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EFTA SURVEILLANCE AUTHORITY

# 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 criteria for access to in-patient treatment in other EEA States, in breach of Article 20 of Regulation 883/2004, Directive 2011/24 and Article 36 EEA**

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## 1 Introduction and correspondence

1. The present case deals with the general rules and the system in place in Norway concerning access to hospital treatment in other EEA States (hereinafter referred to, alternatively, as "hospital treatment" or "in-patient treatment").[1]

2. By several letters dated 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), respectively, 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 addition, the Authority received several other letters and e-mails from patients in Norway with similar problems to those outlined by the complainants when requesting authorisation or reimbursement for medical treatment in a hospital in another EEA State (hereinafter referred to, alternatively, as "in another EEA State", "in other EEA States" or simply "abroad").

4. In light of the above, the Authority decided to scrutinize the rules and procedures in Norway in general[2] and to open the present general own-initiative case.

5. Having examined the legislation concerning access to in-patient treatment in other EEA States in Norway, as brought to the Authority's attention by the aforementioned complaints, the Authority reached the conclusion that the criteria in the Norwegian legislation concerning access to in-patient treatment abroad were not in line with the EEA Agreement, in particular with Article 20 of Regulation 883/2004 on social security coordination[3] and Article 36 EEA. In light of this, the Authority sent a letter of formal notice to Norway concerning the subject matter on 14 May 2014 (Doc No 692126, hereinafter referred to as "**the initial letter of formal notice**"), which presented the aforementioned conclusion to Norway.

6. The initial letter of formal notice concerned two main aspects. The first aspect related to the right to treatment abroad in cases where it is clear that the medically justifiable deadline for treatment set pursuant to the Norwegian legislation could not be adhered to. The second aspect concerned the conditions for seeking medical treatment abroad when the due treatment was not provided within the medically justifiable deadline set nationally.

7. By letter dated 18 August 2014 (hereinafter referred to as "**the reply to the initial letter of formal notice**"),[4] Norway replied to the initial letter of formal notice and

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[1] Whereas the EFTA Surveillance Authority ("the Authority") has received several complaints concerning the subject matter, the Authority's concerns regard the Norwegian rules in place *as such*.

[2] The cases were discussed at the package meetings in Norway from 2009 to 2013, in order to exchange information with the Norwegian Government and to understand the general functioning of the Norwegian authorisation/reimbursement mechanism for in-patient treatment received in another EEA State (abroad). Most recently, the Authority sent a follow-up letter to the package meeting in Norway on 21 November 2013 on 9 December 2013 (Doc No 691859). The Norwegian Government replied to this letter by letter dated 15 January 2014 (Doc No 695845, your ref.: 13/4326).

[3] The Act referred to at point 1 of Chapter I of Annex VI to the EEA Agreement (*Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems*), as adapted to the EEA Agreement by Protocol 1 thereto.

[4] Doc No 718533, your ref.: 12/5292.

stated that it would resolve the deadline issue by extending the reimbursement scheme under *Regulation No 1466/2010 on reimbursement of health care services received in another EEA State* (hereinafter referred to as "**the Reimbursement Regulation**"),[5] to in-patient treatment (previously, the Regulation was only applicable to out-patient treatment). Thus, the legislation would no longer prevent concerned patients from turning directly to another EEA medical service provider to receive the in-patient treatment to which they would be entitled to under the Norwegian system, should they wish to go abroad without the assistance of the Norwegian Health Economics Administration, HELFO.[6]

8. The case was discussed during the package meeting in October 2014.

9. Norway subsequently informed the Authority that the abovementioned legislative change had been enacted and entered into force on 1 March 2015.[7]

10. Despite the adoption of the changes brought by the new legislation, the Authority considered that, in several respects, the Norwegian criteria for access to in-patient treatment abroad were still not in line with EEA law.

11. Additionally, the Patients' Rights Directive 2011/24[8] ("the Patients' Rights Directive", "Directive 2011/24" or "the Directive") entered into force for the EEA EFTA States on 1 September 2015, codifying and enhancing EEA citizens' rights to go to another EEA State for treatment and get reimbursed for it.

12. The case was discussed during the package meeting in Norway in November 2015.

13. Subsequently, the Authority issued a supplementary letter of formal notice to Norway on 3 February 2016 (Doc No 772442) in which the Authority's outstanding issues with the Norwegian legislation were outlined, in light also of the Patients' Rights Directive, which had not entered into force at the time of the initial letter of formal notice. The Norwegian Government replied to this letter on 3 May 2016 (Doc No 803414).

14. The case was further discussed at the package meeting in Norway in November 2016.

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[5] Forskrift av 22. November 2010 nr. 1466 om stønad til helsehjelp mottatt i annet EØS-land.

[6] Helfo is a sub-ordinate institution directly linked to the Norwegian Directorate of Health. Helfo is responsible for direct payments to various health service providers, individual reimbursement for certain medicines, dental services and health services abroad. More information about Helfo is available on its webpage: https://helfo.no/english

[7] Doc No 748228, email dated 9 February 2015.

[8] The Act referred to at point 2 of Annex X to the EEA Agreement (*Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare*), as adapted to the EEA Agreement by Protocol 1 thereto.

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## 2 Relevant national law

### 2.1 Entitlement to in-patient medical treatment in Norway

15. Section 2-1b(2) Act of 2 July 1999 No. 63 relating to Patients' Rights ("**the Patients' Rights Act**", "**the PRA**") provides:[9]

> "*The patient is entitled to receive necessary health care from the specialist health service. [...] The specialist health service shall set a time limit within which, when justified for medical reasons, a patient with such a right shall receive necessary health care. [...]*"[10]

16. Section 2 of Regulation of 1 December 2000 no. 1208 *concerning prioritisation of health care services and the right to treatment abroad* ("**the Prioritisation Regulation**", "**PR**") further provides:[11]

> "*The patient is entitled to receive necessary health care from the specialist health service pursuant to Section 2-1b [(2) PRA] when:*
>
> *a) The patient, with the exception mentioned in Section 3 second paragraph, has an expected benefit of the health care and*
> *b) The expected costs are reasonable, taking due account to the effect of the measure.*
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> *By "expected benefit of the health care" is meant that there is good[/solid] documentation that an active medical or interdisciplinary specialised treatment can improve the patient's life expectancy or life quality with a certain duration, that the condition may worsen without treatment or that treatment options are forfeited by postponing the treatment.*"

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[9] Unofficial translation by the Authority.

[10] The provision has been amended since the supplementary letter of formal notice. However, it remains substantively the same as regards the necessity assessment. The new provision reads: "*The patient is entitled to receive necessary health care from the specialist health service. The specialist health service shall, within the assessment period pursuant to 2-2(1) PRA, set a time limit within which the patient at the latest shall be entitled to received necessary health care. The deadline should be set in accordance with what professional responsibility would require. [...]*" The preparatory works to the new provision, Prop 118L (2012-2013) on page 102, provide for the continuation of the cost/benefit assessment as a basis for right to medical treatment. The new wording in this provision does, however, bring about some changes relevant to patients who may previously not have been entitled to medical treatment within a specific deadline, see Section 2.3 of this reasoned opinion.

[11] Unofficial translation by the Authority. Section 2 of the PR was amended by Regulation of 10 April 2015 no 339, and consequently shortened. However, the substantive content has not changed. The entitlement to health care is still tied to an expected benefit which can be derived from the health care, and that the estimated costs will be reasonable, taking into account the effect of the health care.

## 2.2 Entitlement to in-patient medical treatment abroad

17. Provided that the necessity condition in Section 2-1b(2) PRA[12] is met, Section 2-1b(4) and (5) PRA foresees two alternative situations in which patients could be entitled to treatment abroad. The first only becomes active *following the expiry of the time limit* set pursuant to Section 2-1b(2), entitling the patient to treatment abroad or with a private service provider on specific conditions. The second concerns the right to medical treatment abroad if there are *no adequate medical services in the realm*, and is also applicable *prior* to the expiry of the aforementioned time limit:[13]

> *"[4.] If the regional health enterprise has not ensured that a patient who is entitled to necessary health care from the specialist health service receives such care within the time limit fixed pursuant to the second paragraph, the patient has the right to receive necessary health care immediately, if necessary from a private service provider or service provider outside the realm.*
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> *[5.] If the regional health enterprise cannot provide health care for a patient who is entitled to necessary health care, because there are no adequate medical services in the realm, the patient has the right to receive necessary health care from a service provider outside Norway within the time limit fixed pursuant to the second paragraph."*

### *2.2.1 Entitlement to in-patient medical treatment abroad due to passed deadline for treatment (Section 2-1b(4) PRA)*

18. If the medically set deadline for treatment has passed and the patient falls under Section 2-1b(4) PRA, **Section 6(2)-(3)of the PR** provides further criteria for the patient's access to in-patient treatment abroad:[14]

> *"If the specialist health services can not provide the patient with a commencement date for the medical assessments/treatment which is before the deadline for when necessary medical care at the latest should be provided, or the appointment time must be amended so that the deadline cannot be met, or if the deadline is exceeded, the health specialist shall immediately contact HELFO, cf. Section 2-1b(4). If the deadline is exceeded the patient can also contact HELFO.*
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> *HELFO shall promptly provide the patient a service from public service or, if necessary, from a private service in the kingdom or, if necessary, abroad. The patient cannot freely choose the service provider."*

19. Section 6 of the PR is to be amended by Regulation of 10 April 2015 no 339, however, the substantive content of the provision remains the same.[15]

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[12] See Section 2 PR.
[13] Unofficial translation by the Authority, emphasis added.
[14] Unofficial translation by the Authority, emphasis added.
[15] The new legislation also foresees that the patient or the specialist health care services should contact HELFO if the medically justifiable deadline for treatment cannot be adhered to. HELFO shall then ensure that a treatment offer is provided by a public service provider or if necessary from a private service provider or if necessary abroad, and the patient cannot freely choose the service provider.

