JUDGMENT OF THE COURT

7 May 2025*

(Regulation (EC) No 883/2004 – Inpatient treatment abroad – Alternative schemes – Effective protection of EEA rights – Legal certainty – Article 20(2) of Regulation No 883/2004 – Article 36 EEA – Admissibility – Article 31 SCA)

In Case E-9/23,

EFTA Surveillance Authority, represented by Claire Simpson, Erlend Møinichen Leonhardsen, Marte Brathovde and Ewa Gromnicka, acting as Agents,

applicant,

v

The Kingdom of Norway, represented by Lotte Tvedt, Simen Hammersvik, Andreas Runde and Marie Munthe-Kaas, acting as Agents,

defendant,

APPLICATION seeking a declaration that, in relation to certain national rules and practices governing access to inpatient 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,

* Translations of national law are unofficial.

THE COURT,

composed of: Páll Hreinsson, President, Bernd Hammermann and Michael Reiertsen (Judge-Rapporteur), Judges,

Registrar: Ólafur Jóhannes Einarsson,

having regard to the written pleadings of the applicant and the defendant, and the written observations submitted on behalf of:

- the European Commission ("the Commission"), represented by Bernd-Roland Killmann, Freya van Schaik and Nicola Yerrell, acting as Agents,

having regard to the Report for the Hearing,

having heard the oral arguments of the EFTA Surveillance Authority, represented by Claire Simpson, Marte Brathovde and Erlend Møinichen Leonhardsen; Norway, represented by Lotte Tvedt and Andreas Runde; and the Commission, represented by Nicola Yerrell, at the hearing on 20 March 2024,

gives the following

JUDGMENT

I INTRODUCTION

1 By an application lodged at the Court's Registry on 26 July 2023, the EFTA Surveillance Authority ("ESA") brought an action under 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 of the Agreement on the European Economic Area ("the EEA Agreement" or "EEA"), 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 (OJ 2004 L 166, p. 1, as corrected by OJ 2004 L 200, p. 1; Norwegian EEA Supplement 2015 No 76, p. 40) ("Regulation 883/2004" or "the Regulation"), as well as the principle of legal certainty, by maintaining in force legislation and an administrative practice related to inpatient treatment abroad.

2 In summary, the declaration sought entails various complaints relating to how the Norwegian legislation and administrative practice related to inpatient treatment abroad do not ensure patients' rights to access inpatient treatment in other EEA States when the same

or equally effective treatment cannot be provided in Norway within a medically justifiable time, as required by Article 20(2) of Regulation 883/2004 and/or Article 36 EEA.

II LEGAL BACKGROUND

EEA law

3 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.*

4 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.*

5 Article 31 SCA reads:

> *If the EFTA Surveillance Authority considers that an EFTA State has failed to fulfil an obligation under the EEA Agreement or of this Agreement, it shall, unless otherwise provided for in this Agreement, deliver a reasoned opinion on the matter after giving the State concerned the opportunity to submit its observations.*
>
> *If the State concerned does not comply with the opinion within the period laid down by the EFTA Surveillance Authority, the latter may bring the matter before the EFTA Court.*

6 Regulation (EC) No 883/2004 was incorporated into the EEA Agreement at point 1 of Annex VI (Social security) by Decision of the EEA Joint Committee No 76/2011 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. Those requirements were fulfilled by 31 May 2012 and the decision entered into force on 1 June 2012.

7 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.*

National law

8 The EEA Agreement is implemented in Norwegian law by virtue of Section 1 of the Act No 109 of 27 November 1992 on the implementation in Norwegian law of the main part of the Agreement on the European Economic Area etc. (*Lov om gjennomføring i norsk rett av hoveddelen i avtale om Det europeiske økonomiske samarbeidsområde (EØS) m.v. / EØS-loven*).

9 Regulation 883/2004 has been made part of Norwegian law by Section 1-3a of the National Insurance Act No 19 of 28 February 1997 (*Lov om folketrygd / folketrygdloven*) ("the NIA").

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

11 At the end of the period laid down in the Reasoned Opinion of 20 September 2017 ("the first compliance deadline"), the second paragraph of Section 2-1b PRA, also referred to as

Section 2-1b(2) PRA, entitled "Right to necessary healthcare from the specialist healthcare services", read, in extract:

> *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. …*

12 At the end of the period laid down in the Supplementary Reasoned Opinion of 20 October 2022 ("the second compliance deadline"), the second paragraph of Section 2-1b PRA, also referred to as Section 2-1b(2) PRA, read, in extract:

> *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.*

13 At the first compliance deadline, the fourth paragraph of Section 2-1b PRA, also referred to as Section 2-1b(4) 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.*

14 At the second compliance deadline, the fourth paragraph of Section 2-1b PRA, also referred to as Section 2-1b(4) 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.*

15 At the first compliance deadline, the fifth paragraph of Section 2-1b PRA, also referred to as Section 2-1b(5) 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.

16 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.

17 At the first and second compliance deadlines, the first paragraph of Section 7-2 PRA, entitled "Complaint etc.", 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.*

18 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. …*

19 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. …*

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

21 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.*

22 At the second compliance deadline, the first paragraph of Section 3 PR, entitled "Healthcare abroad if the service is not offered in Norway", 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.

23 At the first and second compliance deadlines, the fourth paragraph of Section 3 PR, also referred to as Section 3(4) 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.

24 At the first and second 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.

25 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.

26 At the second 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. The patient is not free to choose a service provider.

27 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.*

28 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 State 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 State are made by Helfo, cf. the National Insurance Act s. 21-11a.*

29 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].*

30 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.*
>
> *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.*

31 At the first and second 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

32 In 2009, after receiving complaints about the Norwegian system for inpatient 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.

33 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 inpatient 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.

34 In its reply of 15 August 2014, the Norwegian Government did not accept that ESA's concerns were well founded. Nevertheless, the Norwegian 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.

35 On 3 February 2016, ESA issued a supplementary letter of formal notice. Although Norway had adopted legislation extending the Norwegian reimbursement scheme to inpatient treatment abroad, ESA considered that the rest of its concerns had not been addressed.

36 On 3 May 2016, the Norwegian Government replied by letter to the supplementary letter of formal notice.

37 On 20 September 2017, ESA delivered a reasoned opinion to Norway ("the Reasoned Opinion") 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. The operative part of the Reasoned Opinion reads as follows:

FOR THESE REASONS,

THE EFTA SURVEILLANCE AUTHORITY

pursuant to the first paragraph of Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice, and after having given Norway the opportunity of submitting its observations,

HEREBY DELIVERS THE FOLLOWING REASONED OPINION

that

- *by maintaining in force legislation, such as Section 2-1b(2) PRA and Section 2 PR, which provides for a necessity test as a basis for entitlement to in-patient treatment, which does not ensure that what is accepted according to international medical science is taken into account when evaluating the expected benefit of treatment, the Kingdom of Norway has failed to fulfil its obligations under Article 20 of the Act referred to at point 1 of Chapter I of Annex VI to the EEA Agreement (Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems), as adapted to the EEA Agreement by Protocol 1 thereto and/or Article 36 EEA and/or Articles 7(6), 7(9)-7(11), 8(1), 8(3)-(5) and 9(1) of the Act referred to at point 2 of Annex X to the EEA Agreement (Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare), as adapted to the EEA Agreement by Protocol 1 thereto.;*

