Brussels, 14 May 2014
Case No: 72376 (related to complaints no: 66927, 74734, 72754, 71454 and 74770)
Event No: 692126
Decision No: 203/14/COL

EFTA SURVEILLANCE AUTHORITY

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

Dear Sir or Madam,

Subject: **Letter of formal notice to Norway concerning the criteria for access to in-patient treatment in other EEA States - breach of Article 20 of Regulation 883/2004 and/or Article 36 EEA**

1 Introduction and correspondence

The present case deals with the general rules and the system in place in Norway concerning access to hospital treatment in other EEA States (so-called "in-patient treatment").[1]

By several letters dated 29 July 2009 (Event No 525862), 6 November 2012 (Event No 652021), 13 September 2012 (Event No 646466), 6 December 2013 (Event No 692434) and 13 December 2013 (Event 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.

Since then, the Authority has received several additional letters and e-mails from patients in Norway with other medical conditions but similar problems when requesting authorisation for medical treatment in a hospital abroad or reimbursement of such treatment.

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.

[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 (Event No 691859). The Norwegian Government replied to this letter by letter dated 15 January 2014 (Event No 695845, your ref.: 13/4326).

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 has now reached the conclusion that certain provisions in the Norwegian legislation are 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.

The above conclusion follows from the Authority's scrutiny of the Patients' Rights Act and the Prioritisation Regulation, and the lack of criteria provided therein to ensure a comprehensive assessment on a case-by-case basis of whether *equally effective treatment* can be provided to the *individual* patient *within a medically justifiable deadline* in Norway, as concerns in-patient (hospital) treatment. Such criteria and individual assessment would be, in the Authority's opinion, the only valid basis for refusing applications for authorisation or reimbursement of medical treatment abroad.

The Authority has several further concerns regarding the Norwegian legislation. These relate in particular to rules prohibiting patients whose medically justifiable deadlines for treatment, as set under the national legislation, have expired from turning directly to another EEA medical service provider to receive the treatment to which they are entitled upon the expiry of this deadline. This is not in line with EEA law. Additionally, the Authority has reached the conclusion that Norway has failed to fulfil its obligations under Regulation 883/2004 on social security coordination and Article 36 EEA, by failing to ensure, where it has been established that a patient cannot be given the medical treatment to which he is entitled under the national legislation *within a medically justifiable time limit* under the national system, that such a patient will obtain the necessary authorisation under Article 20(2) of Regulation 883/2004 to turn to an EEA medical service provider, and/or that the patient will obtain reimbursement under Article 36 of the EEA Agreement for such treatment.

In this context, the Authority notes that whereas a system of prior authorisation for access to in-patient treatment abroad is as such permissible under EEA law, EEA law requires that any such system must be easily accessible and capable of ensuring that a request for authorisation will be dealt with objectively and impartially within a reasonable time.[4] Furthermore, it must be possible to obtain sufficient knowledge of the grounds of such decisions from the administration, and refusals to grant authorisation must be capable of being challenged in judicial or quasi-judicial proceedings.[5]

2 Relevant national law

2.1 Entitlement to in-patient medical treatment in Norway

In general, anyone who either resides or is employed in Norway is compulsorily insured under the National Insurance Scheme and entitled to healthcare. The provision of healthcare outside of hospitals is mostly a municipal responsibility, whereas hospital treatment generally is the responsibility of the State through four Regional Health Enterprises.

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

[4] See Case C-222/86 *Heylens* [1987] ECR I-4097, paragraphs 15 and 17; Case C-249/88 *Commission v Belgium* [1991] ECR I-1275, paragraph 25; Case C-340/89 *Vlassopoulou* [1991] ECR I-2357, paragraph 22; and Case C-19/92 *Kraus* [1993] ECR I-1663, paragraph 40.

[5] Case C-157/99 *Smits and Peerbooms*, cited above, paragraph 90; Case C-385/99 *Müller-Fauré*, cited above, paragraph 85; Case C-372/04 *Watts*, cited above, paragraphs 115-116; Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*, cited above, paragraph 48.

A pre-requirement for entitlement to treatment abroad, is, firstly, that the patient is entitled to *necessary healthcare* in Norway within the meaning of Section 2-1b(2) of Act of 2 July 1999 No. 63 relating to Patients' Rights (**"the Patients' Rights Act", "PRA"**). This means that the Norwegian health care system does not simply have a list of treatments that are covered by its system, but provides any treatment to its patients that is "*necessary*".