*2.2.2 Entitlement to in-patient medical treatment abroad due to lack of adequate medical services (Section 2-1b(5) PRA)*

20. If the patient is applying for treatment abroad or reimbursement thereof due to lack of adequate medical services in Norway and the patient falls under Section 2-1b(5) PRA, further criteria are specified in **Section 3 of the PR**:[16]

> *"Health care abroad due to lacking competence in Norway*
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> *A patient who is entitled to necessary health care, but who cannot get health care because the treatment cannot be performed properly in Norway according to an accepted method, is entitled to medical care abroad, see the [PRA] § 2-1 fifth paragraph [now Section 2-1b(5)]. It is a prerequisite [for this provision to apply] 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 satisfies the requirements of § 2 [PR].*
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> *[...]*
>
> *Insufficient capacity in specialist health services does not render patients eligible for treatment abroad under this provision. Right to treatment does not include shipment/sending of laboratory samples for analysis with a foreign service provider if it is not part of treatment abroad."*

21. Section 3 of the PR has been amended by Regulation of 10 April 2015 no 339, but the substance of this provision remains unchanged.

22. Concerning the more precise content of the right to treatment abroad for patients encompassed by Section 2-1b(5) PRA, the preparatory works state:[17]

> *"By adding [Section 2-1b(5)],[18] it is proposed to determine that the so-called "rights patients", i.e. patients who have a right to necessary health care under the second paragraph, shall be entitled to necessary medical care abroad if there is no adequate medical treatment in Norway. In practice this will particularly apply to those patients who, under applicable law, may apply for a contribution to hospital treatment abroad under the National Insurance Act § 5-22, second paragraph, when the necessary competence in Norway is lacking. The patient will not be entitled to necessary medical treatment abroad if there is a recognised treatment option in Norway, even if a possibly more advanced treatment option might have been developed abroad. The fact that there is a lack of capacity and long waiting time for medical treatment, will not make the patient entitled to necessary medical care abroad under this paragraph.*

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[16] Unofficial translation by the Authority.

[17] The most recent preparatory works, namely Prop. 118L (2012-2013), do not mention this provision at all since it was not amended. However, the other relevant preparatory works, namely Prop. 91 L (2010-2011), refer to Ot.prp nr.63 (2002-2003) *Om lov om endringer i lov 2. juli 1999 nr. 63 om pasientrettigheter (pasientrettighetsloven) m.m.*, which provides the above cited passage as guidance to the provision on page 61. Unofficial translation by the Authority, emphasis added.

[18] Numbering changed with amending Act, substance remained unchanged, see the preparatory works *Prop.91 L (2010-2011)*, Chapter 48.

*The proposal means that the above-mentioned patient groups have a legal entitlement/right to treatment abroad. That is to say that the patients' needs will be assessed by the specialist health services, such as a hospital, not by the Social Security, which is the case under the current arrangements. Patients do not have to obtain a statement from the Norwegian regional hospitals condoning this, as the current regulations require.*"

23. *Rundskriv IS-12/2004 om lov om pasientrettigheter* previously provided:[19]

> *"A basic requirement for contributions to treatment abroad has been a lack of medical competence in Norwegian hospitals. If treatment can be performed properly in Norway according to accepted methods, the Social Security Administration[20] has not been allowed to pay contributions [to the treatment abroad]. This limitation will be continued under the present legislation. The general rule is that one should utilize the treatment found in Norway, even though a possibly more advanced treatment may have been developed abroad. This applies even if the patient wants treatment performed at a foreign institution for a method that is not used in Norway."*

24. The Authority notes that a new administrative circular has replaced *Rundskriv IS-12/2004*.[21] The currently applicable administrative circular, IS-8/2015 provides (emphasis added):

> "*Pursuant to the [Section 2-1b(5) PRA] patients have the right to necessary medical care abroad if no adequate medical treatment exists in Norway. [...] The Prioritisation Regulation contains detailed provisions on the right to health care abroad due to lack of adequate treatment in Norway. If the patient can be provided with adequate health care in Norway, the patient will not have a right to receive the reimbursement of costs of health care in other States pursuant to this provision. This applies even if a more advanced treatment offer could have been developed abroad. An individual assessment of the patient's need for health care is called for when deciding whether there is adequate treatment in Norway. The evaluation shall take into consideration international, scientific evidence on the treatment of the medical indication.*
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> *[...]*
>
> *The specialist health services shall set a deadline for when treatment abroad at the latest is to be provided so that these patients have a similarly clear legal situation as patients who receive health care in Norway, cf. Section 4 of the Prioritisation Regulation. If the regional health undertaking has not ensured that a patient which is entitled to necessary specialist health care is given the necessary health care*

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[19] *Rundskriv IS-12/2004 om lov om pasientrettigheter*, page 54, which was previously accessible under the following hyperlink: http://helsedirektoratet.no/publikasjoner/lov-om-pasientrettigheter/Publikasjoner/lov-om-pasientrettigheter.pdf. Unofficial translation by the Authority.

[20] The Authority notes that this is no longer the competent body. Currently the regional health enterprises' offices for treatment abroad deal with such applications, whose decision may subsequently be appealed to the AB.

[21] *Rundskriv IS-8/2015* on page 24-25, accessible under the following hyperlink: https://helsedirektoratet no/Lists/Publikasjoner/Attachments/945/IS-%208%202015%20Rundskrivpasientogbrukerrettighetsloven.pdf, updated to include the cited amendment in May-August 2016.

*within the prescribed period, the patient has the right to necessary medical care without delay, if necessary from a private service provider or service outside the realm, see Section 2-1, fourth paragraph b of the PR. It is HELFO which in such cases find a treatment offer for the patient.*

*Complaints concerning a lack of fulfilment of obligations under the fifth subparagraph [of 2-1(b)] shall be assessed by the Norwegian Appellate Body for Treatment Abroad [("**the AB**")], cf. § 7-2 second paragraph and Chapter II of the Prioritisation Regulation.*

*In cases where the patient is offered adequate health care in Norway, but wants to receive corresponding health care from a provider in another EEA State, the patient can apply for reimbursement of treatment costs to Helfo pursuant to Regulation of 22 November 2010 No 1466 relating to benefits for healthcare received in another EEA State.*"

## 2.3 Legislative amendments to the Patients' Rights Act, the Reimbursement Regulation and the Prioritisation Regulation

25. The Authority notes that Norway has adopted legislative changes to the Patients' Rights Act and other related Acts[22] with a view to implementing the Patients' Rights Directive.

26. These legislative changes are certainly welcome, and they have addressed one of the main concerns highlighted by the Authority in its initial letter of formal notice, namely a big part of the reimbursement issue under Article 36 EEA.[23]

27. The Authority observes that these legislative changes *inter alia* also entail that Section 2-1b(2) PRA now provides that patients who may previously not have been entitled to medical treatment from the specialist health services within a specific deadline following the prescribed necessity assessment under this provision, now have the explicit right to medically justifiable deadline to be set for treatment.[24] Additional rights are further awarded to patients, for example in the new Section 2-2 PRA, as regards *inter alia* maximum evaluation periods of referrals to the specialist health services.

28. Furthermore, a new reimbursement arrangement (*refusjonsordning*) has been enacted regarding in-patient treatment in other EEA States by amendments to the Reimbursement Regulation, which entered into force on 1 March 2015 and extended an arrangement for reimbursement of medical treatment in another EEA State to in-patient treatment. Pursuant to these legislative changes, patients may also go abroad independently of the authorisation route, provided that they would be entitled to in-patient treatment nationally, and obtain subsequent reimbursement of the relevant costs. The reimbursement is subject to the conditions set out in the Reimbursement Regulation.

29. Section 2(1) of the Reimbursement Regulation provides:

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[22] Act of 21 June 2013 no 79.

[23] In amending Sections 2 and 7 of the national Reimbursement Regulation.

[24] See pages 42, 47 and 68 of Prop. 118 L(2012-2013); see also Section 4.2 of the initial letter of formal notice.

> *"Reimbursement is granted only for health care which the [social security] member would have received benefits for according to the Social Security Act or which would have been paid for in the public health and care services if the relevant health care was received in Norway."*

30. The health care refunded pursuant to the Reimbursement Regulation include health services which would have been provided fully or partially without cost pursuant to the Specialist Health Services Act, which regulates, *inter alia*, in-patient treatment, see Section 3(1)(d). Following the aforementioned amendments to the Reimbursement Regulation, the explicit exemption for reimbursement of medical treatment, previously found in Section 3(2) of the Reimbursement Regulation, in cases where patients spend the night in the treatment institution, was repealed.

    Furthermore, the Norwegian Government added a provision in Section 7(9) of the Reimbursement Regulation, clarifying that patients entitled to authorisation under Regulation 883/2004, who for some reason did not receive it at all or in time, are entitled to a refund as if such authorisation had been given duly or in time. This is certainly a welcome change, however, for legal certainty purposes, Section 6 of the Prioritisation Regulation should be amended accordingly, since its content seems to be in contradiction to the Reimbursement Regulation, and in breach of Norway's obligations under Article 20 of Regulation 883/2004 and/or Article 36 EEA and/or Articles 7(6), 7(9)-7(11), 8(1), 8(3)-(5) and 9(1) of Directive 2011/24.

## 3 Relevant EEA law

### 3.1 Regulation 883/2004 and Article 36 EEA

31. As regards the applicable EEA law, namely Article 36 and the Act referred to at point 1 and 2 of Chapter I of Annex VI to the EEA Agreement (Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems ("**Regulation 883/2004**")), reference is made to Section 3 of the Authority's initial letter of formal notice, since there have been no substantive changes in the relevant legislation.

32. The Patients' Rights Directive entered into force in the EEA on 1 August 2015, and the obligations therein will be briefly reiterated in this Section.

### 3.2 The Patients' Rights Directive No 2011/24

33. The Patients' Rights Directive was incorporated into the EEA Agreement by Joint Committee Decision No 153/2014, which entered into force on 1 August 2015.