- *by maintaining in force legislation, such as Section 2-1b(5) PRA and Section 3 PR, which does not adequately ensure a case-by-case assessment of whether equally effective treatment can be provided to the individual patient within a medically justifiable deadline nationally, in relation to authorisation or reimbursement applications for medical in-patient treatment in other EEA States, the Kingdom of Norway has failed to fulfil its obligations under Article 20 of Regulation 883/2004 and/or Article 36 EEA and/or Articles 7(6), 7(9)-7(11), 8(1), 8(3)-(5) and 9(1) of Directive 2011/24;*

- *by maintaining in force legislation, such as Section 6 PR, which prohibits patients whose justifiable deadlines for medical treatment set under the Prioritisation Regulation and/or under the Patients' Rights Act have expired from turning directly to another EEA medical service provider to receive the medical treatment to which they are entitled upon the expiry of this deadline,*

thereby failing to ensure that such a patient will obtain the necessary authorisation under Article 20(2) of Regulation 883/2004, and/or that such a patient will obtain reimbursement under Article 36 of the EEA Agreement, the Kingdom of Norway has failed to fulfil its obligations under Article 20 of Regulation 883/2004 and/or Article 36 EEA and/or Articles 7(6), 7(9)- 7(11), 8(1), 8(3)-(5) and 9(1) of Directive 2011/24;

- *by failing to ensure that the criteria applicable to applications for authorisation or reimbursement of in-patient medical treatment abroad in Norway, such as Section 2-1b(2) PRA and Section 2 PR, Section 3 PR and Section 2-1b(5) PR, as well as Section 6 PR, meet the requirements established in the aforecited case law concerning objectivity, clarity, transparency and precision, as required also by Articles 7(6), 7(9)-7(11), 8(1), 8(3)-(5) and 9(1) of Directive 2011/24, the Kingdom of Norway has failed to fulfil its obligations under that Directive, and/or under Article 36 EEA and/or Article 20 of Regulation 883/2004.*

38 On 19 January 2018, the Norwegian Government replied to the Reasoned Opinion maintaining that, at the first compliance deadline, there was no breach of EEA law. The Norwegian Government stated 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.

39 On 18 December 2019, ESA, considering the legislative amendments to be unsatisfactory, decided to bring the matter before the Court.

40 On 7 May 2021, in the course of preparing its application to the Court, ESA sent a request for information to the Norwegian Government after having received and assessed additional information in an individual complaint. In light of the Norwegian Government's reply to the request for information of 18 June 2012, and having examined further legislative changes which the Norwegian Government introduced after the expiry of the first compliance deadline, ESA decided to issue a second supplementary letter of formal notice on 18 May 2022.

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

42 On 20 October 2022, ESA delivered a supplementary reasoned opinion ("the Supplementary Reasoned Opinion"). One of ESA's concerns was that, as a consequence of the manner in which Regulation 883/2004 had been incorporated into Norwegian law, provisions of the Regulation would not prevail over conflicting provisions of national law: in this case, the Patients' Rights Act. ESA considered this to be in breach of Articles 3 and 7 EEA and Protocol 35 EEA. The operative part of the Supplementary Reasoned Opinion reads as follows:

FOR THESE REASONS,

THE EFTA SURVEILLANCE AUTHORITY,

pursuant to the first paragraph of Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice, and after having given Norway the opportunity of submitting its observations,

HEREBY DELIVERS THE FOLLOWING REASONED OPINION

that

- *Norway has failed to give full effect and priority to Article 20 of Regulation 883/2004 over conflicting provisions of the PRA (such as Section 2-4a(2)a and Section 2-1(b)(4) PRA), and has thereby also acted in breach of its obligations under Articles 3 and 7 and Protocol 35 EEA.*

- *by maintaining in force an appeals and procedural structure under Section 7-2 PRA and Sections 7 and 8 PR, under which the relevant appeals bodies and Helfo:*

    - *are prevented and/or discouraged from applying a legal test which complies with the requirements of Article 20 of Regulation 883/2004 and/or Article 36 EEA,*

    - *and/or fail to apply such requirements in practice,*

    - *which makes it excessively difficult or impossible for the individuals and persons concerned to rely on and/or enforce their rights before such bodies and Helfo,*

  Norway has, in breach of Article 3, failed to ensure the effectiveness of Article 20 of Regulation 883/2004 and/or Article 36 EEA, in breach also of those provisions.

- *by maintaining a system for seeking access to in-patient treatment in other EEA States in which it is very difficult for the competent institutions and bodies to apply the correct rules correctly, and which makes it impossible or excessively difficult for patients to identify, understand, and effectively enforce their rights under EEA law, Norway has created a state of ambiguity and lack of legal certainty which is not in compliance with Articles 3 and 36 EEA and Article 20 of Regulation 883/2004.*

43 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.

44 ESA thereafter considered that the matter of incorporation and priority of Regulation 883/2004 had been sufficiently resolved. In ESA's view, the other issues raised by the Reasoned Opinion and the Supplementary Reasoned Opinion remain to be resolved. On 26 July 2023, ESA decided to bring the remaining matters before the Court. ESA considers that Norway still fails to ensure patients' rights to access inpatient treatment in other EEA States, in breach of its EEA obligations.

IV PROCEDURE AND FORMS OF ORDER SOUGHT

45 On 26 July 2023, ESA lodged an application pursuant to the second paragraph of Article 31 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").

46 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) [PRA] 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.

47 On 9 October 2023, Norway submitted its defence ("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.

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

49 On 8 December 2023, the Commission submitted written observations pursuant to Article 20 of the Statute of the EFTA Court.

50 Reference is made to the Report for the Hearing for a fuller account of the facts, the procedure and pleas and arguments of the parties, which are mentioned or discussed in the following only insofar as it is necessary for the reasoning of the Court.

V FINDINGS OF THE COURT

Scope of the action brought before the Court

51 According to the information submitted to the Court, there are four different routes to inpatient treatment abroad under Norwegian law at the first and second compliance deadlines.

52 First, patients can seek reimbursement for inpatient treatment in other EEA States under the Reimbursement Scheme, which implements Directive 2011/24/EU ("the Patients' Rights Directive"). This is the most commonly used route to inpatient treatment abroad in the Norwegian system: in the period between 2017 to 2022, there were 6808 totally and 33

partially approved claims under the Reimbursement Scheme for inpatient treatment in other EEA States. This route to inpatient treatment abroad is not part of the case before the Court. Although alleged breaches of the Patients' Rights Directive were included in the Reasoned Opinion, ESA has not pursued those complaints in the present action.

53 Second, Section 1-3a NIA incorporates Regulation 883/2004, including Article 20(2), into Norwegian law ("the Regulation Scheme"). Patients are informed about their right to inpatient treatment in other EEA States under the Regulation Scheme in other parts of the Norwegian legislation, such as letter b of the second paragraph of Section 2-4a PRA and Section 6 PR. Between 2017 to 2022, 94 patients applied for inpatient treatment under the Regulation Scheme and 6 claims were granted. It follows from the application that the present action is not concerned with this particular aspect of Norwegian law.

54 In addition, Norway has additional two routes to inpatient treatment abroad based purely on national law, established under the PRA, and which do not constitute an implementation of specific legal acts incorporated into the EEA Agreement.