Section 2-1b(2) PRA specifies:[6]

> *"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. [...]"*

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: [7]

> *"The patient is entitled to receive necessary health care from the specialist health service pursuant to Section 2-1b [(2) PRA] when:*
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> 1. *The patient has a certain prognosis of 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."*

2.2 Entitlement to in-patient medical treatment abroad

Provided that the necessity condition in Section 2-1b(2) PRA[8] 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

[6] Unofficial translation by the Authority.
[7] Unofficial translation by the Authority.
[8] Cf. Section 2 PR.

are *no adequate medical services in the realm*, and is also applicable *prior* to the expiry of the aforementioned time limit:[9]

> *"[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)

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:[10]

> *"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,[11] which shall ensure that such services from public service provider or if necessary from a private service provider or if necessary abroad. 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)

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**:[12]

> *"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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> *[...]*

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[9] Unofficial translation by the Authority, emphasis added.
[10] Unofficial translation by the Authority, emphasis added.
[11] That is, HELFO. See Section 4.2 of this letter.
[12] Unofficial translation by the Authority.

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 without, as part of treatment abroad."

Concerning the more precise content of the right to treatment abroad for patients encompassed by Section 2-1b(5) PRA, the preparatory works state:[13]

"*By adding [Section 2-1b(4)],*[14] *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.*

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."

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:[15]

"*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*[16] *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.*"

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[13] Ot.prp.nr.63 (2002-2003) *Om lov om endringer i lov 2. juli 1999 nr. 63 om pasientrettigheter (pasientrettighetsloven) m.m.* on page 61. Unofficial translation by the Authority, emphasis added.

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

[15] *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.

[16] 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.

Additionally, the abovementioned interpretation of the legislation indicated in the preparatory works and relevant administrative circulars are repeated and reaffirmed in several decisions of the Norwegian Appellate Body for Treatment Abroad (**"the AB"**).[17]

2.3 Legislative amendments to the Patients' Rights Act etc.

The Authority notes that Norway has adopted legislative changes to the Patients' Rights Act and other related Acts[18] with a view to implementing the Patients' Rights Directive (which is not yet incorporated into the EEA Agreement).[19]

The Authority observes that these legislative changes *inter alia* entail that Section 2-1b(2) of the Patients' Rights Act will give 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, even if they were in need of such treatment, now the explicit right to treatment within a deadline.[20] 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.

Furthermore, a new reimbursement arrangement (*refusjonsordning*) is foreseen in relation to in-patient treatment in other EEA States. This new arrangement's legal basis will be an addition to the Social Security Act's Section 5-24a(2)(c). However, the Ministry has not yet decided on the detailed provisions of this arrangement.[21]

Whereas these changes are welcome, they would not seem to meet the concerns raised by the Authority in the present letter of formal notice. The legislative changes foreseen in connection with the future implementation of the Patients' Rights Directive do not specifically address or remedy the issues dealt with in the present letter of formal notice.

3 Relevant EEA law

3.1 The EEA Agreement

Article 29 of the EEA Agreement provides for the coordination of social security schemes to facilitate the free movement of workers and self-employed persons within the EEA.

Annex VI to the EEA Agreement contains the provisions necessary to implement Article 29 of the EEA Agreement. The Acts referred to at points 1 and 2 of Chapter I of Annex VI to the EEA Agreement, namely Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems[22] ("Regulation 883/2004") and Regulation (EC) No 987/2009 of the European Parliament and of the Council of 16 September 2009 laying down the procedure for implementing

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[17] In Norwegian: *Klagenemnda for behandling i utlandet*. See for example decisions UKN-2012-5, UKN-2011-105, UKN-2011-102, UKN-2011-97, UKN-2011-107, UKN-2011-90, UKN-2011-64, UKN-2011-63, UKN-2011-48, UKN-2011-58, UKN-2011-54, UKN-2011-43, UKN-2011-38, UKN-2011-38, UKN-2011-28, UKN-2011-17, UKN-2011-13. UKN-2011-97, UKN-2011-90, UKN-2011-64, UKN-2010-108, UKN-2009-95, UKN-2009-89, UKN-2008-79, UKN-2008-77, UKN-2007-109.

