ESA | EFTA Surveillance Authority

Brussels, 20 October 2022
Case No: 72376
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SUPPLEMENTARY REASONED OPINION

delivered in accordance with Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice concerning Norway's breach of Regulation 883/2004 and Article 36 EEA

1 Introduction

1. The present case concerns the general rules and the system in place in Norway for access to hospital treatment in other EEA States (hereafter referred to as "**in-patient treatment***").*

2. By several letters sent in the period 2009-2013,[1] the EFTA Surveillance Authority ("**the Authority***"*) informed the Norwegian Government that it had received complaints against Norway regarding access to in-patient medical treatment in other EEA States.

3. In light of these complaints, the Authority decided to open a general own-initiative case. On 14 May 2014, having concluded that the criteria in Norwegian law concerning access to in-patient treatment in other EEA States were not in line with the requirements of the EEA Agreement, the Authority issued a letter of formal notice to Norway (Doc No 62126).[2] On 3 February 2016, the Authority issued a supplementary letter of formal notice to Norway (Doc No 772442).[3]

4. Following further correspondence and meetings, on 20 September 2017, the Authority issued a reasoned opinion ("**RDO**") to Norway (Doc No 828764).[4] The RDO required the Norwegian Government to take the necessary measures to comply with the RDO within two months of its receipt.

5. Having examined the Norwegian Government's reply to the RDO of 19 January 2018 (Doc No 894506),[5] the Authority decided on 18 December 2019 to refer the matter to the EFTA Court.[6]

6. In the course of preparing its application to the EFTA Court, the Authority received additional information from a complainant (Case No 74770).[7] Having assessed this information, the Authority on 7 May 2021 sent a request for information to the Norwegian Government (Doc No 1200103). In light of the reply to that request for information on 18 June 2021 (Doc No 1208723, *"***the Reply to the RQI***"*) and having examined further legislative changes which the Norwegian Government introduced after the expiry of the compliance date set out by the RDO,[8] the Authority decided to

[1] See letters of 29 July 2009 (Doc No 525862), 6 November 2012 (Doc No 652021), 13 September 2012 (Doc No 646466), 6 December 2013 (Doc No 692434) and 13 December 2013 (Doc No 693405).
[2] The Norwegian Government replied to this letter by letter dated 15 August 2014 (Doc No 718533).
[3] The Norwegian Government replied to this letter by letter dated 3 May 2016 (Doc No 803414).
[4] For further details on the correspondence and meetings up to this point, see paragraphs 2-14 of the Authority's RDO of 20 September 2017.
[5] And in light of the Authority's letter of 26 February 2018 and the Norwegian Government's response of 11 April 2018, as well as a letter of 15 June 2018 which informed the Authority of further legislative proposals. See Doc Nos 899934, 908910 and 918787 respectively.
[6] Decision No 091/19/COL.
[7] Since 2009 and until today, the Authority has received a number of other letters and e-mails from patients and patient groups in Norway with similar difficulties accessing in-patient treatment in other EEA States. For instance, on 2 March 2020, the Authority received an e-mail expressing hope that it is able to bring the case to the EFTA Court and attaching a petition document with the title "*Ensure patients' rights to treatment in other EEA-states*" (In Norwegian "*Sikre pasienters rettigheter til behandling i andre EØS-land*"), signed by 846 people (Doc No 1117886). On 6 February 2020, the Authority received an email from a group of 293 patients that had covered their own expenses for medical treatment in other EEA States because they were not offered treatment in Norway (Doc No 1115687).
[8] See Parts 3.2.1.2 and 3.2.2.3 below.

issue a second supplementary letter of formal notice on 18 May 2022 (Doc No 1256687).

7. Having examined the Norwegian Government's reply of 8 July 2022 to the second supplementary letter of formal notice (Doc No 1301709) ("**Reply of 8 July 2022**"), the Authority decided to issue the present, supplementary reasoned opinion.

8. The Authority maintains its assessments and conclusions as set out in its second supplementary letter of formal notice as well as those set out in its RDO of 20 September 2017. The present reasoned opinion is supplementary to and must be read with those findings. As its information presently stands, the Authority concludes in this supplementary reasoned opinion that:

   - Norway has failed to give full effect and priority to Article 20 of Regulation 883/2004[9] over conflicting provisions of the Patients' Rights Act (such as Section 2-4a(2)a and Section 2-1(b)(4) of that Act), 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 of the Patients' Rights Act and Sections 7 and 8 of the Prioritisation Regulation, 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 EEA, 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.

2 Relevant EEA law

9. Article 3 EEA provides:

   "*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*

[9] Act referred to at point 1 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* (OJ 2004 L 166, p. 1), as corrected by OJ L 200, 7.6.2004, p. 1 and OJ L 204, 4.8.2007, p. 30, incorporated into the EEA Agreement by Decision of the EEA Joint Committee No 76/2011 of 1 July 2011, with entry into force on 1 June 2012 ("**Regulation 883/2004**" or "**the Regulation**").

objectives of this Agreement. Moreover, they shall facilitate cooperation within the framework of this Agreement."

10. Article 7 EEA provides, in relevant part:

"*Acts referred to or contained in the Annexes to this Agreement or in decisions of the EEA Joint Committee shall be binding upon the Contracting Parties and be, or be made, part of their internal legal order as follows:*

(a) an act corresponding to an EEC regulation shall as such be made part of the internal legal order of the Contracting Parties."

11. Article 36(1) EEA provides, in relevant part:

"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."

12. Article 119 EEA provides:

"*The Annexes and the acts referred to therein as adapted for the purposes of this Agreement as well as the Protocols shall form an integral part of this Agreement*."

13. Protocol 35 EEA provides:

"*Whereas this Agreement aims at achieving a homogeneous European Economic Area, based on common rules, without requiring any Contracting Party to transfer legislative powers to any institution of the European Economic Area; and*
Whereas this consequently will have to be achieved through national procedures;

Sole Article

For cases of possible conflicts between implemented EEA rules and other statutory provisions, the EFTA States undertake to introduce, if necessary, a statutory provision to the effect that EEA rules prevail in these cases."

14. In order to facilitate the free movement of workers and self-employed persons, Regulation No 883/2004 provides for the coordination of social security systems, together with its implementing regulation, (EC) No 987/2009 ("Regulation 987/2009").[10]

15. Article 20 of Regulation 883/2004 provides:

*"***Travel with the purpose of receiving benefits in kind — authorisation to receive appropriate treatment outside the [EEA] State of residence**

[10] Act referred to at points 1 and 2 of Annex VI to the EEA Agreement, *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* (OJ 2009 L 284, p.1), incorporated into EEA Agreement by Decision of the EEA Joint Committee No 76/2011 of 1 July 2011, with entry into force on 1 June 2012.

> *1. Unless otherwise provided for by this Regulation, an insured person travelling to another [EEA] State with the purpose of receiving benefits in kind during the stay shall seek authorisation from the competent institution.*[11]
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> *2. An insured person who is authorised by the competent institution to go to another [EEA] 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 [EEA] 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.*
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> *3. Paragraphs 1 and 2 shall apply mutatis mutandis to the members of the family of an insured person."* (emphasis added)

3 Relevant national law

3.1 Incorporation of Regulation 883/2004, Article 36 EEA and Protocol 35 EEA

16. According to the Norwegian Government in its Reply to the RQI, Norway has "incorporated Regulation No 883/2004 on social security coordination, as such, into Norwegian law, see Regulation 22 June 2012 No 585 on the incorporation of the [sic] social security into the EEA Agreement [(the "**Incorporating Regulation**")]" and "Regulation 883/2004 is incorporated nationally 'as is', and is not further regulated by national legislation."[12]

17. Norway states that the Regulation provides an "independent basis for in-patient treatment abroad", and that, "[i]f the criteria in Article 20 of Regulation (EC) 883/2004 are met, the patient will have a right to receive an authorisation or reimbursement in accordance with the Regulation."[13]

18. Section 1(1) of the Incorporating Regulation provides:

> "*Annex VI No 1 of the EEA Agreement (Regulation (EC) No 883/2004, 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 and Regulation (EU) No 1368/2014) on the coordination of social security schemes and No 2 (Regulation (EC) No 987/2009 as amended by Regulation (EU) No 1244/2010, Regulation (EU) No 465/2012, Regulation (EU) No 1224/2012, Regulation (EU) No 1372 / 2013 and Regulation (EU) No 1368/2014) on rules for the implementation of Regulation (EC) No 883/2004, apply as [domestic] regulations with the adaptations that follow*

[11] "*Competent institution*" is defined by Article 1(q) of the Regulation and is generally the 'home' State institution with which the patient is insured.
[12] See Reply to RQI, pp. 2 and 18, also asserting on p. 2 that "[t]*he obligations with regard to the incorporation of the Regulation (EC) No 883/2004 are therefore complied with*."
[13] *Ibid*, p.2.

from Annex VI, Protocol 1 to the [EEA] Agreement and the [EEA] Agreement in general."[14]

19. Section 1(3) of the Incorporating Regulation provides that the provisions of Regulation 883/2004 and Regulation 987/2009 shall prevail in case of conflict with certain specified national acts, such as the National Insurance Act ("**NIA**").[15]

20. Section 1(3) of the Incorporating Regulation provides:

> "*Provisions in the following Acts are deviated from to the extent necessary in accordance with the provisions mentioned in the first and second paragraphs:*
>
> *Act of 3 December 1948 No 7 on pension benefits for seafarers*
> *Act of 28 July 1949 No 26 on the Public Service Pension Fund*
> *Act of 28 June 1957 No 12 on pension benefits for fishermen*
> *Act of 22 June 1962 No 12 on pension scheme for nurses*
> *Act of 30 May 1975 No 18 on seafarers*
> *Act of 28 February 1997 No 19 on social security* [the National Insurance Act]
> *Act of 26 June 1998 No 41 on cash benefits for parents of young children*
> *Act of 8 March 2002 No 4 on child benefits.*"[16]

21. The list of national acts over which Regulation 883/2004 and Regulation 987/2009 (as incorporated via the Incorporating Regulation) will prevail in case of conflict does not include the key domestic act at issue in this case, the Patients' Rights Act.

22. Section 1 of the Norwegian EEA Act,[17] provides:

> "*The provisions of the main part of the Agreement on the European Economic Area shall apply as Norwegian law, as amended by the Protocol adjusting the Agreement of 17 March 1993, the EEA Enlargement Agreement of 14 October 2003, the EEA Enlargement Agreement for Bulgaria and Romania in 2007 and by the EEA Enlargement Agreement for Croatia of 2014. The same applies to*

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[14] In Norwegian: "*EØS-avtalen vedlegg VI nr. 1 (forordning (EF) nr. 883/2004, som endret ved forordning (EF) nr. 988/2009, forordning (EU) nr. 1244/2010, forordning (EU) nr. 465/2012, forordning (EU) nr. 1224/2012, forordning (EU) nr. 517/2013, forordning (EU) nr. 1372/2013 og forordning (EU) nr. 1368/2014) om koordinering av trygdeordninger og nr. 2 (forordning (EF) nr. 987/2009 som endret ved forordning (EU) nr. 1244/2010, forordning (EU) nr. 465/2012, forordning (EU) nr. 1224/2012, forordning (EU) nr. 1372/2013 og forordning (EU) nr. 1368/2014) om regler for gjennomføring av forordning (EF) nr. 883/2004, gjelder som forskrift med de tilpasninger som følger av vedlegg VI, protokoll 1 til avtalen og avtalen for øvrig*."

[15] Act of 28 February 1997 No 19 on social security. In Norwegian: *Lov 28. februar 1997 nr. 19 om folketrygd.*

[16] In Norwegian: *"Bestemmelsene i følgende lover fravikes i den utstrekning det er nødvendig i henhold til bestemmelsene nevnt i første og andre ledd:*
Lov 3. desember 1948 nr. 7 om pensjonstrygd for sjømenn
Lov 28. juli 1949 nr. 26 om Statens Pensjonskasse
Lov 28. juni 1957 nr. 12 om pensjonstrygd for fiskere
Lov 22. juni 1962 nr. 12 om pensjonsordning for sykepleiere
Lov 30. mai 1975 nr. 18 om sjømenn
Lov 28. februar 1997 nr. 19 om folketrygd
Lov 26. juni 1998 nr. 41 om kontantstøtte til småbarnsforeldre
Lov 8. mars 2002 nr. 4 om barnetrygd."
For the sake of good order, it is noted that the Act of 30 May 1975 No 18 on seafarers has not been in force since 1 January 2014.

[17] In Norwegian: *Lov 27. november 1992 nr. 109 om gjennomføring i norsk rett av hoveddelen i avtale om Det europeiske økonomiske samarbeidsområde (EØS) m.v.*

Articles 1 to 3 of Protocol 25 to the Agreement on competition in coal and steel production."[18] (emphasis added)

23. Section 2 of the Norwegian EEA Act, implementing Protocol 35 EEA,[19] provides:

> "*Provisions in [Norwegian] acts that serve to fulfil Norway's obligations under the [EEA] Agreement shall, in the event of a conflict, take precedence over other provisions that regulate the same matters. The same applies if a regulation that serves to fulfil Norway's obligations under the [EEA] Agreement is in conflict with another regulation, or conflicts with a later act*."[20] (emphasis added)

24. The Norwegian Government on 1 April 2022 issued a proposal to amend some of the rules which incorporate or otherwise relate to Regulation 883/2004 and its implementing Regulation 987/2009 ("**the 2022 Proposal**")[21]. The Authority welcomes any step by the EFTA States towards improved compliance with obligations under EEA law. In particular, the Authority considers that the 2022 Proposal's aim to increase the visibility and awareness of Norway's international legal obligations, in particular Regulation 883/2004 with respect to social security coordination, is commendable.[22]

25. At the same time, the Authority notes that a number of legal issues concerning access to in-patient treatment in other EEA states identified in the RDO, as well as the present supplementary reasoned opinion, remain either unaddressed by the 2022 Proposal or remain unresolved. Although the 2022 Proposal has not yet been adopted, the Authority will, for the sake of good order and continuing fruitful dialogue as well as open communication with the Norwegian Government, reference and address the 2022 Proposal in this supplementary reasoned opinion as appropriate.

3.2 In-patient treatment under Norwegian law

3.2.1 Substantive provisions

26. The Act of 2 July 1999 No 63 on the Rights of Patients ("**the Patients' Rights Act**" or "**PRA**")[23] provides certain rights to in-patient treatment, in Norway and abroad (both in the EEA and third countries).

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[18] In Norwegian: *"Bestemmelsene i hoveddelen i avtale om Det europeiske økonomiske samarbeidsområde skal gjelde som norsk lov, med de endringer som følger av protokoll om justering av avtalen av 17. mars 1993, av EØS-utvidelsesavtalen av 14. oktober 2003, av EØS-utvidelsesavtalen for Bulgaria og Romania i 2007 og av EØS-utvidelsesavtalen for Kroatia av 2014. Det samme gjelder artikkel 1 til 3 i avtalens Protokoll 25 om konkurranse innen kull- og stålproduksjon."*

[19] See the preparatory works Ot.prp. No 79 (1991-1992) p. 5.

