

Brussels, 3 February 2016
Case No: 72376
Document No: 772442
Decision No: 027/16/COL

Ministry of Health and Care Services
Postboks 8011 Dep
0030 Oslo
Norway

Dear Sir or Madam,

Subject: Supplementary letter of formal notice to Norway concerning criteria for access to in-patient treatment in other EEA States from Norway - breach of Regulation 883/2004, Directive 2011/24 and Article 36 EEA

1 Introduction

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 general² 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

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).

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 coordination³ 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.
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 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*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 HELFO.
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 by email dated 9 February 2015.⁶
10. Despite the adoption of the changes brought by the new legislation, the Authority considers that, in several respects, as will explained in detail in the present, supplementary letter of formal notice, the Norwegian criteria for access to in-patient treatment abroad is still not in line with EEA law.
11. Additionally, the Patients’ Rights Directive No 2011/24⁷ 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 Authority’s remaining concerns were discussed during the package meeting in Norway in November 2015.

³ The Act referred to at point 1 of Chapter I of Annex VI to the EEA Agreement.

⁴ Doc No 718533, your ref.: 12/5292

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

⁶ Doc No 748228.

⁷ The Act referred to at point 2 of Annex X to the EEA Agreement.

2 Relevant national law

2.1 Entitlement to in-patient medical treatment in Norway

13. Section 2-1b(2) Act of 2 July 1999 No. 63 relating to Patients' Rights ("**the Patients' Rights Act**", "**the PRA**") provides:⁸

"The patient is entitled to receive necessary health care from the specialist health service. This right only applies if the patient can be expected to benefit from the health care, and the costs are reasonable in relation to the effect of the measure. 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. [...]"

14. 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:⁹

"The patient is entitled to receive necessary health care from the specialist health service pursuant to Section 2-1b [(2) PRA] when:

1. *The patient has a prognosis of certain loss with regards to duration of life or a not insignificant reduction of quality of life if the health care is postponed and*
2. *The patient, with the exception mentioned in Section 3 second paragraph, has an expected benefit of the health care and*
3. *The expected costs are reasonable, taking due account to the effect of the measure.*

By "not insignificant reduction of quality of life" is meant that the patient's quality of life without treatment will be noticeably reduced as a consequence of pain or suffering, problems related to vital life functions such as nutrition intake, or a reduced physical or psychological level of functionality.

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."

15. Section 2 of the PR is to be amended by Regulation of 10 April 2015 no 339 (however, this Regulation has not yet entered into force), and will consequently be shortened. However, the substantive content does not change.¹⁰

⁸ Unofficial translation by the Authority.

⁹ Unofficial translation by the Authority.

¹⁰ 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. The "expected benefit" elaboration in the new Section 2(2) PR is substantially almost identical to the current Section 2(5) PR.

2.2 Entitlement to in-patient medical treatment abroad

16. Provided that the necessity condition in Section 2-1b(2) PRA¹¹ 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:¹²

“[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.

[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)

17. If the medically set deadline for treatment has passed and the patient falls under Section 2-1b(4) PRA, **Section 6 of the PR** provides further criteria for the patient's access to in-patient treatment abroad:¹³

“When the deadline set in accordance with § 4 or § 4a second paragraph has expired without the patient having received an offer for health care that the person is considered to be entitled to according to the [PRA] § 2-1, the patient may approach directly the public body that the Directorate of Health appoints,^[14] which shall ensure that a treatment offer is provided from a public service provider or if necessary from a private service provider or if necessary abroad. The patient cannot freely choose the service provider.”

18. Section 6 of the PR is to be amended by Regulation of 10 April 2015 no 339 (however, this Regulation has not yet entered into force and it has not yet been decided when this Regulation will enter into force). In the new Section 6, however, the main substantive content of the provision remains.¹⁵

¹¹ Cf. Section 2 PR.

¹² Unofficial translation by the Authority, emphasis added.