[18] Cf. Act of 21 June 2013 no 79, most of which has not yet entered into force.

[19] *Directive 2011/24/EU on patients' rights in cross-border healthcare.*

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

[21] Cf. page 80 of Prop. 118 L(2012-2013).

[22] OJ L 166, 30.4.2004, p. 1.

Regulation (EC) No 883/2004 on the coordination of social security systems[23] ("Regulation 987/2009"), both as amended and as adapted to the EEA Agreement by Protocol 1 thereto, coordinate the application of social security schemes within the EEA.

Article 36 of the EEA Agreement provides that there shall be no restrictions on the freedom to provide services within the EEA in respect of EEA State nationals who are established in an EEA State other than that of the person for whom the services are intended.

This provision must, in light of the case law of the Court of Justice of the European Union ("the CJEU"), be interpreted as conferring rights not only on the provider of services, but also on the recipient.[24] Thus, the freedom to provide services involves removing restrictions not only on the freedom of the provider to offer and supply services to recipients in an EEA State other than that in which he is located, but also on the freedom to receive or benefit as a recipient from the services offered by a provider established in another EEA State.[25]

Article 33 EEA, in conjunction with Article 39 EEA, provides that Article 36 EEA shall not prejudice the applicability of provisions laid down by law, regulation or administrative action providing for special treatment of foreign nationals on grounds of public policy, public security or public health.

Furthermore, rules restricting the freedom to provide services may be justified by overriding reasons relating to the general interest, provided that the rules are suitable for securing the attainment of their objective and are proportionate.[26]

3.2 The right to planned medical treatment abroad in light of CJEU and EFTA Court case law

3.2.1 Article 20 of Regulation 883/2004[27]

Article 20 of Regulation 883/2004 contains no automatic right to an authorisation for health care in another EEA State.

The CJEU has held that by guaranteeing that insured persons, who are covered by the legislation of one EEA State and have been granted authorisation, have access to treatment in the other EEA States on conditions as favourable as those enjoyed by persons covered by the legislation of those other EEA States, Article 20 of Regulation 883/2004[28] helps to facilitate the free movement of persons covered by social insurance and, to the same

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[23] OJ L 284, 30.10.2009, p. 1.

[24] Case C-294/97 *Eurowings Luftverkehrs AG* [1999] ECR I-7447, paragraph 34, and the cases cited therein; Case C-512/08 *European Commission v France* [2010] ECR I-8833, paragraph 32.

[25] Case C-173/09 *Elchinov* [2010] ECR I-8889, paragraphs 36-37 and the case-law cited therein.

[26] See, *inter alia*, Case C-398/95 *SETTG v. Ypourgos Ergasias* [1997] ECR I-3091, paragraph 21; Case C-76/90 *Säger* [1991] ECR I-4221, paragraph 15; Case C-288/89 *Gouda and Others* [1991] ECR I-407, paragraphs 13–15; Case C-19/92 *Kraus* [1993] ECR I-1663, paragraph 32; and Case C-55/94 *Gebhard* [1995] ECR I-4165, paragraph 37; Case C-509/12 *Instituto Portuário e dos Transportes Marítimos (IPTM)*, judgment of 6 February 2014, not yet published, paragraph 18.

[27] Regulation 883/2004 largely replaced Regulation 1408/71, see Article 90(1) of Regulation 883/2004. The main substantive content of these acts is, however, the same, especially as concerns Article 22 of Regulation 1408/71 and Article 20 of Regulation 883/2004. Therefore, the rationale of the case-law under Article 22 of Regulation 1408/71 remains applicable.

[28] Ibid. Previously this provision was enshrined in Article 22 of Regulation 1408/71.

extent, the cross-border provision of medical services between EEA States.[29] It should be stressed in this regard that EEA law does not detract from the power of the Member States to organise their social security systems and that, in the absence of harmonisation at EEA level, it is for the legislation of each EEA State to determine the conditions for the granting of social security benefits.[30] However, when exercising that power, EEA States must comply with EEA law, in particular with the provisions on the freedom to provide services, as will be addressed in greater detail in Section 3.2.2 of this letter.

