the rights to treatment abroad are not optional. Further, in ESA's submission, patients seeking treatment abroad should be able to rely on EEA law at each and every stage of the PRA Schemes. It is not a defence to assert that the patients must turn to the specific EEA Schemes as this requires the patient to "start again", making it excessively difficult or practically impossible to exercise their EEA law rights.

147. According to ESA, the contention by Norway that unsuccessful patients were correctly redirected to the specific EEA route is unsupported by evidence. First, the letter in Annex 5 to the Defence from the Ministry to the Offices for Medical Treatment Abroad is recent (from October 2022) and only requires the relevant bodies to ensure that the patients receive information on the other schemes. It contains nothing on the importance of securing patients their EEA rights. ESA further contends that the letter was not addressed to the Appellate Body for Treatment Abroad. Second, the letter in Annex A.24 to the Application is, in ESA's submission, not relevant, as it targets the bodies administering the EEA Schemes. Third, the rejection decisions from the Offices for Medical Treatment Abroad refer to helsenorge.no and the possibility of seeking reimbursement for healthcare received in another EEA State. ESA submits that this generic reference does not correctly reflect the EEA right and does not advise patients of their alternative EEA rights on an individual basis. For example, a patient in the No Adequate Treatment Scheme may have a right to equally-effective treatment in time where the State must authorise treatment and will generally fund the treatment directly – hence, no reimbursement is needed. Fourth, ESA submits that the decisions mentioned in Annex 6 to the Defence are not relevant as they involve a reference from the EEA Schemes to the PRA Schemes and not a reference to the EEA Schemes.

148. ESA does not dispute the fact that decisions from the County Governor and the Appellate Body for Treatment Abroad may be appealed to the national courts. ESA disagrees with the contention, however, that such an appeals structure fulfils the requisite EEA law requirements of accessibility, effectiveness, and the right to an effective legal remedy.[61] ESA submits that if the national courts tasked with reviewing administrative decisions are not required to apply EEA law (because, on Norway's view, the PRA Schemes do not implement or apply EEA law), such an appeals system is necessarily defective from an EEA law perspective.

149. In relation to the administrative practice under the Regulation 883/2004 Scheme, ESA submits that nothing in Norway's defence calls into question ESA's conclusion

[60] Reference is made to Case E-1/21 *ISTM*, judgment of 14 December 2021, paragraph 36; Case E-2/21 *Norep*, judgment of 14 December 2021, paragraph 43; and Case E-11/22 *RS*, judgment of 4 July 2022, paragraph 41, and to the judgments in *Minister for Justice and Equality*, C-378/17, EU:C:2018:979, paragraph 3, and *DX* v *INSS*, C-113/22, EU:C:2023:665, paragraphs 41-42.

[61] Reference is made to *RS*, cited above, paragraphs 52-53, and *Rindal and Slinning*, cited above, paragraph 48.

that the practice is not compliant with EEA law. First, ESA avers that it has established sufficient proof of a consistent and general failure of the bodies to apply EEA law correctly. ESA considers paragraph 116 of the Application and Annex A.28 to the Application to show that the National Insurance Court in an almost eight-year period failed to apply Article 36 EEA in cases concerning in-patient treatment in other EEA States. Further, ESA considers paragraph 117 of the Application and Annexes A.28 and A.29 to the Application to show that the complaint and appellate body rarely, if ever, correctly applied Article 20 of the Regulation and Article 36 EEA.

150. Second, ESA submits that these findings are not contested by Norway and that Norway also does not identify alternative samples of decisions which would lead to a different conclusion.

151. Third, although ESA does not dispute that the National Insurance Court has the competence to apply Article 20(2) of Regulation 883/2004 and Article 36 EEA, it submits that the court has been inconsistent. ESA submits that Norway disputes neither this inconsistency nor the circumstance that the bodies may have failed to correctly apply the criteria of the Second Condition. In the Defence, Norway argued that cases of non-assessment of the Second Condition are generally those where the First Condition is not met because the treatment is not available in Norway. ESA submits that this argument must be rejected for the reasons it provided under the first plea.