¹³ Unofficial translation by the Authority, emphasis added.

¹⁴ That is, HELFO. See Section 4.2 of this letter.

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 from 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)*

19. 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

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].

[...]

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.”

20. Section 3 of the PR is also to be amended by Regulation of 10 April 2015 no 339, which has not yet entered into force, but the substance will not change.
21. 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.

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 did not amend it. 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, cf. 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."

22. The above considerations as concerns patients encompassed by Section 2-1b(5) PRA provided in the preparatory works are repeated in the administrative circular *rundskriv IS-12/2004 om lov om pasientrettigheter*, which provides: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 Administration²⁰ 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."

23. The Authority notes that a new administrative circular is underway, set to replace *IS-12/2004*, however, as concerns Chapter 2 of the PRA, hereto Section 2-1b(5) of the PRA, this part of the circular has not yet been adopted and published.²¹

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

24. The Authority notes that Norway has adopted legislative changes to the Patients' Rights Act and other related Acts²² with a view to implementing the Patients' Rights Directive.²³
25. 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 the reimbursement issue under Article 36 EEA.
26. The Authority observes that these legislative changes *inter alia* also entail that Section 2-1b(2) of the Patients' Rights Act now provides that patients who may previously not have been entitled to medical treatment from the specialist health services within a

¹⁹ *Rundskriv IS-12/2004 om lov om pasientrettigheter*, page 54, 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 15, accessible under the following hyperlink: <https://helsedirektoratet.no/Lists/Publikasjoner/Attachments/945/IS-%208%202015%20Rundskrivpasientogbrukerrettighetsloven%2004-2015.pdf>

²² Cf. Act of 21 June 2013 no 79.

²³ The Act referred to at point 2 in Annex X to the EEA Agreement, *Directive 2011/24/EU on patients' rights in cross-border healthcare*.

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.

27. Furthermore, a new reimbursement arrangement (*refusjonsordning*) has been enacted regarding in-patient treatment in other EEA States by *Regulation of 19 December 2014*, amending *Regulation No 1466/2010 on reimbursement of health care services received in another EEA State* (“**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 *Regulation No 1466/2010 on reimbursement of health care services received in another EEA State*.

28. Section 2 (1) of the Regulation provides:

"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."

29. The health care refunded pursuant to the 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, cf. 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 Regulation, in cases where patients spend the night in the treatment institution, was repealed.

30. Section 7(2) of the Regulation provides for the following rule as concerns the reimbursement:

"For health care equivalent to health services that is reimbursed pursuant to the National Insurance Act Sections 5-4, 5-5, 5-7, 5-8 and 5-12 and specialist health services as mentioned in Section 3[(1)(d)] of this Regulation, [...] the reimbursement constitutes the actual costs unless the amount exceeds the estimated costs which the public [health care services] would have been charged if the health care was received in Norway. The reimbursement is limited in this case to an amount equivalent to the estimated cost which the public [health care services] would have had to pay if the if the health care was received in Norway."

²⁴ Cf. Pages 42, 47 and 68 of Prop. 118 L(2012-2013).

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 No 2011/24²⁵ (hereinafter referred to as "the Patients' Rights Directive" or "Directive 2011/24") 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

²⁵ The Act referred to at point 2 of Annex X to the EEA Agreement.

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

4.1.1 Legislative changes in Norway and remaining issues

37. Despite the legislative changes to national law addressed in Section 2.3 of the present letter of formal notice, which remedied part of the breach identified in the initial letter of formal notice, and despite the Norwegian Government's extensive reply to the initial letter of formal notice and subsequent follow-up thereof, important elements remain to be addressed by the Norwegian Government, and are, in the Authority's opinion, still not in line with EEA law.
38. The Authority's remaining concerns relate to the lack of criteria which are clear and in line with EEA law. These concerns relate to four issues.
39. First, the necessity test, pursuant to Section 2-1b(2) PRA, which determines whether a patient is entitled to in-patient treatment at all, and thus subsequently also to in-patient treatment abroad, does not appear to 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) Directive 2011/24. This issue will be further addressed in Section 4.2.