Article 20, paragraph 2, second sentence, of Regulation 883/2004 regulates the conditions for refusing such an authorisation. This provision states that an authorisation shall be accorded where the treatment in question is among the benefits provided for by the legislation in the Member State where the person concerned resides and where he 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.[31] The CJEU has deduced from this provision that its sole purpose is to identify the circumstances in which the competent national institution is precluded from refusing authorisation. That provision is not designed to limit the circumstances in which such authorisation may be granted pursuant to that provision.[32]

To conclude, a national health insurance administration cannot refuse, under Article 20 of Regulation 883/2004, a request for an authorisation for in-patient treatment abroad, which is covered by its own system, when equally effective treatment cannot, at all or within a medically justifiable time-limit, be provided to the patient under its own health care system.[33]

3.2.2 Article 36 EEA

It is settled case law that medical activities fall within the scope of Article 36 EEA, there being no need to distinguish in that regard between care provided in a hospital environment and care provided outside such an environment.[34]

The CJEU has held that Article 56 TFEU, corresponding to Article 36 EEA, requires the abolition of any national rule which is liable to prohibit, impede or render less attractive the provision of services between EEA States more difficult than the provision of services purely within an EEA State.[35] This applies not only to rules which regulate the right to seek treatment abroad as such, but also to rules on reimbursement from national social security systems of costs for treatment provided abroad.[36]

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[29] Case C-368/98 *Vanbraekel and Others* [2001] ECR I-5363, paragraph 32; Case C-56/01 *Inizan* [2003] ECR I-12403, paragraph 21; Case C-145/03 *Keller* [2005] ECR I-2529, paragraph 46; Case C-372/04 *Watts* [2006] I-4325, paragraph 135; Case C-466/04 *Herrera* [2006] ECR I-5341, paragraph 27.

[30] Case C-173/09 *Elchinov*, cited above, paragraph 57 and the case-law cited therein.

[31] Case C-372/04 *Watts*, cited above, paragraph 79.

[32] Case C-368/98 *Vanbraekel*, cited above, paragraph 31; Case C-173/09 *Elchinov*, cited above, paragraph 39 and the case-law cited therein.

[33] Case C-173/09 *Elchinov*, cited above, paragraph 65 and the case-law cited therein; Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*, cited above, paragraphs 83-84.

[34] See, Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, paragraph 53; Case C-385/99 *Müller-Fauré* [2003] I-4509, paragraph 38; and Joined cases E-11/07 and E-1/08 *Rindal and Slinning*, cited above, paragraph 42.

[35] Case C-265/12 *Citroën Belux NV*, judgment of 18 July 2013, not yet reported, paragraph 35 and the case-law cited therein.

[36] Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*, cited above, paragraph 44; Case C-173/09 *Elchinov*, cited above, paragraphs 40-41 and the case-law cited therein.

In relation to health care, the Court of Justice has held that rules that deter or prevent insured persons from applying to providers of medical services established in another EEA State other than that of the insurance fund constitute, both for insured persons and service providers, a barrier to freedom to provide services.[37]

As highlighted in the above section in relation to Regulation 883/2004, EEA law does not detract from the power of the EEA States to organise their social security systems and, in the absence of harmonisation at EEA level, it is for the legislation of each EEA State to determine the conditions for the granting of social security benefits.[38] However, when exercising that power, EEA States must comply with EEA law, in particular with the provisions on the freedom to provide services. Those provisions prohibit the EEA States from introducing or maintaining unjustified restrictions on the exercise of that freedom in the healthcare sector.[39]

The CJEU has expressly acknowledged the rationale of a prior authorisation for the entitlement to the abovementioned rights.[40]

According to settled case-law of the Court, in order for an administrative prior authorisation scheme to be justified even though it derogates from a fundamental freedom, it is necessary that it be based on objective, non-discriminatory criteria which are known in advance, in such a way as to circumscribe the exercise of the national authorities' discretion, so that it is not used arbitrarily.[41]

It should be noted that the applicability of Article 20 of Regulation 883/2004[42] to a national measure does not remove that measure from the scope of the main provisions of the EEA Agreement, including Article 36 EEA. For instance, it has been clearly held that the applicability of Article 20 of Regulation 883/2004[43] to a given situation does not exclude that the person concerned may have the right under Article 36 EEA to have access to healthcare in another EEA State under rules on the assumption of costs different from those laid down by Article 20 of Regulation 883/2004.[44]