34. Article 7 of the Patients' Rights Directive provides (emphasis added):

> *"1. Without prejudice to Regulation (EC) No 883/2004 and subject to the provisions of Articles 8 and 9, the Member State of affiliation shall ensure the costs incurred by an insured person who receives cross-border healthcare are reimbursed, if the healthcare in question is among the benefits to which the insured person is entitled in the Member State of affiliation.*

*[...]*

*6. For the purposes of paragraph 4,* ***Member States shall have a transparent mechanism for calculation of costs of cross-border healthcare that are to be reimbursed to the insured person by the Member State of affiliation.*** *This mechanism shall be based on objective, non-discriminatory criteria known in advance and applied at the relevant (local, regional or national) administrative level.*

*7.* ***The Member State of affiliation may impose on an insured person seeking reimbursement of the costs of cross-border healthcare****, including healthcare received through means of telemedicine,* ***the same conditions, criteria of eligibility and regulatory and administrative formalities,*** *whether set at a local, regional or national level, as it would impose if this healthcare were provided in its territory. This may include an assessment by a health professional or healthcare administrator providing services for the statutory social security system or national health system of the Member State of affiliation, such as the general practitioner or primary care practitioner with whom the patient is registered, if this is necessary for determining the individual patient's entitlement to healthcare.* ***However, no conditions, criteria of eligibility and regulatory and administrative formalities imposed according to this paragraph may be discriminatory or constitute an obstacle to the free movement of patients, services or goods****, unless it is objectively justified by planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources.*

*8. The Member State of affiliation shall not make the reimbursement of costs of cross-border healthcare subject to prior authorisation except in the cases set out in Article 8.*

*9. The Member State of affiliation* ***may limit the application of the rules on reimbursement for cross-border healthcare based on overriding reasons of general interest,*** *such as planning requirements relating to the aim of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources.*

*10. Notwithstanding paragraph 9, Member States shall ensure that the cross-border healthcare for which a prior authorisation has been granted is reimbursed in accordance with the authorisation.*

*11.* ***The decision to limit the application of this Article pursuant to paragraph 9 shall be restricted to what is necessary and proportionate, and may not constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of goods, persons or services****. Member States shall notify the Commission of any decisions to limit reimbursement on the grounds stated in paragraph 9.*"

35. Article 8 of the Patients' Rights Directive provides (emphasis added):

*"1. The Member State of affiliation may provide for a system of prior authorisation for reimbursement of costs of cross-border healthcare, in accordance with this Article and Article 9. The system of prior authorisation, including the criteria and the application of those criteria, and individual decisions of refusal to grant prior authorisation, shall be restricted to what is necessary and proportionate to the objective to be achieved, and may not constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of patients.*

*[...]*

*3.* ***With regard to requests for prior authorisation made by an insured person with a view to receiving cross-border healthcare, the Member State of affiliation shall ascertain whether the conditions laid down in Regulation (EC) No 883/2004 have been met. Where those conditions are met, the prior authorisation shall be granted pursuant to that Regulation unless the patient requests otherwise.***

*4. When a patient affected, or suspected of being affected, by a rare disease applies for prior authorisation, a clinical evaluation may be carried out by experts in that field. If no experts can be found within the Member State of affiliation or if the expert's opinion is inconclusive, the Member State of affiliation may request scientific advice.*

*5. Without prejudice to points (a) to (c) of paragraph 6,* ***the Member State of affiliation may not refuse to grant prior authorisation when the patient is entitled to the healthcare in question in accordance with Article 7, and when this healthcare cannot be provided on its territory within a time limit which is medically justifiable****, based on an objective medical assessment of the patient's medical condition, the history and probable course of the patient's illness, the degree of the patient's pain and/or the nature of the patient's disability at the time when the request for authorisation was made or renewed.*

*6. The Member State of affiliation may refuse to grant prior authorisation for the following reasons:*

*(a) the patient will, according to a clinical evaluation, be exposed with reasonable certainty to a patient-safety risk that cannot be regarded as acceptable, taking into account the potential benefit for the patient of the sought cross-border healthcare;*

*(b) the general public will be exposed with reasonable certainty to a substantial safety hazard as a result of the cross-border healthcare in question;*

*(c) this healthcare is to be provided by a healthcare provider that raises serious and specific concerns relating to the respect of standards and guidelines on quality of care and patient safety, including provisions on supervision, whether these standards and guidelines are laid down by laws and regulations or through accreditation systems established by the Member State of treatment;*

*(d) this healthcare can be provided on its territory within a time limit which is medically justifiable, taking into account the current state of health and the probable course of the illness of each patient concerned.*

*7. The Member State of affiliation shall make publicly available which healthcare is subject to prior authorisation for the purposes of this Directive, as well as all relevant information on the system of prior authorisation.*

36. Article 9 of the Patients' Rights Directive provides (emphasis added):

"*1. **The Member State of affiliation shall ensure that administrative procedures regarding the use of cross-border healthcare and reimbursement of costs of healthcare incurred in another Member State are based on objective, non-discriminatory criteria** which are necessary and proportionate to the objective to be achieved.*

*2. Any administrative procedure of the kind referred to in paragraph 1 shall be easily accessible and information relating to such a procedure shall be made publicly available at the appropriate level. Such a procedure shall be capable of ensuring that requests are dealt with objectively and impartially.*

*3. Member States shall set out reasonable periods of time within which requests for cross-border healthcare must be dealt with and make them public in advance. When considering a request for cross-border healthcare, Member States shall take into account:*

*(a) the specific medical condition;*

*(b) the urgency and individual circumstances.*

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

*5. This Directive is without prejudice to Member States' right to offer patients a voluntary system of prior notification whereby, in return for such notification, the patient receives a written confirmation of the amount to be reimbursed on the basis of an estimate. This estimate shall take into account the patient's clinical case, specifying the medical procedures likely to apply.*

*Member States may choose to apply the mechanisms of financial compensation between the competent institutions as provided for by Regulation (EC) No 883/2004. Where a Member State of affiliation does not apply such mechanisms, it shall ensure that patients receive reimbursement without undue delay.*"

## 4 The Authority's Assessment

### 4.1 Introduction

37. Despite the legislative changes to national law addressed in Section 2.3 of the present reasoned opinion, which remedied part of the breach identified in the initial and supplementary letters of formal notice, and despite the Norwegian Government's replies to these letters and subsequent follow-up thereof, important elements remain to

be addressed by the Norwegian Government, which are, in the Authority's opinion, still not in line with EEA law.

38. The Authority's remaining concerns relate to four issues.

39. First, the necessity test, pursuant to Section 2-1b(2) PRA and 2 PR, which determine whether a patient is entitled to in-patient treatment at all, and thus subsequently also to in-patient treatment abroad, does not ensure that what is recognised by international medical science is taken into account when evaluating the efficiency of the in-patient treatment, which is not in line with Article 20 of Regulation 883/2004 and/or Article 36 EEA, and/or Articles 7(6), 7(9)-(11), 8(1), 8(3)-(5) and 9(1) of Directive 2011/24. This issue will be further addressed in Section 4.2.

40. Second, Section 2-1b(5) of the Patients' Rights Act and Section 3 of the Prioritisation Regulation along with relevant preparatory works and guidelines, provides for a right to get in-patient treatment abroad authorised (but in some cases this has also been reimbursed *ex post*), in cases where the Norwegian medical services are not considered to be "adequate," or where there is a lack of competence. The introduction of such a prerequisite is not in line with EEA law. By maintaining in force legislation, such as Section 2-1b(5) PRA and Section 3 PR, which, as illustrated also by relevant administrative practice, does not adequately ensure a case-by-case assessment of whether equally effective treatment can be provided to the individual patient within a medically justifiable deadline nationally, in relation to authorisation or reimbursement applications for medical in-patient treatment in other EEA States, Norway has failed to fulfil its obligations under Article 20 of Regulation 883/2004 and/or Article 36 EEA and/or Articles 7(6), 7(9)-7(11), 8(1), 8(3)-(5) and 9(1) of Directive 2011/24. This issue will be further addressed in Section 4.3.

    Third, there is still a requirement in Section 6 PR, according to which the patient must contact HELFO upon the expiry of the set deadline in order to find a treatment offer, with no exception provided therein for situations in which the patient would have been entitled to an authorisation under Regulation 883/2004, but for some reason did not obtain it at all or in time. This provision does not contain a reference to Section 7(9) of the Reimbursement Regulation in order to clarify that in such cases, reimbursement can nevertheless be provided as if an authorisation had been granted. Similarly, the patient is entitled to go directly abroad and be reimbursed under Article 36 EEA if the deadline for treatment has expired. The Authority is therefore of the view that this provision renders the national legal framework unclear for patients seeking in-patient treatment under Article 36 EEA. The provision seemingly precludes patients from actually realizing the right granted to them under the CJEU's case law in two respects, namely (i) full reimbursement in the event that he or she would be entitled to an authorisation under Regulation 883/2004, but for some reason did not get it at all or in time (despite Section 7(9) of the Reimbursement Regulation providing for the opposite), and (ii) reimbursement under Article 36 EEA, if the treatment cannot be provided within the set deadline. This issue also renders Norway in breach of Articles 7(6), 7(9)-7(11), 8(1), 8(3)-(5) and 9(1) of Directive 2011/24, and will be further addressed in Section 4.4.

41. Fourth, there are legal certainty concerns as regards the Norwegian criteria on access to in-patient treatment abroad. By failing to ensure that the criteria applicable to applications for authorisation or reimbursement of in-patient medical treatment abroad in Norway, such as Section 2-1b(2) PRA and Section 2 PR, Section 3 PR and Section

2-1b(5) PR, as well as Section 6 PR, meet the requirements established in the aforecited case law concerning objectivity, clarity, transparency and precision, as required also by Articles 7(6), 7(9)-7(11), 8(1), 8(3)-(5) and 9(1) of Directive 2011/24, Norway has failed to fulfil its obligations under that Directive, and/or under Article 36 EEA and/or Article 20 of Regulation 883/2004. This issue will be further addressed in Section 4.5.