[20] In Norwegian: *"Bestemmelser i lov som tjener til å oppfylle Norges forpliktelser etter avtalen, skal i tilfelle konflikt gå foran andre bestemmelser som regulerer samme forhold. Tilsvarende gjelder dersom en forskrift som tjener til å oppfylle Norges forpliktelser etter avtalen, er i konflikt med en annen forskrift, eller kommer i konflikt med en senere lov."*

[21] Prop. 71 L (2021–2022) Endringer i folketrygdloven mv. (*synliggjøring av folkerettslige forpliktelser til trygdekoordinering*). "Amendments to the National Insurance Act etc. (making international legal requirements for national insurance coordination visible)".

[22] *Ibid*, p.6

[23] In Norwegian: *Lov 2. juli 1999 nr. 63 om pasient- og brukerrettigheter.*

3.2.1.1 Substantive provisions at the RDO deadline (20 January 2018)

27. At the RDO deadline, as described in the RDO, certain rights to in-patient treatment abroad (including in the EEA) were provided by Section 2-1b(4) and (5) PRA,[24] which read:

> *"[4] If the regional health undertaking has not ensured that a patient who is entitled to necessary healthcare from the specialist health service receives such care within the time limit fixed pursuant to the second paragraph,[25] the patient has the right to receive necessary healthcare without delay, if necessary from a private service provider or a service provider outside the realm.*
>
> *[5] If the regional health undertaking cannot provide healthcare for a patient who is entitled to necessary healthcare, because there are no adequate medical services in the realm, the patient has the right to receive necessary healthcare from a service provider outside the realm within the time limit fixed pursuant to the second paragraph."*[26]

28. As described in the RDO, Sections 3 and 6 of the Regulation of 1 December 2000 No 1208 on Prioritisation of Health Services and the Right to Treatment Abroad ("**the Prioritisation Regulation**", or "**PR**")[27] supplemented Sections 2-1b(5) and 2-1b(4) PRA, respectively.

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[24] See RDO p. 5 et seq. The Norwegian Government considers that these PRA rules provide 'additional' rights and are not directed at the EEA in particular, see reply to the supplementary letter of formal notice (Doc No 803414), pp. 2, 4 *et seq* and Reply of 8 July 2022 (Doc No 1301709), pp.3, 4 and 5. While this may be the case, the Authority recalls that such rules must still be compatible with the EEA Agreement. Section 2-1b(4) and (5) PRA was for example the subject of consideration in Judgment of 19 December 2008, Joined Cases E-11/07 and E-1/08 *Rindal and Slinning* v *Norway ("**Rindal and Slinning**")*, [2008] EFTA Ct. Rep, p.320, see paragraph 43. Its replacement provision, Section 2-4a PRA, clearly concerns healthcare within the EEA, see e.g. Prop. 80 L (2018-2019) p. 14.

[25] i.e. within a deadline which is set under Section 2-1b(2) PRA in accordance with what professional responsibility would require (a medically appropriate or justifiable time-limit).

[26] In Norwegian:
"[4] Dersom det regionale helseforetaket ikke har sørget for at en pasient med rett til nødvendig helsehjelp fra spesialisthelsetjenesten får den nødvendige helsehjelpen innen tidspunkt fastsatt i medhold av annet ledd, har pasienten rett til nødvendig helsehjelp uten opphold, om nødvendig fra privat tjenesteyter eller tjenesteyter utenfor riket.
[5] Dersom det regionale helseforetaket ikke kan yte helsehjelp til en pasient som har rett til nødvendig helsehjelp fordi det ikke finnes et adekvat tilbud i riket, har pasienten rett til nødvendig helsehjelp fra tjenesteyter utenfor riket innen den frist som er fastsatt etter annet ledd."

[27] In Norwegian: *Forskrift 1. desember 2000 nr. 1208 om prioritering av helsetjenester, rett til nødvendig helsehjelp fra spesialisthelsetjenesten, rett til behandling i utlandet og om klagenemnd.*
At the RDO deadline, the relevant parts of Section 3 PR read:
"§ 3. Health care abroad due to lack of competence in Norway
[1] A patient who is entitled to necessary health care, but who cannot receive health care because treatment cannot be carried out properly in Norway according to an accepted method, is entitled to health care abroad, cf. the Patients' Rights Act § 2-1b fifth paragraph. It is a prerequisite that the health care can be performed properly by the service provider abroad according to accepted method and that the patient's condition and the treatment in question satisfy the requirements in § 2 [PR]. The assessment of the patient's benefit from the treatment must be individual and based on international medical science.
[…]
[4] Lack of capacity in the specialist health service does not give the right to treatment abroad according to this provision. The right to treatment does not include the sending of laboratory samples for analysis by a foreign service provider without as part of treatment abroad."
At the RDO deadline, Section 6 PR read:
"§ 6. Deadline breach
[1] The regional health authority in the patient's region of residence shall ensure that patients who are entitled to necessary health care pursuant to § 2 [PR], or are entitled to health care abroad

3.2.1.2 Substantive provisions currently in force

29. On 1 March 2020, a new Section 2-4a PRA ("Section 2-4a") entered into force.[28] According to the Norwegian Government, it provides an overview of the various schemes for covering expenses for health care abroad.[29] Section 2-4a(2)a repeals and replaces Section 2-1b(5) PRA on the adequacy/availability of national healthcare. The provision reads:

> *"§ 2-4 a. Health care abroad*
>
> ***Patient has the right to have expenses for health care received in another EEA State, fully or partially covered***

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pursuant to § 3 [PR], are offered health care from the specialist health service within the deadline stipulated pursuant to § 4 [PR] or § 4a [PR].
[2] If the specialist health service cannot give the patient a time to start the assessment or treatment before the deadline for necessary health care 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 § 2-1b fourth paragraph. If the deadline is exceeded, the patient can also contact HELFO.
[3] HELFO shall without delay obtain the patient an offer 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.
[4] Irrespective of whether there is a deadline breach, the patient can apply for reimbursement of expenses for health services received in another EEA State in accordance with Regulation on reimbursement of health care received in another EEA State. The patient may also be entitled to reimbursement of expenses for health services in other EEA countries in accordance with the conditions in Council Regulation (EC) No 883/2004. An application for reimbursement in accordance with Regulation on reimbursement of health care received in another EEA State or prior approval pursuant to Council Regulation (EC) No 883/2004 is processed by HELFO."

[28] The provision is explained in part in the following manner in the preparatory works, Prop. 80 L (2018-19) p.16: "*The background for the proposed amendment is ESA's reasoned opinion of 20 September 2017. In ESA's assessment, the Norwegian regulations do not ensure that an individual assessment is made of whether there is treatment in Norway that is as effective as the patient can receive in other EEA States. ESA points out that the regulations only provide an assessment of whether there is a lack of competence or whether there is an adequate treatment offer in Norway. Instead, in ESA's assessment, an assessment should be made of whether the patient can be offered as effective treatment in Norway as abroad. In the Ministry's assessment, the current regulations meet the EEA law requirements for patients to be reimbursed for their treatment costs in other EEA countries. The Patients' Rights Directive has been implemented in the Regulation on reimbursement of health care received in another EEA State* [the Reimbursement Regulation]. *The Regulation gives patients, for whatever reason, the right to be reimbursed for treatment costs for health care in another EEA State that corresponds to health care that the patient would have been reimbursed in Norway. In order to further clarify the legal situation, the Ministry nevertheless proposes a clarification in the regulations. It is clarified that the right that currently appears in § 2-1b fifth paragraph also applies to health care abroad that is documented to be more effective than the health care offered by the public sector in Norway. At the same time, the condition is maintained that the patient must fulfil the conditions for the right to necessary health care according to the Patients' Rights Act § 2-1b.*" (translation by the Authority).

[29] See Reply to the RQI p. 12, where Section 2-4a PRA is described in the following manner: *"The Ministry is of the opinion that the new provision Section 2-4 a gives patients a better overview over the different legal grounds for publicly paid healthcare abroad and also gives more transparency to the conditions for receiving publicly paid health care in those cases where the necessary health care is not available in Norway or the health care abroad is documented to be more effective than the health care offered by the public health services in Norway, cf. Section 2-4 a(2) subparagraph a. This will be helpful both for the patient and for the administrators of these regulations. The new provision is mainly given for informational purposes."*

a) pursuant to the National Insurance Act § 5-24 a with regulations that implement the Patients' Rights Directive in Norwegian law. This applies when the health care in question corresponds to health care that the patient would had 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, gives the right to be reimbursed for necessary health care during temporary stays and for planned health care in other EEA States if the health care is not provided within a reasonable time in Norway.

Patient has the right to have expenses for health care received abroad fully or partially covered

a) if the patient is entitled to necessary health care from the specialist health service according to § 2-1 b and there is no offer in the country or the health care abroad is documented to be more effective than the health care offered by the public sector in Norway.
b) pursuant to the National Insurance Act § 5-24 and provisions issued pursuant to it, which, among other things, gives the right to receive benefits for health services for members of the National Insurance who stay abroad over time.
Expenditure on health care that has been decided not to be introduced in Norway is not covered, cf. the Specialist Health Services Act § 4-4. However, this does not apply to health care during temporary stays pursuant to the first paragraph, letter b.

The Ministry may issue regulations with further provisions on the types of health care that are covered by the expenditure coverage, conditions for having the expenses covered and the calculation of the expenditure coverage."[30]

30. The first paragraph of Section 2-4a covers provisions which only apply to healthcare received in the EEA, whereas the second paragraph contains provisions which apply to healthcare in general: both within and outside the EEA.[31]

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[30] In Norwegian: *"§ 2-4 a. Helsehjelp i utlandet.*
Pasient har rett til å få utgifter til helsehjelp som mottas i et annet EØS-land, helt eller delvis dekket
a) etter folketrygdloven § 5-24 a med forskrifter som gjennomfører pasientrettighetsdirektivet i norsk rett. Dette gjelder når den aktuelle helsehjelpen tilsvarer helsehjelp som pasienten hadde fått tilbud om i den offentlige helse- og omsorgstjenesten i Norge.
b) etter rådsforordning (EF) nr. 883/2004 og 987/2009, som blant annet gir rett til å få dekket utgifter til nødvendig helsehjelp under midlertidig opphold og til planlagt helsehjelp i andre EØS-land dersom helsehjelpen ikke ytes innen forsvarlig tid i Norge.
Pasient har rett til å få utgifter til helsehjelp som mottas i utlandet helt eller delvis dekket
a) dersom pasienten har rett til nødvendig helsehjelp fra spesialisthelsetjenesten etter § 2-1 b og det ikke finnes et tilbud i riket eller helsehjelpen i utlandet er dokumentert mer virkningsfull enn den helsehjelpen som tilbys av det offentlige i Norge.
b) etter folketrygdloven § 5-24 og bestemmelser gitt i medhold av den, som blant annet gir rett til å få stønad til helsetjenester for medlemmer av folketrygden som oppholder seg i utlandet over tid.
Utgifter til helsehjelp som er besluttet ikke innført i Norge, dekkes ikke, jf. spesialisthelsetjenesteloven § 4-4. Dette gjelder likevel ikke helsehjelp under midlertidig opphold etter første ledd bokstav b.
Departementet kan gi forskrifter med nærmere bestemmelser om hvilke typer helsehjelp som omfattes av utgiftsdekningen, vilkår for å få dekket utgiftene og beregningen av utgiftsdekningen."

[31] See the preparatory works, Prop. 80 L (2018-2019) p. 14-15:
"*Health care abroad in general*
The second paragraph of the draft covers the expenditure coverage schemes that apply to health care abroad in general, also in countries outside the EEA area. […] *Furthermore, the second paragraph will regulate the right to treatment abroad in the event of a lack of services in Norway or when health care abroad has been documented to be more effective*."

31. According to the preparatory works, "[t]he first paragraph of the draft new Section 2-4a in the Patients' Rights Act discusses the schemes that only apply to health care received in another EEA State. The provision continues the current legal situation and does not involve any change beyond giving patients a better overview."[32] The first paragraph of Section 2-4a does not therefore itself purport to implement Regulation 883/2004 (or the Patients' Rights Directive) in the Norwegian legal order.[33]

32. Section 3 PR further reflects the rights in Section 2-4a(2)a PRA. It provides:

> *"A patient who is entitled to necessary health care, but who cannot receive health care because there is no service in the realm or health care abroad is documented to be more effective than the health care offered by the public sector in Norway, is entitled to health care abroad, cf. the Patients' Rights Act § 2-4a second paragraph a. It is a prerequisite that the health care can be performed properly by the service provider abroad according to accepted method and that the patient's condition and the relevant treatment satisfy the requirements in § 2. The assessment of the patient's benefit shall be individual and based on international medical science."*[34]

33. Sections 4 and 6 PR concern the time-limit for treatment in Norway, and relate *inter alia* to Section 2-1b(4) PRA, which remains in force. In particular, Sections 4 and 6 PR set out rules for patient rights when medical treatment cannot be given within a medically justifiable timeline. Following amendment on 1 March 2020, Section 2-1b(4) PRA and Section 6(3) PR themselves no longer confer rights to (or potentially involving) in-patient treatment <u>in another EEA State</u> when a medically justifiable timeline is or will be breached.[35]

34. Section 4 PR, which is entitled "Assessment of and determination of a deadline for necessary health care", reads:

> *"Anyone who is obliged to make an assessment of a patient according to the Patients' Rights Act § 2-2, shall assess whether patients who are referred fulfil the conditions in Section 2 and possibly in § 3 [PR]. If a patient is entitled to necessary health care, a deadline shall be set for when professional soundness*

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[32] Prop. 80 L (2018-2019) p. 14. In Norwegian: *"I første ledd i utkast til ny § 2-4 a i pasient- og brukerrettighetsloven omtales ordningene som kun gjelder for helsehjelp som mottas i et annet EØS-land. Bestemmelsen viderefører gjeldende rett og innebærer ingen endring utover å gi pasienter en bedre oversikt."*

[33] Norway agrees with this: p.6 of its Reply of 8 July 2022 states "*The Ministry also agrees that Section 2-4a(1)(b) PRA does not incorporate Regulation 883/2004 and Regulation 987/2009. The reference to Regulation 883/2004 and Regulation 987/2009 is of informational purposes only*."

[34] In Norwegian:
"En pasient som har rett til nødvendig helsehjelp, men som ikke kan få helsehjelp fordi det ikke finnes et tilbud i riket eller helsehjelpen i utlandet er dokumentert mer virkningsfull enn den helsehjelpen som tilbys av det offentlige i Norge, har rett til helsehjelp i utlandet, jf. pasient- og brukerrettighetsloven § 2-4a annet ledd bokstav a. Det er en forutsetning at helsehjelpen kan utføres forsvarlig av tjenesteyter i utlandet etter akseptert metode og at pasientens tilstand og den aktuelle behandlingen tilfredsstiller kravene i § 2. Vurderingen av pasientens nytte av behandlingen skal være individuell og ta utgangspunkt i internasjonal medisinsk vitenskap."