In this regard it should be underlined that, as the CJEU has pointed out, there is no reason which seriously justifies different interpretations depending on whether the context is Article 20 of Regulation 883/2004[45] or Article 36 EEA, since in both cases the question is whether the hospital treatment required by the patient's medical condition can be provided on the territory of his state of residence within an acceptable time which ensures its usefulness and efficacy.[46] The difference lies in reimbursement, as under Regulation 883/2004 an *ex ante* authorisation is given and the patient does not have to pay for the

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[37] Case C-157/99 *Smits and Peerbooms*, cited above, paragraph 69; Case C-385/99 *Müller-Fauré*, cited above, paragraph 44.
[38] Case C-173/09 *Elchinov,* cited above, paragraph 57 and the case-law cited therein.
[39] Joined cases E-11/07 and E-1/08 *Rindal and Slinning* [2008] EFTA Ct. Rep. 322, paragraph 43 and the case-law cited therein.
[40] Case C-173/09 *Elchinov*, cited above, paragraph 41 and the case-law cited therein.
[41] Case C-157/99 *Smits and Peerbooms*, cited above, paragraph 90; Case C-385/99 *Müller-Fauré*, cited above, paragraph 85; Case C-169/07 *Hartlauer* [2009] ECR I-1721 paragraph 64 and the case-law cited therein; Case C-367/12 *Susanne Sokoll-Seebacher,* judgment of 13 February 2014, not yet published, paragraph 27.
[42] Previously: Article 22 of Regulation 1408/71.
[43] Previously: Article 22 of Regulation 1408/71.
[44] See Case C-372/04 *Watts*, cited above, paragraphs 47-48; Case C-173/09 *Elchinov,* cited above, paragraph 38 and the case-law cited therein.
[45] Previously: Article 22 of Regulation 1408/71.
[46] Case C-372/04 *Watts*, cited above, paragraph 60.

treatment up-front, while under Article 36 EEA the cost of the treatment is only reimbursed *ex post*. However, whereas Regulation 883/2004 applies to the coordination of social security systems, and therefore only concerns institutions affiliated with such, Article 36 also encompasses private service providers.

Thus, an assessment must also be conducted of the compatibility of the refusal to grant the authorisation or reimbursement request by the Norwegian authorities in these cases with the freedom to provide services enshrined in Article 36 EEA.

3.3 Concluding remarks on EEA law requirements

As outlined above, the case law of the CJEU and the EFTA Court has established that a national social security administration cannot refuse under Article 36 EEA a request for reimbursement for in-patient treatment abroad, which is covered by its own system, when effective treatment cannot, at all or within a medically justifiable time-limit, be provided to the patient under its national health care system.[47] Similarly, an authorisation for in-patient treatment abroad, cannot be refused under Article 20 of Regulation 883/2004 by a national social security administration, when the medical treatment is covered by its own system, when effective treatment cannot, at all or within a medically justifiable time-limit, be provided to the patient under its national health care system.[48]

An assessment must therefore be conducted by the national administrative body evaluating, where a patient is entitled to medical treatment under the national system, both *whether effective treatment can be provided* in the home State, and if the answer to this question is in the affirmative, *whether such treatment can be provided within a medically justifiable time-limit.*

Although the administrative procedure to be followed when deciding to grant or refuse authorisations or reimbursement requests is primarily a matter for national administrative law, EEA law does establish certain procedural requirements that must be met regarding the authorisation/reimbursement procedure. It must be ensured that the discretion of an authority to grant or refuse an authorisation or reimbursement cannot be exercised arbitrarily.

The system of prior authorisation must be easily accessible and capable of ensuring that a request for authorisation will be dealt with objectively and impartially within reasonable time. Concerned persons must be able to obtain sufficient knowledge of the grounds of such decisions from the administration,[49] and refusals to grant authorisation must be capable of being challenged in judicial or quasi-judicial proceedings.[50]

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[47] 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, paragraph 80.

[48] Case C-173/09 *Elchinov*, cited above, paragraph 67.