42. Following the entry into force of the Patients' Rights Directive, the Authority's concerns have only been enhanced. The Directive does not affect EEA States' obligations under Regulation 883/2004, nor does it affect EEA States' obligations to reimburse patients for in-patient treatment abroad as enshrined in the case-law under Article 36 EEA.[25] However, the Directive codifies and makes more general several principles already established in the case-law, relating to both authorisation and reimbursement, in addition to imposing several procedural requirements, *inter alia* on the State of affiliation. In particular, the aforecited Articles 7-9 of the Directive set out requirements to legislative criteria for reimbursement, prior authorisation and administrative procedures relating to cross-border healthcare. These provisions are important insofar as they make clear that national legislative criteria regarding reimbursement, prior authorisation and administrative procedures need to satisfy certain criteria relating to objectivity, clarity, non-discrimination and transparency.

43. The provisions of the Directive reinforce the Authority's arguments, which are already well-founded on the case-law relating to Regulation 883/2004 and the provision of the TFEU equivalent to Article 36 EEA. All of the Authority's four concerns as outlined in Sections 4.2-4.5 relate to both the legislative criteria for prior authorisation and reimbursement in relation to in-patient treatment in other EEA States, *and* the administrative procedures in relation thereto, therefore Articles 7-9 remain relevant to all of the Authority's remaining concerns.

## 4.2 The necessity test

### *4.2.1 The substantive content of the necessity test*

44. A pre-condition for reimbursement is that the patient is entitled to treatment in Norway in accordance with Section 2-1b(2) PRA and Section 2 PR. Having such a pre-condition is foreseen by Article 20(2) second sentence of Regulation 883/2004, which explicitly states that (emphasis added): "***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 cannot be given such treatment within a time-limit which is medically justifiable, taking into account his current state of health and the probable course of his illness*." Therefore, in order to know whether a patient will be entitled to treatment, it is necessary to check the benefits' list.

45. In Norway, there is no exhaustive list of benefits provided. Instead, Section 2-1b(2) PRA and Section 2 PR entail a *necessity* assessment. Norway grants patients the right to *necessary medical treatment,* insofar as the patient has an expected benefit from his health care, and the costs are reasonable taking into account the expected benefits of

[25] Paragraphs 12 and 21 of the preamble, Article 2(m) of the Directive.

this health care. If the condition in Section 2-1b(2) PRA is not fulfilled, the patient is not entitled to medical treatment neither nationally nor abroad.

46. Having the necessity assessment enshrined therein as a criterion for entitlement to medical treatment nationally is not contrary to EEA law. The Norwegian Government is certainly free to determine the criteria for entitlement to in-patient treatment; this is a national competence.

47. However, Norwegian rules related to this pre-condition must be clearly and precisely defined, otherwise they might limit considerably the use by patients of the right to be treated abroad. Indeed, if there is no list of treatments, the right to have access to a treatment abroad relies on the interpretation given by Norway of the necessity test. Section 2-1b(2) PRA and Section 2 PR give two criteria to implement the necessity test: the patient has an expected benefit from this health care, and the costs are reasonable taking into account the expected benefits of this health care.

48. The Authority wishes to underline that, while performing that analysis, Norway has to follow the guidelines established by the jurisprudence of the CJEU and the EFTA Court. Expected benefits have to be measured taking into account recognised international medical science. The CJEU and the EFTA Court have specified that when it has been established according to international medicine that the treatment abroad is indeed more effective than in the home State for a patient, who under the social security system of his or her home State, fulfils the criteria for entitlement to treatment, the home State may no longer justify prioritising its own offer of treatment.[26] Such treatment, which may not exist in Norway, but is considered to be more effective in international medicine, must be taken into account in the cost/benefit assessment under the necessity test. The anticipated benefits, as part of the cost/benefit assessment must be those which the most effective treatment recognised by international medicine can provide.[27]

49. Of course, the consideration of anticipated benefits need not consider any potential benefits from experimental or test treatment. It is for EEA States to decide whether hospital treatment has been sufficiently tried and tested before the costs thereof are assumed by the EEA State in question.[28] However, national authorities called on to make such an assessment, distinguishing test or experimental treatment from treatment recognised by international medicine, must take into consideration all the relevant available information, including, in particular, and *inter alia*, existing scientific literature and studies and the authorised opinions of specialists.[29]

50. The application of the necessity test has led to numerous refusals of treatment abroad. Therefore, the Authority considers that the current interpretation of the necessity test jeopardises the effective application of EEA law. As matter of examples, the Authority has selected some cases[30] to illustrate the infringement of EEA law by Norway.

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[26] Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*, [2008] EFTA Ct. Rep. 322, paragraphs 84-85. See also Case C-173/09 *Elchinov*, ECLI:EU:C:2010:581, paragraphs 65-67 and the case-law cited therein.
[27] Ibid.
[28] Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*, cited above, paragraph 51 and the case-law cited therein.
[29] Case C-157/99 *Smits and Peerbooms*, ECLI:EU:C:2001:404, paragraphs 97-98; Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*, cited above, paragraph 51.
[30] Additional cases are developed in the letter of formal notice.

*4.2.2 Examples from complaint cases*[31]

51. By way of example, one complainant's status as a "rights patient"[32] within the meaning of Section 2-1b(2) PRA was revoked on appeal under the PRA.[33] In that appeal, the relevant administrative body explicitly stated that jaw related conditions such as the one of the complainant do not, as a rule, make patients "rights patients" within the meaning of Section 2-1b(2) PRA,[34] contrary to what this patient was informed of originally. Similarly, in the latest decision of the Norwegian Appellate Body for Treatment Abroad ("**the AB**") directed to the complainant in case 66927, the AB questioned whether the status of his then (ever deteriorating) medical condition would still make him a "rights patient" under Section 2-1b(2) PRA.[35] When the refusal of the authorisation for treatment abroad in this case was appealed to the AB, the complainant put forth nine foreign expert opinions supporting his claim that sufficiently specialised doctors, with relevant experience with the disease at hand, would be required in order to successfully treat (surgically) the complainant's condition.[36] The AB consulted four medical experts in Norway and Sweden in the context of the appeal. These experts were all of the opinion that there was sufficient competence in the field to treat the complainant in Norway. One of the Norwegian experts doubted whether the sought treatment would have any effect at this stage, making it uncertain whether the complainant would be entitled to medical treatment following a cost-benefit analysis under the PRA and/or the PR. This expert opinion was also reiterated in the AB's conclusion, in which it was maintained that just because nine foreign experts considered that it would be medically beneficial to offer the complainant surgery, it did not mean that the criteria for entitlement to treatment abroad in Norway would be fulfilled.[37]

52. In both of the two aforementioned cases, it is not clear what these conclusions were based on, and whether only the expected benefits of the treatment from a Norwegian perspective were taken into account, or whether these considerations were indeed based on what has been established according to international medicine, as required by the case law.

*4.2.3 Concluding remarks*

53. In its response to the supplementary letter of formal notice,[38] the Norwegian Government highlights that all health personnel are required to conduct their work in accordance with the requirements to professional responsibility and diligent care, including changes in ethical values and international knowledge of best practice; doctors in Norway evaluate whether a patient has the right to *necessary* healthcare based on his or her professional knowledge of treatment options available nationally or internationally. Furthermore, the Norwegian Government emphasises the use of

[31] Discussed in respectively Section 4.3.2 of the initial letter of formal notice and Section 4.4. of the supplementary letter of formal notice.

[32] [redacted]

[33] [redacted]

[34] [redacted]

[35] UKN-2010-108, AB decision of 20 June 2011.

[36] UKN-2010-108, AB decision of 20 June 2011 no 10/108 on pages 5 through 6.

[37] UKN-2010-108 at page 13, third paragraph fourth sentence.

[38] See section 4.2 of the response to the supplementary letter of formal notice (pages 6-8).

international systems such as GRADE and the fact that several other European countries use similar criteria for prioritisation as Norway.[39]

54. In this respect, the Norwegian Government also makes reference to a study by Velasco-Garrido,[40] in which it is stated: "*Overall, the most widespread criteria are need, effectiveness, cost and cost/effectiveness. Usually, these criteria are stated without further specification in the legal framework texts defining the benefit basket, and may apply to both the integration of broad areas of care and decisions related to specific technologies.*" In that same report, however, it is acknowledged that this approach comes with a number of shortcomings, including uncertainty and lack of transparency regarding how such cost/effectiveness criteria are applied.[41] Nothing in the information provided by Norway shows that what has been recognised by international medicine is in fact taken into account in the necessity assessment. The Authority's concerns, as raised in the supplementary letter of formal notice[42] thus remain, insofar as transparency and legal certainty in relation to this criterion are still lacking.

55. The Authority's concerns have been strengthened by the explicit provisions in the Patients' Rights Directive, as explained in Section 4.1.2 of the supplementary letter of formal notice. Articles 7, 8 and 9 of the Directive concern, respectively, provisions on reimbursement, prior authorisation and administrative procedures regarding cross border health care.

56. Article 7(6) of the Directive provides that, as regards reimbursement of costs related to cross-border healthcare, the mechanism for calculating medical expenses to be reimbursed shall be based on objective, non-discriminatory criteria known in advance. The necessity test, governing the very entitlement to treatment nationally, and affecting patients' rights to treatment abroad, does not contain sufficiently objective, non-discriminatory criteria known in advance to patients, insofar as it is not clear from the legislation, nor the preparatory works nor the applicable guidelines, that the efficacy of treatment, in accordance with what has been accepted in international medical science, is taken into account. This constitutes a breach of Article 7(6) of the Directive. Article 7(9)-(11) of the Directive provide for EEA States' rights to limit the application of rules on reimbursement for cross-border healthcare based on overriding reasons of general interest, which may nevertheless only be restricted to what is necessary and proportionate and does *not* constitute a means of arbitrary discrimination. The lack of clarity of the necessity test as regards the factors taken into account when evaluating the *efficacy of treatment*, renders the necessity test problematic also under those provisions.

57. Similarly, and as the necessity test concerns the mere entitlement to treatment, forming part of the assessment whether patients are to receive prior authorisation to go abroad

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[39] Ibid.

[40] Accessible under the following hyperlink: https://www.cairn.info/revue-francaise-des-affaires-sociales-2006-6-page-63.htm.