152. ESA submits that, when sufficient evidence is produced, Norway cannot merely deny that Helfo and the National Insurance Court have incorrectly applied or failed to apply EEA law. Instead, Norway must "contest substantively and in detail the information produced and the consequences thereof".[62] ESA submits that Norway has failed to do this.

153. In its Rejoinder, the Norwegian Government first elaborates on why the PRA Schemes do not render Article 20(2) of Regulation 883/2004 ineffective or unavailable to patients. Norway takes issue with ESA's argument that a problem exists because (i) patients who "commence their journey" under the PRA Schemes need to "start again" under the EEA Schemes, and (ii) patients who are denied authorisation under the PRA Schemes are not redirected to the EEA Schemes "by default". Norway argues that there is no hierarchy between the schemes where the PRA Scheme is the default in the Norwegian system. Patients who must "start" again are the patients who for some reason have chosen not to seek treatment abroad under the EEA Schemes from the beginning.

154. Further, Norway submits that ESA has not substantiated why there is an EEA law requirement that the patients denied authorisation under the PRA Schemes must be redirected to the EEA Schemes "by default" in order not to render Article 20(2) of the Regulation ineffective or unavailable. In any event, Norway avers that it did demonstrate that patients were redirected to the EEA Schemes by default. According to Norway, ESA's assertion that this is not enough, because it is only a "generic reference" to the

[62] Reference is made to the judgments in *Commission* v *Hellenic Republic*, C-272/86, EU:C:1988:433, paragraphs 30-31; *Commission* v *Italy*, C-297/08, EU:C:2010:115, paragraph 102; and *Commission* v *Ireland*, C-444/21, EU:C:2023:524; paragraph 166.

EEA Schemes, must be rejected. Norway does not see the significance of ESA's objections to the letters from the Ministry encouraging the relevant bodies to provide guidance for patients regarding their EEA rights when, according to Norway, it is undisputed that the relevant PRA bodies did in fact redirect patients to the EEA Schemes.

155. Norway then argues that ESA has not provided sufficient proof of an administrative practice by the National Insurance Court and the Office for Health Service Appeals under the EEA Schemes which is in breach of EEA law. According to Norway, ESA contends that its findings are "without prejudice to whether the substantive conditions were or were not met by any individual patient in any given case"; the alleged breach consists instead in the fact that the "test was systematically formulated in the wrong way in administrative practice". Irrespective of whether the tests was formulated correctly, Norway emphasises that ESA "may not rely on any presumption" when establishing proof that there has been a failure to fulfil an obligation on the basis of an administrative practice.[63] Norway submits that a wrong formulation of the applicable test does not in itself constitute a wrong "application" of Article 20 of the Regulation if the result is nevertheless EEA compliant. Norway submits that ESA has not provided evidence of cases where a patient has been wrongly denied authorisation under Article 20(2) of Regulation 883/2004. Norway submits that ESA reached its conclusion rather on the basis of a presumption that a wrongly formulated test subsequently led to a wrong application.

156. Moreover, Norway contends that the test has not been formulated wrongly by the National Insurance Court and the Office for Health Service Appeals. Norway submits that these bodies have assessed the First Condition of Article 20(2) of Regulation 883/2004 and considers this to be a correct formulation and application of the test, which is not satisfied when the treatment in question is "not offered" in Norway.