40. Second, the Reimbursement Regulation has set up a system for reimbursement of in-patient treatment abroad, which the Authority considers accommodates its concerns with respect to Article 36 EEA. The Reimbursement Regulation entails a cost cap, which is in line with Norway's obligations under Article 36 EEA. However, there is no legal basis for reimbursing the patient in full, in cases where he or she would have been entitled to a refund under Regulation 883/2004, but for some reason did not receive authorisation for treatment abroad at all or in good time. This issue is problematic both with respect to Article 20 of Regulation 883/2004 and/or Article 7(6) of Directive 2011/24, and will be addressed in Section 4.3.
41. Third, 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. By maintaining in force this legislation, 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 such 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)-(11), 8(1), 8(3)-(5) and 9(1) of Directive 2011/24. This issue will be further addressed in Section 4.4.
42. Fourth, there are legal certainty concerns as regards the Norwegian criteria on access to in-patient treatment abroad. By failing to ensure that the Norwegian criteria applicable to applications for authorisation or reimbursement of in-patient medical treatment abroad, such as Section 2-1b(2) PRA, Section 3 PR and Section 2-1b(5) PR, as well as Section 6 PR and 7(2) of the Reimbursement Regulation, meet the requirements established in the case law concerning objectivity, clarity, transparency and precision, as required also by Articles 7(7), 7(9)-(11), 8(1), 8(3)-(5) and 9(1) of the Patients' Rights Directive, 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.

4.1.2 New secondary legislation – Directive 2011/24 on Patients' Rights

43. Following the entry into force of the Patients' Rights Directive, the Authority's concerns in this respect have only been enhanced.
44. 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.²⁶ 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.
45. Following the entry into force of the Directive, there is now a clear obligation on EEA States to have, as regards both authorisation and reimbursement, objective and non-

²⁶ Paragraphs 12 and 21 of the preamble, Article 2(m)

discriminatory criteria which are necessary and proportionate, in relation to access to cross-border health care.

4.2 The necessity test

46. A pre-condition for reimbursement is that the patient is entitled to treatment in Norway in accordance with Section 2-1b(2) PRA.²⁷ Having such a pre-condition is indeed foreseen by Article 20(2) second sentence of Regulation 883/2004 and by Article 7 of Directive 2011/24, 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.***”
47. In Norway, there is no exhaustive list of benefits provided. Instead, Section 2-1b(2) PRA and Section 2 PR entail a *necessity* assessment. They grant the patient the right to *necessary medical treatment*, insofar as 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. If the condition in Section 2-1b(2) PRA is not fulfilled, the patient is not entitled to medical treatment neither nationally nor abroad. 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. However, such criteria must respect the principles of EEA law.²⁸
49. Therefore, rules related to this pre-condition must be clearly and precisely defined, otherwise it might limit considerably the use by patients of the right to be treated abroad. The Authority wishes to stress in this context that 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.²⁹ 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.³⁰
50. However, 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 will be assumed by the EEA State in question.³¹ 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

²⁷ Cf. Section 2 PR.

²⁸ Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*, cited above, paragraph 43.

²⁹ Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*, cited above, paragraphs 84-85. See also Case C-173/09 *Elchinov*, cited above, paragraphs 65-67 and the case-law cited therein.