[49] See Case C-222/86 *Heylens* [1987] ECR I-4097, paragraphs 15 and 17; Case C-249/88 *Commission v Belgium* [1991] ECR I-1275, paragraph 25; Case C-340/89 *Vlassopoulou* [1991] ECR I-2357, paragraph 22; and Case C-19/92 *Kraus* [1993] ECR I-1663, paragraph 40.

[50] Case C-157/99 *Smits and Peerbooms*, cited above, paragraph 90; Case C-385/99 *Müller-Fauré*, cited above, paragraph 85; Case C-372/04 *Watts*, cited above, paragraphs 115-116; Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*, cited above, paragraph 48.

EFTA SURVEILLANCE AUTHORITY

4 The Authority's assessment

4.1 Introduction - the Norwegian legislation concerning access to in-patient medical treatment abroad

As outlined in Section 2 of this letter, Section 2-1b(4) and (5) of the PRA foresees two types of situations in which patients in Norway would be entitled to treatment abroad, namely either (a) if the treatment cannot be provided within the medically justifiable time-limit; or (b) if there is a lack of adequate treatment options/medical services.

A pre-condition in both cases is that the patient is entitled to treatment in Norway in accordance with Section 2-1b(2) PRA.[51] As highlighted above, 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.*"

In Norway, there is no exhaustive list of benefits provided. Instead, Section 2-1b(2) PRA and Section 2 PR entail a *necessity* assessment; giving the patient 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.

Such a necessity assessment as a criterion for entitlement to medical treatment nationally does not in principle appear to be contrary to EEA law. However, the Authority would like 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 not longer justify prioritising its own offer of treatment.[52] In light of this, the Authority is of the opinion that the evaluation of the expected benefits of the patient, as part of the aforementioned necessity assessment, should be conducted considering expected benefits in accordance with what has been established by international medical science, in applying the usual principles of interpretation and on the basis of objective and non-discriminatory criteria, taking into consideration all the relevant medical factors and available scientific data.[53]

The assessment in Sections 4.1.2 through 4.2.2 of this letter presupposes that the entitlement to treatment criterion has been 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.

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[51] Cf. Section 2 PR.

[52] 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.

[53] 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.

4.2 Situation type (a) – treatment not provided within a medically justifiable deadline

As pointed out in section 3.2 of this letter, 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 of 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 does not seem to sufficiently reflect this.

Firstly, Section 2-1b(4) of the PRA provides that "rights patients", i.e. patients entitled to treatment following the cost/benefit analysis established under Section 2-1b(2) of the PRA, 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.[54]

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.

Below are the statistics provided by Norway[55] on persons who have received treatment abroad according to Section 2-1b(4) PRA between 2007 and 2011.

2011	2010	2009	2008	2007
13	4	0	9	6

Secondly, the Authority notes that Section 2-1b(4) PRA establishes that the patient will only be accorded an *immediate* right to treatment abroad upon the expiry of the fixed time limit set under Section 2-1b(2) PRA.[56] Article 20(2) of Regulation 883/2004 and the case-law under Article 36 EEA have established that the patient is entitled to such a treatment *within* a medically justifiable time limit, not merely after such a medically justifiable time limit has passed. Where it is clear that *equally effective treatment*, to which the patient is entitled, cannot be provided *within* such a medically justifiable time-limit, or, *without*

[54] 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.
[55] See Event 621601 on page 3.
[56] Cf. Section 2 PR.

undue delay, the patient should have the right to go abroad immediately, without having to wait until the medically justifiable time limit for treatment has expired.

Ideally, 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 of the PR 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.

Additionally, the Authority notes that Section 2-1b(2) of the PRA and Section 2 PR, which establish the obligation on the specialist health services to set a time-limit for the treatment to be provided for concerned patients entitled to *necessary* health care, seems to have opened up for unfortunate administrative practices. According to a report[57] published by the Office of the Auditor General of Norway (*Riksrevisjonen*) in 2012, national waiting list statistics were for example not found to accurately reflect the actual waiting time for treatments in specific hospitals, leading to several situations in which the treatment in question could not be provided within the set medically justifiable deadline to patients.[58] According to the same report, the waiting times were in several cases registered as ended even if the in-patient treatment had not yet been provided.[59]

In this regard, the Authority would like to highlight that the rights of patients as enshrined in EEA law by explicit case law thereon by the CJEU and the EFTA Court, entail that the patients have the right to go abroad if *equally effective treatment* cannot be provided *within a medically acceptable time limit*.[60] This right is not sufficiently realized merely by allowing patients to see a doctor for a polyclinic consultation instead of receiving the actual in-patient treatment to which they are entitled. Such an interpretation would render the rights guaranteed to patients under the EEA Agreement ineffective.