[41] Ibid. "*Usually, these criteria are stated without further specification in the legal framework texts defining the benefit basket, and may apply to both the integration of broad areas of care and decisions related to specific technologies. Information on how the criteria are to be made operational and how they are applied, appraised and weighted in the decision-making process is, however, widely lacking. [...] However, the formalisation and transparency of the decision-making process have been important targets of recent health care reform in some European countries, such as Germany and Hungary (Busse and Riesberg 2004; Gaal 2005b)*".

[42] See Section 4.2 of the supplementary letter of formal notice.

pursuant to Section 2-1b(5) PRA and Section 3 PR, several parts of Article 8 of the Directive are also applicable. In particular, Article 8(1) of the Directive provides that criteria and application of criteria related to prior authorisation, and individual decisions of refusal to grant prior authorisation, shall be restricted to what is necessary and proportionate to the objective to be achieved, and does not constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of patients. Due to the lack of clarity in the necessity test, as outlined above, the Norwegian legislation is also in breach of Article 8(1) of the Directive. Article 8(3)-(5) provide for the conditions upon which prior authorisation is to be granted, namely when the conditions in Regulation 883/2004 are met (unless the patient requests otherwise), or when the patient is entitled to the healthcare in question in accordance with Article 7 of the Directive, and when the healthcare in question cannot be provided on the home State's territory within a time limit which is medically justifiable. Since the necessity test does not sufficiently ensure that what is accepted in international medical science is taken into account, in turn, patients' entitlement to healthcare and subsequent possibilities to obtain prior authorisation are weakened, contrary to the requirements in Article 8(3)-(5) of the Directive.

58. Finally, Article 9(1) of the Directive provides that the EEA State of affiliation shall ensure that administrative procedures regarding the use of cross-border healthcare and reimbursement of costs of healthcare incurred in another EEA State are based on objective, non-discriminatory criteria which are necessary and proportionate to the objective to be achieved. Due to the above mentioned concerns related to the lack of clarity of the necessity test, the provisions related to prior authorisation, reimbursement and administrative procedures concerning cross border health care are not compliant with Article 9(1) of the Directive.

59. In light of the above, the Authority is of the opinion that by maintaining in force legislation, such as Section 2-1b(2) PRA and Section 2 PR, which entail a necessity test as a basis for entitlement to in-patient treatment, which does not ensure that what is accepted according to international medical science is taken into account when evaluating the expected benefit of treatment, Norway has failed to fulfil its obligations under Article 20 of Regulation 883/2004 and/or Article 36 EEA, and/or under Articles 7(6), 7(9)-(11), 8(1), 8(3)-(5) and 9(1) of the Patients' Rights Directive.

### 4.3 Lack of competence or adequate medical services in Norway

60. The assessment in Section 4.3 of this reasoned opinion is based on the assumption that the entitlement to treatment criterion is fulfilled, i.e. that the necessity criterion is fulfilled so that the patients are, at the outset, entitled to the treatment, or *necessary* health care nationally, under Section 2-1b(2) PRA and the PR.

#### *4.3.1 The substantive content of the lack of adequate medical services/lack of competence criterion*

61. EEA law requires EEA States to consider whether equally effective treatment can be obtained by the individual patient in the home State without undue delay, as established explicitly by Article 20(2) of Regulation 883/2004 in relation to authorisations, and as established in the aforementioned case-law as regards Article 36 EEA. Therefore, if a patient is entitled to medical treatment nationally, i.e. the treatment would be covered by the national insurance system, and it is established,

according to international medicine, that the treatment abroad is *indeed* more effective, the home State can no longer justify prioritising its own offer of treatment.[43]

62. The Norwegian legislation and guidance on the legislation in this respect remains unchanged in substance since the initial letter of formal notice was sent and is to be considered contrary to EEA law. Section 2-1b(5) of the PRA provides that a lack of adequate medical services in Norway entitles patients[44] to receive *necessary health care* from a service provider outside Norway. It follows from Section 2-1b(5) of the PRA in conjunction with the preparatory works to the provision[45] and the relevant administrative circular (*rundskriv*),[46] and Section 3 PR that the "*lack of adequate medical services*" is to be understood literally or as a "*lack of medical competence*".

63. The consideration of whether medical competence in Norway is lacking, and/or whether the actual health care in Norway is "adequate," is a key criterion for entitlement to reimbursement or authorisation for in-patient medical treatment abroad under the applicable Norwegian legislation. This interpretation of the PRA and the PR is also found in several decisions of the AB. More than 15 decisions of the AB explicitly refer to and consider that this criterion is the primary one when evaluating whether adequate medical services or competence exist in Norway.[47] Similar interpretations are found in Norwegian case law concerning Section 3 PR and Section 2-1(b)(5) PRA.[48]

64. As a matter of consequence, it appears that Norway has added an additional condition to be fulfilled, i.e. "the lack of competence" or "the lack of adequate medical services", before a patient is entitled to go abroad for medical treatments. The consequence is the denial of patient rights based on a condition not foreseen by EEA law. In that way, Norway hinders the free movement of patients by making more difficult for patients to be treated in another EEA State.

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[43] Case C-157/99 *Smits and Peerbooms*, cited above, paragraph 103-104, 107; Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*, cited above, paragraphs 83-85; Case C-173/09 *Elchinov*, cited above, paragraph 67.

[44] Patients that are entitled to medical treatment in Norway pursuant to Section 2-1b(2) PRA.

[45] Ot.prp nr.63 (2002-2003) *Om lov om endringer i lov 2. juli 1999 nr. 63 om pasientrettigheter (pasientrettighetsloven) m.m.*

[46] *Rundskriv IS-12/2004 om lov om pasientrettigheter,* page 54.

[47] UKN-2012-35, UKN-2012-5, UKN-2011-97, UKN-2011-90, UKN-2011-64, UKN-2011-102, UKN-2011-107, UKN-2011-63, UKN-2010-130, UKN-2010-127, UKN-2010-111, UKN-2009-95, UKN-2009-89, UKN-2008-79, UKN-2008-77, UKN-2007-109. There are no publically available decisions from the AB after 2014 in the Norwegian legal database *Lovdata*, nor on the previous homepage of the AB, which seemingly no longer exists.

[48] See LB-2014-31679. The Court stated: "*Pursuant to Section 2-1(b)(5) PRA it is a precondition [in order to obtain] health care abroad that there is no adequate offer of health services in Norway. In the preparatory works (Ot.prp.nr.63 (2002-2003) on page 61) it is specified that lacking capacity does not entitle patients to receive health care abroad. The same follows from the heading of Section 3 PR – "lacking competence in Norway".*

*[...]*

*The majority of the AB held that there is good competence in Norway to treat MS, and that the treatment in Norway was similar to other States which it would be Norway to compare itself with. The majority [of the AB] also held that there were no special circumstances regarding the patient which would imply that there would not be any competence to offer adequate health care according to accepted methods in Norway.*" The Court agreed with the AB's assessment in this respect. The Court also agreed with the AB's conclusion that when there is competence to provide justifiable medical treatment in Norway, the patient is not entitled to coverage of costs for medical treatment abroad pursuant to Section 2-1(5) PRA and Section 3 PR.

65. Furthermore, it should be evaluated whether the treatment can be provided *without undue delay* in conjunction with the assessment of whether equally effective treatment can be provided. However, the strict separation of Section 2-1b(4) and 2-1b(5) does not appear to allow for this, and Section 3 fourth paragraph of the PR explicitly precludes it. It therefore appears that the relevant criterion under EEA law, namely whether *equally effective treatment* can be provided *in due time*, is not given full effect in Norway.

66. As regards the detailed reasoning concerning the breach under Regulation 883/2004 and Article 36 in this respect, reference is made to Sections 4.3.1 through 4.3.3. of the Authority's initial letter of formal notice. A summary of some of the complaints received by the Authority are indicative in this regard.

*4.3.2 Complaints received by the Authority – the application of Sections 2-1b(5) PRA and 3 PR in practice*

67. Case 71454 concerns an application for treatment abroad from a patient with [redacted] as well as Temporomandibular joint dysfunction/disorder ("TMD"), and neck and jaw injuries. A letter from the centre for rare diagnoses of Oslo University Hospital, department *Rikshospitalet*, to the complainant, dated 28 July 2011, confirms that there is "*little resources on* [redacted]" in Norway.[49] A refusal of the authorisation for treatment abroad concerning the neck/jaw injury aspect of the case was appealed to the AB.[50]

68. In its decision, the AB stated that whereas it acknowledged that the complainant had encountered numerous difficulties in finding a treatment offer in Norway, it did not consider that this was due to a lack of competence in Norway.[51] Therefore, the reimbursement for medical treatment (surgery) in another EEA State could not be accepted. In this specific case, the AB *inter alia* stated that: "*a lacking treatment option in Norway does not mean that Norwegian competence does not exist*".[52] Whether a treatment option existed in Norway for the complainant *in this very case* thus appears to have been given little regard, or emphasis, by the AB. This indeed highlights the very core of what in the Authority's view is the most problematic aspect of the *lack of competence* criterion; namely that a mere consideration of whether the general competence in Norway is lacking does not adequately consider whether *equally effective treatment* can be provided to the individual patient within a medically justifiable deadline, as required by EEA law.

69. Case 72754 was opened following a complaint from one of the Norwegian Patient Ombudsmen. This specific Patient Ombudsman's concern is that specific patient groups are not being provided with any treatment option in Norway, and encounter difficulties in obtaining authorisation or reimbursement for in-patient treatment abroad even if no treatment can be provided to them, *at all* or *in due time*. The specific Patient Ombudsman stated that these patient groups typically are being told by administrative bodies dealing with such applications that there are "*proper/adequate*" ("*forsvarlige*") treatment options for these patients in Norway. However, exactly *where* such treatment options would exist in Norway these bodies often cannot respond to,

[49] [redacted]
[50] UKN-2009-74, AB decision of 16 November 2009.
[51] Ibid.
[52] UKN-2009-74 on page 4.

according to this Patient Ombudsman. Explicitly referred to was the example of patients with severe TMD, Moyamoya and other medical conditions which the relevant Ombudsman perceived as rare in Norway.