[35] Section 2-1b(4) was amended by removing the words in strikethrough:
"*If the regional health undertaking has not ensured that a patient who is entitled to necessary healthcare from the specialist health service receives such care within the time limit fixed pursuant to the second paragraph, the patient has the right to receive necessary healthcare without delay, if necessary from a private service provider ~~or a service provider outside the realm~~."* In Norwegian: *"Dersom det regionale helseforetaket ikke har sørget for at en pasient med rett til nødvendig helsehjelp fra spesialisthelsetjenesten får den nødvendige helsehjelpen innen tidspunkt fastsatt i medhold av annet ledd, har pasienten rett til nødvendig helsehjelp uten opphold, om nødvendig fra privat tjenesteyter ~~eller tjenesteyter utenfor riket~~."*
Section 6 PR was amended as described in footnote 37 below.

requires that the specialist health service must at the latest provide healthcare to the patient in question in order to fulfil the patients' rights. When setting the deadline, prioritization shall be made in accordance with § 2 a [PR]."[36]

35. Section 6 PR is entitled "Deadline breach". It provides:

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

[2] If the specialist health service cannot give the patient a time to start the assessment or treatment before the deadline for necessary health care 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 § 2-1b fourth paragraph. If the deadline is exceeded, the patient can also contact HELFO.

[3] 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 kingdom. The patient is not free to choose a service provider. [37]

[4] 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 regulations on benefits for health services received in another EEA State. 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 Regulation on reimbursement of health care received in another EEA State or prior approval pursuant to Council Regulation (EC) No 883/2004 is processed by HELFO."[38]

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[36] In Norwegian:
"Den som er forpliktet til til å foreta en vurdering av en pasient etter pasient- og brukerrettighetsloven § 2-2, skal vurdere om pasienter som henvises oppfyller vilkårene i § 2 og eventuelt i § 3. Dersom en pasient har rett til nødvendig helsehjelp, skal det fastsettes en frist, for når faglig forsvarlighet krever at spesialisthelsetjenesten senest må yte helsehjelp til vedkommende pasient for å oppfylle pasientens rettighet. Ved fristfastsettelsen skal prioritering gjøres etter § 2 a."

[37] On 1 March 2020, Section 6(3) PR was amended by removing the words in strikethrough:
"*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 kingdom ~~or, if necessary, abroad~~. The patient is not free to choose a service provider."* In Norwegian: "*HELFO skal uten opphold skaffe pasienten et tilbud fra offentlig tjenesteyter eller om nødvendig fra privat tjenesteyter i riket ~~eller om nødvendig i utlandet~~*".

[38] In Norwegian:
"[1] Det regionale helseforetaket i pasientens bostedsregion skal sørge for at pasienter som har rett til nødvendig helsehjelp etter § 2, eller har rett til helsehjelp i utlandet etter § 3, får tilbud om helsehjelp fra spesialisthelsetjenesten innen den fristen som er fastsatt i medhold av § 4 eller § 4a.
[2] Dersom spesialisthelsetjenesten ikke kan gi pasienten et tidspunkt for oppstart av utredning eller behandling før fristen for nødvendig helsehjelp senest skal gis, eller tidspunktet senere må endres slik at fristen ikke kan overholdes, eller dersom fristen er oversittet, skal spesialisthelsetjenesten umiddelbart kontakte HELFO, jf. pasient- og brukerrettighetsloven § 2-1b fjerde ledd. Dersom fristen er oversittet kan også pasienten kontakte HELFO.
[3] HELFO skal uten opphold skaffe pasienten et tilbud fra offentlig tjenesteyter eller om nødvendig fra privat tjenesteyter i riket. Pasienten kan ikke fritt velge tjenesteyter.
[4] Uavhengig av om det foreligger fristbrudd kan pasienten søke om å få refundert utgifter til helsetjenester mottatt i et annet EØS-land i samsvar med forskrift om stønad til helsetjenester mottatt i et annet EØS-land. Pasienten kan også ha rett til å få dekket utgifter til helsetjenester i

3.2.2 Procedural provisions: Appeals system

3.2.2.1 Introduction

36. A number of national complaints bodies handle appeals from denied applications for authorisation of in-patient treatment abroad, or for reimbursement of such costs. The procedural provisions governing the appeals procedures are split between several instruments of national legislation. These include the PRA and the PR.

37. The introduction of Section 2-4a PRA, as described in Part 3.2.1.2 above, led to consequential technical amendments to the provisions governing the appeals system in the PRA and the PR. These technical amendments were not, to the Authority's understanding, intended to change the actual allocation of jurisdiction or competence between the various complaints bodies.[39]

3.2.2.2 The provisions governing the appeals system in the PRA and the PR at the RDO deadline (20 January 2018)

38. At the RDO deadline,[40] Section 7-2 PRA set out a split of competence for handling complaints regarding rights under the PRA and PR to in-patient treatment abroad. Competence was divided between the County Governor and the Appellate Body for Treatment Abroad ("Klagenemnda for behandling i utlandet") ("**the Appellate Body**").

39. Section 7-2(1) PRA set out the general rule that complaints concerning breaches of Section 2-1b, which formed part of chapter 2 PRA, would go to the County Governor:

> *"A patient or user or their representative who believes that the provisions in chapters 2, 3 and 4, as well as § 5-1, § 6-2 and § 6-3 have been breached, can complain to the County Governor* [In Norwegian: *Fylkesmann*]*. The complaint is sent to the body that made the decision."*[41]

40. Section 7-2(2) PRA provided an exception to this rule. It read:

> "*A patient or a representative for the patient who considers that the provision in Section 2-1b(5) has not been complied with* [i.e. no adequate treatment was available in Norway], *may complain to an appellate body* [(the Appellate Body)] *which is established by the Ministry. The appellate body shall have five members. The Chair shall be a lawyer. The Ministry appoints members and their personal substitutes for two years at the time. It is possible to reappoint members and substitutes*."[42]

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andre EØS-land etter vilkårene i rådsforordning (EF) nr. 883/2004. Søknad om refusjon etter forskrift om stønad mottatt i et annet EØS-land eller forhåndsgodkjenning etter rådsforordning (EF) nr. 883/2004 behandles av HELFO."

[39] See Prop. 80 L (2018-19) p. 14, as referred to in footnote 32 above.

[40] The deadline for compliance with the RDO was 20 January 2018.

[41] In Norwegian: *"Pasient eller bruker eller dennes representant som mener at bestemmelsene i kapitlene 2, 3 og 4, samt § 5-1, § 6-2 og § 6-3 er brutt, kan klage til Fylkesmannen. Klagen sendes til den som har truffet enkeltvedtaket eller avgjørelsen."* On 1 January 2021, the title *Fylkesmann* was changed to *Statsforvalter*.

[42] In Norwegian: "*Pasient eller representant for pasienten som mener at bestemmelsen i § 2-1 b femte ledd ikke er overholdt, kan klage til en klagenemnd som oppnevnes av departementet. Klagenemnda skal ha fem medlemmer. Lederen skal være jurist. Departementet oppnevner medlemmer og deres personlige varamedlemmer for to år om gangen. Det er adgang til å gjenoppnevne medlemmer og varamedlemmer."*

41. Thus, complaints regarding a breach of the medically-appropriate time-limit pursuant to Section 2-1b(4) PRA would go to the County Governor under the general rule, whereas complaints regarding a lack of adequate services in Norway according to Section 2-1b(5) PRA would go to the Appellate Body.

42. The procedural provisions in the PRA were mirrored in the PR. The split competence for handling or reviewing complaints was therefore equally reflected in Section 7 PR, which provided:

> "*A patient who disagrees with the assessment made pursuant to § 2, 2a, 3, 4, or 4a* [PR] *or who considers that no such assessment has been made, may complain to the County Governor, cf. the Patients' Rights Act § 7-2. If the assessment the specialist health service makes concerns whether the patient has a right to treatment abroad, see § 3* [i.e. § 3 PR, which provides for healthcare abroad where competence is lacking in Norway]*, he may complain to the appellate body which is mentioned in § 9* [PR] [i.e. the Appellate Body for Treatment Abroad]."

43. Under Section 8 PR, which mirrored Section 7-2(2) PRA, the Appellate Body only decided on complaints concerning Section 3 PR. Section 8(1) PR provided:[43]

> *"The Appellate Body decides on complaints against decisions pursuant to § 3, cf. the Patients' Rights Act § 7-2 second paragraph."*[44]

44. Sections 8 and 3 PR thus confirmed that the Appellate Body only had competence to decide on complaints concerning Section 2-1b(5) PRA (thus on the lack of adequate treatment in Norway), and not on cases concerning the time-limit in Section 2-1b(4) PRA, over which the County Governor had jurisdiction.

3.2.2.3 The current provisions governing the appeals system in the PRA and the PR

45. At the time of this supplementary reasoned opinion, Section 7-2(1) and (2) PRA still splits the competence for handling complaints in relation to the PRA and PR between the County Governor and the Appellate Body.

46. Section 7-2(1) PRA sets out the general rule, that complaints concerning breaches of the provisions of Section 2-4a PRA regarding healthcare abroad, which forms part of Chapter 2 PRA, go to the County Governor:

> *"(1) A patient or user or their representative who believes that the provisions in Chapters 2, 3 and 4, as well as § 5-1, § 6-2 and § 6-3 have been breached, can complain to the County Governor. The complaint is sent to the body which made the individual decision or decision."*[45]

47. Section 7-2(2) PRA still provides an exception to this rule. It reads:

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[43] In Norwegian: "*En pasient som er uenig i den vurdering som er foretatt etter § 2, § 2a, § 3, § 4 eller § 4a, eller som mener at det ikke er foretatt slike vurderinger, kan klage til Fylkesmannen, jf. pasient- og brukerrettighetsloven § 7-2. Dersom den vurderingen spesialisthelsetjenesten foretar gjelder om pasienten har rett til behandling i utlandet, jf. § 3, kan han klage til den klagenemnda som er omtalt i § 9*."

[44] In Norwegian: *"Klagenemnda avgjør klage over vedtak etter § 3, jf. pasient- og brukerrettighetsloven § 7-2 annet ledd."*

[45] In Norwegian: *"Pasient eller bruker eller dennes representant som mener at bestemmelsene i kapitlene 2, 3 og 4, samt § 5-1, § 6-2 og § 6-3 er brutt, kan klage til statsforvalteren. Klagen sendes til den som har truffet enkeltvedtaket eller avgjørelsen."*

> *"(2) A patient or a representative of the patient who believes that the provision in § 2-4a second paragraph, subparagraph a, has not been complied with* [i.e no treatment in Norway or treatment abroad is more effective]*, may complain to an appellate body appointed by the Ministry* [i.e. the Appellate Body]*. […]."*[46]

48. Complaints not covered by the exception in Section 7-2(2) PRA are consequently covered by the main rule in Section 7-2(1). Thus:

    - according to the main rule in Section 7-2(1) PRA, complaints concerning breaches of Section 2-4a(1) a and b PRA (including complaints concerning certain parts of Regulations 883/2004 and 987/2009), and complaints concerning breaches of Section 2-4a(1)b PRA, must be made to the County Governor;[47]

    - in accordance with the exception in Section 7-2(2) PRA, complaints concerning breaches of Section 2-4a(2)a PRA,[48] regarding a lack of treatment (or of effective treatment) in Norway must be made to the Appellate Body.

49. The split competence to handle or review complaints is still reflected in Section 7 PR, which again provides the main rule in the first sentence, and the exception in the second sentence:

> *"A patient who disagrees with the assessment made pursuant to § 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 § 7-2. If the assessment made by the specialist health service relates to whether the patient has the right to treatment abroad, cf. § 3* [PR]*, he may appeal to the Appellate Body referred to in § 9."*[49]

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[46] In Norwegian: *"Pasient eller representant for pasienten som mener at bestemmelsen i § 2-4 a annet ledd bokstav a ikke er overholdt, kan klage til en klagenemnd som oppnevnes av departementet."* Whilst Section 2-4a was introduced on 1 March 2020, amendments to reflect this in Section 7-2(2) PRA were only introduced on 1 January 2021, as the Government originally omitted to propose the necessary amendments to Section 7-2(2), see Prop. 59 L (2019-2020) p. 27. During that period therefore, Section 7-2(2) PRA continued to refer to Section 2-1b(5) PRA, albeit that provision was no longer in force.

[47] The relevant parts of Section 2-4a PRA (set out in full in Part 3.2.1.2 above) read:

*"**Patient has the right to have expenses for health care received in another EEA State, fully or partially covered***

[1] a) pursuant to the National Insurance Act § 5-24 a with regulations that implement the Patient Rights Directive in Norwegian law. This applies when the health care in question corresponds to health care 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, gives the right to be reimbursed for necessary health care during temporary stays and for planned health care in other EEA countries **if the health care is not provided within a reasonable time in Norway**.*

[2] Patient has the right to have expenses for health care received abroad fully or partially covered

[…]

b) pursuant to the National Insurance Act § 5-24 and provisions issued pursuant to it, which, among other things, gives the right to receive benefits for health services for members of the National Insurance who stay abroad over time." (emphasis added)

[48] Section 2-4a(2)a, provides:

"a) if the patient is entitled to necessary health care from the specialist health service according to § 2-1 b and there is no offer in the country or the health care abroad is documented to be more effective than the health care offered by the public sector in Norway."

[49] In Norwegian: *"En pasient som er uenig i den vurdering som er foretatt etter § 2, § 2a, § 3, § 4 eller § 4a, eller som mener at det ikke er foretatt slike vurderinger, kan klage til statsforvalteren, jf. pasient- og brukerrettighetsloven § 7-2. Dersom den vurderingen spesialisthelsetjenesten foretar*

50. The Appellate Body's competence is again set out in Section 8(1) PR, which mirrors Section 7-2(2) PRA and reads:

> *"The Appellate Body decides on appeals against decisions pursuant to § 3* [PR]*, cf. the Patients' Rights Act § 7-2 second paragraph."*[50]

51. Section 3(1) PR provides:

> *"A patient who is entitled to necessary health care, but who cannot receive health care because there is no service in the realm or health care abroad is documented to be more effective than the health care offered by the public sector in Norway, is entitled to health care abroad, cf. the Patients' Rights Act § 2-4a second paragraph a. It is a prerequisite that the health care can be performed properly by the service provider abroad according to accepted method and that the patient's condition and the relevant treatment satisfy the requirements in § 2. The assessment of the patient's benefit shall be individual and based on international medical science."*[51]

52. Thus, Sections 8 and 3 PR confirm that the Appellate Body continues to have competence only to decide on complaints related to the availability or effectiveness of treatment in Norway (thus under Section 2-4(a)(2)a PRA). Section 7 PR confirms that the County Governor continues to have competence over complaints related to the other provisions of Section 2-4a PRA and, *inter alia*, to breach of the time-limit provided in Section 2-1b(4) PRA. In particular, as the provisions of Section 2-4a(1) PRA (which refer to rights under Regulations 883/2004 and 987/2009 and the Patients' Rights Directive) are not covered by the exception in Section 7-2(2) PRA, such complaints should, according to Section 7-2(1) PRA, go to the County Governor. As further described in Part 4.3.2 below, this appears however not to be the case in practice.[52]

3.2.2.4 Cases decided by The Norwegian Health Economics Administration

53. In addition to the above, according to the Norwegian Government, The Norwegian Health Economics Administration (Helfo) deals with applications for authorisation or reimbursement:

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gjelder om pasienten har rett til behandling i utlandet, jf. § 3, kan han klage til den klagenemnda som er omtalt i § 9."