157. In relation to the alleged failure by the National Insurance Court to apply Article 36 EEA, Norway submits that a body being inconsistent on whether it has jurisdiction to apply Article 36 EEA is not in itself proof that the body has in fact failed to apply Article 36 EEA. Norway repeats that ESA may not rely on a presumption when establishing proof of an unlawful administrative practice. Furthermore, Norway submits that ESA's claim that the National Insurance Court has been inconsistent over an eight-year period regarding its competence to apply Article 36 EEA is exaggerated and misleading. It is based solely on one judgment (TRR-2014-2389) with a dissenting opinion, in which the National Insurance Court denied that it could handle claims "directly under the EEA Agreement" in a case primarily concerning whether it could handle cases under Article 20 of the Regulation. It is the latter question that has been central to the National Insurance Court's later judgments, and TRR-2016-301 cannot be understood as consciously maintaining a position that the court lacks competence to apply Article 36 EEA. Norway submits that there might be many explanations for why Article 36 EEA has not been mentioned and ESA must demonstrate that the National

[63] Reference is made to the judgment in *Commission* v *Germany*, C-160/08, EU:C:2010:230, paragraph 107.

Insurance Court has failed to apply this provision in cases where EEA law requires its application, which, in Norway's submission, ESA has not done.

158. In its Written Observations, the Commission shares ESA's concerns regarding the existence of organisational and procedural hurdles within the Norwegian healthcare system as a whole, which undermine the effectiveness of the rights deriving from Article 20(2) of Regulation 883/2004.

159. The Commission argues that a national system cannot be subject to organisational or procedural hurdles which undermine the effectiveness of the rights deriving from Article 20(2) of Regulation 883/2004. In light of the duty of cooperation laid down in Article 3 EEA, it is well-established that national measures must facilitate the application of EEA law, and not hinder its implementation or effectiveness. The Commission argues that this requires patients to be properly informed of their rights in a timely manner.[64] The burden of ensuring that a patient is informed of the correct procedures and that these are followed, which includes "guidance on administrative procedures",[65] is placed upon the competent institution. The Commission argues that the principle of effective judicial protection similarly requires individuals to be made aware of rights deriving from Article 20(2) of Regulation 883/2004.[66]

160. The Commission observes that it appears from the evidence adduced by ESA, especially in Annexes A.21 and A.22 to the Application, that patients have significant difficulty in practice in navigating the system and are not systematically redirected to a route under which they can effectively enforce their rights under Article 20(2) of Regulation 883/2004. It appears to the Commission that, if patients start by seeking authorisation under the PRA Schemes, this may lead to a situation where they are in practice left without reimbursement, despite fulfilling the conditions for authorisation under Article 20(2) of Regulation 883/2004.

161. The Commission argues that legal uncertainty may be created or enhanced by the fact that a different test is applied under the PRA Schemes to that under Article 20(2) of Regulation 883/2004, as well as the fact that, in all cases, the patient must satisfy the general pre-condition of having a right to "necessary healthcare" in accordance with Section 2-1b PRA and Section 2 PR.

162. The Commission further observes that whilst the fourth paragraph of Section 6 PR refers to the fact that the patient may also be entitled to reimbursement of expenses for healthcare services in other EEA countries according to the conditions of Regulation 883/2004, the patient must nevertheless make an express (and separate) request under that scheme. In other words, if a patient does not meet all the requirements under the PRA Schemes, the Norwegian authorities do not automatically also examine the request under the Regulation 883/2004 Scheme,[67] nor do they appear to at least advise patients

[64] Reference is made to Article 76(4) of Regulation 883/2004 and Article 22(1) of Regulation 987/2009.
[65] Reference is made to Recital 22 of Regulation 987/2009.
[66] Reference is made to Case E-15/12 *Jan Anfinn Wahl* [2013] EFTA Ct. Rep. 534, paragraph 52.
[67] Reference is made to the judgment in TRR-2012-268 in Annex A.28 to the Application, p. 2.

to apply for prior authorisation under that scheme.[68] In the Commission's view, a failure to adequately inform patients of their rights, or of the correct procedures for obtaining those rights not only clearly infringes the express requirements of Article 76(4) of Regulation 883/2004 but also undermines the full effectiveness of the rights granted to patients by Article 20(2) of Regulation 883/2004.