³⁰ *Ibid.*

³¹ Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*, cited above, paragraph 51 and the case-law cited therein.

available information, including, in particular, and *inter alia*, existing scientific literature and studies and the authorised opinions of specialists.³²

51. The relevant legislation and complaints received by the Authority show that there does not seem to be a requirement that expected benefits are evaluated in accordance with what is established by international medical science. In fact, the lack of clear guidelines with respect to this criterion appears to give rise to conclusions which it is unclear how the relevant administrative bodies have come to.
52. By way of example, one complainant's status as a "rights patient"³³ within the meaning of Section 2-1b(2) PRA was revoked on appeal under the PRA.³⁴ In the aforementioned 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,³⁵ contrary to what this patient was informed of originally. Similarly, in the Norwegian Appellate Body for Treatment Abroad ("the AB")'s latest decision 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.³⁶ 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 specialists, with relevant experience with the disease at hand, would be required in order to successfully treat (surgically) the complainant's condition.³⁷ 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.³⁸
53. 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.³⁹
54. In light of all 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

³² Case C-157/99 *Smits and Peerbooms*, cited above, paragraphs 97-98; Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*, cited above, paragraph 51.

³³ Complainant in case 74770; Letter from Fylkesmannen i Hordaland to the complainant dated 26 November 2013, ref. 2013/9469 736.1

³⁴ See letter from Helse Bergen dated 29 September 2004.

³⁵ Letter from Fylkesmannen i Hordaland to the complainant dated 26 November 2013, ref. 2013/9469 736.1

³⁶ UKN-2010-108, AB decision of 20 June 2011.

³⁷ UKN-2010-108, AB decision of 20 June 2011 no 10/108 on pages 5 through 6.

³⁸ UKN-2010-108 at page 13, third paragraph fourth sentence.

³⁹ 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 65-67.

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.⁴⁰

4.3 Treatment not provided within a medically justifiable deadline

55. As pointed out in Section 3 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 individual concerned. 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 State to get treatment by a medical service provider there follows from Article 20(2) of Regulation 883/2004, and the corresponding case-law under Article 36 EEA.⁴¹
56. The Norwegian Government informed the Authority that it had set up a reimbursement system for in-patient treatment abroad, encompassed in *Regulation No 1466/2010 on reimbursement of health care services received in another EEA State*. That is certainly a most welcome improvement of the Norwegian system. Following the extension of the Reimbursement Regulation to in-patient medical treatment, the breach under Article 36 has been rectified.
57. However, the new reimbursement system, laid down in the consolidated version of the Reimbursement Regulation⁴² entails a cost cap, which is problematic in cases where patients would have been entitled to receive authorisation under Regulation 883/2004 since they could not receive authorisation for *equally effective* in-patient treatment abroad in *due time*.⁴³ In such a situation, the patient is entitled to a full refund as if (s)he had received due authorisation under Regulation 883/2004 but for some reason did not receive it at all or in time. In this respect, and since there is no exception for the cost cap in such a situation, Section 7(2) of the Reimbursement Regulation is problematic.
58. Following information received from the Norwegian Government, it appears, however, that the guidance document to the incorporating regulation for Regulation 883/2004⁴⁴ provides that in such cases, i.e. where a patient would have been entitled to authorisation under Regulation 883/2004,⁴⁵ he or she will receive the due coverage of costs, even if the authorisation route was not followed (e.g. in cases where the application was not approved in due time or in cases where the application was (possibly unduly) rejected and is awaiting processing by the complaint body).

⁴⁰ 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 65-67.

⁴¹ Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*, cited above, paragraph 83.

⁴² Forskrift av 22. November 2010 nr. 1466 om stønad til helsehjelp mottatt i annet EØS-land

⁴³ Case C-173/09 *Elchinov* [2010] ECR I-8889, 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* ECR I-00000, paragraph 25 onwards; Case C-368/98 *Vanbraekel and Others* [2001] ECR I-5363, paragraph 53.