[50] In Norwegian: *"Klagenemnda avgjør klage over vedtak etter § 3, jf. pasient- og brukerrettighetsloven § 7-2 annet ledd."*

[51] In Norwegian: *"En pasient som har rett til nødvendig helsehjelp, men som ikke kan få helsehjelp fordi det ikke finnes et tilbud i riket eller helsehjelpen i utlandet er dokumentert mer virkningsfull enn den helsehjelpen som tilbys av det offentlige i Norge, har rett til helsehjelp i utlandet, jf. pasient- og brukerrettighetsloven § 2-4a annet ledd bokstav a. Det er en forutsetning at helsehjelpen kan utføres forsvarlig av tjenesteyter i utlandet etter akseptert metode og at pasientens tilstand og den aktuelle behandlingen tilfredsstiller kravene i § 2. Vurderingen av pasientens nytte av behandlingen skal være individuell og ta utgangspunkt i internasjonal medisinsk vitenskap."*

[52] More generally, it seems to the Authority that the issues arising from the division of competence described in this section of this supplementary reasoned opinion will not be resolved by the 2022 Proposal. For example, the Appellate Body would not be able to question the absence in Section 2-4a(2)(a) PRA of the EEA law Time-Limit Element derived from Article 20 of Regulation 883/2004 (see Part 4.3.2 below), as the Appellate Body does not (under Section 7-2(2) PRA) have jurisdiction to apply the NIA, through which Regulation 883/2004 would, under the 2022 Proposal, be incorporated.

- under Regulation of 22 November 2010 No 1466 on reimbursement of health care received in another EEA State ("**the Reimbursement Regulation**")[53] (which Norway says implements Directive 2011/24/EU on the application of patients' rights in cross-border healthcare)[54],
- as well as under Article 20 of Regulation 883/2004,[55]

in a scheme wholly separate from that in the PRA and PR.[56]

54. Complaints in relation to Helfo under the Reimbursement Regulation are handled by the National Office for Health Service Appeals (Nasjonalt klageorgan for helsetjenesten).[57] In the Authority's understanding, there is no provision in any legislative act which confers competence on any particular body for deciding on Regulation 883/2004 cases. The Authority notes, as described in Part 3.2.2.3 above that, in the absence of any such particular provision, the formal competence under Norwegian law to decide on cases relating to Regulation 883/2004 seems to lie with the County Governor pursuant to the main rule in Section 7-2(1) PRA.

55. The Authority however also notes:

(i) that Section 6(4) PR states that applications for authorisation or reimbursement of costs for in-patient treatment in other EEA States pursuant to Article 20 of Regulation 883/2004 are handled by Helfo;[58] and

(ii) that the Norwegian Government has consistently maintained that this competence rests with Helfo.[59]

56. The Authority therefore assumes that, despite what the provisions of the PRA, rather than e.g. the PR, would themselves seem to require, in practice these cases go to Helfo, and that the Norwegian Government's description is therefore correct in the sense that it describes that practice. While the Authority has not been able to find any publicly available decisions made by Helfo under Regulation 883/2004, an

[53] In Norwegian: *Forskrift 22. November 2010 nr. 1466 om stønad til helsetjenester mottatt i et annet EØS-land.*

[54] Reply to the RQI p. 2.

[55] Reply to the RQI p. 19.

[56] Reply to the RQI p. 3.

[57] Section 10(2) of the Reimbursement Regulation. Some decisions made by Helfo under the Reimbursement Regulation can be appealed to the National Insurance Court ("**NIC**"), which is a court-like administrative body replacing the ordinary courts of first instance in certain cases, whilst other appeals go to the ordinary courts of first instance, cf. Sections 21-12(1) and 5-24a of the National Insurance Act, Section 10(2) of the Reimbursement Regulation and Section 1 of the Regulation of 15 April 1997 No 324 on exemptions from appeals to the NIC.

[58] See Reply to the RQI pp. 12 referred to above in footnote 29, whereby this provision is, according to the Norwegian Government, "*for information purpose only*". (see also the Reply to the RQI p. 18.), A reference to Helfo is also found in the preparatory works to the new Section 2-4a PRA (referred to in Part 3.2.1.2), which contains a description of Article 20 of Regulation 883/2004 and the system of pre-authorisations found there: "*In Norway, application for such preauthorisation is handled by HELFO.*" (In Norwegian "*I Norge behandles søknad om slik forhåndsgodkjenning av HELFO*.") Prop. 80 L (2018-2019) p. 10. See also e.g. Reply to the RQI p. 19.

[59] Norway's Reply to the LFN, footnote 2 above, pp 15-17 and footnote 58 above. The Authority also takes note of the Norwegian Government's Reply of 8 July 2022, where it states (p.7) that benefits in Chapter 5 NIA *"are considered as sickness benefits according to Regulation 883/2004 Part III*", and that, therefore, Section 21-11a(2) NIA confers the competence to decide on Regulation 883/2004 cases on the Norwegian Directorate of Health (i.e. Helfo). The Authority observes however that Article 20 of Regulation 883/2004 is *not* among the benefits listed in Chapter 5 NIA, nor among what seems to be the exhaustive list of benefits referred to in the preparatory works as being covered by Section 21-11a NIA (which seems to correspond with the benefits listed in Chapter 5): See Prop. 9 L (2015-2016) p. 10-11. It is not therefore clear to the Authority that Helfo's power to apply Article 20 of Regulation 883/2004 derives from the NIA.

examination of decisions of the National Insurance Court relating to Article 20 shows that at least some such cases do in practice seem to originate from Helfo.[60]

4 The Authority's Assessment

4.1 Rights to in-patient treatment abroad under Regulation 883/2004 and Article 36 EEA

57. EEA law recognises that States may require people to seek authorisation before travelling to another State to receive medical care.[61] Neither Article 36 EEA nor Article 20 of Regulation 883/2004 grant an automatic right to be authorised to receive health care in another EEA State.

58. However, if two conditions are met, Article 36 EEA and the second paragraph of Article 20(2) provide that the home State cannot refuse such authorisation. This is settled case-law[62] and provides a type of 'minimum guarantee.'[63]

59. Authorisation must be granted where:
    - first, the treatment in question is among the benefits provided for by the legislation in the State where the person concerned resides;[64] and
    - second, cumulatively, the (i) same or equally effective treatment compared to the treatment offered abroad cannot be provided in the home/residence State ("**the EET Element**"); (ii) within a time-limit which is medically justifiable, taking into account the person's current state of health and the probable course of their illness ("**the Time-Limit Element**").[65]

60. If the first condition is fulfilled, the second condition consists of two elements: The EET Element and the Time-Limit Element (the Authority refers to these elements together as "**the EEA Law Requirements**"). It is only if both of these elements are present (the same or equally-effective treatment can be provided in time) that authorisation can be refused.

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[60] See footnote 118 below.

[61] Such national prior authorisation requirements, which are in principle restrictions on the freedom to provide services, must however meet certain criteria, otherwise they will not be objectively justified, and will breach Article 36 EEA, see E-11/07 and E-1/08 *Rindal and Slinning*, paragraph 48.

[62] In respect of Article 36 EEA, see e.g. E-11/07 and E-1/08 *Rindal and Slinning*, paragraph 83, and Judgment of 12 July 2001, B.S.M Geraets-*Smits and H.T.M. Peerbooms v Stichting CZ Groep Zorgverzekeringen* ("***Smits and Peerbooms***", Case C-157/99, EU:C:2001:404, paragraphs 103-104; and in respect of Article 20 of Regulation 883/2004, see e.g. Judgment of 23 September 2020, Case C-777/18 ***WO*** EU:C:2020:745, paragraph 42; Judgment of 29 October 2020, *A* v *Veselības ministrija* ("***A***"), C-243/19, EU:C:2020:872, paragraph 25; Judgment of 9 October 2014, *Petru* v *Casa Județeană de Asigurări de Sănătate Sibiu, Casa Națională de Asigurări de Sănătate* ("***Petru***"), Case C-268/13, EU:C:2014:2271, paragraphs 30-31; Judgment of 5 October 2010, *Elchinov v Natsionalna zdravnoosiguritelna kasa* ("***Elchinov***"), Case C-173/09, EU:C:2010:581, paragraph 39; Judgment of 12 July 2001, *Vanbraekel and Others*, Case C-368/98, EU:C:2001:400, paragraph 31.

[63] Opinion of Advocate General Geelhoed, Case C-372/04 *Watts*, EU:C:2005:784, paragraph 102.

[64] In the absence of harmonisation at EEA level, States retain discretion in relation to the conditions for entitlement to benefits (e.g. which types of treatment should be covered by a national sickness insurance scheme), provided that EEA law is otherwise respected: E-11/07 and E-1/08 *Rindal and Slinning*, paragraph 43; Case C-157/99, *Smits and Peerbooms*, paragraphs 44-46: Case C-777/18 *WO*, paragraph 43.

[65] Case C-173/09 *Elchinov*, paragraph 65 and the case-law cited therein; Judgment of 16 May 2006, *Watts v Bedford Primary Care Trust and Secretary of State for Health* ("***Watts***"), Case C-372/04, EU:2006:325, paragraphs 59-61; Case C-268/13 *Petru*, paragraph 31; C-243/19 *A*, paragraph 29.

4.2 Failure to give full effect and priority to Regulation 883/2004 with respect to authorisation to receive appropriate treatment outside the EEA State of residence

61. The Authority maintains that Article 20 of Regulation 883/2004, and its conditions/requirements, as set out above, has not been incorporated in the Norwegian legal order in a way that gives full effect and priority to it, when in conflict with provisions of the PRA, such as Section 2-4(a)2(a) PRA[66] and Section 2-1(b)4 PRA.[67]

62. In its Reply of 8 July 2022, the Norwegian Government has *inter alia* reiterated that Regulation 883/2004 and Regulation 987/2009 have been incorporated "as such" in Norwegian legislation by the Incorporating Regulation, c.f. Article 7(1) (a) EEA. Moreover, Norway has emphasised that Article 7 EEA limits the possibility to split up, rewrite, reproduce, supplement or further explain the content of EEA regulations in national law.

63. The Authority recognises that Article 7 EEA considerably limits the EEA EFTA States' discretion as to how to transpose EEA regulations into the national legal order. Moreover and for the sake of good order, the Authority does not contest that Regulation 883/2004 has been made part of the Norwegian legal order, "as such". As set out below, the Authority takes issue with the effectiveness of the incorporation of Article 20 of Regulation 883/2004 into the Norwegian legal order.

64. In its Reply of 8 July 2022, the Norwegian Government also refers to the judgment of the Norwegian Supreme Court in HR-2021-1453-S, paragraph 89, in support of the view that the Incorporating Regulation constitutes "a clear and unambiguous incorporation of Regulation 883/2004 in the Norwegian legal order."[68]

65. This paragraph however merely states: "Regulation 883/2004 was implemented in Norwegian law through Regulations of 22 June 2012 No. 585 on the Incorporation of Social Security Benefits in the EEA Agreement."[69] The Authority has never contested this fact, which is wholly uncontroversial.[70]

66. As described in Part 3.1 above, Norway considers that Regulation 883/2004 and Regulation 987/2009 were incorporated via the Incorporating Regulation. Section 1(3) of the Incorporating Regulation provides that the provisions of Regulation 883/2004 and Regulation 987/2009 shall prevail in case of conflict with certain specified national acts, such as the National Insurance Act (NIA). There are, however, notable differences in the incorporation of Regulation 883/2004 vis-à-vis the NIA and the PRA, most prominently, as also confirmed by the Norwegian Government in its Reply to the second supplementary letter of formal notice, that there is no clause in the PRA allowing to deviate from it to the extent necessary to comply with international law obligations (such as Regulation 883/2004). Further, the PRA is not (unlike the NIA)

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[66] See paragraphs 84-86 of the Authority's second supplementary letter of formal notice and point 4.3.2 below for an explanation of the conflict which arises.
[67] See paragraphs 89-91 of the Authority's supplementary letter of formal notice and point 4.3.2 below for an explanation.
[68] Reply of 8 July 2022 p. 2.
[69] HR-2021-1453-S, paragraph 89. The quote is from the official translation at https://www.domstol.no/globalassets/upload/hret/decisions-in-english-translation/hr-2021-1453-s.pdf, but the Authority has also analysed the judgment and the relevant paragraph in Norwegian.
[70] The Authority further observes that that judgment concerns the incorporation of Regulation 883/2004 in relation to the NIA, rather than in relation to the PRA, which is at issue here.

listed among the acts over which the Incorporating Regulation will prevail.[71] In case of conflict, therefore, the PRA will (in accordance with the standard conflict of law rule where acts of parliament have higher rank than administrative regulations),[72] prevail over the Incorporating Regulation and the relevant provisions of Regulation 883/2004 and Regulation 987/2009.[73]

67. In its Reply of 8 July 2022, the Norwegian Government has reiterated that there is, in its view, no conflict between Article 20 of Regulation 883/2004 and the rights set out under Section 2-1b(4) and (5) PRA, c.f. Section 2-4a(2)(a) PRA. To that effect, the Norwegian Government emphasises again that there are three different schemes in Norway for publicly paid in-patient treatment abroad and that these are complementary in the sense that a patient not fulfilling the conditions under one scheme is not precluded from requesting reimbursement under of the other schemes.[74] The Authority maintains its view that as provisions such as Section 2-4a(2)(a) and Section 2-1(b)(4) are in conflict with the rights set out in Article 20 of Regulation 883/2004[75] and maintains that alternative schemes must comply with EEA law, in particular when substantial numbers of patients are channelled in practice into the "PRA system".[76]

68. The Authority maintains that this conflict issue is not resolved by Section 2 of the Norwegian EEA Act, which does not provide that a regulation which serves to fulfil Norway's obligations to incorporate EEA legislation, in the event of a conflict, shall prevail over earlier legislative acts.[77] The result is that, in the event of conflict, the provisions of the Incorporating Regulation (given its status as a regulation) will prevail

[71] On 28 January 2020, the EEA EFTA States and the United Kingdom entered into an Agreement on arrangements between Iceland, Liechtenstein, Norway and the United Kingdom following the withdrawal of the United Kingdom from the European Union, the EEA Agreement and other agreements applicable between the United Kingdom and the EEA EFTA States by virtue of the United Kingdom's membership of the European Union ("**the Separation Agreement**"). That agreement is implemented into Norwegian law by the *Act of 27 November 2020 No 131 on transitional rules etc. on the United Kingdom's withdrawal from the European Union* ("**the Brexit Act**"). In contrast to the way Regulation 883/2004 is incorporated in Norwegian law as a matter of EEA law, Section 2(3)(h) of the Brexit Act *does* list the PRA as one of the acts over which the acts listed in Article 29-34 (which includes Regulation 883/2004) of the agreement between the United Kingdom and the EEA EFTA States shall prevail.

[72] Often expressed as "*lex superior derogat legi inferiori*".