70. The Authority has also received a complaint from a patient association.[53] Moreover, from the correspondence/e-mails received from several patients by the Authority in 2013, it appears that numerous patients have encountered difficulties in relation to obtaining medical treatment in other EEA States. Furthermore it appears that none of these inquirers/patients had received any offer of medical treatment in Norway at the time, nor to date.

71. One of the issues highlighted in some of the abovementioned complaints/e-mails is a letter of 1 March 2012[54] from the Ministry of Health and Care Services to the Directorate of Health in which it was stated that according to a report from the Directorate, what can be offered to TMD patients in Norway was not good enough, and in accordance with the Directorate's report, there was therefore a need to strengthen the competence in relation to TMD patients in all levels of the treatment chain ("*behandlingskjeden*"). The request implies that any actual treatment option available in Norway in this regard was lacking as regards patients with severe TMD, at least prior to the point in time at which the letter was sent. Yet, it appears that no applications for treatment abroad from patients with TMD had been approved by the AB due to lack of competence or lack of adequate medical services even prior to this date,[55] even in a case where *the Norwegian Government had acknowledged that there was a need to strengthen the competence* nationally concerning that specific disease (TMD). In such a situation one would at least presume that the acknowledged shortcomings in national competence would lead to the *lack of competence* criterion being considered fulfilled. However, it appears that the AB did not reach this conclusion in any TMD cases even prior to that point in time, in part, it seems, because the *general competence and treatment offer in Norway* was not considered to be lacking.[56]

72. The Authority refers to the initial letter of formal notice for a more complete list of examples of the application of these legislative criteria in practice.[57]

*4.3.3 Norway's replies to the letters of formal notice*

73. Norway has provided several counter-arguments to the Authority's letters of formal notice, some of which are relevant, but which the Authority disagree with, and some of which are irrelevant to the substance of the letters of formal notice.

4.3.3.1 Arguments and statements irrelevant to the case at hand

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[53] Case 74734.
[54] Your ref.: 200604348-/CD.
[55] UKN-2012-19, UKN-2011-95, UKN-2011-107, UKN-2011-38, UKN-2010-127, UKN-2008-30 and decision of the office for treatment abroad at Oslo Universitetssykehus (their ref. 2012/15214). It should however be noted that some of these decisions concern applications for authorisation or reimbursement for medical treatment outside of the EEA.
[56] UKN-2012-19, UKN-2011-95, UKN-2011-107, UKN-2011-38, UKN-2010-127, UKN-2008-30, UKN-2010-18.
[57] See Section 4.3.2. of the initial letter of formal notice.

74. In its response to the supplementary letter of formal notice,[58] the Norwegian Government focuses on the theoretical generosity provided for in Sections 2-1(b)(5) PRA and Section 3 PR, insofar as these provisions provide for the possibility to obtain treatment abroad outside of the EEA. Whereas this might be true, the criteria for access to medical treatment in other EEA States must be in line with EEA law. The criteria for access to medical treatment in non-EEA States are not relevant for the purposes of this reasoned opinion.

75. In any case, the actual cost coverage under Sections 2-1(b)(5) PRA and Section 3 PR has not been raised by the Authority in either the initial nor the supplementary letter of formal notice. The Authority's concerns relate to the fact that the international medicine and the particular situation of a patient are not taken into account when assessing their rights to treatment in another EEA State, as well as to the lack of precision, transparency and clarity of these criteria, as illustrated by preparatory works, guidelines and administrative practice.

76. The Norwegian Government emphasises over several pages, in its response to the supplementary letter of formal notice,[59] that the criteria in relation to access to medical treatment abroad cannot have the effect of expanding the criteria for entitlement to medical treatment in the EEA State in question. The Authority certainly agrees with this proposition, which it underlined in the supplementary letter of formal notice[60].The Authority does not contest that it is for Norway to decide which treatment methods its social security system is to cover.

4.3.3.2 Arguments relevant to the case at hand

77. In its reply to the initial letter of formal notice of 18 August 2014, the Norwegian Government enclosed,[61] anonymous assessments for treatment abroad illustrating that "*the offices perform an individual assessment in each case.*" The Norwegian Government also provided further statistics, illustrating that between 67% and 77% of applications for treatment abroad were granted under this provision.

78. The Authority acknowledges that individual assessments might be made before both the offices for treatment abroad (*Utenlandskontor*) with the relevant regional health enterprises and before the AB, and that a number of applications for treatment abroad are indeed granted in Norway. However, the Norwegian criteria for in-patient treatment abroad, as they currently read - in conjunction with relevant preparatory works and guidelines - do not properly ensure that individual assessments of the specific patient's medical needs are made, and that an assessment of whether the treatment abroad would be *indeed more effective* is conducted when assessing applications for treatment abroad.

79. That is of course not to say, that such assessments, or similar assessments, are *never* being made correctly by the relevant competent bodies in Norway. However, the current criterion leaves unnecessary room for interpretation contrary to EEA law.

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[58] See Section 4.4 of the response to the supplementary letter of formal notice, on page 10.
[59] See Section 4.4 of the response to the supplementary letter of formal notice, pages 9-13.
[60] Paragraph 65 of the supplementary letter of formal notice, and in Section 4.1, in the very last paragraph on page 11 of the initial letter of formal notice.
[61] See annex 3 to that letter.

80. EEA law requires EEA States to consider whether *equally effective treatment* can be obtained by the individual patient in the home State without undue delay, as established explicitly by Article 20(2) of Regulation 883/2004 in relation to authorisations, and as established in the aforementioned case-law as regards Article 36 EEA.[62]

81. In doing so, EEA States' national authorities are required to take due account of all the circumstances of *each specific case* and to take due account not only of the patient's medical condition at the time when the authorisation is sought but also of his past record and, where appropriate, the degree of pain or the nature of the patient's disability which might, for example, make it impossible or extremely difficult for him to carry out a professional activity,[63] rather than the (general) medical competence or medical services in the relevant EEA State.

82. In this respect, the Norwegian Government stated, in its reply to the Authority's initial letter of formal notice, that, in its opinion, the term "*equally effective treatment*" does not imply that "*all EEA citizens from all EEA States have a legal claim for the best hospital services available at any given time within the entire EEA.*"[64] The Authority in principle does not dispute with this argument. However, once it is clear that the patient is entitled to medical treatment nationally, i.e. that the treatment would be covered by the national insurance system, and it is established, according to international medicine, that treatment abroad is more effective, the home State can no longer justify prioritising its own offer of treatment.[65]

83. The "*lack of competence/lack of adequate medical services*" criterion seems to entail an assessment pursuant to which patients need to claim, and get the competent body to approve, that the medical service or competence in question is not adequate or available in Norway. This is, in the Authority's view, goes even further than requiring patients to demonstrate why it is medically necessary for the particular health case in question to be received in another EEA State. As indeed the European Commission points out in its *Report on the operation of Directive 2011/24 on the application of patients' rights in cross-border health care*,[66] requiring such a demonstration of medical necessity does not seem to be in line with Article 36 EEA and Articles 7(9) and 7(11) of the Patients' Rights Directive. However, the Norwegian legislation goes even further, in requiring a demonstration that the Norwegian health services are not competent or inadequate. In any case, such criteria would need to pass a proportionality test, as required by Articles 7(9), 7(11) and 8(1) of the Patients' Rights Directive, and no proportionality assessment has been provided in this respect by the Norwegian Government.

84. The consideration of whether medical competence in Norway is lacking, and/or whether the actual health care in Norway is "adequate," is currently a key criterion for entitlement to reimbursement or authorisation for in-patient medical treatment abroad under the applicable Norwegian legislation. This interpretation of the PRA and the PR

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[62] See Section 3 of the initial letter of formal notice, as referenced in Section 3 of this reasoned opinion.
[63] Case C-173/09 *Elchinov,* cited above, paragraph 66 and the case-law cited therein.
[64] Page 13 of the response to the initial letter of formal notice.
[65] Case C-157/99 *Smits and Peerbooms*, cited above, paragraph 92-98, 107; Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*, cited above, paragraphs 83-85; Case C-173/09 *Elchinov,* cited above, paragraph 67.
[66] Report from the Commission to the European Parliament and the Council COM(2015) 421 final *Commission Report on the operation of Directive 2011/24 on the application of patients' rights in cross-border health care* on page 4.

is also found in several decisions of the AB. More than 15 decisions of the AB explicitly refer to and reflect that this criterion is the primary one when evaluating whether adequate medical services exist in Norway.[67] Similar interpretations are found in Norwegian case law concerning Section 3 PR and Section 2-1(b)(5) PRA.[68] Additionally, reference is made to Section 4.3.2 of this reasoned opinion.[69]

85. The Norwegian Patient Association also refers to several cases in their annual report from 2015 concerning difficulties as regards reimbursement of medical treatment abroad.[70] In one case, the refusal was linked to what the competent authorities in Norway considered to be an "*adequate treatment offer*" in Norway, despite the patient in question not being offered any treatment nationally, and despite the patient experiencing almost a full recovery pursuant to the operation undertaken abroad.

86. The above cases, including those mentioned in Section 4.3.2, serve to illustrate, in the Authority's opinion, the problematic nature of a criterion focusing on *lack of adequate medical services* or *lack of competence in Norway*, rather than *whether equally effective treatment* can be provided in *due time* in Norway, which is the evaluation which EEA law requires. The temporal aspect, as outlined under Section 4.2 in the initial letter of formal notice, is also an issue in several of the aforementioned cases.