⁴⁴ See *Rundskriv Hovednr. 45 – kapittel 5*, at point 5.5.2. e), accessible under the following hyperlink: <https://www.nav.no/rettskildene/Rundskriv/Hovednr.+45+-+Kapittel+5+-+Rett+til+naturalytelse+%28helsetjenester%29.311711.cms>

⁴⁵ Which has been incorporated into the Norwegian legal order by Regulation of 22 June 2012 no 585

59. The Norwegian Government has informed the Authority that the administrative interpretative circular⁴⁶ to the Regulation incorporating Regulation 883/2004⁴⁷ provides that:⁴⁸

“An application for authorisation under Article 20(1) should be sent before the trip [abroad], and at the latest within the time at which the relevant treatment commences. However, an application should not be rejected on the basis that it has not been put forth before the planned treatment was conducted. The CJEU has, in several judgments, held that applications concerning refund of already incurred expenses for planned treatment in another EEA State shall always be processed since, in all cases, a concrete assessment of whether prior approval would have been granted if the application had been made before the patient travelled abroad and at the latest within [the time of] commencement of the treatment. “The requirement” of prior authorisation is thus not absolute and does not constitute a separate basis for rejection. [...] As concerns the case where the applicant has appealed the rejection in the first instance, this also does not, in itself, give the right to reject the application concerning a refund of the applicant’s expenses relating to the completed medical treatment in another EEA State.”

60. Such interpretation of the relevant national legislation seems to be in line with EEA law. However, the circular is just a guidance document, and is not explicitly mentioned in the legislation. Quite to the contrary, Section 7(2) of the Reimbursement Regulation seems to preclude such an interpretation in setting a cost cap for the reimbursement of in-patient treatment, without any exception for situations in which a patient would be entitled to a full reimbursement if (s)he would have been entitled to an authorisation under Regulation 883/2004 but for some reason did not receive it at all or in time.
61. The maintenance of the absolute cost cap provision creates an uncertainty for persons seeking to avail themselves of their rights under Regulation 883/2004 *ex post*, even if the guidance document to the national measure transposing Regulation 883/2004 appears to disregard these implications of Section 7(2) of the Reimbursement Regulation. Similarly to the judgment in Case C-167/73 *Commission v France*, such uncertainties arising from national rules in conflict with EEA law must be regarded as obstacles to the full application of EEA law.⁴⁹
62. In light of this, the Authority is of the opinion that, by maintaining in force Section 7(2) of the Reimbursement Regulation (without any exceptions being provided therein), Norway still does not ensure that patients will have the right to be fully reimbursed for in-patient treatment abroad in cases where it is clear that they cannot be given such treatment within a medically justifiable deadline in Norway, and that they would have been entitled to authorisation under Regulation 883/2004 but for some reason did not receive it at all or in due time, contrary to Article 20 of Regulation 883/2004 and/or Article 7(6) of Directive 2011/24.⁵⁰

⁴⁶ Rundskriv til Folketrygdloven - Hovednr. 45 - Kapittel 5 - Rett til naturalytelser, utarbeidet av Helsedirektoratet ved avdeling behandlingsrefusjon 31.03.2012, at point 5.5.2(e).

⁴⁷ Namely Regulation of 22 June 2012 no 585 (*Forskrift om inkorporasjon av trygdeforordningene i EØS-avtalen*)

⁴⁸ Unofficial translation by the Authority.

⁴⁹ Case C-167/73 *Commission v France* [1974] ECR I-00359 paragraphs 41-42 and 47.

⁵⁰ Case C-173/09 *Elchinov* [2010] ECR I-8889, 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* ECR I-00000, paragraph 25 onwards; Case C-368/98 *Vanbraekel and Others* [2001] ECR I-5363, paragraph 53.