163. The Commission observes that, even in the context of the Regulation 883/2004 Scheme, patients appear, on the basis of the evidence submitted by ESA, to have been denied in practice the right to in-patient treatment abroad contrary to Article 20(2) of Regulation 883/2004. By way of example, there appear to the Commission to have been a significant number of cases where the competent authorities merely assessed whether a specific type of treatment was available in Norway, and thus failed to consider the key issue of whether there was an "equally effective treatment", compared with the treatment abroad which could not be provided in Norway, "within a time limit which is medically justifiable".[69]

Third plea – failure to comply with the principle of legal certainty

164. The third plea concerns an alleged failure to comply with the principle of legal certainty in breach of Article 36 EEA and Article 20(2) of Regulation 883/2004 and/or Article 3 EEA. In its Application, ESA submits that this is a general principle of law,[70] which is especially important when people in vulnerable situations are involved.[71] ESA submits that the principle of legal certainty involves two requirements.

165. According to ESA, the first requirement is that national rules which restrict or impact on the exercise of fundamental freedoms and EEA rights must, *inter alia*, satisfy the principle of legal certainty. ESA submits that the provisions must be clear, precise and predictable regarding their effects,[72] and their application must be foreseeable by those subjected to them.[73] More generally, this principle entails that "those concerned [must] … know precisely the extent of the obligations which are imposed on them, and those persons must be able to ascertain unequivocally their rights and obligations and take steps accordingly".[74] Furthermore, ESA submits that the criteria for prior administrative approval must be objective, non-discriminatory, and known in advance to persons concerned. ESA submits that where national law does not meet the requirements of clarity, precision, and predictability, this in itself suggests that the relevant measure restricts the rights conferred by EEA law to a disproportionate extent, and that it is, therefore, in breach of EEA law.[75]

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[68] Reference is made to Annexes A.21 and A.22 to the Application.
[69] Reference is made to paragraphs 117-121 of the Application and Annexes A.28 and A.29 to the Application.
[70] Reference is made to Case E-9/11 *ESA* v *Norway* [2012] EFTA Ct. Rep. 442, paragraph 99.
[71] Reference is made to Case E-24/13 *Casino Admiral* [2014] EFTA Ct. Rep. 732, paragraph 56, and to the judgment in *Banco de Portugal and Others*, C-504/19, EU:C:2021:335, paragraphs 51-52.
[72] Reference is made to the judgment in *VYSOČINA WIND*, C-181/20, EU:C:2022:51, paragraph 47.
[73] Reference is made to the judgment in *Călin*, C-676/17, EU:C:2019:700, paragraph 50.
[74] Reference is made to Joined Cases E-10/11 and E-11/11 *Hurtigruten and Norway* v *ESA* [2012] EFTA Ct. Rep. 758, paragraph 281, and to the judgment in *Banco de Portugal*, cited above, paragraph 51.
[75] Reference is made to Case E-9/11 *ESA* v *Norway*, cited above, paragraphs 99-101, and to the judgment in *SIAT*, C-318/10, EU:C:2012:415, paragraphs 57-59.

166. ESA submits that several provisions of the PRA, PR and NIA regarding in-patient treatment abroad fail to meet the requirements of clarity. First, at the Second Compliance Deadline, it was unclear which body or bodies have jurisdiction or competence to hear complaints in cases relating to rights under Article 20(2) of Regulation 883/2004. The uncertainty is twofold: (i) the first paragraph of Section 7-2 PRA provided that the Country Governor had competence to hear complaints related to a breach of the provisions of letter (b) of the first paragraph of Section 2-4a, and thus of Article 20 of Regulation 883/2004; (ii) Norway contended that this competence actually rests with the Office for Health Service Appeals. ESA submits that the second paragraph of Section 21-11a NIA, entitled "Case handling etc. pursuant to Chapter 5 Benefits for health services", did not establish the legal basis for the Office for Health Service Appeals' competence, as claimed by Norway, as in-patient treatment is not among the benefits listed in Chapter 5 NIA. ESA notes that, before the Second Compliance Deadline, Norway introduced a new legal provision in Section 5-1a NIA in this connection.