[73] In light of the situation described in footnote 71 above, therefore, it appears that with respect to the individuals covered by the Brexit Act, the Norwegian Government has taken certain steps to ensure that Regulation 883/2004 will prevail over the PRA. In contrast, with respect to individuals covered by the EEA agreement, no such steps have been taken and it is instead clearly the PRA which will prevail over Regulation 883/2004.

[74] Reply of 8 July 2022, p. 3.

[75] Reference is made to paragraphs 60 and 84-86 of the Authority's second supplementary letter of formal notice and part 4.3.2 of this supplementary reasoned opinion.

[76] C.f. also paragraph 75 of the Authority's second supplementary letter of formal notice and part 4.3.1 of this supplementary reasoned opinion.

[77] In that vein, when proposing the legislative act ensuring that Regulation 883/2004 still applies to persons covered by the Separation Agreement between the United Kingdom and the EEA EFTA States, the Norwegian Government noted that *"Rules on social security coordination sets further requirements for the application of national social security legislation and leads to conditions and restrictions in the national regulations not being applicable to the extent that something else follows from the social security coordination rules. In Regulation of 22 June 2012 No 585 on the incorporation of the social security regulations in the EEA Agreement § 1 second paragraph* [Section 1(3) of the Incorporating Regulation following amendments on 20 September 2019]*, an explicit derogation right has therefore been included to ensure the correct implementation of the social security regulations. The consultation paper therefore proposed a list of laws that could be deviated from to the extent necessary."* (emphasis added), see Prop. 10 LS (2020-2021) p. 56. The Norwegian Supreme Court has confirmed that Section 1(3) has the effect that Regulation 883/2004 prevails over earlier Norwegian acts such as the NIA, see HR-2021-1453-S paragraph 89.

only over later acts. The Incorporating Regulation of 22 June 2012, which serves to fulfil Norway's obligation to incorporate Regulation 883/2004 into Norwegian law will conversely, pursuant to Section 2, not prevail over earlier acts.[78] The PRA was enacted in 1999 and is therefore an earlier act. In case of conflict with the Incorporating Regulation, the PRA will therefore prevail, as evidenced by practice of the Appellate Body.[79]

69. In its Reply of 8 July 2022, the Norwegian Government argues that the wording "later acts" (in Norwegian: "senere lov") in Section 2 of the Norwegian EEA Act includes – as a general rule – later acts amending the basic (consolidated act).[80] Consequently, the Norwegian Government opines that, if the parts of the provisions contained in the PRA that the Authority considers to be in conflict with Article 20 of Regulation 883/2004 stem from amending acts adopted after the adoption of the Incorporating Regulation, Section 2 of the Norwegian EEA Act would "normally" apply.

70. The Authority recalls, first, that the PRA was enacted in 1999, thus before the Incorporating Regulation. It is therefore an 'earlier act'. While subsequently there may

[78] The Authority notes that the 2022 Proposal proposes to repeal the Incorporating Regulation (and the priority clause found in its Section 1(3)). Instead, it is proposed to incorporate Regulation 883/2004 into the NIA, i.e. a legislative act, while also introducing a rule of conform interpretation in Section 1-3 NIA and in a new Section 1-4 PRA.
If the 2022 Proposal is adopted, it would appear, at least on the face of it, to address the problem of the national regulation incorporating Regulation 883/2004 not prevailing over earlier legislative acts. To the Authority however, it appears that the proposal would not alleviate in practice some of the problems with respect to EEA law which are set out in the present supplementary reasoned opinion, in particular in relation to legal certainty and ensuring that Regulation 883/2004 is effective and takes precedence. The Authority observes, for instance, that the 2022 Proposal does not appear to ensure the effective application and priority of Article 20 of Regulation 883/2004. In that context, the Authority observes that the 2021 White Paper, drafted by an independent committee and which the 2022 Proposal builds upon, notes in Section 14.4.3: "*The Committee considers clear that the requirement of loyal implementation of EEA obligations and the requirement of legal certainty cannot be considered fulfilled solely through the incorporation of a regulation combined with a reference to the general priority principle in section 2 of the EEA Act*." The Committee therefore proposed to introduce a clause in the NIA to ensure that EEA law would prevail in case of conflict. The 2022 Proposal does not explain or address this issue as raised by the White Paper. The Authority is therefore concerned that the 2022 Proposal's removal of the priority clause, combined with the introduction of rules of conform interpretation might *in practice and given the specific legal context in Norway relating to in-patient treatment in other EEA States* run counter to the requirement of legal certainty required when incorporating, giving effect and priority to Regulation 883/2004, and its substantive provisions. The Authority refers here to the evidence presented in Part 4.3.2 of this supplementary reasoned opinion documenting that the Appellate Body only has competence to apply Section 2-4a(2)a PRA and that it has at least in practice never considered itself competent to apply Article 36 EEA, making no use of Section 2 of the EEA Act. Also, the 2021 White Paper noted in Section 14.4.4 that "*[t]here is a danger that allegations that a Norwegian rule of law must be set aside as a result of the EEA Act § 2, will be met with scepticism by the administration and perhaps also the courts, which in itself could prevent the effective impact of the regulation*". The Authority shares the concerns raised by the White Paper, which it considers would also arise in the current legal context if the 2022 Proposal were to be adopted.

[79] C.f. Appellate Body Decision No N2017/8826 of 12 February 2018 where the Appellate Body held that a potential conflict between the PRA/PR and EEA law requirements (in that case Article 20 of Regulation 883/2004 and Article 36 EEA) must be resolved by amending Norwegian law, and that, until that happens, the Appellate Body is obliged to apply the PRA and the PR. To the Authority's knowledge, there are no other Appellate Body decisions where the conflict between EEA rules and the PRA/PR is considered by the Appellate Body. This seems to be due to, as further demonstrated in footnotes 101 and 111 below, that out of the 226 Appellate Body decisions concerning access to treatment in other EEA States, only six decisions consider EEA law relevant at all. In other words, the Appellate Body seems to have been unaware of the existence of Section 2 of the EEA Act, and of its ability and duty to apply Article 20 of Regulation 883/2004 and/or Article 36 EEA to the cases before it.

[80] Reply of 8 July 2022, p. 6.

have been some amendments to individual provisions of the PRA, these have been limited in nature and scope, and classifying them as "a later act" 'regulating the same provisions' would seem to stretch Section 2 of the Norwegian EEA Act beyond any reasonable interpretation.[81] Second, at the RDO deadline (20 January 2018), none of the provisions of the PRA which the Authority considered to be in conflict with EEA law had been amended, therefore Norway's argument about 'later acts' is, even if it were correct (which is not accepted) wholly ineffective in respect of those provisions. Finally on this point and on any view, Norway's 'later acts' argument raises major issues of legal certainty. Even on a practical level, the Authority cannot see how such an approach would be administrable. It would require a judge, practitioner or individual to, for each legal provision, be aware of its precise history, what had been amended and when, and to then take a view on whether the amendment was of a nature such as to turn it into a 'later act'.[82] Such a lack of clarity or legal certainty would be incompatible with Articles 3 and 36 EEA and Article 20 of Regulation 883/2004.

71. The Authority further observes that the preparatory works to Section 2 of the Norwegian EEA Act recognise the problem that Section 2 does not contain a provision that a regulation that serves to fulfil Norway's EEA obligations shall, in the event of conflict, take precedence over earlier legislation regulating the same matters. The preparatory works provide: "[i]f the possibility of such a conflict is identified [between a regulation incorporating EEA law and an earlier legislative act], one must seek to avert it by repealing or amending the law which is in breach of international law by decision of the Storting, or by obtaining special legal authority to make an exception from the relevant law by regulation."[83] However, as explained above, such a solution did not materialise in the specific case at hand.

72. This issue was also not solved by the entry into force of Section 2-4a PRA. As set out above in Part 3.2.1.2 and as confirmed by the Norwegian Government in its Reply to the RQI of 21 June 2021, this provision is meant to give patients an overview of the right to treatment abroad and does not incorporate Regulation 883/2004.[84]

73. It follows from Protocol 35 EEA that for cases of possible conflicts between implemented EEA rules and other statutory provisions, the EFTA States undertake to introduce, if necessary, a statutory provision to the effect that EEA rules prevail in these cases. This means the States must ensure that EEA rules, which have been implemented into national law, prevail over other conflicting national provisions. Moreover, pursuant to Article 7 EEA, regulations shall, as such, be made part of the internal legal order of the EEA States. As the Court has explained, the effect of Article 7 and Protocol 35 is that when a Regulation such as Regulation 883/2004 has been

[81] The Authority refers to the preparatory works to the Norwegian EEA Act: Ot. prp No 79 (1991-1992) p. 5, Section 4.4.

[82] The Authority observes that, as referenced in paragraph 69 above, the Norwegian Government states that the wording 'later act[s]' in Section 2 of the Norwegian EEA Act includes "*as a general rule*" later acts amending the basic (consolidated) act. The Norwegian Government also states that, if parts of the conflicting provisions of the PRA were adopted after the adoption of the Incorporating Regulation, Section 2 of the Norwegian EEA Act "*would normally apply*". The Authority wonders what is meant by "*as a general rule*", and why the Norwegian Government has caveated its position in this way. In the Authority's view, this is a tacit recognition of the inherent difficulties and legal certainty issues raised by this argument.

[83] See Ot.prp No 79 (1991-1992) p. 5 (in Norwegian*: «Identifiseres muligheten for en slik konflikt, må man søke å avverge den ved å oppheve eller endre den folkerettsstridige lov ved Stortingsvedtak, eventuelt skaffe seg særskilt lovhjemmel til å gjøre unntak fra vedkommende lov ved forskrift*.») Authority's translation.

[84] See footnotes 28, 29 and 33 above.

incorporated into national law, it must be binding in its entirety and directly applicable and must prevail over other, conflicting, national provisions.[85]

74. In Wahl and ESA v Iceland, the EFTA Court held:

> *"Article 3 EEA requires the EEA States to take all measures necessary, regardless of the form and method of implementation, to ensure that a directive which has been implemented […] prevails over conflicting national law and to guarantee the application and effectiveness of the directive."*[86]

75. The Authority considers that a fortiori the same applies in respect of regulations.

76. The Authority takes the view that the way in which the Norwegian Government has incorporated Regulation 883/2004 and Regulation 987/2009 with respect to in-patient treatment does not comply with these requirements of Protocol 35 and Articles 3 and 7 EEA. The failure to ensure that the provisions of these EEA Regulations will prevail over conflicting law also necessarily means that they have not been incorporated with binding force. The Norwegian Government has therefore also failed to give effect to the relevant substantive provisions of those regulations.

77. For completeness, the Authority also wishes to raise a recent parallel case, Case 84329. In that case, the Authority *inter alia* examined how Regulation 883/2004 was incorporated into the Norwegian legal order, to the extent it related to Article 21 thereof (on the exportability of sickness benefits in cash). It concluded that Norway had failed to incorporate the Regulation in a manner which fulfilled its obligations under EEA law and issued a letter of formal notice.[87] The Norwegian Government raised a number of arguments in its reply of 25 February 2021, asserting *inter alia* that Regulation 883/2004 had been correctly incorporated in the Norwegian legal order in relation to the National Insurance Act ("NIA"). In that reply, Norway stated:

> *"17. Section 1-3 of the NIA states that the King in Council may conclude mutual agreements with foreign countries regarding rights and obligations pursuant to this law, hereunder, make exceptions to the provisions of the law. Regulation 883/2004 is implemented in the Norwegian legal system, and made part of Norwegian Legislation, through incorporation by* [the Incorporating Regulation], *cf. Section 1-3 of the NIA, in force as of 1 June 2012, on the Incorporation of the Social Security Regulations of the EEA Agreement Section 1. In compliance with Art. 7(1)(a) EEA, the Regulation has been incorporated as such into the national legislation. EEA law does not require a regulation to be incorporated in a specific law/act, as long as the incorporation assure that the legal situation remains sufficiently clear and unambiguous.*
> *18. It is clearly provided in Paragraph 3 of Section 1 of [the Incorporating Regulation] that the NIA must be deviated from to the extent necessary to secure compliance with Regulation 883/2004. The Government therefore argues that the relationship between Regulation 883/2004 and NIA is neither ambiguous nor uncertain.*
> *(…)*

[85] Case E-6/12 *ESA v Norway*, paragraphs 65-67. See in particular paragraph 67: "*Therefore, the Commission is correct to assume that, in a situation such as in the present case, where the Regulation has been incorporated into national law, it is binding in its entirety and directly applicable and shall prevail over other national provisions (see, to that effect, Cases E-1/07 Criminal proceedings against A, cited above, paragraphs 38 and 39, and E-4/07 Þorkelsson [2008] EFTA Ct. Rep. 3, paragraph 47).*" On Protocol 35 see more generally, e.g. judgment of 16 December 1994, E-1/94 *Restamark* [1994-1995] EFTA Ct. Rep. 15, paragraph 77.

[86] Case E-15/12 *Wahl*, cited above, paragraph 54 and Case E-12/13 *EFTA Surveillance Authority v Iceland*, cited above, paragraph 73.

[87] Doc No 1138850.

> *21. (…) the Government underlines that in case of conflict between the national law and EEA law, Section 2 of the Act relating to the implementation in Norwegian law of the main part of the Agreement on the European Economic Area (EEA) etc. ensures that EEA law will prevail.*
> *22. (…) National law will have to be interpreted in light of our EEA obligations and in the case of conflict national legislation will have to be deviated from. We also refer to what is stated above regarding the change of practice that has been made by the Norwegian Labour and Welfare Service to assure compliance with EEA law (…)"*[88]

78. The Authority was not persuaded by these arguments, for the reasons given in its reasoned opinion of 9 June 2021 (Doc No 1200885, at p. 20-23). The Authority anticipates that the Norwegian Government might nevertheless raise the same or similar arguments in the present case and therefore, in the interests of administrative efficiency, considers them below.

79. First, in contrast to what is argued by the Norwegian Government in the context of Case 84329, in the present case Section 1(3) of the Incorporating Regulation does not ensure that the PRA is deviated from to the extent necessary to ensure compliance with Regulation 883/2004. There is, furthermore, no provision in the PRA comparable to the provision found in Section 1-3 of the NIA.[89] This was confirmed by the Norwegian Government in its Reply of 8 July 2022.[90] With no information to the contrary, the Authority must therefore conclude that Regulation 883/2004 has not been given the necessary priority over the PRA since its incorporation.

80. Second, and again in contrast with the argument raised by the Norwegian Government in Case 84329 in relation to the NIA, Section 2 of the Norwegian EEA Act does not entail that provisions of Regulation 883/2004, as implemented in Norwegian law by the Incorporating Regulation, will prevail over the PRA in the event of conflict, as explained above.

81. In sum, even if the Authority had been persuaded by the Norwegian Government's arguments in Case 84329 on the incorporation of Regulation 883/2004 with respect to sickness benefits in cash, none of the arguments which the Norwegian Government made there, are present or effective in relation to in-patient treatment. Because none of these arguments can be made in the present case, applying the Norwegian Government's own logic in Case 84329 also results in the conclusion that the national incorporation of Regulation 883/2004 does not meet the requirements necessary to make EEA law effective in the national legal order.