4.4 Lack of competence or adequate treatment in Norway

63. As regards the second aspect of the initial letter of formal notice, namely the use of the terms “no adequate medical treatment/no competence” in the Norwegian legislation, this issue was discussed at the package meeting in Norway in October 2014. Following the package meeting, the Norwegian Government provided further information on both possible plans to amend these criteria, by letter dated 15 December 2014.⁵¹ However, the criterion relating to “no adequate medical treatment/no competence” remains in the Norwegian legislation, and the mentioned potential project to amend this has not yet materialized.⁵²
64. By letter dated 9 October 2015 (Doc No 775927, your ref.: 12/3887), the Norwegian Government informed the Authority that new guidelines had been adopted with respect to Section 3 PR. No substantial change to Section 3 PR was made, and the new guidelines emphasise that the patient will be entitled to treatment abroad pursuant to this provision if the treatment in question “*cannot be performed properly in Norway according to an accepted method. If an adequate treatment offer exists in Norway, the patient will not be entitled to treatment abroad pursuant to this provision. This is the case even if there is a possibly more advanced treatment option might have been developed abroad, or the patient would like to obtain treatment pursuant to a method which is not offered in Norway.*”
65. Norway is certainly free to decide which treatment methods its social security system will cover. The Authority notes, however, that treatment which is “*possibly more advanced*” would not necessarily be considered more effective, so long as it is not established according to international medicine that the treatment abroad is indeed more effective. 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.⁵³ The aforementioned guidance on Section 3 PR does thus not seem to bring about any substantial change, in emphasising primarily the same elements as Section 2-1b(5) along with guidance documents and preparatory works focus on. Furthermore, Section 3 PR in itself remains unchanged, and is still titled “Health care abroad due to lacking competence in Norway.”
66. In addition, the guidelines/preparatory works to the PRA remain unchanged. Section 2-1b(5) of the PRA provides that a lack of adequate medical services in Norway will give patients entitled to treatment in Norway within a specific deadline established pursuant to Section 2-1b(2) PRA⁵⁴ (“*rights patients*”) the right to receive *necessary health care* from a service provider outside Norway. It follows from Section 3 PR and Section 2-1b(5) of the PRA in conjunction with the preparatory works to the provision⁵⁵ and the relevant administrative circular (*rundskriv*),⁵⁶ which has still not been revised with respect to this section, that the “*lack of adequate medical services*”

⁵¹ Doc No 732995, your ref.: 12/3887.

⁵² Doc No 748232 and 761895.

⁵³ Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*, cited above, paragraphs 84-85. See also Case C-173/09 *Elchinov*, cited above, paragraphs 65-67 and the case-law cited therein.

⁵⁴ Cf. Section 2 PR.

⁵⁵ Ot.prp.nr.63 (2002-2003) *Om lov om endringer i lov 2. juli 1999 nr. 63 om pasientrettigheter (pasientrettighetsloven) m.m.*

⁵⁶ *Rundskriv IS-12/2004 om lov om pasientrettigheter*, page 54.

is to be understood as a “*lack of medical competence*” criterion, which indeed remains the heading of Section 3 PR.

67. The consideration of whether medical competence in Norway is lacking and/or whether the actual health care in Norway is “adequate,” is thus a key criterion for entitlement to reimbursement or authorisation for in-patient medical treatment abroad under the applicable Norwegian legislation, rather than whether actual equally effective treatment can be provided to the patient within a medically justifiable deadline. 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 reflect that this criterion is considered the primary one when evaluating whether adequate medical services exist in Norway.⁵⁷
68. As regards the detailed reasoning concerning the breach under Regulation 883/2004 and Article 36 in this respect, reference is made to Section 4.3.1. through 4.3.3. of the Authority’s initial letter of formal notice.
69. In its reply to the initial letter of formal notice of 18 August 2014, the Norwegian Government enclosed, in the letter’s annex 3, 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 up to between 67% and 77% of applications for treatment abroad were granted under this provision.
70. The Authority does not contest that a number of applications for treatment abroad are indeed granted in Norway. However, the Norwegian legislation providing for criteria for in-patient treatment abroad, as they currently read – read in conjunction with relevant preparatory works and guidelines, and as illustrated also by the AB’s practice – does not properly ensure that individual assessments of the specific patients’ 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.⁵⁸ That is of course not to say, that such assessments are *never* being made by the relevant competent bodies in Norway. However, the current criterion does not ensure the proper application of EEA law.
71. 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.⁵⁹
72. 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

⁵⁷ UKN-2014-53, 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.