167. Second, at the Second Compliance Deadline, ESA submits that there was a difference between national law and national administrative practice regarding which body has competence over complaints related to Article 20(2) of Regulation 883/2004. Further, there was a conflict between the relevant provisions of national primary and secondary law. On the day before the Second Compliance Deadline, Norway amended Section 7 PR to allow complaints to be made to the Office for Health Service Appeals – which then conflicted with the corresponding provision of the first paragraph of Section 7-2 PRA. With effect from 1 July 2023 ESA notes that Norway has removed complaints under Article 20(2) of the Regulation from the competence of the County Governor under the first paragraph of Section 7-2 PRA. However, ESA contends that this removal does not confer this competence on Helfo and the Office for Health Service Appeals.

168. Third, ESA submits that, at the First Compliance Deadline, the relevant criteria of the No Adequate Treatment Scheme (the fifth paragraph of Section 2-1b PRA and the fourth paragraph of Section 3 PR) were not sufficiently precise and failed to meet the requirements of sufficient clarity, precision, and predictability. The provision in the PR stated that a lack of capacity and long waiting lists would not in itself result in the right to treatment abroad, whereas the corresponding provision in the PRA did confer a right to treatment within the medically justified national time limit.

169. Fourth, at the First Compliance Deadline and until the day before the Second Compliance Deadline, Section 7 PR was in itself unclear because it gave two bodies the competence to hear complaints under Section 3 PR. Further, Section 7 PR was inconsistent with the primary law provision of the second paragraph of Section 7 PRA, under which competence was clearly split between the County Governor and the Appellate Body for Treatment Abroad as discussed under the second plea.

170. ESA submits that the second requirement of the principle of legal certainty is that States may not maintain in force national legislation which is incompatible with EEA law, even if the State in practice acts in accordance with EEA law (which ESA does not

accept in the present case).[76] ESA asserts that maintaining in force such legislation gives rise to an ambiguous state of affairs and makes it unclear for those subject to the legislation whether and in which circumstances they may rely on EEA law.[77] ESA emphasises that, according to settled case law concerning Article 3 EEA, national measures must, in general, facilitate the application of EU/EEA regulations, and must not hinder their implementation or effectiveness.[78] In the Application, ESA submits that a number of provisions breach this requirement of the principle of legal certainty.

171. First, the No Adequate Treatment Scheme referred to in letter (a) of the second paragraph of Section 2-4a PRA only confers a right to treatment abroad where there is no treatment offer in Norway or where the healthcare abroad is documented to be more effective than the healthcare in Norway – in conflict with Article 20(2) of Regulation 883/2004 and Article 36 EEA. ESA also notes that the immediately preceding provision, letter (b) of the first paragraph of Section 2-4a PRA, contains a generic reference to rights available under Regulation 883/2004. ESA submits that there is nothing in the two provisions to indicate how the two provisions are intended to interact, and which test should be applied when. Further, the description of the right available under Regulation 883/2004 only refers to the in-time element and not equally-effective treatment. This is confusing for patients, especially because letter (a) of the second paragraph of Section 2-4a refers to the higher threshold of treatment abroad being more effective.

172. Second, ESA submits that the Breach of Deadline Scheme referred to in the fourth paragraph of Section 2-1b PRA and the third paragraph of Section 6 PR does not permit patients to seek in-patient treatment abroad where national treatment is not available within a medically justifiable time limit (in such cases they may only receive treatment in Norway). This conflicts with, and is in clear breach of, the rights granted under Article 36 EEA and Article 20(2) of Regulation 883/2004.