Finally, the Authority recalls that case-law has established that a refusal to grant prior authorisation for in-patient treatment abroad which is based solely on the ground that there are waiting lists on national territory for the hospital treatment concerned, without account being taken of the specific circumstances attaching to the patient's medical condition, cannot amount to a properly justified restriction on the freedom to provide services.[61] Consequently, refusals of authorisation or *ex post* reimbursement cannot be based exclusively on the existence of waiting lists in the home State, without taking account of the specific circumstances of the patient's medical condition.[62]

To summarise, the Authority is of the opinion that the Norwegian legislation does not adequately ensure that the patient will have a right to in-patient treatment abroad in cases where it is clear that he cannot be given such treatment within a medically justifiable

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[57] The Office of the Auditor General of Norway's report on its control of the administration of state owned companies for 2011 (*Riksrevisjonens kontroll med forvaltningen av statlige selskaper for 2011*), presented to the Parliament on 25 November 2012. The report is accessible under the following hyperlink: http://www.riksrevisjonen.no/Rapporter/Documents/2012-2013/Dokumentbase_3_2_2012_2013.pdf. The hyperlink was last visited on 5 May 2014.

[58] Ibid on page 39-40.

[59] Ibid on page 38-39.

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

[61] 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 79.

[62] Case C-372/04 *Watts*, cited above, paragraph 63; Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*, cited above, paragraph 79.

deadline in Norway, contrary to what Article 20 of Regulation 883/2004 and Article 36 EEA require. In fact, Section 2-1b(4) PRA only foresees that the patient can go abroad upon the *expiry* of the medically justifiable deadline, and even then, he is first obliged to be in contact with HELFO whereas he should have the right to go abroad and obtain the relevant treatment from a service provider of his choice already at the point in time at which it is clear that he cannot be given treatment in Norway within a medically justifiable deadline.

4.3 Situation type (b) – lack of competence in Norway

4.3.1 The substantive content of the lack of competence criterion

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) PRA[63] ("*rights patients*") the right 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[64] and the relevant administrative circular (*rundskriv*),[65] that the "*lack of adequate medical services*" is to be understood as a "*lack of medical competence*" criterion.

The consideration of whether medical competence in Norway is lacking is thus 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 reflect that this criterion is the primary one when evaluating whether adequate medical services exist in Norway.[66]

The Authority notes that the Norwegian Government, in its letter dated 15 January 2014, stated that "*the term 'lack of medical competence' is identical in substance with the term 'no adequate medical treatment' as these have been applied in administrative practice and by the courts in Norway*". However, the Norwegian Government does not cite any relevant cases which support this claim. In any event, the Authority considers that the criterion does not adequately ensure that Norway's obligations under EEA law is met. A general assessment of whether there are *"adequate"* medical services in Norway would not, in the same manner as a lack of competence criterion would not, satisfy the requirements of EEA law. The Authority fails to see how the criterion laid down in Section 2-1b(5) PRA ensures 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 the more effective in-patient medical treatment for the concerned patient who is entitled to treatment under the Norwegian legislation.[67] Rather, as also emphasized in the preparatory works and in the relevant *rundskriv* to Section 2-1b(5) PRA,[68] the criterion's focus appears to be on the

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[63] Cf. Section 2 PR.

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

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

[66] 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.

[67] 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.

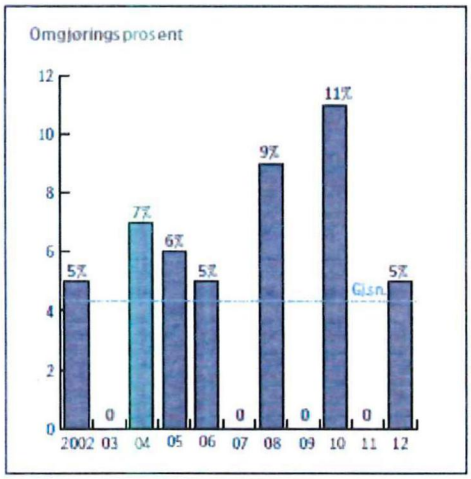
[68] Cited in Section 2 of this letter.

general competence or the general adequacy of medical services in Norway. Section 2-1b(5) PRA does not, therefore, appear to adequately ensure an overall medical assessment of whether *equally effective treatment* can be provided to the individual patient within a medically justifiable deadline.