55 The first of these PRA Schemes is the Breach of Deadline Scheme established under the fourth paragraph of Section 2-1b PRA. If the regional health authority responsible for providing specialist healthcare services to a patient anticipates that it will not be able to provide the patient with inpatient treatment within the deadline set in accordance with the second paragraph of Section 2-1b PRA, that authority must start the procedure under the Breach of Deadline Scheme by notifying the Norwegian Health Economics Administration ("Helfo") about the anticipated breach. If Helfo finds that the conditions under the Breach of Deadline Scheme are met, Helfo organises inpatient treatment by healthcare service providers with whom Helfo has a public procurement contract. Such healthcare service providers can, in theory, be established in other EEA States. No foreign service providers have, however, applied to provide services under the Breach of Deadline Scheme. No patients have therefore received inpatient treatment in other EEA States under this scheme since 2013. Patients can also directly approach Helfo to receive inpatient treatment under the Breach of Deadline Scheme, but only after a breach of the deadline set in accordance with the second paragraph of Section 2-1b PRA.

56 The second route to treatment abroad based on national law, under the PRA Schemes, is the No Adequate Treatment Scheme. At the first compliance deadline, the No Adequate Treatment Scheme was established under the fifth paragraph of Section 2-1b PRA and granted treatment abroad provided that no adequate treatment offer was available in Norway. At the second compliance deadline and onwards, the No Adequate Treatment Scheme has been established under letter a of the second paragraph of Section 2-4a PRA and the condition for this scheme has been changed so that inpatient treatment abroad is granted in situations where no treatment offer exists in Norway or the healthcare abroad is documented to be more effective than the healthcare offered in Norway. The patient's treating doctor typically applies for treatment abroad under the No Adequate Treatment

Scheme to the regional Offices for Medical Treatment Abroad on behalf of the patient. If the Office for Medical Treatment Abroad finds that the conditions under the No Adequate Treatment Scheme are fulfilled, the Office for Medical Treatment Abroad together with the treating doctor organise the treatment abroad for the patient. The patients themselves can, however, apply to their regional Office for Medical Treatment Abroad for treatment under the No Adequate Treatment Scheme and the patients can also request subsequent reimbursement of expenses covered by the No Adequate Treatment Scheme.

57 ESA argues, in essence, that an EEA State may have parallel or additional schemes for inpatient treatment in other EEA States but submits that all schemes must comply with the minimum requirements under Article 20(2) of Regulation 883/2004 and Article 36 EEA ("the minimum EEA law right to inpatient treatment abroad"). ESA essentially submits that routes to inpatient treatment abroad that do not in themselves ensure the minimum requirements deny patients their rights under EEA law. By maintaining in force the strictly national PRA Schemes that do not fully reflect Article 20(2) of Regulation 883/2004, Norway has consequently failed to fulfil its obligations under EEA law.

58 Norway submits that the incorporation and enforcement of Article 20(2) of Regulation 883/2004 through the Regulation Scheme established under Section 1-3a NIA means that the situation envisaged by ESA cannot arise: namely, that national law denies insured persons their rights under Article 20(2) of Regulation 883/2004 and Article 36 EEA. Norway contends that patients always have the right to apply for inpatient treatment abroad in accordance with Article 20(2) of Regulation 883/2004, but such applications must be directed to the appropriate competent authority under the Regulation Scheme. Institutions responsible for applying the PRA Schemes are not authorised to apply that provision outside their competence under national law.

59 The Commission argues that EEA States may have additional or alternative schemes for inpatient treatment abroad as it is for the EEA States to organise their healthcare system as they see fit. This is, however, subject to the key condition that the system as a whole ensures that EEA law is complied with. Put simply, a patient must be able to benefit from the rights deriving from EEA law regardless of how this result is formally achieved under the national system.

Admissibility

Admissibility in general

60 At the outset, it must be noted that the Court may consider of its own motion whether the conditions laid down in Article 31 SCA for an action for failure to fulfil obligations to be

brought are satisfied (see the judgment of 20 December 2024 in *ESA* v *Norway*, E-13/23, paragraph 60 and case law cited).

61 Article 31 SCA provides that if ESA considers that an EFTA State has failed to fulfil an obligation under the EEA Agreement or the SCA, it shall, unless otherwise provided for in the SCA, deliver a reasoned opinion on the matter after giving the State concerned the opportunity to submit its observations. If the State concerned does not comply with the opinion within the period laid down by ESA, ESA may bring the matter before the Court.

62 Article 108(1) EEA provides that the EFTA States shall establish an independent surveillance authority – the EFTA Surveillance Authority – as well as procedures similar to those existing in the European Union including procedures for ensuring the fulfilment of obligations under the EEA Agreement. It follows from the Court's case law that Article 31 SCA corresponds in substance to Article 258 of the Treaty of the Functioning of the European Union (see the order of 31 January 2011 in *Aleris Ungplan AS* v *ESA*, E-13/10, paragraph 27).

63 It should be recalled that the purpose of the pre-litigation procedure is to give the EFTA State concerned the opportunity to comply with its obligations arising from EEA law or to present its case effectively against the complaints put forward by ESA. The proper conduct of that procedure constitutes an essential guarantee not only in order to protect the rights of the State concerned, but also so as to ensure that any contentious procedure will have a clearly defined dispute as its subject matter (see the judgment in *ESA* v *Norway*, E-13/23, cited above, paragraph 64, and compare the judgment of 17 April 2018 in *Commission* v *Poland*, C-441/17, EU:C:2018:255, paragraph 64).

64 The opportunity for the EFTA State concerned to submit its observations, even if it chooses not to make use of it, is an essential guarantee intended by the SCA, adherence to which is an essential formal requirement of the procedure for finding that an EFTA State has failed to fulfil its obligations (compare the judgment of 8 May 2024 in *Commission* v *Czech Republic*, C-75/22, EU:C:2024:390, paragraph 49 and case law cited).

65 The letter of formal notice issued by ESA to the EFTA State concerned and subsequently the reasoned opinion delivered by ESA delimit the subject matter of the dispute, so that it cannot thereafter be extended. Consequently, the reasoned opinion and the application must be based on the same grounds and pleas (see the judgment in *ESA* v *Norway*, E-13/23, cited above, paragraph 63, and compare the judgment of 24 November 2016 in *Commission* v *Spain*, C-461/14, EU:C:2016:895, paragraph 26, and the judgment in *Commission* v *Poland*, C-441/17, cited above, paragraph 64). If a charge was not included in the reasoned opinion, it is inadmissible at the stage of proceedings before the Court (compare the judgment of 15 January 2002 in *Commission* v *Italy*, C-439/99, EU:C:2002:14, paragraph 11).

66 However, that requirement cannot be carried so far as to mean that in every case the statement of complaints in the letter of formal notice, the operative part of the reasoned opinion and the form of order sought in the application must be exactly the same, provided that the subject matter of the proceedings has not been extended or altered but simply limited (compare the judgment of 5 June 2014 in *Commission* v *Bulgaria*, C-198/12, EU:C:2014:1316, paragraph 16). Nevertheless, the complaints stated in the application cannot as a rule be extended beyond the infringements alleged in the operative part of the reasoned opinion and in the letter of formal notice (compare the judgment of 24 May 2011 in *Commission* v *Portugal*, C-52/08, EU:C:2011:337, paragraph 42).