173. Third, ESA submits that the need to consult Helfo under the second and third paragraphs of Section 6 PR on the expiry of the national treatment deadline (or where it will expire) makes it unclear whether patients have a right under Article 20(2) of the Regulation and/or Article 36 EEA to go abroad for equally-effective treatment in such circumstances. ESA submits that there is nothing in Section 6 PR that makes it clear that patients have a right to go abroad when the deadline is exceeded and the Second Condition is met.

174. Fourth, ESA submits that the split competence under which each of the County Governor and the Appellate Body for Treatment Abroad is required to have tunnel vision in respect of the PRA Schemes they apply and neither body seems to be entitled to apply Article 20 of Regulation 883/2004 appears to have left these bodies confused about the

[76] Reference is made to the judgment in *Commission* v *Belgium*, C-469/02, EU:C:2004:489, paragraph 13.
[77] Reference is made to the judgments in *Commission* v *France*, C-307/89, EU:C:1991:245, paragraphs 13-14; *Salomie and Oltean*, C-183/14, EU:C:2015:454, paragraph 32; and *Safeway Ltd*, C-171/18, EU:C:2019:839, paragraph 25.
[78] Reference is made to Case E-3/15 *Liechtensteinische Gesellschaft für Umweltschutz* [2015] EFTA Ct. Rep. 512, paragraph 33, and to the judgment in *Adidas*, C-223/98, EU:C:1999:500, paragraph 25.

extent of their ability to apply EEA law. Such bodies almost never consider the overall equally-effective treatment in time criteria of the Second Condition.

175. In the Defence, the Norwegian Government repeats its submission that patients' rights under Article 36 EEA and Article 20(2) of Regulation 883/2004 are ensured in Norwegian legislation through the implementation of Regulation 883/2004 in Section 1-3a NIA and the Norwegian reimbursement regulation, respectively, and that EEA law does not require every national route to in-patient treatment in other EEA States to depend upon whether the same or equally effective treatment cannot be provided in Norway within a time limit that is medically justifiable. Whether the conditions under the PRA Schemes breach the principle of legal certainty is contingent on the Court's view on this main question. Norway therefore does not consider it necessary to respond to ESA's submissions related to Norway maintaining in force the PRA Schemes and the clarity of these schemes.

176. However, Norway denies that the PRA Schemes are designed in a way that undermines the effectiveness of Article 20 of Regulation 883/2004 or makes patients' rights under this provision insecure in practice. Norway submits that (i) Section 2-4a PRA provides an overview of all the schemes; (ii) the patient is always free to apply for authorisation or reimbursement under the EEA Schemes; and (iii) the bodies administering the PRA Schemes usually redirect the patients to the EEA Schemes if relevant.

177. Norway then confines its submissions to the alleged imprecision concerning which bodies handle complaints under Article 20 of Regulation 883/2004. Norway argues that, in practice, there has never been any insecurity with regards to the competence of Helfo and the Office for Health Service Appeals to handle complaints and appeals under Regulation 883/2004. This follows from the third paragraph of Section 6 PR and the third paragraph of Section 7 PR, is thoroughly explained on helesnorge.no, and upon receiving a rejection from Helfo it is explicitly stated in the decision that the patient may appeal to the Office for Health Service Appeals. The decisions from the National Insurance Court referred to by ESA concern decisions from Helfo or the Office for Health Service Appeals.[79]

178. Norway submits that the competence of Helfo and the Office for Health Service Appeals concerning decisions under Regulation 883/2004 follows from the second paragraph of Section 21-11a NIA, where Helfo is given competence through delegation from the Directorate of Health in accordance with Norwegian administrative law. This competence can be established from the wording of the provision read in context with Chapter 5 NIA and the third paragraph of Section 7 and the fourth paragraph of Section 6 PR. This is also assumed in preparatory works.