*4.3.4 Concluding remarks*

87. Despite the elements presented by Norway in its responses to the initial and supplementary letters of formal notice, the Authority does not consider that the criteria in the Norwegian legislation, and, in particular, in Section 3 PR and Section 2-1b(5) PRA, adequately ensure that Norway's obligations under Article 20 of Regulation 883/2004 and/or Article 36 EEA and/or Articles 7(9)-(11), 8(1), 8(3)-(5) and 9(1) of Directive 2011/24 are respected. The Authority does not consider that the criteria laid down in Section 3 PR and Section 2-1b(5) PRA ensure that, where it has been established according to international medicine that the treatment abroad is more effective than in Norway, Norway will not prioritise its own offer of treatment, but authorise or reimburse in full the *more* effective in-patient medical treatment for the concerned patient who is entitled to treatment under the Norwegian legislation. Rather, as also emphasised in the preparatory works and in the relevant *rundskriv* to Section 2-1b(5) PRA,[71] and as reflected in several cases before the AB cited in Section 4.3.3 of the initial letter of formal notice, the criteria in Section 3 PR and Section 2-1b(5) PRA focus on the general competence or adequacy of the treatment offered in Norway, and do not adequately ensure that an overall medical assessment of whether *equally effective treatment* can be provided to the individual patient *within a medically justifiable deadline* is undertaken.

In order to give full effect to the "*equally effective treatment*" criterion established under Article 20 of Regulation 883/2004 and/or Article 36 EEA, legislation should be

[67] UKN-2012-35, UKN-2012-5, UKN-2011-97, UKN-2011-90, UKN-2011-64, UKN-2011-102, UKN-2011-107, UKN-2011-63, UKN-2010-130, UKN-2010-127, UKN-2010-111, UKN-2009-95, UKN-2009-89, UKN-2008-79, UKN-2008-77, UKN-2007-109. There are no publically available decisions from the AB after 2014 in the Norwegian legal database *Lovdata*, nor on the previous homepage of the AB, which seemingly no longer exists.

[68] See footnote 47.

[69] And Section 4.3.2 of the initial letter of formal notice and Section 4.4 of the supplementary letter of formal notice.

[70] See http://www.pasient no/resources/nett_Norsk-pasientforening-arsrapport1-2015.pdf on page 18-19.

[71] Cited in Section 2 of this reasoned opinion.

enacted which ensures that the required assessment of whether *equally effective treatment* can be provided to the individual patient *within a medically justifiable deadline* in Norway would be the only valid basis for refusing applications for authorisation or reimbursement of medical treatment abroad.

88. The Authority's concerns have been strengthened by the explicit provisions in the Patients' Rights Directive, as explained in Section 4.1.2 of the supplementary letter of formal notice. Articles 7, 8 and 9 of the Directive concern, respectively, provisions on reimbursement, prior authorisation and administrative procedures regarding cross border health care.

89. Article 7(6) of the Directive provides that, as regards reimbursement of costs related to cross-border healthcare, the mechanism for calculating medical expenses to be reimbursed shall be based on objective, non-discriminatory criteria known in advance. The criterion of *lack of adequate medical services/lack of medical competence* test, does not, as outlined above, sufficiently meet the requirements as regards objective, non-discriminatory criteria known in advance to patients, insofar as it is not clear from the legislation, nor the preparatory works nor the applicable guidelines, that the evaluation in this respect will concern *whether equally effective treatment* can be provided to the patient in question *within a medically justifiable time limit*. This constitutes a breach of Article 7(6) of the Directive. Article 7(9)-(11) of the Directive provide for EEA States' rights to limit the application of rules on reimbursement for cross-border healthcare based on overriding reasons of general interest, which may nevertheless only be restricted to what is necessary and proportionate and does *not* constitute a means of arbitrary discrimination. The lack of clarity of the *lack of adequate medical services/lack of medical competence* test as regards the factors taken into account when evaluating whether there is adequate medical competence or a lack of medical competence in Norway is problematic also under those provisions.

90. Similarly, and as the *lack of adequate medical services/lack of medical competence* test affects the assessment whether the patient is entitled to prior authorisation to go abroad pursuant to Section 2-1b(5) PRA and Section 3 PR, several parts of Article 8 of the Directive are also applicable. In particular, Article 8(1) of the Directive provides that criteria and application of criteria related to prior authorisation, and individual decisions of refusal to grant prior authorisation, shall be restricted to what is necessary and proportionate to the objective to be achieved and does not constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of patients. Due to the lack of clarity and the subsequent possible misapplication and/or discriminatory application of the Norwegian criteria as regards the *lack of adequate medical services/lack of medical competence* test, as outlined above, the Norwegian legislation is also in breach of Article 8(1) of the Directive. Article 8(3)-(5) provide for the conditions upon which prior authorisation is to be granted, namely when the conditions in Regulation 883/2004 are met (unless the patient requests otherwise), or when the patient is entitled to the healthcare in question in accordance with Article 7 of the Directive, and when the healthcare in question cannot be provided on the home State's territory within a time limit which is medically justifiable. Since the *lack of adequate medical services/lack of medical competence* test does not sufficiently ensure that these requirements are respected, but rather require case handlers to assess whether there is a lack of adequate medical services or medical competence in Norway in order to grant a prior authorisation pursuant to Section 2-1b(5) PRA and Section 3 PR, the *lack of adequate medical services/lack of medical competence* test is not in line with the requirements of Article 8(3)-(5) of the Directive.

91. Finally, Article 9(1) of the Directive provides that the EEA State of affiliation shall ensure that administrative procedures regarding the use of cross-border healthcare and the reimbursement of costs of healthcare incurred in another EEA State are based on objective, non-discriminatory criteria which are necessary and proportionate to the objective to be achieved. Due to the above mentioned concerns related to the *lack of adequate medical services/lack of medical competence* test, the provisions relating to prior authorisation, reimbursement and administrative procedures concerning cross border health care are not compliant with Article 9(1) of the Directive.

92. In light of the recent entry into force of the Patients' Rights Directive in the EEA, Norway must furthermore consider the compatibility of its legislative criteria with Articles 7(6), 7(9)-7(11), 8(1), 8(3)-(5) and 9(1) thereof, and, if it would wish to keep the criteria or substantively similar criteria, a proportionality assessment pursuant to Articles 7(11) and 8(1) of the Patients' Rights Directive must, in any case, be undertaken by Norway.

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

### 4.4 Treatment not provided within a medically justifiable deadline

94. As pointed out in sections 3.2 and 4.2 of the initial letter of formal notice, EEA law provides that, if there is a waiting time for hospital treatment, the competent institution is required to establish that the waiting time for this medical treatment to which the patient is entitled under national law does not exceed the period which is acceptable on the basis of an objective medical assessment of the clinical needs of the person concerned in the light of all the factors characterising his medical condition at the time when the request for authorisation is made or renewed. Where the patient cannot be given such medical treatment within a medically justifiable time-limit, the right of the patient to go to another EEA medical service provider to get treatment there follows from Article 20(2) of Regulation 883/2004, and the corresponding case-law under Article 36 EEA. The applicable Norwegian legislation *still* does not seem to sufficiently reflect this.

95. Norway has amended Section 7 of the Reimbursement Regulation by adding a provision in Section 7(9) of the Reimbursement Regulation, clarifying that patients entitled to authorisation under Regulation 883/2004, who for some reason did not receive it at all or in time, are entitled to a refund as if such authorisation had been given duly or in time. This is certainly a welcome change, however, for legal certainty purposes, Section 6 of the Prioritisation Regulation should be amended accordingly, since its content seems to be in contradiction to the Reimbursement Regulation, and in breach of Norway's obligations under Article 20 of Regulation 883/2004 and/or Article 36 EEA.

96. Section 2-1b(4) of the PRA provides that patients entitled to treatment following the cost/benefit analysis established under Section 2-1b(2) of the PRA[72], for which the time-limit fixed by the specialist health care services has passed, are entitled to medical treatment from a private service provider or to get it abroad. Section 6 of the PR provides, however, that the patient cannot freely choose the service provider in such a situation, but must, rather, contact the responsible administrative body (HELFO). The CJEU has, however, unequivocally established that once it is clear that a treatment covered by the national health insurance system cannot be provided by a contracted establishment within a medically justifiable time-limit, it is not acceptable that hospitals having contractual arrangements with the insured person's sickness insurance fund be given priority over hospitals in other EEA States.[73]

97. It might be the case that some patients prefer to get their trip abroad organised and to wait a bit longer for this, but they cannot be obliged to wait for this if they do not want to, as exceeding the time-limit provides them with a free-standing right to receive the necessary authorisation or reimbursement for medical treatment in another EEA State.

98. The Authority's concerns have been strengthened by the explicit provisions in the Patients' Rights Directive, as explained in Section 4.1.2 of the supplementary letter of formal notice. Articles 7, 8 and 9 of the Directive concern, respectively, provisions on reimbursement, prior authorisation and administrative procedures regarding cross border health care.

99. Article 7(6) of the Directive provides that, as regards reimbursement of costs related to cross-border healthcare, the mechanism for calculating medical expenses to be reimbursed shall be based on objective, non-discriminatory criteria known in advance. However, Section 6 PR creates an unclear legal situation insofar as, *first*, it makes no link to Section 7(9) of the Reimbursement Regulation; *second*, it seems to preclude patients from turning directly to an EEA medical service provider and from subsequently having in-patient treatment from such provider reimbursed; and *third*, it requires patients to contact HELFO first as the patient cannot freely choose a service provider. Article 7(9)-(11) of the Directive provide for EEA States' rights to limit the application of rules on reimbursement for cross-border healthcare based on overriding reasons of general interest, which may nevertheless only be restricted to what is necessary and proportionate, and which does *not* constitute a means of arbitrary discrimination. Article 7(11) of the Directive obliges EEA EFTA States to notify any decisions to limit reimbursement to the EFTA Surveillance Authority. Section 6 PR constitutes a *de jure* limitation on patients' possibilities to go abroad and obtain subsequent reimbursement from Norway since it obliges them to contact HELFO first, and prohibits them from turning directly to another EEA medical service provider. Additionally, the provision has not been notified to the EFTA Surveillance Authority in accordance with Article 7(11) of the Directive.

100. Similarly, Section 6 PR limits *de jure*, in part because no link is made to Section 7(9) of the Reimbursement Regulation, patients' possibilities to obtain the due reimbursement if they were entitled to reimbursement under Regulation 883/2004 but somehow did not receive it at all or in time.

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[72] Read in conjunction with the preparatory works.