67 Furthermore, whether an EFTA State has failed to fulfil its obligations must be determined by reference to the situation prevailing in the EFTA State at the end of the period laid down in the reasoned opinion and the Court cannot take account of any subsequent changes. If the Court were to extend its review to legislation of the EFTA State concerned which was not covered by the pre-litigation procedure and was referred to for the first time in the form of order sought in the application, the procedure laid down in Article 31 SCA would be rendered meaningless, which would constitute an abuse of that procedure. The Court's examination will thus relate only to the provisions of the legislation in question which were in force at the time when the period laid down in the reasoned opinion expired and to the extent that they are set out in the application in a sufficiently clear manner to permit review by the Court (see the judgment of 19 June 2015 in *ESA* v *Norway*, E-19/14, paragraph 43, and compare the judgment of 7 June 2007 in *Commission* v *Greece*, C-156/04, EU:C:2007:316, paragraphs 66 and 67).

68 Finally, it must be noted that it follows from Article 101(1)(c) of the Rules of Procedure ("RoP") that an application initiating proceedings must state clearly and precisely the subject matter of the proceedings and set out a summary of the pleas in law relied on, so as to enable the defendant to prepare its defence and the Court to rule on the application. It follows that the essential points of fact and law on which such an action is based must be indicated coherently and intelligibly in the application itself and that the forms of order sought must be set out unambiguously so that the Court does not rule *ultra petita* or fail to rule on a complaint (see the judgment in *ESA* v *Norway*, E-13/23, cited above, paragraph 62, and compare the judgment of 21 December 2023 in *Commission* v *Denmark*, C-167/22, EU:C:2023:1020, paragraph 25).

69 Where an action is brought under Article 31 SCA, the application must set out the complaints coherently and precisely, so that the EFTA State concerned and the Court can know exactly the scope of the alleged infringement of EEA law, a condition that must be satisfied if the EFTA State is to be able to present an effective defence and the Court to determine whether there has been a breach of obligations, as alleged (see the judgment in *ESA* v *Norway*, E-13/23, cited above, paragraph 65 and case law cited).

70 In particular, ESA's application must contain a coherent and detailed statement of the reasons which have led it to conclude that the EFTA State in question has failed to fulfil one of its obligations under the EEA Agreement (see the judgment in *ESA* v *Norway*, E-13/23, cited above, paragraph 65 and case law cited).

71 In the present case, the application relates to two reasoned opinions, the Reasoned Opinion of 20 September 2017 and the Supplementary Reasoned Opinion of 20 October 2022. Those two reasoned opinions lay down two different periods by which the EFTA State concerned was required to take measures necessary to remedy the alleged infringements. Accordingly, the alleged infringements identified in each reasoned opinion can only be examined by reference to the situation prevailing in the EFTA State concerned at the end of the period laid down in each reasoned opinion.

72 It is in the light of these considerations that the admissibility of the present action must be examined. In particular, it must be examined whether the alleged infringements identified in the form of order sought by ESA in its application correspond to the alleged infringements identified in the operative parts of the Reasoned Opinion and the Supplementary Reasoned Opinion.

The scope of the form of order sought

73 It follows from Article 20 of the Statute of the Court that although the Commission is not a party or an intervener in a case before the Court it is entitled to submit statements of case or written observations to the Court. Under this Article, the Commission is not precluded from commenting on the admissibility of an action even though the defendant does not avail itself of this possibility (see the judgment of 21 July 2005 in *Fesil ASA and Others* v *ESA*, Joined Cases E-5/04, E-6/04, and E-7/04, paragraph 51).

74 In response to a question from the bench at the hearing, the Commission submitted that a complaint according to which the Norwegian system for inpatient treatment abroad as a whole does not ensure patients their minimum EEA law right would entail a reduction in the scope of the complaints put forward by ESA in the present application. According to the Commission, examining the system as a whole is a perspective that is part and parcel of the effectiveness of Article 20(2) of Regulation 883/2004. Consequently, according to the Commission, the Court has jurisdiction within the scope of the present action to address whether the Norwegian system as a whole complies with EEA law.

75 The Commission submits that the relevant assessment is not whether *each* national scheme for inpatient treatment abroad authorises and reimburses costs for inpatient treatment in other EEA States when the treatment is among the benefits under national legislation and the same or equally effective treatment cannot be provided in Norway within a medically

justifiable time. Rather, the decisive issue is whether the system for inpatient treatment as a whole ensures that patients are able to benefit from their rights deriving from EEA law.

76 It is settled case law that EEA law does not detract from the EEA States' power to organise their social security systems, including as regards inpatient treatment abroad. Moreover, it is settled case law that Regulation 883/2004 does not set up a common social security scheme but allows different national social security schemes to exist. Its sole objective is to ensure the coordination of those schemes in order to guarantee the effective exercise of the freedom of movement of persons. In the absence of harmonisation at the EEA level, it is for the legislator of each EEA State to determine the conditions for which social security benefits are granted. However, when exercising that power, the EEA State must comply with EEA law (see the judgment of 5 December 2024 in *K*, E-15/23, paragraph 47, and compare the judgment of 11 April 2024 in *Sozialministeriumservice*, C-116/23, EU:C:2024:292, paragraph 68).

77 Article 20(1) of Regulation 883/2004 provides that the insured person shall seek authorisation from the "competent institution". The sole purpose of the second sentence of Article 20(2) is to identify the circumstances in which the competent institution is precluded from refusing the authorisation sought on the basis of Article 20(1) (compare the judgment of 29 October 2020 in *Veselības ministrija*, C-243/19, EU:C:2020:872, paragraph 25 and case law cited). It follows from the definitions in Article 1(p), (q)(iii) and (m) of Regulation 883/2004, read in conjunction with Article 3(1)(a) thereof, that EEA States can designate which body or authority shall be the "competent institution" responsible for applying all or part of its legislation relating to sickness benefits.

78 In its written observations, the Commission pointed out, in essence, that any further routes to inpatient treatment abroad must, in principle, satisfy three conditions to be compatible with EEA law. First, any further routes to inpatient treatment abroad in the national system must be genuine alternatives and/or additions to the minimum EEA right to inpatient treatment abroad. This means that they must not preclude or prohibit patients from exercising their minimum EEA right to inpatient treatment abroad. Second, any further routes to inpatient treatment abroad must comply with EEA law, in particular the prohibition of discrimination based on nationality. Third, the system for inpatient treatment abroad as a whole must ensure that patients receive their minimum EEA right to inpatient treatment abroad.

79 The Court notes that, although certain aspects of the form of order sought by ESA correspond in part to the understanding advanced by the Commission, an assessment of whether the system as a whole effectively ensures patients their minimum EEA right to inpatient treatment abroad would entail a wider complaint than the totality of the form of order sought by ESA in the application and hence would be asking the Court to rule *ultra*

petita in the present action (compare the judgment in *Commission* v *Denmark*, C-167/22, cited above, paragraph 25).

80 That the system as a whole must ensure that patients receive their minimum EEA right to inpatient treatment abroad implies that neither the PRA Schemes nor the Regulation Scheme must render impossible in practice or excessively difficult the exercise of rights conferred by EEA law, in the present case the minimum EEA right to inpatient treatment abroad (see the judgment of 4 July 2023 in *RS*, E-11/22, paragraph 55, and the judgment of 30 June 2021 in *Criminal proceedings against P*, E-15/20, paragraph 56).