82. Thus, the Authority considers 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 Sections 2-4a(2)a and 2-1b(4) PRA), thereby also acting in breach of its obligations under Articles 3 and 7 and Protocol 35 EEA.

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[88] See Reply to letter of formal notice to Norway concerning the exportability of sickness benefits in cash, 25 February 2021, p. 4-5 (Doc No 1184098).

[89] The Authority understands that the Norwegian Government considers that, by virtue of a provision such as Section 1-3 NIA, Parliament has empowered the King in Council to conclude international agreements relating to the NIA, as well as to make exceptions to the provisions of the law. In the Authority's view, any such 'exceptions' relied upon by Norway in Case 84329 are ineffective. In relation to the 2022 Proposal, the Authority understands that a primacy clause, such as the one present in Section 1(3) of the Incorporating Regulation today, will not be present in the proposed Sections 1-4 PRA and 1-3 NIA. This part of the proposed amendments appears therefore to weaken, rather than strengthen, the effectiveness of Regulation 883/2004 and its implementing regulation.

[90] Reply of 8 July 2022, p. 5.

4.3 Institutional set-up and procedural rules and practice which make the application of Article 20 of Regulation 883/2004 and Article 36 EEA ineffective

4.3.1 Introduction

83. It is recalled that the Norwegian Government has consistently maintained that the rights to in-patient treatment abroad granted by the PRA and PR (e.g. Section 2-1b(5) PRA) are 'extra' and do not purport to implement or guarantee rights deriving from EEA law as such.[91] Whether or not this is the case, even 'extra' or 'more favourable'[92] provisions must comply with EEA law, particularly when substantial numbers of patients are channelled in practice into the 'extra PRA system'. In the context of in-patient rights, as set out at Part 4.1 above, it is particularly important, as a matter of EEA law, that patients are granted the right to treatment abroad[93] where both the following elements are present:

    - the *same or equally-effective treatment* compared to the treatment offered abroad (the EET Element) cannot be offered in the home state
    - within a time-limit which is medically justifiable (the Time-Limit Element).

84. Any domestic system (whether or not specifically intended to implement EEA law) must therefore comply with these requirements (the EEA Law Requirements).

85. Norway has however constructed a complex domestic complaints/appeals system:

    - where the relevant appeals bodies (the County Governor/Helfo and the Appellate Body):
        - have been or are prevented and/or discouraged by the relevant procedural rules from applying a legal test which comprises, as required by EEA law,[94] *both* the EET Element and the Time-Limit Element; and/or
        - fail or have failed to apply such EEA Law Requirements in practice;
    - where it is unclear which body or bodies have jurisdiction to apply Article 20 of Regulation 883/2004;

    which makes it excessively difficult or impossible for the individuals and persons concerned to rely on and/or enforce their EEA law rights before such bodies.

86. These matters are set out in more detail below. For the avoidance of doubt, the Authority again wishes to make clear that it does not take issue with how Norway structures its complaints/appeals system as such. Thus the Authority entirely agrees with Norway[95] that the allocation of competence to handle complaints under different

[91] See Reply to RQI p. 3, where it is stated: "*The two first set of rules* [i.e. first, Regulation 883/2004 and, second, the rights to reimbursement according to case-law as well as the Patients' Rights Directive] *are incorporated into Norwegian legislation in order to fulfil our obligations according to EEA law. The third set of rules (under the PRA and PR) has a different function and character*." On p. 2, the third set of rules is described as referring to PRA "*Section 2-1b(4) and (5) (in force at the RDO deadline 20 January 2018, amended 1. March 2020, cf. PRA section 2-4 a(2) subparagraph a) with further provisions in* [the PR]."

[92] Norway contends in its Reply to the Supplementary LFN of 3 May 2016 on p. 2 that the PRA and the PR system give "*additional rights to access to health care abroad*.", and, in the same vein, in the Reply to the RQI on p. 3, *"*[t]*his right to access to health care services and full cost coverage does, in our view, go beyond our obligations under EEA law."*

[93] For ease of reference, the Authority here uses "abroad", as meaning in another EEA State.

[94] Both under Article 20 of Regulation 883/2004 and Article 36 EEA.

[95] Reply of 8 July 2022, Section 2.1, page 7.

schemes to different bodies is not as such contrary to EEA law. The Authority has never alleged that allocating competence in this way is, of itself, problematic. The issue is that the present system does not meet Norway's obligations under the EEA Agreement to make Article 20 of Regulation 883/2004 and Article 36 EEA effective.

87. In its reply to the Authority's second supplementary letter of formal notice, the Norwegian Government has *inter alia* contended that the split or limited jurisdiction under the PRA appeals procedure has not prevented or discouraged the Appellate Body from considering relevant EEA law.[96] Having read the arguments of the Norwegian Government to support that position, the Authority maintains its conclusions as set out in its second supplementary letter of formal notice and as recalled in the following.

4.3.2 PRA appeals bodies are hindered from applying a legal test which complies with the requirements of Article 20 of Regulation 883/2004 and Article 36 EEA, and/or fail to apply such requirements in practice

88. By way of introductory remark, the Authority observes that it appears that, as required by EEA law,[97] all relevant appeals or complaints bodies are in principle empowered (and where necessary required) to apply Article 36 EEA, as a matter of Norwegian law (Section 1 of the Norwegian EEA Act).[98] With respect to Article 20 of Regulation 883/2004 however, it appears that such bodies must be given explicit competence by the Norwegian system to apply Article 20, or that such bodies at least consider it necessary that competence is explicitly conferred.

89. It is against this background that the following observations are made.

The Appellate Body

90. As set out in Part 3.2.2.2 above, at the RDO deadline, under Section 7-2 PRA, complaints about a lack of adequate services in Norway under Section 2-1b(5) PRA would go to the Appellate Body, while complaints about a breach of the time-limit under Section 2-1b(4) PRA would go to the Country Governor. As a consequence, neither complaint/appeal body was permitted under the PRA to consider both the adequacy of national services and whether they could be provided in time. This allocation or 'split' of competence therefore prevented or at least discouraged each body from making, as it should have done under Article 20 of Regulation 883/2004 and/or Article 36 EEA, an overall assessment of whether treatment was both equally-

[96] Reply of 8 July 2022, p. 9. The Authority observes that the Norwegian Government is silent on whether the allocation of powers between the Appellate Body and County Governor has prevented or discouraged the *Country Governor* from considering or applying relevant EEA law.

[97] See e.g. Case C-378/17 *Minister for Justice and Equality, Commissioner of An Garda Síochána v Workplace Relations Commission*, EU:C:2018:979, paragraphs 31-39.

[98] As the Norwegian Supreme Court, in accordance with EU and EEA law, correctly held in case HR-2021-1453-S at paragraph 61: "(…) *In the area of civil law, the Court of Justice of the European Union (CJEU) has stated several times that where national courts can go beyond the scope of the parties' contentions, they are also obliged to do so, to the extent the application of EU rules is at issue. Similarly, it must be so that where the appellate court in criminal cases can review the application of the law beyond the scope of the appeal, it is also obliged to do so, if there is doubt whether it will be contrary to EEA law to apply punishment.*") English translation by the Norwegian Supreme Court, available at https://www.domstol.no/globalassets/upload/hret/decisions-in-english-translation/hr-2021-1453-s.pdf As will be seen from the below, the relevant bodies do not however raise or apply Article 36 EEA, despite being empowered to do so.

effective[99] and could be provided in time (the EEA Law Requirements). At the RDO deadline, neither body was granted competence under the PRA to handle cases dealing with Article 20 of Regulation 883/2004.

91. In practice, the combination of these factors seems to have resulted in a situation where the Appellate Body did not consider itself competent to handle the timing aspect of any complaint[100] (as it must if it is to apply a test in conformity with EEA law), nor did it consider itself competent to apply EEA law: whether Article 20 of Regulation 883/2004, or Article 36 EEA.[101] For example, in its decision in case N2017/8826 of 12 February 2018, a complainant referred to the arguments raised in the Authority's RDO in the present case as the basis for a reversal of an initial rejection of authorisation for treatment abroad. The Appellate Body held that:

> "*The implementation of the EEA regulations in Norwegian law has necessitated several legislative amendments, also in the [PRA]. To the extent that the [PRA] and the Prioritisation Regulation are not in accordance with the EEA regulations, this requires further amendments to the law and regulations. The Appellate Body must nevertheless comply with current regulations and the conditions set out in the [PRA] and the Prioritisation Regulation until this happens. The Complainant's allegation that the decision may be reversed with reference to ESA's opinion of 20 September 2017 can therefore not be substantiated*."[102]

92. This split or limited jurisdiction also resulted in a situation where patients seeking to rely on EEA rights were (and are still) required to run parallel cases before each of the County Governor (and/or Helfo) and the Appellate Body, making the enforcement of those rights excessively difficult or virtually impossible.[103]

93. Under the current PRA appeals procedure, the above problems persist. As set out in Part 3.2.2.3 above, under Section 7-2(2) PRA and Sections 7 and 8 PR, the Appellate

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[99] The RDO addresses the separate failure of the *adequacy* assessment made under Section 2-1b(5) PRA to comply with the need to ensure a case-by-case assessment of whether *equally effective* treatment can be provided nationally.

[100] See to this effect e.g. Appellate Body decisions UKN-2008-2, UKN-2008-29, UKN-2009-53, UKN-2009-95, UKN-2010-21, UKN-2010-103, UKN-2010-111, UKN-2012-63, and UKN-2012-108 where the Appellate Body, while blatantly disregarding its own obligation towards the complainants to apply Article 36 EEA, holds that complaints concerning breaches of the time-limit must be made to the Specialist Health Service and/or HELFO, and not the Appellate Body, as it itself does not have competence to decide on that matter.

[101] There are to the Authority's knowledge only six decisions since the establishment of the Appellate Body in 1999 where the relevance of EEA law is at all discussed: see decisions UKN-2003-14, UKN-2003-17, UKN-2004-58, UKN-2010-54, UKN-2011-97 and UKN-2017-8826. The Authority has not found any Appellate Body decisions where the right to in-patient treatment was granted on the basis of EEA law.

[102] Decision No N2017/8826 of 12 February 2018 (Doc Nos 1220168 (original) (Annex 1 to the second supplementary LFN) and 1220156 (translation), (Annex 2 to the second supplementary LFN), p. 3, Authority's translation. This Decision concerned the complainant in Case No 74770, see paragraph 6 above. In 2020 the complainant asked the Appellate Body to make a renewed assessment. In its decision of 10 February 2020, the Appellate Body maintained its earlier view, see UKN-2017-8826.

[103] See Appellate Body decisions UKN-2008-2, UKN-2008-29, UKN-2009-53, UKN-2009-95, UKN-2010-21, UKN-2010-103, UKN-2010-111, UKN-2012-62, UKN-2012-63, UKN-2012-108, UKN-2019-5637, UKN-2019-6144, UKN-2020-4722-1, UKN-2021-8790 and UKN-2022-542. In UKN-2019-6144, while disregarding its own legal obligation towards the applicant to apply Article 36 EEA, the Appellate Body took the time to note that HELFO was running a parallel case in relation to the same applicant, and recorded that *"*[i]*t is unfortunate that the case is run in parallel, but the complainant believes that she meets the conditions for both schemes"* (in Norwegian: *"Det er uheldig at saken kjøres parallelt men klageren mener at hun oppfyller vilkårene for begge ordningene").*

Body does not have jurisdiction to apply Regulations 883/2004 and 987/2009.[104] The Appellate Body only applies the 'national' scheme pursuant to Section 2-4a(2)a (ex 2-1b(5)) PRA and Section 3 PR. This means that its jurisdiction under the PRA continues to be restricted, so that it cannot take (or is discouraged from taking) into account whether equally-effective treatment can be provided in time. The formulation of the test in Section 2-4a(2)a is also problematic. Section 2-4a(2)a PRA provides a right to treatment abroad:

> "*a) if the patient is entitled to necessary health care from the specialist health service according to § 2-1 b and there is no offer in the country or the health care abroad is documented to be* ***more effective*** *than the health care offered by the public sector in Norway."* (emphasis added)

94. However, this test is not consistent with the two-fold EEA Law Requirements: namely that the right to treatment abroad is engaged where the same or equally-effective treatment domestically cannot be provided in time.[105] There is no requirement that the treatment abroad be documented to be more effective before EEA law rights are engaged. The Authority understands that Section 2-4(2)a is intended to supplement rights available to individuals under EEA law, but, by introducing a higher effectiveness threshold, which would also presumably apply if the time-limit is exceeded, as well as failing to also refer to the time-limit component of the test, this provision runs counter to EEA law requirements and is at best confusing.

95. Thus, the Appellate Body is accordingly prevented or discouraged from applying Section 2-4a(2)a PRA in a way which is consistent with EEA law, and in practice, as outlined in the preceding paragraphs,[106] it does not appear to apply EEA law correctly or at all.

96. In its reply to the Authority's second supplementary letter of formal notice, the Norwegian Government argues, seemingly only with respect to the Appellate Body, that it is an "*independent body, and the Ministry is unable to instruct its discretion and individual decisions*".[107] The Authority in this regard notes that it is settled case-law of the CJEU that it is incumbent on the State to ensure that all bodies of government follow EEA law, and, if necessary, to let EEA law prevail over conflicting national law.[108] It is therefore the responsibility of the Norwegian Government to ensure that all of its appellate bodies, including *inter alia* the Appellate Body for Treatment Abroad, applies EEA law and applies it correctly.

97. It is therefore excessively difficult or in practice impossible for patients to obtain a decision in relation to the PRA from one and the same PRA appeals body which will apply the relevant national criteria in line with Article 20 of Regulation 883/2004 and/or Article 36 EEA, or will directly apply those provisions themselves. For example, instead of applying Article 36 EEA as it should, even if this was not raised by the complainant,[109] a number of decisions of the Appellate Body simply reject the complaint and refer patients to Helfo, stating that the Appellate Body does not have

[104] This is not contested by Norway in its Reply of 8 July 2022.
[105] See E-11/07 and E-1/08 *Rindal and Slinning*, paragraph 83, reflecting the settled case-law that "*prioritisation of home State treatment, such as in the case at hand, cannot be justified unless the home State itself can provide treatment which is the same or equally effective for the patient as the treatment abroad within a medically justifiable time limit*." While the Court refers at paragraph 84 to "*more effective treatment*," this was in answer to a question of the national court which specifically related to more effective treatment (i.e. if the treatment abroad is more effective, a State certainly cannot justify prioritising home treatment).
[106] See also footnotes 100-103 above.
[107] Reply of 8 July 2022, p. 9.
[108] See for example Case C-453/00 *Kühne & Heitz,* EU:C:2004:17, paragraph 20 and the case-law cited therein.
[109] See footnote 91 above.

jurisdiction over such (timing) matters.[110] Further and finally on this point, the administrative practice of the Appellate Body does not, as far as the Authority is aware, provide any examples of applicants being granted authorisation or reimbursement of costs for in-patient treatment in accordance with their EEA rights.[111]

The County Governor

98. As set out in Part 3.2.2.2 above, and as reflected in Part 4.3.2 immediately above, at the RDO deadline, under Section 7-2 PRA, complaints about a lack of adequate services in Norway under Section 2-1b(5) PRA would go to the Appellate Body, while complaints about a breach of the time-limit under Section 2-1b(4) PRA would go to the County Governor. Neither complaint/appeal body was therefore permitted under the PRA to consider both the adequacy of national services and whether they could be provided in time. This therefore discouraged or prevented them from making, as they must under EEA law, an overall assessment of whether treatment was both equally-effective and could be provided in time. Further, as set out above, this appears to have made it in practice impossible for patients to obtain an EEA-compliant decision on the PRA from one and the same appeals body.