[73] Case C-157/99 *Smits and Peerbooms*, cited above, paragraph 107; Case C-385/99 *Müller-Fauré*, ECLI:EU:C:2003:270, paragraph 92; Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*, cited above, paragraph 103; Case C-173/09 *Elchinov*, cited above, paragraph 73.

101. Finally, Article 9(1) of the Directive provides that the EEA State of affiliation shall ensure that administrative procedures regarding the use of cross-border healthcare and the reimbursement of costs of healthcare incurred on another EEA State are based on objective, non-discriminatory criteria which are necessary and proportionate to the objective to be achieved. Due to the above mentioned prohibition for patients to turn directly to an EEA medical service provider in order to receive the treatment which they are entitled to upon the expiry of the medically justifiable deadline, Section 6 PR is not in line of Article 9(1) of the Directive.

102. In light of the above the Authority is of the opinion that by maintaining in force legislation, such as Section 6 PR, which prohibits patients whose justifiable deadlines for medical treatment set under the Prioritisation Regulation and/or under the Patients' Rights Act have expired from turning directly to another EEA medical service provider to receive the medical treatment to which they are entitled upon the expiry of this deadline, thereby failing to ensure that such a patient will obtain the necessary authorisation under Article 20(2) of Regulation 883/2004, and/or that such a patient will obtain reimbursement under Article 36 of the EEA Agreement, the Kingdom of Norway has failed to fulfil its obligations under Article 20 of Regulation 883/2004 and/or Article 36 EEA and/or Articles 7(6), 7(9)-7(11), 8(1), 8(3)-(5) and 9(1) of Directive 2011/24.

### 4.5 Legal certainty

103. The Authority notes that the full scope of the criteria applied in Norway to applications for authorisations or reimbursement of costs relating to medical treatment abroad are not fully objective, and are not fully known in advance to potential applicants for such.

104. As the EFTA Court has held, *inter alia* in Case E-9/11 *EFTA Surveillance Authority v The Kingdom of Norway,*[74] the principle of legal certainty requires, that national rules of the EEA States that restrict fundamental freedoms, entailing for example restrictions on patients' abilities to be reimbursed when going to a medical service provider of his choice in an EEA State other than that of affiliation, must satisfy the principle of legal certainty, implying that e.g. criteria for prior administrative approval must be objective, non-discriminatory and known in advance to concerned persons. Where national law does not live up to this EEA law requirement of legal certainty, clarity and precision, the lack of transparency in itself suggests that the relevant measure restricts the rights conferred by EEA law to a disproportionate extent,[75] and therefore is not in line with EEA law.

105. In this context, the Authority recalls that the EFTA Court stated the following concerning the criteria applicable to 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*

[74] 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.
[75] Case C-318/10 *SIAT*, EU:C:2012:415, paragraphs 58-59 and the case-law cited therein.

*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. 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).*"[76]

106. Following the entry into force of the Patients' Rights Directive, and the obligations therein, Norway is required to have objective, necessary, proportionate and non-discriminatory criteria pursuant to its obligations thereunder.[77]

107. Firstly, it is not clear what elements are taken into account in the "necessity" assessment pursuant to Section 2-1b(2) PRA and Section 2 PR, and whether the benefits in the cost/benefit analysis are considered in line with expected benefits of in-patient medical treatment recognised in international medical science.[78]

108. Secondly, as the relevant criteria under Section 3 PR and Section 2-1b(5) PRA primarily appear to entail an assessment of whether there is a *lack of competence* or a *lack of adequate medical services* in Norway, the criteria may give rise to subjective and potentially discriminatory assessments. This is particularly so because all medical specialisations are present in Norway. In order to prevent the arbitrary use of the competent authorities' discretion in relation to applications for authorisation or reimbursement of in-patient treatment abroad, the criteria in relation thereto should be worded in an objective and precise manner, reflecting what would actually be required in order to obtain the relevant authorisation or reimbursement, as required also by Articles 7(6), 7(9)-7(11), 8(1), 8(3)-(5) and 9(1) of the Patients' Rights Directive.

109. Additionally, there is still a requirement in Section 6 PR, according to which the patient must contact HELFO upon the expiry of the set deadline in order to find a treatment offer. This provision does not contain a reference to the Reimbursement Regulation, or Section 7(9) thereof, in order to clarify that in such cases, reimbursement can nevertheless be provided, under Regulation 883/2004 if the patient would have been entitled thereto, or else under Article 36 EEA. The patient is entitled to go directly abroad and be reimbursed under Article 36 EEA if the deadline for treatment has expired.[79] The CJEU has unequivocally established that once it is clear that a treatment covered by the national health insurance system cannot be provided by a contracted establishment within a medically justifiable time-limit, it is not acceptable that hospitals having contractual arrangements with the insured person's sickness insurance fund be given priority over hospitals in other EEA

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[76] See Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*, cited above, paragraph 48.
[77] Articles 7(6), 8(1), 8(3)-(5) and 9(1) of Directive 2011/24.
[78] Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*, cited above, paragraphs 84-85; Case C-173/09 *Elchinov*, cited above, paragraph 62; Case C-157/99 *Smits and Peerbooms*, cited above, paragraph 94-98.
[79] Case C-157/99 *Smits and Peerbooms*, cited above, paragraph 107; Case C-385/99 *Müller-Fauré*, cited above, paragraph 92; Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*, cited above, paragraph 103; Case C-173/09 *Elchinov*, cited above, paragraphs 67 and 73.

States.[80] The Authority is therefore of the view that this provision renders the national legal framework unclear for patients seeking in-patient treatment abroad under Regulation 883/2004 or under Article 36 EEA. The provision seemingly precludes patients from actually realizing the right granted to them under the CJEU's case law in two respects, namely (i) full reimbursement in the event that he or she would be entitled to an authorisation under Regulation 883/2004, but for some reason did not get it at all or in time (despite Section 7(9) of the Reimbursement Regulation providing for the opposite), and (ii) reimbursement under Article 36 EEA, if the treatment cannot be provided within the set deadline.[81] The provision is also in breach of Articles 7(6), 7(9)-7(11), 8(1), 8(3)-(5) and 9(1) of Directive 2011/24.

110. In its response to the supplementary letter of formal notice,[82] the Norwegian Government states that all the legislative criteria are based on international medicine, without referencing any sources of law supporting such an interpretation, instead referencing criteria to certified medical personnel, the requirements to professional responsibility therein, and various databases and other working tools, as mentioned in Section 4.2.3 of this reasoned opinion.

111. Furthermore, the Norwegian Government states, in its response to the supplementary letter of formal notice,[83] that "*common decisions*" are being made concerning new health technologies, new medical procedures and pharmaceutical treatments. Whereas the Authority does not dispute this information, this does not address the Authority's concerns relating to the legislative criteria, as raised in this reasoned opinion, and *these criteria's* lack of transparency, precision, clarity and objectivity.

112. Additionally, the Norwegian Government notes that the legislative task in this field is particularly difficult since all patients are different, and there are countless numbers of possible treatment that should be adapted in each case, the field is very dynamic and new treatments are constantly available.

113. Whereas the Authority certainly acknowledges the challenges of the field, this does not change the above issues concerning the currently applicable criteria.

114. In light of the above, the Authority considers that the criteria applicable to applications for authorisations or reimbursement of in-patient medical treatment abroad in Norway do not meet the requirements of the above-cited case law concerning objectivity, clarity, transparency and precision, and thus do not sufficiently allow individuals to determine the full scope of their rights, as required also by Articles 7(6), 8(1), 8(3)-(5) and 9(1) of the Patients' Rights Directive. The Norwegian rules applicable to patients access' to in-patient treatment abroad under Section 2-1b(2) PRA and Section 2 PR, Section 3 PR and Section 2-1b(5) PR, as well as Section 6 PR, must therefore be considered disproportionate in themselves, [84] rendering them *as such* incompatible with Article 36 EEA and/or Article 20 of

[80] Case C-157/99 *Smits and Peerbooms*, cited above, paragraph 107; Case C-385/99 *Müller-Fauré*, cited above, paragraph 92; Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*, cited above, paragraph 103; Case C-173/09 *Elchinov*, cited above, paragraphs 67 and 73.

[81] Case C-173/09 *Elchinov*, cited above, paragraph 45 onwards; Order of the Court of Justice of the European Union of 11 July 2013 in Case C-430/12 *Elena Luca v Casa de Asigurări de Sănătate* Bacău, EU:C:2013:467, paragraph 25 onwards; Case C-368/98 *Vanbraekel and Others*, ECLI:EU:C:2001:400, paragraph 53.

[82] See page 6 of the response to the supplementary letter of formal notice.

[83] See page 7 of the response to the supplementary letter of formal notice.

[84] Case *C-318/10 SIAT*, cited above, paragraph 58-59 and the case-law cited therein.

Regulation 883/2004 and/or Articles 7(6), 7(9)-7(11), 8(1), 8(3)-(5) and 9(1) of Directive 2011/24.

## 5 Conclusion

FOR THESE REASONS,

THE EFTA SURVEILLANCE AUTHORITY,

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

HEREBY DELIVERS THE FOLLOWING REASONED OPINION

that

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

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

- by maintaining in force legislation, such as Section 6 PR, which prohibits patients whose justifiable deadlines for medical treatment set under the Prioritisation Regulation and/or under the Patients' Rights Act have expired from turning directly to another EEA medical service provider to receive the medical treatment to which they are entitled upon the expiry of this deadline, thereby failing to ensure that such a patient will obtain the necessary authorisation under Article 20(2) of Regulation 883/2004, and/or that such a patient will obtain reimbursement under Article 36 of the EEA Agreement, the Kingdom

of Norway has failed to fulfil its obligations under Article 20 of Regulation 883/2004 and/or Article 36 EEA and/or Articles 7(6), 7(9)-7(11), 8(1), 8(3)-(5) and 9(1) of Directive 2011/24;

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

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, 20 September 2017

For the EFTA Surveillance Authority

Frank J. Büchel
College Member

Carsten Zatschler
Director

*This document has been electronically signed by Frank J. Buechel, Carsten Zatschler.*