81 It is settled case law that the question of whether a national procedural provision makes the application of EEA law impossible or excessively difficult must be analysed by reference to the role of that provision in the procedure, its conduct and its special features, viewed as a whole, before the various national bodies. For those purposes, account must be taken, where appropriate, of the basic principles of the domestic judicial system, such as protection of the rights of defence, the principle of legal certainty and the proper conduct of procedure (see, to that effect, the judgment of 9 August 2024 in *Låssenteret*, E-11/23, paragraph 54).

82 The Court observes that ESA has not addressed the principle of effectiveness in the application in a way that encompasses the above assessment.

83 First, ESA explicitly addresses "effectiveness" in point 4 of the form of order sought in the application. That point is, however, based on the third plea in ESA's application, which is titled "failure to comply with the principle of legal certainty in breach of Article 36 EEA and Article 20(2) of the Regulation, and/or of Article 3 EEA". The grounds put forward under that plea concern two requirements of legal certainty. In paragraphs 126 and 127 of the application, ESA states that legal certainty requires, first, that rules must be sufficiently clear and, second, that EEA States cannot maintain in force national legislation which is incompatible with EEA law, even if the State in practice acts in accordance with EEA law. Although ESA in paragraph 149 uses the formulation "impossible or excessively difficult" this is a description of the national provisions and not the alleged EEA law breach. As ESA explicitly states in paragraph 143 of the application, the alleged breach of EEA law concerns the principle of legal certainty.

84 Second, the Court observes that point 3 of the form of order sought in the application alleges a breach of Article 3 EEA by Norway maintaining in force the two PRA Schemes and an administrative practice of the two PRA Schemes that does not secure the minimum EEA law right to inpatient treatment abroad. A central ground for this plea is that patients who are denied authorisation under the two PRA Schemes are not redirected to the Reimbursement Scheme or the Regulation Scheme. At the outset, this plea and ground

could be understood as targeting a global assessment of whether patients are able to effectively enforce their minimum EEA right to inpatient treatment abroad.

85 However, as pointed out by Norway at the hearing, assessing the two PRA Schemes in isolation is not the same as assessing whether the system as a whole ensures the minimum EEA law right to inpatient treatment abroad. Although the issue of whether patients are redirected from the two PRA Schemes to the Regulation Scheme would be central in a global assessment, other elements regarding how, for instance, the Regulation Scheme works and interacts with the PRA Schemes would also be relevant. Hence, an assessment of whether the system for inpatient treatment abroad as a whole ensures that patients are able to benefit from their rights deriving from EEA law must necessarily encompass more elements than those put forward by ESA in its pleas and grounds supporting the form of order sought in the application.

86 At the hearing, in response to a question from the bench, ESA confirmed that it seeks specific declarations that constitute a finding of specific identified breaches of EEA law. In essence, ESA submits that if its declarations are granted, Norway would have to examine the drafting of the two PRA Schemes and their potential conflict with EEA law, as well as ensuring that the complaint bodies apply EEA law. However, as pointed out by Norway, there may be other ways to rectify a complaint that the system as a whole does not ensure patients their minimum EEA law right to inpatient treatment abroad. Hence, point 4 of the form of order sought by ESA cannot encompass the complaint that the system as a whole is incompatible with EEA law.

87 The Court recalls that when important elements of law are first introduced after the written submissions of the parties to the dispute – in this case, by the Commission – it casts doubt on whether the infringement procedure has enabled the EFTA State concerned to present an effective defence and whether the Court has been provided with the information needed to determine whether there has been a breach of obligations (see the judgment in *ESA* v *Norway*, E-13/23, cited above, paragraph 74).

88 This concern is reinforced by the other purpose of the pre-litigation procedure: to give the EFTA State concerned an opportunity to comply with its obligations under EEA law. For this objective to be achieved, ESA must ensure that the EFTA State is in a position to fully understand the nature of the alleged breach. This requires that ESA conducts a thorough investigation and properly defines the case at the administrative stage of the procedure, rather than deferring essential analysis until the final phase, such as the oral hearing (see the judgment in *ESA* v *Norway*, E-13/23, cited above, paragraph 75).

89 In the light of the foregoing, the Court concludes that an assessment of whether the Norwegian system for inpatient treatment abroad as a whole does not ensure that patients can benefit from their minimum EEA rights does not correspond to the alleged

infringements identified in the form of order sought. It must therefore be held that such a complaint goes beyond the scope of the form of order sought in the application.

The form of order sought by ESA

90 At the outset, it must be observed that the alleged infringements set out in the form of order sought by ESA in its application and the alleged infringements identified in the operative parts of the two reasoned opinions do not clearly correspond. Those infringements are described in different terms and, in many instances, contain references to different provisions of national and/or EEA law.

91 The Court notes that, according to the application, the infringement alleged in the first point of the operative part of the Supplementary Reasoned Opinion is not pursued in the present action but that the other issues raised by the two reasoned opinions remain.

92 However, the Court observes that the first point of the operative part of the Reasoned Opinion concerns how entitlement to inpatient treatment in the Norwegian system is based on a necessity test, established under Section 2-1(b) PRA and Section 2 PR, which does not ensure that what is accepted according to international medical science is taken into account when evaluating the expected benefit of treatment. In paragraph 48 of its application, ESA explicitly states that it "does not take issue with the conditions for the basic entitlement to in-patient treatment in Norwegian law (i.e. the Necessity Test and circumstances in which the First Condition [that the treatment in question must be among the benefits provided for by the legislation in the State where the person concerned resides] will be met)." Accordingly, that alleged infringement is not maintained in the form of order sought by ESA in the present case.

93 Furthermore, although ESA was asked at the hearing to specifically identify which points of the operative parts of the two reasoned opinions corresponded to points 1 and 2 of the form of order sought in the application, ESA was unable to provide a clear answer.

94 Accordingly, the Court must examine whether the alleged infringements set out in the form of order sought by ESA in the present case sufficiently correspond to the alleged infringements identified in the operative parts of the two reasoned opinions in order to verify whether the pre-litigation procedure has been properly conducted or if the alleged infringements have been altered or extended.

Point 1 of the form of order sought by ESA

95 By point 1 of its form of order sought, ESA requests the Court to declare that, by maintaining in force legislation, such as Section 2-1b(4) PRA and Section 6 PR, which unjustifiably restricts or does not include the right to seek inpatient treatment in another EEA State when a medically-justifiable deadline for providing treatment cannot be met,

Norway has failed to fulfil its obligations under Article 20(2) of Regulation 883/2004 and/or Article 36 EEA.

96 Point 1 of the form of order sought concerns, in essence, the compatibility of the Norwegian Breach of Deadline Scheme with EEA law, in particular Article 20 of Regulation 883/2004 and/or Article 36 EEA. Point 1 of the form of order sought is reflected to a certain extent in the third point of the operative part of the Reasoned Opinion.

97 The third point of the operative part of the Reasoned Opinion identifies the alleged infringement as maintaining in force legislation, such as Section 6 PR, which prohibits patients whose justifiable deadlines for medical treatment set under the Prioritisation Regulation and/or under the Patients' Rights Act have expired from turning directly to another EEA medical service provider to receive the medical treatment to which they are entitled upon the expiry of this deadline, thereby failing to ensure that such a patient will obtain the necessary authorisation under Article 20(2) of Regulation 883/2004, and/or that such a patient will obtain reimbursement under Article 36 EEA, as a result of which Norway has failed to fulfil its obligations under Article 20 of Regulation 883/2004 and/or Article 36 EEA and/or Articles 7(6), 7(9)–7(11), 8(1), 8(3)–(5) and 9(1) of Directive 2011/24.