179. Norway argues that it is incorrect that the first paragraph of Section 7-2 PRA allegedly provided the County Governor with competence over complaints related to Article 20(2) of Regulation 883/2004. Rights under Article 20(2) of the Regulation have

[79] Reference is made to Annex A.29 to the Application.

traditionally not been part of the chapters referred to in the first paragraph of Section 7-2 PRA. The EEA Schemes were included in Chapter 2 PRA for informational purposes, and Norway submits that it was quite clear that this inclusion did not have the effect of extending the County Governor's competence to the Regulation 883/2004 Scheme. To avoid misunderstandings, the Ministry has included an exception in the second paragraph of Section 7-2 PRA for Section 2-4a PRA. However, Norway maintains that it was sufficiently clear also before this amendment that the Office for Health Service Appeals decided on cases related to rights under Article 20(2) of Regulation 883/2004.

180. Any imprecision related to the fact that benefits under NIA Chapter 5 generally excludes in-patient treatment, or to the fact that, for a short period, the second paragraph of Section 7-2 PRA did not explicitly make any exception for decisions under Article 20(2) of Regulation 883/2004, is not of such a character that it breaches the principle of legal certainty. The fact that one needed to consult with other sources of law to establish the correct interpretation of a provision, is in Norway's view, not in itself a breach of the principle of legal certainty.[80]

181. In its Reply, ESA submits that national bodies have not been conferred competence to apply Article 20(2) of Regulation 883/2004 under sufficiently clear rules. As regards the difference between national law (which conferred competence to the County Governor) and administrative practice (where complaints were handled by the Office for Health Service Appeals), ESA submits, first, that the fact that administrative practice may reflect the desired intention of the State cannot rectify the legal uncertainty resulting from the fact that the law says something different. ESA maintains that the supposed legal basis for the competence of Helfo and the Office for Health Services Appeals in the second paragraph of Section 21-11a NIA is unclear.

182. Second, ESA emphasises that previously Norway claimed that the wording of the first paragraph of Section 7-2 PRA providing for complaints under Chapter 2 PRA to be made to the County Governor was a drafting error, whereas, in the Defence, Norway now claims that the provision should not be read in isolation. However, ESA submits that the first paragraph of Section 7-2 PRA does not become clear when read in context because the reference to Sections 6 and 7 PR adds to the confusion. In ESA's submission, Section 7 PR is in contradiction with the first paragraph of Section 7-2 PRA.

183. Third, ESA emphasises the submission made in the Application to the effect that Norway failed to give competence to Helfo and the Office for Health Service Appeals to handle in-patient treatment cases under Article 20 of Regulation 883/2004. ESA maintains, contrary to Norway's submission, that in-patient treatment is excluded from the scope of Section 5-24 NIA and that Section 5-24a NIA concerns the implementation of the Patients' Rights Directive and is irrelevant for the conferral of competence under Article 20 of Regulation 883/2004. Moreover, ESA maintains, also contrary to Norway's submission, that the statements in the preparatory works which imply that

[80] Reference is made to the judgments in *Belgium* v *Commission*, C-110/03, EU:C:2005:223, paragraph 31, and *Marco Tranchetti Provera and Others*, C-206/16, EU:C:2017:572, paragraphs 40-42.

Chapter 5 NIA does not encompass in-patient treatment are not read out of context because the statement on which ESA relies entails an exhaustive list of benefits included in the scope of the review competence of the Office for Health Service Appeals. Further, according to ESA, the absence of a legislative basis for the competence in relation to in-patient treatment cannot be remedied by factual descriptions in preparatory works or by provisions made by a Ministry in a national regulation without a proper legal basis.