⁵⁸ Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*, cited above, paragraphs 83-85

⁵⁹ See *inter alia* Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*, cited above, paragraph 85, Case C-173/09 *Elchinov*, cited above, paragraphs 67 and 80.

to carry out a professional activity,⁶⁰ rather than the (general) medical competence or general adequacy of medical services in the relevant EEA State. 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.⁶¹

73. 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 citizen from all EEA States have a legal claim for the best hospital services available at any given time within the entire EEA.*" The Authority in principle does not disagree with this assertion. However, the Authority would once again like to underline that the EFTA Court and the CJEU have held that when it has been established according to international medicine that the treatment abroad is *indeed* more effective, the home State can no longer prioritise its own treatment offer, as concerns patients who are entitled to medical treatment according to the national criteria.⁶²
74. The "*lack of competence/lack of adequate medical services*" criterion furthermore seems to entail an assessment pursuant to which patients need to claim, and get the competent body to approve, that the medical services/competence in question is not adequate in Norway. This is, in the Authority's view, tantamount to having to demonstrate why it is medically necessary for the particular health care 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*,⁶³ requiring such a demonstration of medical necessity does not seem to be in line with Articles 7(9)-(11), 8(1), 8(3)-(5) and 9(1) of the Patients' Rights Directive. 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.
75. In light of the examples developed in the initial letter of formal notice and despite the elements presented by Norway in the reply to the initial letter 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), 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

⁶⁰ Case C-173/09 *Elchinov*, cited above, paragraph 66 and the case-law cited therein.

⁶¹ 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.

⁶² Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*, cited above, paragraphs 84-85. See also Case C-173/09 *Elchinov*, cited above, paragraphs 65-67 and the case-law cited therein.

⁶³ 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.

treatment under the Norwegian legislation.⁶⁴ Rather, as also emphasised in the preparatory works and in the relevant *rundskriv* to Section 2-1b(5) PRA,⁶⁵ 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 appear to focus on the general competence or adequacy of the treatment offered in Norway, and do not appear to 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.

76. 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 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.
77. 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) and 7(9), 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.

4.5 Legal certainty

78. The Authority notes that it appears that the full scope of the criteria applied in Norway to applications for authorisations or reimbursement of costs relating to medical treatment abroad do not seem fully objective, and do not appear to be fully known in advance to potential applicants for such.
79. As the EFTA Court has held, *inter alia* in Case E-9/11 *EFTA Surveillance Authority v The Kingdom of Norway*,⁶⁶ the principle of legal certainty requires that national rules of the EEA States which 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,⁶⁷ must satisfy the principle of legal certainty. This implies that, *inter alia*, criteria for prior administrative approval must be objective, non-discriminatory and known in advance to concerned persons. Where national law does not satisfy 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,⁶⁸ and therefore is not in line with EEA law.
80. 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):

⁶⁴ Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*, cited above, paragraphs 84-85. See also Case C-173/09 *Elchinov*, cited above, paragraphs 65-67 and the case-law cited therein.

⁶⁵ Cited in Section 2 of this letter of formal notice.

⁶⁶ 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.

⁶⁷ Case C-385/99 *Müller-Fauré*, cited above, paragraph 103 and the case-law cited therein.

⁶⁸ Case C-318/10 *SIAT* [2012] ECR I-0000, paragraphs 58-59 and the case-law cited therein.