98 A comparison of point 1 of the form of order sought in the application with the third point of the operative part of the Reasoned Opinion reveals two substantive differences.

99 First, while the third point of the operative part of the Reasoned Opinion includes a reference to Section 6 PR, as point 1 of the form of order sought by ESA does also, it omits any reference to Section 2-1b(4) PRA.

100 At the hearing, ESA submitted that Section 2-1b(4) PRA is referred to in recital 96 of the Reasoned Opinion. In this respect, the Court observes that Section 2-1b(4) PRA is referenced a total of six times in the Reasoned Opinion: four times in the section of the Reasoned Opinion describing Norwegian law and twice in passing in different sections of the Reasoned Opinion. It clearly follows from the Reasoned Opinion that Section 2-1b(4) PRA did not form part of the alleged infringements identified in the statement of reasons of the Reasoned Opinion, which are summarised in recitals 37 to 43 thereof.

101 The complaint that Section 2-1b(4) PRA itself, not just Section 6 PR, was incompatible with EEA law was addressed in the Supplementary Reasoned Opinion. In recitals 100 and 101, ESA contends that this provision is in itself contrary to EEA law. However, this view was not included in the operative part of the Supplementary Reasoned Opinion. Although Section 2-1b(4) PRA was mentioned in the first point of the operative part of the Supplementary Reasoned Opinion, that point dealt with a complaint that Norway has failed to give full effect and priority to Article 20 of Regulation 883/2004 over conflicting provisions and has thereby also acted in breach of its obligations under Articles 3 and 7 and Protocol 35 EEA. This, however, is a different complaint, which, according to ESA in

its application, has been resolved due to the manner in which Regulation 883/2004 has been incorporated into Norwegian law from 25 November 2022.

102 Accordingly, the inclusion of Section 2-1b(4) PRA in point 1 of the form of order sought by ESA in its application extends the complaint beyond the scope of the alleged infringements identified in the operative parts of the two reasoned opinions.

103 Second, whereas the infringement is described in specific detail in the third point of the operative part of the Reasoned Opinion, the infringement set out in point 1 of the form of order sought by ESA is described more generally as an infringement with a wider scope. Specifically, the third point of the operative part of the Reasoned Opinion describes the alleged infringement as relating to "prohibiting" patients whose justifiable deadlines for medical treatment under the relevant national legislation have expired "from turning directly to another EEA medical service provider to receive the medical treatment to which they are entitled upon the expiry of [that] deadline". In contrast, point 1 of the form of order sought contends more generally that the national legislation "unjustifiably restricts or does not include the right to seek inpatient treatment in another EEA State when a medically-justifiable deadline for providing treatment cannot be met".

104 The Court observes that the terms "unjustifiably restricting or not including" indicate a different legal assessment than the term "prohibiting". A patient will only be "prohibited" from making use of their minimum EEA law right if the national provisions establishing the Breach of Deadline Scheme oblige a patient to receive inpatient treatment within Norway in situations where the patient is at liberty to seek inpatient treatment in another EEA State at Norway's expense under Article 20(2) of Regulation 883/2004 and Article 36 EEA. If the Breach of Deadline Scheme provides treatment abroad where the Regulation Scheme does not or the patient has a choice under Norwegian law to utilise the Breach of Deadline Scheme or the Regulation Scheme, the patient is not prohibited from utilising their minimum EEA law right by the existence of both schemes but faced with additional and/or alternative schemes. In contrast, that the national legislation "unjustifiably restricts or does not include" the minimum EEA law right to inpatient treatment abroad entails that the additional and/or alternative schemes are themselves not compatible with EEA law. The Court observes that by shifting the assessment from whether there was a prohibition, as set out in the Reasoned Opinion, to an assessment of whether there was a restriction which could be justified, the nature of the allegation was altered.

105 It follows from the above that ESA has altered and extended the scope and nature of the infringement alleged in point 1 of the form of order sought compared to the third point of the operative part of the Reasoned Opinion.

106 Finally, it must be noted that the fact that an application refers to the same legal provisions as was done during the pre-litigation procedure is not capable of calling into question the above finding, since the citation of a provision is not sufficient in itself to define a

complaint raised by ESA (compare the judgment in *Commission* v *Czech Republic*, C-75/22, cited above, paragraph 174). Accordingly, the fact that the application refers to the same provisions of national and EEA law as was done during the pre-litigation procedure is not sufficient to define the complaint alleged by ESA and is thus not capable of remedying the defects identified above.

107 It follows from the above that the alleged infringements identified in point 1 of the form of order sought do not correspond to the alleged infringement identified in the third point of the operative part of the Reasoned Opinion.

108 In those circumstances, ESA's application must be dismissed as inadmissible in so far as it relates to the alleged infringement identified in point 1 of the form of order sought.

Point 2 of the form of order sought by ESA

109 By point 2 of its form of order sought, ESA requests the Court to declare that by maintaining in force legislation, such as Section 2-1b(5) and Section 3(4) PR and Section 2-4a(2)a PRA and Section 3 PR, which failed or fails to correctly 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, Norway has failed to fulfil its obligations under Article 20(2) of Regulation 883/2004 and/or Article 36 EEA.

110 Point 2 in the form of order sought concerns, in essence, the compatibility of the Norwegian No Adequate Treatment Scheme with EEA law, in particular Article 20(2) of Regulation 883/2004 and/or Article 36 EEA. Point 2 of the form of order sought bears the closest resemblance to the second point of the operative part of the Reasoned Opinion.

111 The second point of the operative part of the Reasoned Opinion identifies the alleged infringement as maintaining in force legislation, such as Section 2-1b(5) PRA and Section 3 PR, which does not adequately ensure a case-by-case assessment of whether equally effective treatment can be provided to the individual patient within a medically justifiable deadline nationally, in relation to authorisation or reimbursement applications for medical inpatient treatment in other EEA States, as a result of which Norway has failed to fulfil its obligations under Article 20 of Regulation 883/2004 and/or Article 36 EEA and/or Articles 7(6), 7(9)–7(11), 8(1), 8(3)–(5) and 9(1) of Directive 2011/24.

112 A comparison of point 2 of the form of order sought in the application with the second point of the operative part of the Reasoned Opinion reveals two substantive differences.

113 First, while the second point of the operative part of the Reasoned Opinion includes a reference to Section 2-1b(5) PRA and Section 3 PR, as point 2 of the form of order sought by ESA also does, it does not include a reference to Section 2-4a(2)a PRA. This follows from legislative amendments subsequent to the delivery of the Reasoned Opinion. The

legal basis for the No Adequate Treatment Scheme was moved to the newly created Section 2-4a PRA after the first compliance deadline. Nevertheless, the Court must assess whether the inclusion in the form of order sought of the new legal basis for the No Adequate Treatment Scheme at the time of the second compliance deadline is admissible.

114 At the hearing, ESA submitted that the fact that Section 2-4a(2)a PRA is not referred to in the Reasoned Opinion is not problematic, because it is the new version of Section 2-1b(5) PRA and the basic complaint remains the same. Furthermore, ESA submitted that the new Section 2-4a(2)a PRA was mentioned in the first point of the operative part of the Supplementary Reasoned Opinion, where it was described as a provision conflicting with Article 20 of Regulation 883/2004.