184. Fourth, ESA submits that the case law Norway cited in its Defence does not help its case because the case law concerns situations where abstract legal concepts or inherently uncertain legal rules were used, and where e.g. States could not therefore be required to define in advance all the specific hypotheses to which the concepts or rules might apply. In this case, no such abstract concepts exist, and the matter is simple, specific, and concrete: which body or bodies have competence to receive applications and complaints in relation to Article 20(2) of the Regulation. ESA submits that there is no authority in support of Norway's contention that it is acceptable to maintain "fragmented national legislation where several provisions must be read in combination in order to establish the actual state of the law".[81]

185. In its Rejoinder, the Norwegian Government asserts that the parties appear to agree that if the contested provisions in the PRA are not contrary to Regulation 883/2004 or Article 36 EEA, the maintaining in force of those provisions does not breach the principle of legal certainty, and vice versa. Norway submits that, thus, the only point of disagreement under the third plea concerns whether the provisions governing the competence to handle complaints regarding Article 20(2) of Regulation 883/2004 breach the principle of legal certainty.

186. Norway submits that a correct interpretation of the second paragraph of Section 21-11a NIA confers competence on the Office for Health Service Appeals in relation to in-patient treatment abroad, and that it is not correct that Sections 5-24 and 5-24a NIA do not cover in-patient treatment abroad. Even if ESA is correct that the second paragraph of Section 21-11a NIA fails to confer powers on the Office for Health Service Appeals, it does not mean, in Norway's submission, that the Office for Health Service Appeals lacks competence over such complaints: under Norwegian administrative law the competence of the Office for Health Service Appeals does not need to have a legislative basis. The organisation of the administration is a matter for the Ministry of Health and Care Services alone, and consistent practice and the third paragraph of Section 7 PR makes it clear that the Ministry has conferred competence in such cases to the Office for Health Service Appeals.

187. Norway submits that the relevant question therefore is whether the provisions in the second paragraph of Section 21-11a NIA and Section 7-2 PRA make the state of law too unclear for the patients, thereby breaching the principle of legal certainty. Norway submits that the appeals body is clear from the patient's perspective because upon receiving a negative decision from Helfo, the patient is always informed that the appeal body is the Office for Health Service Appeals. Norway further submits that the fact that

[81] Reference is made to the Defence footnote 157 and paragraph 247.

(i) the second paragraph of Section 21-11a NIA must be read in light of other provisions and (ii) Section 7-2 PRA in a short period needed to be read in light of the second paragraph of Section 21-11a NIA and the third paragraph of Section 7 PR to establish that it did not confer competence on the County Governor is a normal contextual interpretation. Such contextual interpretation cannot amount to a breach of the requirements of clarity and foreseeability under the principle of legal certainty, at least not when other mechanisms ensure that the patient will always know which body to address complaints to. Norway maintains that the case law referred to in the Defence supports this.

188. Finally, Norway submits that ESA overlooks the fact that the right to appeal to the Office for Health Service Appeals is not an implementation of EEA law, but something the Norwegian legislator has chosen to introduce. Norway emphasises that the EEA principle of legal certainty, here understood as the specific requirements for clarity and foreseeability of the wording of national provisions, relates, under ECJ case law, to "situations and legal relationships governed by [EEA law]".[82] Norway submits that this suggests that the specific requirements apply to national provisions on the substantive right to receive treatment abroad, and to provisions on the enforcement of those rights before national courts, but not to provisions on the right to appeal within the administrative system as such, which is not governed by EEA law. Norway does not contend that provisions of the latter type fall completely outside the scope of the principle of legal certainty as such but submits that it cannot see that such provisions need to satisfy the specific legal certainty requirements ESA refers to, as long as there is no insecurity in practice regarding how to challenge a refusal before national courts. Norway submits that the latter is uncontested by ESA and demonstrated by Norway in its Defence.

189. In its Written Observations, the Commission observes the apparent longstanding lack of clarity in the Norwegian healthcare system regarding the authorities which are competent to review complaints relating to the application of Article 20(2) of Regulation 883/2004.

Michael Reiertsen
Judge-Rapporteur

[82] Reference is made to the judgment in *Schulin*, C-305/00, EU:C:2003:218, paragraph 58. Another common formulation is "areas covered by EU law", for which reference is made to the judgments in *Commission* v *Italy*, 257/86, EU:C:1988:324, and *Salomie and Oltean*, cited above, paragraph 32.