*“In order to ensure that the rules and standards mentioned at paragraphs 46 and 47 above are indeed applied in a way which does not discriminate against suppliers of medical services established in other EEA States, the rules and standards **must be based on objective, non-discriminatory criteria**, see for comparison Case 238/82 Duphar [1984] ECR 523, at paragraph 20–21. 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).”⁶⁹*

81. Following the entry into force of the Patients’ Rights Directive, and the obligations therein, Norway is now also required to have objective, necessary, proportionate and non-discriminatory criteria pursuant to its obligations thereunder.⁷⁰
82. Firstly, it is not clear what elements are taken into account in the “necessity” assessment pursuant to Section 2-1b(2) of the PRA, 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.⁷¹
83. Secondly, by maintaining in force Section 7(2) of the Reimbursement Regulation (without any provided exceptions therein), Norway still does not ensure that patients will have the right to be fully reimbursed for in-patient treatment abroad in cases where it is clear that they could not be given such treatment within a medically justifiable deadline in Norway, and that they would have been entitled to authorisation under Regulation 883/2004 but for some reason did not receive it at all or due time, contrary to what Article 20 of Regulation 883/2004 requires,⁷² as explained in Section 4.3.⁷³ This is also contrary to what is required by Articles 7(6), 7(9)-7(11), 8(1), 8(3)-(5) and 9(1) of the Patients’ Rights Directive.
84. Thirdly, 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.

⁶⁹ See Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*, cited above, paragraph 48.

⁷⁰ Articles 7(7), 8(1), 8(3)-(5) and 9(1) of Directive 2011/24.

⁷¹ *Ibid.*

⁷² Case C-173/09 *Elchinov* [2010] ECR I-8889, 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* ECR I-00000, paragraph 25 onwards; Case C-368/98 *Vanbraekel and Others* [2001] ECR I-5363, paragraph 53.

⁷³ See Section 4.4.1.

85. 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, 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 also does not contain a reference to the Reimbursement Regulation. 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, and (ii) reimbursement under Article 36 EEA, as provided for by the Reimbursement Regulation.⁷⁴
86. 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(7), 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 7(2) of the Reimbursement Regulation, Section 3 PR and Section 2-1b(5) PR, as well as Section 6 PR, must therefore be considered disproportionate in themselves, rendering them *as such* incompatible with Article 36 EEA and/or Article 20 of Regulation 883/2004 and/or Articles 7(6), 7(9)-7(11), 8(1), 8(3)-(5) and 9(1) of Directive 2011/24.⁷⁵

5 Conclusion

Accordingly, as its information presently stands, the Authority must conclude that:

- by maintaining in force legislation, such as Section 2-1b(2) PRA and Section 2 PR, which entails 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 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 the Patients' Rights Directive;
- by maintaining in force Section 7(2) of the Reimbursement Regulation (without any provided exceptions therein), which does not ensure that patients will have the right to be fully reimbursed for in-patient treatment abroad in cases where it is clear that they cannot be given equally effective treatment within a medically justifiable deadline in Norway, and that they would have been entitled to authorisation under

⁷⁴ Case C-173/09 *Elchinov* [2010] ECR I-8889, 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* ECR I-00000, paragraph 25 onwards; Case C-368/98 *Vanbraekel and Others* [2001] ECR I-5363, paragraph 53.

⁷⁵ Case C-318/10 *SIAT* [2012] ECR I-0000, paragraph 58-59 and the case-law cited therein.

Regulation 883/2004 but for some reason did not receive it at all or in due time, the Kingdom of Norway has failed to fulfil its obligations under Article 20 of Regulation 883/2004 and/or Articles 7(6) of the Patients' Rights Directive;

- by maintaining in force legislation, such as Section 2-1b(5) of the Patients' Rights Act and Section 3 of the Prioritisation Regulation, 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, 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 7(2) of the Reimbursement Regulation, 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 the Patients' Rights Directive, 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.

In these circumstances, and acting under Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice, the Authority requests that the Norwegian Government submits its observations on the content of this letter *within two months* of its receipt.

After the time limit has expired, the Authority will consider, in the light of any observations received from the Norwegian Government, whether to deliver a reasoned opinion in accordance with Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice.

For the EFTA Surveillance Authority

Frank Büchel
College Member

This document has been electronically signed by Sven Erik Svedman, Frank Buechel on 03/02/2016