115 In this respect, the Court observes that the first point of the operative part of the Supplementary Reasoned Opinion identified the alleged infringement as Norway having failed to give full effect and priority to Article 20 of Regulation 883/2004 over conflicting provisions of the PRA, such as Section 2-4a(2)a and Section 2-1b(4) PRA, and having thereby also acted in breach of its obligations under Article 3 and 7 and Protocol 35 EEA.

116 In its application, ESA explains that Norway had amended the manner in which Regulation 883/2004 had been incorporated into Norwegian law. ESA thus considered that this issue was sufficiently resolved. Accordingly, it did not pursue that alleged infringement in the application lodged before the Court.

117 It follows that ESA cannot refer to the first point of the operative part of the Supplementary Reasoned Opinion, which relates to a different alleged infringement to that set out in the form of order sought in the present case, in order to support its contention that the alleged infringements set out in the form of order sought correspond to those identified in the operative parts of the Reasoned Opinion and the Supplementary Reasoned Opinion.

118 The Court further observes that the description of the alleged breach in the operative part of the Reasoned Opinion is closely linked to the grounds put forward in that reasoned opinion. In recitals 62 to 64, ESA describes the problematic national legislation in Section 2-1b(5) PRA as adding a condition to be fulfilled before patients can receive treatment abroad, i.e. “the lack of competence” or “the lack of adequate medical services” in Norway. Hence, the assessment is tied to a general assessment of the medical services and competences in Norway and not the particular inpatient treatment sought by the patient. In recital 93, ESA concludes that it is the fact that the legislation, as illustrated by practice, does not adequately ensure a “case-by-case assessment” of whether equally effective treatment can be provided to the individual patient within a medically justifiable deadline nationally that results in it violating EEA law.

119 By contrast, in the Supplementary Reasoned Opinion, ESA no longer considered the lack of an individual assessment an issue. Rather, in recitals 93 and 94, ESA addresses how the change in the Norwegian legislation when the provision was moved to Section 2-4a(2)a

PRA requires the treatment in another EEA State to be "more effective". ESA seems to allege that this is a higher threshold than that permitted under EEA law, which requires the treatment offered in Norway in comparison with the treatment sought in another EEA State to be the "same or equally effective". This new ground for an alleged breach of EEA law is however not reflected in the operative part of the Supplementary Reasoned Opinion.

120 It follows that the inclusion of Section 2-4a(2)a PRA in point 2 of the form of order sought in the application alters the nature of the alleged infringement identified in the second point of the operative part of the Reasoned Opinion and that this altered complaint was not included in the operative part of the Supplementary Reasoned Opinion.

121 The second substantive difference between the application and the Reasoned Opinion is closely linked to the above. The second point of the operative part of the Reasoned Opinion describes the alleged infringement as maintaining legislation which does "not adequately ensure a case-by-case assessment" of whether "equally effective treatment" can be provided to the individual patient within a medically justifiable deadline nationally. In contrast, point 2 of the form of order sought in the application describes the alleged infringement as maintaining in force legislation which "failed or fails correctly to reflect the right 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 Court finds that this formulation in the application has altered and extended the subject matter of the proceedings.

122 It follows from the above that ESA has extended and altered the scope and nature of the infringement alleged in point 2 of the order sought in the application compared to the second point of the operative part of the Reasoned Opinion.

123 In those circumstances, ESA's application must be dismissed as inadmissible in so far as it relates to the alleged infringement identified in point 2 of the form of order sought.

Point 3 of the form of order sought by ESA

124 By point 3 of its form of order sought, ESA requests the Court to declare that 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, 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.

125 Point 3 of the form of order sought concerns, in essence, the appeals and procedural structure under the two PRA Schemes. ESA did not allege that the appeals and procedural

structure infringed EEA law in the Reasoned Opinion but introduced this complaint in the Supplementary Reasoned Opinion.

126 In the second point of the operative part of the Supplementary Reasoned Opinion, the alleged infringement is identified as maintaining in force an appeals and procedural structure under Section 7-2 PRA and Sections 7 and 8 PR, under which the relevant appeals bodies and Helfo: (i) are prevented and/or discouraged from applying a legal test which complies with the requirements of Article 20 of Regulation 883/2004 and/or Article 36 EEA; (ii) and/or fail to apply such requirements in practice; and (iii) which makes it excessively difficult or impossible for the individuals concerned to rely on and/or enforce their rights before such bodies and Helfo, as a result of which Norway has, in breach of Article 3, failed to ensure the effectiveness of Article 20 of Regulation 883/2004 and/or Article 36 EEA, in breach also of those provisions.

127 In this respect, it must first be noted that the second point of the operative part of the Supplementary Reasoned Opinion merely contends that Norway has "in breach of Article 3, failed to ensure the effectiveness of Article 20 of Regulation 883/2004 and/or Article 36 EEA, in breach also of those provisions". Thus, the second point fails to identify the legal basis of what is referred to as "Article 3". Given that the second point refers to both Regulation 883/2004 and the EEA Agreement, it is unclear whether this point of the operative part refers to Article 3 of Regulation 883/2004 or Article 3 EEA. However, the statement of reasons of the Reasoned Opinion makes clear that this part of the operative part should be read as referring to Article 3 EEA, given, inter alia, that Article 3 of Regulation 883/2004 is not cited in the Reasoned Opinion.

128 In the circumstances of the present case this omission has not adversely impacted Norway's rights of defence or entailed the possibility that the Court might rule *ultra petita* or fail to rule on a complaint.

129 A comparison of point 3 of the form of order sought in the application with the second point of the operative part of the Supplementary Reasoned Opinion reveals two substantive differences.

130 First, at the hearing, Norway submitted that ESA's complaint that the practice from the administrative bodies violates Article 20 of Regulation 883/2004 is not reflected in either of the reasoned opinions.

131 In this respect, the Court observes that, whereas point 3 of the form of order sought by ESA in the application specifically describes an independent alleged infringement as "and/or maintaining an administrative practice" in which the rights enumerated in that point "are not secured", the second point of the operative part of the Supplementary Reasoned Opinion does not refer to an independent breach of EEA law by the existence of any administrative practice. The reference in the second bullet point of "and/or fail to apply such a requirement in practice" is a description of how the "maintaining in force an appeals

and procedural structure under Section 7-2 PRA and Sections 7 and 8 PR" breaches EEA law. Therefore, it must be held that point 3 of the form of order sought by ESA in the present case, in so far as it relates to the existence of an administrative practice allegedly in breach of EEA law, has altered and extended the nature and scope of the alleged infringement identified in the second point of the operative part of the Supplementary Reasoned Opinion.