99. The current PRA appeals procedure has changed slightly, but the split-competence issue described above persists, and the provisions remain problematic, for the following reasons.

100. First, Section 2-1b(4) PRA was amended, by removing the words in strikethrough:

> "*If the regional health undertaking has not ensured that a patient who is entitled to necessary healthcare from the specialist health service receives such care within the time limit fixed pursuant to the second paragraph* [i.e. a medically-justifiable time-limit]*, the patient has the right to receive necessary healthcare without delay, if necessary from a private service provider ~~or a service provider outside the realm~~.*"[112]

101. Thus, if the time-limit is exceeded, there is no longer a right under this provision to treatment abroad. In the Authority's view, this means that the provisions of Section 2-1b(4) PRA are themselves contrary to Article 20 of Regulation 883/2004 and Article 36 EEA, which confer the right to treatment abroad where the same or equally-effective treatment in Norway cannot be provided within a medically-justifiable time-limit.

102. Second, Section 2-4a(1)b PRA, read in combination with Section 7-2 PRA (see Part 3.2.2.3 above) appears to confer jurisdiction on the County Governor to handle

[110] See Appellate Body decisions UKN-2008-2, UKN-2008-29, UKN-2009-53, UKN-2009-95, UKN-2010-21, UKN-2010-103, UKN-2010-111, UKN-2012-63 and UKN-2012-108. The reply of the Norwegian Government appears to confirm that, where patients do not meet the criteria of Section 2-1b(5) or Section 2-4a(2)(a) PRA, they are required to apply to Helfo in order to be able to benefit from their rights under Article 20 of the Regulation or Article 36 EEA: "*The Appellate body is to consider whether the conditions in 2-1b(5) PRA, cf. PRA Section 2-4(2)(a) are met. If a patient does not meet the conditions laid down in 2-1b(5) PRA, cf. Section 2-4(2)(a) PRA, the patient may apply to Helfo for reimbursement in accordance with Article 20 of the Regulation or alternatively the Reimbursement Regulation*" (Reply of 8 July 2022, p.9).

[111] The Authority has examined all the 300 publicly available decisions of the Appellate Body. 231 of these concern treatment in other EEA States (applications concerning the United Kingdom are only included to the extent the case relates to an Appellate Body decision made prior to 31 January 2020). The Authority observes that, in its Reply of 8 July 2022, the Norwegian Government has not provided any examples of cases in which the Appellate Body has applied the EEA Law Requirements (whether under Article 36 EEA or Article 20 of Regulation 883/2004).

[112] As described in footnote 37 above, similar consequential amendments were made to Section 6 PR.

complaints relating to a breach of the provisions of Section 2-4a(1)b – and thus of Article 20 of Regulation 883/2004. In practice, however, it seems that it is Helfo which deals with complaints related to the time-limit aspect of Article 20. This practice is reflected in the final sentence of Section 6(4) PR, the preparatory works to Section 2-4a PRA and the Reply to the RQI.[113] In such circumstances it is confusing and difficult for patients to determine where they should enforce their rights and such ambiguity should be resolved.

103. Third, the Authority recalls that Section 2-4a(1)b PRA refers only to the Time-Limit Element (and not also to the EET Element) of the EEA law Requirements:

> *"pursuant to Council Regulations (EC) Nos. 883/2004 and 987/2009, which, among other things, gives the right to be reimbursed for necessary health care during temporary stays and for planned health care in other EEA States* ***if the health care is not provided within a reasonable time in Norway****."* (emphasis added)

104. The failure to include the EET Element appears to be not merely an incomplete description or 'overview,' but rather to reflect a systemic misunderstanding of the requirements of Article 20 of Regulation 883/2004. In other words, the Norwegian Government appears to understand that Article 20 merely requires an assessment of whether the *same* treatment can be provided in time in Norway, rather than (as required by Article 20 and Article 36 EEA in light of the case-law) whether the same or equally effective treatment can be provided **in time**. This understanding can be seen in various statements made by or on behalf of the Norwegian Government[114] and is

[113] Reply to the RQI p. 19: according to the Norwegian Government, Helfo is "*given the task to give authorisation (or reimbursement) if the conditions in Regulation 883/2004 on social security coordination Article 20 is met*". See also Prop. 80 L (2018-2019) p. 14.

[114] This appears to be a long-standing view, which does not take into account the settled case-law (see Part 4.1 above) of the CJEU and EFTA Court on Article 20 of Regulation 883/2004 and/or Article 36 EEA. In its Reply to the RQI, pp. 3-4, the Norwegian Government describes the second condition (thus together the EET Element and the Time-Limit Element) in the following manner: "*the second condition requires that the treatment cannot be given within a medically justifiable time limit, taking into account the patients current state of health and the probable course of his disease*." See also e.g. p. 6, where it is stated: "*The competent institution is only obliged to grant prior authorisation insofar 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. Hence; when the specialist health service makes sure that the individual patient receives necessary healthcare within a medically justifiable time limit, there is no obligation to grant prior authorisation in accordance with article 20 of Regulation (EC) No 883/2004*." See also Norway's Reply to the LFN, 15 August 2014 (Doc No 718533), pp. 15-16. The Authority observes that the current circular, section 5.10, also includes the same understanding (available at https://lovdata.no/nav/rundskriv/r45-00/kap5.10#kap5). For the sake of good order, the Authority notes that when Norway submitted its Reply to the LFN dated 15 August 2014, it included the then applicable version of the circular as an annex to its letter. No doubt by a clerical error, it however omitted the relevant page of the circular (8/16), which described its understanding of Article 20. See also e.g. E-11/07 and E-1/08, *Rindal and Slinning*, *Report for the Hearing,* paragraph 61 ("*It is only if the treatment to which a patient is entitled to domestically could not be provided within a medically justifiable time that this treatment shall be offered abroad*."). This view is set out more fully in the Written Observations of the Norwegian Government in that case, paragraph 93. A decade earlier, Ot.prp. No 53 (1996-1997) Section 1.2.1 explains that the then competent body "*may not, pursuant to Article 22 (2), second paragraph, of the Regulation [1408], refuse to give consent when the treatment is considered to be one of the services provided in Norway, and the treatment cannot be given within the deadline that is normally necessary to receive such treatment in Norway*." Most recently, variations of this understanding has been expressed in preparatory works to the Brexit Act (see Prop. 10 LS (2020-2021) Section 5.3.2) and in the 2022 Proposal, see Section 4.4.5 ("*It is a condition for permission pursuant to Article 20 that there exists in the competent State an approved treatment offer which corresponds to the treatment applied for* [*in another EEA State*]").

reflected in the preparatory works to Section 2-4a(1)b.[115] On this, the Authority observes that the introduction of Section 2-4a(1)b coincided with the partial repeal of the time-limit provision Section 2-1b(4) PRA. Section 2-1b(4) originally granted, but no longer grants, a right to healthcare abroad when the time-limit was exceeded.

105. This effort to try to reduce or align the number of legislative provisions is to be welcomed, but it is regrettable that neither Section 2-1b(4) in its original form, nor Section 2-4a(1)b as introduced, reflect the important EET Element of the legal test – and instead referred or refer only to the Time-limit Element. Indeed, it would appear to follow from the PRA, interpreted in light of the preparatory works, that any competent complaints body is only supposed to apply the Time-Limit Element of Article 20, not the EET Element.[116] This concern or deficiency seems to be borne out in practice: there appears to be no complaints body (whether the County Governor or Helfo) which applies Article 20 of Regulation 883/2004 in full.[117]

Helfo/the National Insurance Court

106. As set out above in Part 3.2.2.4 it appears that, in practice, it is intended that Article 20 of Regulation 883/2004 is to be applied by Helfo, whose decisions may be appealed to the National Insurance Court ("**the NIC**") as the appeals body. While the Authority has been unable to identify any publicly available decisions of Helfo, it has examined the practice of the NIC, which discloses that the NIC does not correctly apply Article 20 of Regulation 883/2004,[118] nor does it apply Article 36 EEA in in-patient treatment cases.[119] In its reply to the Authority's second supplementary letter of formal notice, Norway contends that the Authority has not explained what is

[115] In respect of Section 2-4a(1)b PRA, the preparatory works provide:
"*Secondly, patients can be reimbursed for expenses for health care received in another EEA State in accordance with Council Regulations (EC) Nos. 883/2004 and 987/2009. Among other things, the regulations give the right to be reimbursed for expenses for necessary health care during temporary stays and for planned health care in other EEA States. The latter applies if the health care is not provided within a reasonable time in Norway*." see Prop. 80 L (2018-2019) p. 14 (emphasis added).

[116] See Prop. 80 L (2018-2019) p. 14, footnote 115 above.

[117] If this understanding is incorrect, the Authority again invites the Norwegian Government to provide evidence of how Article 20 (and/or Article 36) rights are being respected and secured before the competent complaints bodies. Further and for the sake of good order, as will be explained in Part 4.4, even if the competent bodies were to apply Article 20 correctly, this would not bring Norwegian law into compliance with Article 20: the legal certainty issue remains.

[118] See e.g. NIC decisions TRR-2012-268, TRR-2012-1883, TRR-2012-2553, TRR-2013-514, TRR-2013-2486, TRR-2014-621, TRR-2014-2387, TRR-2015-591, TRR-2016-301, TRR-2016-439, TRR-2016-633, TRR-2016-1128, TRR-2016-3466, TRR-2017-653 and TRR-2019-1487. In case TRR-2014-2387 the NIC held that it did not have jurisdiction in cases relating to Article 22 of Regulation 1408/71 and Regulation 20 of Article 883/2004. In 2016 the Parliamentary Ombudsman for Scrutiny of the Public Administration concluded that the NIC was in fact competent to handle such cases: see statement SOM-2015-2396. Since then (i.e. from decision TRR-2016-301 onwards), it appears that while the NIC considers that it has jurisdiction to apply Article 20 of Regulation 883/2004, it does not apply it in the manner required by EEA law.

[119] In case TRR-2014-2387, the majority of the NIC explicitly considered that the complainant's "*claim for reimbursement must be assessed on the basis that [the treatment in question] is provided in Norway and [[based on] the EEA Agreement's provisions on free movement of services. Pursuant to section 1 of the [Law on Appeals to the NIC] the [NIC] does not have the competence to process claims directly pursuant to the EEA Agreement. Such competence is also not given by special legal provisions.*" (In Norwegian: "*Flertallet mener at [klagers] refusjonskrav må vurderes på bakgrunn av at det gis ablasjonsbehandling i Norge og EØS-avtalens bestemmelser om fri bevegelighet av tjenester. Etter trygderettsloven § 1 har Trygderetten ikke kompetanse til å behandle krav direkte i medhold av EØS-avtalen. Slik kompetanse er heller ikke gitt ved særlige lovbestemmelser*.")
The Authority notes that, in case TRR-2019-2736 (which was referred to the EFTA Court, see case E-13/20), the NIC seemed to consider that it *did* have jurisdiction to apply Article 36 EEA directly. That case, however, did not concern in-patient treatment, but unemployment benefits.

allegedly wrong in these cases. The Authority refers to paragraph 96 of its second supplementary letter of formal notice and the associated footnotes which together provide examples of the issues.

4.3.3 Conclusion

107. In conclusion, the Authority maintains that the appeals and procedural structure under Section 7-2 PRA and Sections 7 and 8 PR prevents and/or discourages the relevant appeals bodies and Helfo from applying a legal test which complies with the requirements of Article 20 of Regulation 883/2004 and/or Article 36 EEA.

108. Further, in practice, the Authority maintains that none of the bodies mentioned above apply Article 20 of Regulation 883/2004 or Article 36 EEA correctly or at all.[120]

109. The Authority considers that this 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, and that Norway has therefore, 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.

4.4 Legal Certainty

110. In its reply to the Authority's second supplementary letter of formal notice, the Norwegian Government has *inter alia* argued that it is not contrary to EEA law to maintain in force different national routes to in-patient treatment in other EEA States *in addition* to the two routes that follow from Regulation 883/2004 and Directive 2011/24/EU.[121] Moreover, the Norwegian Government contends that "*it would also weaken patients' rights if Norway would be forced to remove patients' rights in accordance with Section 2-1b(5) PRA, c.f. PRA section 2-4a(2)(a).*"[122] The Authority however recalls that any such alternative routes must, at any rate, comply with EEA law, particularly when substantial numbers of patients are channelled in practice into the 'extra PRA system'.[123]

111. Having assessed the arguments provided by the Norwegian Government in its reply to the Authority's second supplementary letter of formal notice, the Authority maintains that, in light of the conclusions in Part 4.2 and 4.3 above, that, by *inter alia*:

- Failing to give full effect to Article 20 of Regulation 883/2004, and its conditions/requirements by ensuring that its provisions will prevail when in conflict with other provisions of the Norwegian legal order;

[120] This includes their duty to disapply national legislation which is contrary to EEA law (which duty applies to all organs of State, including administrative bodies): Case C-378/17 *Minister for Justice and Equality,* paragraph 38. See also E-6/12 *ESA v Norway*, paragraph 67.
[121] Reply of 8 July 2022, p. 10.
[122] *Idem* p. 11.
[123] The Norwegian Government does not appear to contest that substantial numbers of patient applications are first channelled into the 'PRA system': page 11 of the Reply of 8 July 2022 explains how procedures are in place to tell patients of other routes to healthcare abroad (namely the Article 20 Regulation 883/2004 route and reimbursement route under Article 36 EEA/the Patients' Rights Directive) once their applications under the PRA are denied. The fact that procedures are needed suggests that this issue affects a sizeable number of patients, which is also borne out by the complaints received by the Authority, as referred to at footnote 7 above.

- Maintaining in force several national routes to in-patient treatment in other EEA States contrary to or which do not reflect the requirements of Article 36 EEA and Article 20 of Regulation 883/2004, by maintaining in force provisions such as:
    - Section 2-4a(1)b PRA, which, by referring only to the Time-Limit Element and not also to the EET Element, incompletely reflects the rights available under Regulation 883/2004;
    - Section 2-4a(2)a PRA which, by conferring a right to treatment abroad only where there is no treatment offer in Norway or the healthcare abroad is documented to be *more* effective than the healthcare offered in Norway, fails to reflect the rights available to individuals under Article 36 EEA and Article 20 of Regulation 883/2004;
    - Section 2-1b(4) PRA and Section 6(3) PR, which, in their current form, do not permit patients to seek in-patient treatment abroad where national treatment is not available within a medically-justifiable time limit (in breach of the requirements of Article 36 EEA and Article 20 of Regulation 883/2004);

- Maintaining in force a multi-track complaints and appeals procedure with several institutions and bodies in which:
    - it is unclear which body or bodies has jurisdiction/competence to hear complaints in cases relating to rights under Article 20 of Regulation 883/2004;
    - where, in practice, none of the bodies apply primary or secondary EEA law correctly;

which makes it very difficult for the competent institutions and bodies to apply the correct rules, and which in combination makes it impossible or excessively difficult for patients to identify and understand their rights under EEA law, and to effectively enforce them, 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.[124]

The Rules are Not Sufficiently Clear

112. It is settled case-law that national rules which restrict fundamental freedoms must satisfy *inter alia* the principle of legal certainty.[125] This means that the rules must be sufficiently clear and precise, and that criteria for prior administrative approval must be objective, non-discriminatory and known in advance to concerned persons. 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,[126] and that it is therefore in breach of EEA law.