132 Second, the Court observes that the identification and characterisation of the alleged infringement differ substantially between the second point of the operative part of the Supplementary Reasoned Opinion and point 3 of the form of order sought in the application. Whereas the second point of the operative part of the Supplementary Reasoned Opinion alleges that "relevant appeals bodies and Helfo" are prevented and/or discouraged from "applying a legal test which complies with the requirements of Article 20 of Regulation 883/2004 and/or Article 36 EEA", point 2 of the form of order sought alleges that the PRA/PR complaint/appeal bodies are prevented from "applying and securing the rights of patients" to seek treatment in another EEA State. Thus, whereas the discussion in the pre-litigation procedure concerned whether those bodies applied a legal test which complied with the cited provisions, the application before the Court relates more generally to whether they correctly apply and secure the rights of patients. This difference in the identification and characterisation of the alleged infringement is of such a nature that the EFTA State concerned may have had to formulate its defence differently during the pre-litigation procedure and its defence before the Court. Hence, these changes in the application are not simple linguistic adjustments of the second point of the operative part of the Supplementary Reasoned Opinion but changes that extend and alter the subject matter of the proceedings.

133 It follows from the above that the alleged infringement identified in point 3 of the form of order sought does not correspond to the alleged infringement identified in the second point of the operative part of the Supplementary Reasoned Opinion.

134 In those circumstances, ESA's application must be dismissed as inadmissible in so far as it relates to the alleged infringement identified in point 3 of the form of order sought.

Point 4 of the form of order sought by ESA

135 By point 4 of its form of order sought, ESA requests the Court to declare that 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, 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 Article 3 EEA.

136 The alleged infringement put forward by ESA in point 4 of the form of order sought in the application is reflected to a certain degree in both reasoned opinions.

137 The fourth point of the operative part of the Reasoned Opinion identifies the alleged infringement as failing to ensure that the criteria applicable to applications for authorisation or reimbursement of inpatient medical treatment abroad in Norway, such as Section 2-1b(2) PRA and Section 2 PR, Section 3 PR and Section 2-1b(5) PR, as well as Section 6 PR, meet the requirements established in the aforecited case law concerning objectivity, clarity, transparency and precision, as required also by Articles 7(6), 7(9)–7(11), 8(1), 8(3)–(5) and 9(1) of Directive 2011/24, as a result of which Norway has failed to fulfil its obligations under that Directive, and/or under Article 36 EEA and/or Article 20 of Regulation 883/2004.

138 The third point of the operative part of the Supplementary Reasoned Opinion identifies the alleged infringement as maintaining a system for seeking access to inpatient treatment in other EEA States in which it is very difficult for the competent institutions and bodies to apply the correct rules correctly, and which makes it impossible or excessively difficult for patients to identify, understand, and effectively enforce their rights under EEA law, as a result of which Norway has created a state of ambiguity and lack of legal certainty which is not in compliance with Articles 3 and 36 EEA and Article 20 of Regulation 883/2004.

139 A comparison of point 4 of the form of order sought in the application with the relevant operative parts of the Reasoned Opinion and the Supplementary Reasoned Opinion reveals four substantive differences.

140 First, whereas point 4 of the form of order sought refers to a breach of Article 3 EEA, the fourth point of the operative part of the Reasoned Opinion does not refer to Article 3 EEA at all. Accordingly, in so far as ESA can be said to be pursuing the alleged infringement identified in the fourth point of the operative part of the Reasoned Opinion with point 4 of the form of order sought, ESA has altered and extended the scope of the alleged infringement.

141 Second, the Court observes that point 4 of the form of order sought by ESA alleges an infringement of a legal basis not mentioned in the fourth point of the operative part of the Reasoned Opinion or the third point of the operative part of the Supplementary Reasoned Opinion, namely “the principle of legal certainty”. Therefore, it must be held that point 4 of the form of order sought by ESA in the present case, in so far as it relates to an alleged infringement of the principle of legal certainty, has altered and extended the scope of the alleged infringement identified in the operative part of the Reasoned Opinion.

142 Third, whereas point 4 of the form of order sought alleges that “the effectiveness” of the cited legal provisions has been “undermined”, this alleged infringement is not reflected in the Reasoned Opinion or the Supplementary Reasoned Opinion. The fourth point of the Reasoned Opinion alleges that the failure to meet the requirement of “objectivity, clarity, transparency and precision” fails to fulfil the requirements of the cited provisions of EEA law. The third point of the operative part of the Supplementary Reasoned Opinion states

that Norway has "created a state of ambiguity and lack of legal certainty" which is not in compliance with Articles 3 and 36 EEA and Article 20 of Regulation 883/2004.

143 The Court notes that ESA included a reference to "effectiveness" in the second point of the operative part of the Supplementary Reasoned Opinion. However, this point in the Supplementary Reasoned Opinion is particularly targeted at the appeals and procedural structure and how that structure prevented and/or discouraged the relevant appeals bodies and Helfo from applying a legal test complying with EEA law and/or make them fail to apply such requirements in practice. In contrast, point 4 of the form of order sought concerns all the "above" "national rules and practice" and thus the alleged infringement is of a different nature.

144 Hence, point 4 of the form of order sought in the application, in so far as it relates to an alleged infringement of the effectiveness of Article 36 EEA and Article 20(2) of Regulation 883/2004, has altered and extended the nature and scope of the alleged infringements in both reasoned opinions.

145 Fourth, the Court observes that the infringement alleged is characterised very differently in point 4 of the form of order sought in the application in comparison with especially the third point of the operative part of the Supplementary Reasoned Opinion. Whereas point 4 of the form of order sought refers to "the above" "unclear and/or conflicting national rules and practice", the third point of the operative part of the Supplementary Reasoned Opinion refers to the maintenance of "a system" "in which it is very difficult … to apply the correct rules correctly" and which makes it "impossible or excessively difficult for patients to identify, understand, and effectively enforce their rights under EEA law".

146 The ground put forward in recital 114 of the Supplementary Reasoned Opinion focuses on how the multi-track system to inpatient treatment abroad with different appeals bodies makes it excessively difficult for individuals and other actors to understand and enforce the EEA rights to inpatient treatment abroad. In contrast, paragraphs 129 to 142 of the application put forward three grounds for why the rules themselves are not clear enough. ESA thus shifts its perspective from a general assessment of how difficult it is for patients to actually benefit from their EEA law rights in the Supplementary Reasoned Opinion to specific assessments of a technical character in the application.

147 In this regard, the Court recalls its finding above that an assessment of whether the Norwegian system as a whole ensures that patients can benefit from their minimum EEA rights goes beyond the scope of the form of order sought in the application.

148 It follows from the above that the alleged infringement identified in point 4 of the form of order sought does not correspond to the infringement identified in the fourth point of the operative part of the Reasoned Opinion or the third point of the operative part of the Supplementary Reasoned Opinion.

149 In those circumstances, ESA's application must be dismissed as inadmissible in so far as it relates to the alleged infringement identified in point 4 of the form of order sought.

Conclusion

150 In the light of the foregoing, the application in so far as it relates to the four complaints set out in the form of order sought by ESA must be dismissed as inadmissible as those complaints do not satisfy the procedural requirements arising under Article 31 SCA. Consequently, the application in its entirety is dismissed as inadmissible.

VI COSTS

151 Under Article 121(1) RoP, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since Norway has requested that ESA be ordered to pay the costs and ESA has been unsuccessful, ESA must be ordered to bear its own costs and those of Norway. The costs incurred by the Commission are not recoverable.

On those grounds,

THE COURT

hereby:

1. **Dismisses the application.**

2. **Orders the EFTA Surveillance Authority to bear their own costs and those of the Kingdom of Norway.**

Páll Hreinsson Bernd Hammermann Michael Reiertsen

Delivered in open court in Luxembourg on 7 May 2025.

Ólafur Jóhannes Einarsson
Registrar

Páll Hreinsson
President