113. In this context, the EFTA Court stated the following concerning the criteria for authorisation and reimbursement of in-patient treatment abroad (emphasis added):

> "*In order to ensure that the rules and standards mentioned at paragraphs 46 and 47 above are indeed applied in a way which does not discriminate against suppliers of medical services established in other EEA States, the rules and standards* ***must be based on objective, non-discriminatory criteria****, see for comparison Case 238/82 Duphar [1984] ECR 523, at paragraph 20−21.*

[124] The principle of legal certainty is a general principle of EEA law, see e.g. E-9/11 *ESA v Norway*, paragraph 99.

[125] Case E-9/11 *EFTA Surveillance Authority v The Kingdom of Norway* [2012] EFTA Ct. Rep. 442, paragraphs 99-100 and the case-law cited therein.

[126] Case C-318/10 *SIAT*, EU:C:2012:415, paragraphs 57-59 and the case-law cited therein. See also E-9/11 *ESA v Norway*, paragraphs 99-101.

> *Furthermore,* ***the criteria must be known in advance, in such a way as to circumscribe the exercise of the national authorities' discretion, so that this discretion is not used arbitrarily. Such an administrative scheme must likewise be based on a procedural system which is easily accessible and capable of ensuring that a request for authorisation will be dealt with objectively and impartially within a reasonable time. Further, refusals to grant authorisation must be capable of being challenged in judicial or quasi-judicial proceedings*** *(see, for comparison, Smits and Peerbooms, at paragraph 90 and Watts, at paragraphs 115–116).*"[127]

114. By maintaining in force a multi-track system for authorising and accessing in-patient treatment abroad, of the type described in Parts 3.2.2 and 4.3 above, where the legislative provisions conferring or purporting to confer rights to treatment in other EEA States conflict with or are inconsistent with each other, Norway has made it excessively difficult for individuals and other actors to understand what their rights are and which criteria they must meet. Further, by splitting competence to handle complaints or appeals in relation to rights to in-patient treatment abroad between various appeals bodies, which are restricted by legislative provisions from applying in full the appropriate legal tests under Article 20 of Regulation 883/2004 and/or Article 36 EEA, Norway has made it excessively difficult or impossible for individuals and other concerned actors to enforce their EEA rights, in breach also of the principle of legal certainty.

Maintaining Conflicting Rules in force leads to Uncertainty

115. The Authority further recalls the settled case-law that maintaining in force national legislation, which is in itself incompatible with EEA law (even if the EEA State concerned in practice acts in accordance with EEA law), gives rise to an ambiguous state of affairs by maintaining, as regards those subject to the law who are concerned, a state of uncertainty as to the possibilities available to them of relying on EEA law.[128]

116. As set out above in Part 3.1 Norway asserts that it has properly incorporated Regulation 883/2009 via the Incorporating Regulation. *Even if* this incorporation had taken place correctly, by maintaining in force provisions such as Section 2-1b(4) PRA, Section 6(3) PR, and Section 2-4a(2)a PRA, Norway has failed to comply with the duty of EEA States not to incorporate regulations in a manner where conflicting laws remain in force:[129] by making these conflicting laws seem apparently applicable in parallel to the incorporated EEA law, it has created a state of legal uncertainty.

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[127] See E-11/07 and E-1/08 *Rindal and Slinning*, cited above, paragraph 48.

[128] See e.g. C-307/89 *Commission v France*, EU:C:1991:245, paragraphs 13-14.

[129] Norway itself seems to recognise that conflicting rules should be removed when implementing EEA regulations: in the "*Guide to good legal technique and preparation of laws",* issued by the Norwegian Ministry of Justice, it is stated under the headline "Implementation of regulations" that "*National implementation is neither required nor permitted, beyond adoption of necessary sanction rules and clean-up of conflicting national rules*." (emphasis added). See Lovteknikk og lovforberedelse – Veiledning om lov- og forskriftsarbeid p. 176 (available at https://www.regjeringen.no/globalassets/upload/kilde/jd/bro/2000/0003/ddd/pdfv/108138-lovteknikkboka.pdf). The Authority concurs that it is necessary to clean up conflicting national rules, as an expression of the requirements of EEA law. The Authority refers further to the report by the first Government-appointed Commission following the so-called "NAV case". The Authority recalls that, in the NAV case, Regulation 883/2004 was also intended to be incorporated by the Incorporating Regulation. The National Insurance Act (NIA) had provisions which conflicted with Regulation 883/2004, but Section 1-3 NIA referred to the possibility of making exceptions from the provisions of the NIA in e.g. another regulation. The Government-appointed Commission found in a first White Paper ("**the 2020 White Paper**") that *"This* [implementing technique] *creates considerable legal uncertainty, and it is not surprising that such a legislative technique is difficult to reconcile with both EEA law and general principles of good legislative technique."*, see NOU 2020:

117. In *Wahl*, the EFTA Court held:

> "[I]*t is essential that the legal situation resulting from national implementing measures be sufficiently precise and clear and that individuals be made fully aware of their rights so that, where appropriate, they may rely on them before the national courts. The latter condition is of particular importance where the directive in question is intended to confer rights on nationals of other EEA States, as is the case here, as those nationals may not be aware of provisions and principles of national law*."[130]

118. While the Court's judgment in *Wahl* concerned a directive, the Authority considers that the same applies with respect to regulations.

119. In this context, the CJEU has held that:

> *" the principle of legal certainty (…) requires, on the one hand, that the rules of law be clear and precise and, on the other, that their application be foreseeable for those subject to the law, in particular, where they may have adverse consequences for individuals and undertakings. Specifically, in order to meet the requirements of that principle, legislation must enable those concerned to know precisely the extent of the obligations imposed on them, and those persons must be able to ascertain unequivocally their rights and obligations and take steps accordingly.*
>
> *52 Furthermore, the Court has already recalled that the imperative of legal certainty must be observed all the more strictly in the case of rules liable to have financial consequence."*[131]

120. The above problems, in particular regarding Regulation 883/2004, are not isolated to this case. The Authority concluded in its reasoned opinion of 9 June 2021, in Case 84329 (concerning the exportability of sickness benefits in cash), that, by maintaining in force provisions which required benefit recipients to stay in Norway, and which were therefore in conflict with EEA law (*inter alia* Regulation 883/2004), Norway had, contrary to Articles 3 and 7 EEA, created a state of ambiguity and legal uncertainty which, *inter alia*, precluded the possibility for concerned individuals to rely on the rights provided for by Article 21(1) of Regulation 883/2004.[132]

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9 *Blindsonen*, p. 243. It concluded that *"Both* [EEA law and good legislative technique] *indicate that conflicts of rules one is aware of should be resolved through rule changes, not collision principles."* For reference the Authority notes, as described in Part 4.2 of this supplementary reasoned opinion, that the 'collision principles' raised in the NAV case (i.e. under Section 1-3 NIA), are not applicable in the present case, and therefore the situation in the present case is even more severe.

[130] Case E-15/12 *Jan Anfinn Wahl v the Icelandic State* [2013] EFTA Ct. Rep. 534, paragraph 52. See also Case E-3/15 *Liechtensteinische Gesellchaft für Umweltschutz v Municipality of Vaduz* [2015] EFTA Ct. Rep. 512, paragraph 33 (States must ensure the full application of directives not only in fact but also in law; and must abstain from the application of rules which are liable to jeopardise the achievement of the objectives pursued by a directive and, therefore, deprive it of its effectiveness).

[131] Case C-504/19 *Banco de Portugal, Fundo de Resolução, Novo Banco SA, Sucursal en España v VR*, EU:C:2021:335, paragraphs 51 and 52, with further references. See also e.g. Case C-183/14 *Radu Florin Salomie, Nicolae Vasile Oltean v Direcția Generală a Finanțelor Publice Cluj*, EU:C:2015:454, paragraph 32; C-171/18 *Safeway Ltd v Andrew Richard Newton, Safeway Pension Trustees Ltd,* EU:C:2019:839, paragraph 25.

[132] Doc No 1200885. The Authority is aware that the Norwegian Government is currently in the process of proposing legislation which may rectify the problems at issue in Case 84329. See e.g. the second White Paper ("**the 2021 White Paper**"), NOU 2021: 8 *Trygd over landegrensene* —

121. To take a specific example of how keeping conflicting laws in force can be a legal certainty problem in this case, the Authority also refers to the decision of the Appellate Body in Case N2017/8826 of 12 February 2018, see Part 4.3 above.[133] Under Section 7-2(1) and (2) PRA, it appears clear that the Appellate Body was not empowered to apply Regulation 883/2004. Yet it is also clear that the Appellate Body, as a matter of Norwegian law, would have been empowered to (and presumably required to) apply Article 36 EEA, which could have led to a favourable result for the complainant. As the competent body in the matter, the Appellate Body was apparently not aware of this and chose to reject the EEA law-based arguments of the complainant without engaging with them.[134] To the Authority, this demonstrates the fundamental uncertainty that permeates Norwegian law in this area.

Gjennomføring og synliggjøring av Norges trygdekoordineringsforpliktelser (available at https://www.regjeringen.no/no/dokumenter/nou-2021-8/id2860696/).
The Authority welcomes that initiative, but notes that the scope of that work appears not to include in-patient treatment: "*The parts of Norwegian legislation and international agreements that deal with health and care services under the Ministry of Health and Care Services' area of responsibility are not included in the committee's mandate*." See Section 1.3 of the 2021 White Paper, which sets out its mandate.
Further and for the sake of good order, it should be mentioned that the 'exception argument' (or incorporation route), raised by Norway in its reply of 9 September 2021 to the Authority's reasoned opinion in Case 84329, does not solve the problems with how Regulation 883/2004 has been implemented – whether in that case or the present. In that reply, Norway asserted: "*there is a relevant difference between cases where national law correctly interpreted is contrary to EEA law and must be set aside on the basis of general rules on conflicting provisions (e.g. the Norwegian EEA Act Section 2), and cases where provisions in national legislation explicitly provides for exceptions or derogations in supplementary regulations (e.g. Section 1-3 [National Insurance Act*])." The Authority disagrees. While Section 1(3) of the Incorporating Regulation provides that the provisions of the Incorporating Regulation (and therefore Regulation 883/2004) shall prevail in case of conflict with the NIA, Section 2 of the Norwegian EEA Act provides, on the contrary, that regulations shall only prevail in case of conflict with a *later* act. The NIA dates from 1997, and the Incorporating Regulation from 2012, thus according to Section 2 of the Norwegian EEA Act, the NIA will prevail in case of conflict with the Incorporating Regulation (and Regulation 883/2004). Thus, Section 1(3) of the Incorporating Regulation and Section 2 of the Norwegian EEA Act are at odds and result in different conflict of law outcomes. Norway argues that this inconsistency is resolved because Section 1-3 NIA provides that the King in Council may make exceptions to the provisions of the law (thus presumably including to the Norwegian EEA Act itself). Such an incorporation mechanism would appear highly circular, and the Authority questions whether such a mechanism can ever be effective. Even if however this circularity is overlooked, the Authority considers that the sheer complexity of this incorporation mechanism (two conflicting conflict of law provisions are purportedly resolved by a further exception) means that it cannot satisfy the requirements of legal certainty. Rules, especially such fundamental ones, must be sufficiently clear and precise so that individuals know precisely the extent of the obligations imposed on them, and can ascertain unequivocally their rights and obligations and take steps accordingly (see the case-law cited above).
Further, an important component of legal certainty is that the rules are also clear *in practice* for those who interpret and apply them. On this, whether Norway's incorporation mechanism was sufficiently clear and certain *was* tested in practice in Norwegian social security practice and jurisprudence at all levels for two and a half decades from 1994. During this time, not one competent Norwegian body deduced that the incorporation 'exception' mechanism should have been applied in the manner described by Norway. No such body disapplied the unlawful stay requirements as set out in the NIA and instead granted individuals their EEA law rights. This unfortunate outcome serves to confirm that such provisions are lacking in legal certainty, also in practice.

[133] Doc Nos 1220168 (original) (Annex 1) and 1220156 (translation), (Annex 2), see footnote 102 above.

[134] See e.g. also Appellate Body decisions UKN-2011-58, UKN-2011-97 and UKN-2022-542, where, instead of applying Article 36 EEA as it must, the Appellate Body simply rejects the complaints and refers the patients to Helfo.

122. The Authority considers that ensuring legal certainty is particularly important when people in vulnerable situations are involved, such as individuals seeking access to necessary healthcare. Such individuals may be in particularly precarious situations due to their (often long-lasting and serious) health issues, which cannot be effectively alleviated in the national system and which may involve very high costs.[135]

123. Finally, the European Court of Human Rights has similarly emphasised the importance of legal certainty, which it considers relates to "*the quality of the law*".[136] It has held that the principle of legal certainty was not complied with when a domestic statue was "*shown to have been vague enough to cause confusion even amongst the competent State authorities*".[137]

124. To the Authority, it seems clear that the Appellate Body displayed precisely this kind of confusion in its decision in case N2017/8826 of 12 February 2018, when it was asked to apply EEA law, (see Part 4.3.2 and footnote 102 above). This indicates that Norwegian law in this area falls foul of the quality of law requirement inherent in the principle of legal certainty.

125. Therefore, in light of the above, the Authority concludes that the Norwegian Government has created 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, and which makes it impossible or excessively difficult for patients to identify, understand, and effectively enforce their rights under EEA law. In so doing, 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.

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:

[135] See Case C-504/19 *Banco de Portugal,* referred to at footnote 131 above, paragraphs 51-52. The Authority observes that Section 14.4.4 of the recent 2021 White Paper, which dealt with Norway's international obligations in the field of social security, expressed a similar view, see footnote 120 above.
[136] *Nasrulloyev v. Russia*, Application no. 656/06, paragraph 77.
[137] *Jėčius v. Lithuania*, Application no. 34578/97, paragraph 59.

- 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.

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, the EFTA Surveillance Authority requires Norway to take the measures necessary to comply with this reasoned opinion within *two months* of its receipt.

Done at Brussels,

For the EFTA Surveillance Authority

Arne Røksund President	Stefan Barriga Responsible College Member	Árni Páll Árnason College Member

Melpo-Menie Joséphidès
Countersigning as Director,
Legal and Executive Affairs

This document has been electronically authenticated by Arne Roeksund, Melpo-Menie Josephides.