The Authority notes in this regard that in several of its decisions, the AB has stated that the main question to be considered is whether medical competence exists in Norway, which would be able to offer "*proper*" ("*forsvarlig*") diagnostics or treatment.[69] In yet other decisions, the AB has stated that it is *a[n absolute] criterion for entitlement to treatment abroad* that the medical competence in Norway is lacking.[70] In other cases in which it was not clear whether, and if so where, in Norway there would be any available treatment for the relevant patients, the authorisation was refused by the AB, *inter alia* because the general *competence* in the relevant medical field in Norway was considered to be good.[71]

The Authority has previously received statistics on the authorisation/reimbursement requests for treatment abroad from relevant offices connected to each regional health enterprise ("*utenlandskontor*") from the Norwegian Government (Event No 621601), which is the first administrative body the patient deals with when applying for treatment abroad under Section 2-1b(5), and the percentage of approvals seems to be higher before these offices.[72]

The figure below shows the percentage of cases in which treatment abroad has been granted by the AB pursuant to complaint concerning decision from the aforementioned office 2002-2012,[73] as presented in the AB's annual report for 2012:[74]



[69] UKN-2012-5, UKN-2011-105, UKN-2011-102, UKN-2011-97, UKN-2011-107, UKN-2011-90, UKN-2011-64, UKN-2011-63, UKN-2011-48, UKN-2011-58, UKN-2011-54, UKN-2011-43, UKN-2011-38, UKN-2011-38, UKN-2011-28, UKN-2011-17, UKN-2011-13.

[70] UKN-2011-97, UKN-2011-90, UKN-2011-64, UKN-2009-95, UKN-2009-89, UKN-2008-79, UKN-2008-77, UKN-2007-109.

[71] UKN-2011-64, UKN-2011-38, UKN-2010-127.

[72] The stated percentage of approvals by the Norwegian Government in this regard varied between 68% and 71% during the period 2007-2010, and the number of received applications in relation thereto ranged between 302 and 418 annually for these years, see Event No 621601. However these decisions are not retrievable in any database which the Authority has access to, and a systematic examination of substance could therefore not be conducted. The AB's decisions, on the other hand, are retrievable in the Norwegian law database *Lovdata*.

[73] '*Omgjøringsprosent*' meaning '*percentage indicating applications for treatment abroad granted amongst cases decided*'.

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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.[75]

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,[76] rather than the (general) medical competence 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.[77] The Authority notes however that treatment which is "*possibly more advanced*" would not be considered *more effective,* so long as it is not established according to international medicine that the treatment abroad is *indeed* more effective.[78] In the assessment of whether "*equally effective treatment*" exists, due account must furthermore be taken as to whether such treatment can be offered *at all* or in *due time*,[79] and ideally the national legislation should foresee an overall assessment encompassing both criteria, which in their turn would be assessed by the same administrative body, also on appeal.

As all medical specializations are represented in Norway, one would rarely, if ever, be able to conclude that the medical competence is lacking in Norway, as the criterion under the Norwegian legislation is. Focusing on such a criterion does not appear to be in line with what EEA law requires, namely a consideration of whether the *individual* patient can receive an offer in the home State of adequate treatment, in the sense of *equally effective treatment*, being provided within a medically justifiable time-limit.[80] It also has the effect of depriving patients' right to access to in-patient medical treatment in other EEA States, on the conditions established by Regulation 883/2004 and Article 36 EEA and the case law thereunder, of its *effet utile*.

The Authority has thus concluded that Norwegian national legislation, such as Section 2-1b(5) PRA, 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, in relation to authorisation or reimbursement applications for medical in-patient treatment in other EEA States, as required by Article 20 of Regulation 883/2004 and/or Article 36 of the EEA Agreement.

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[74] Accessible under the following hyperlink: http://www.klagenemnda.no/klagenemnda/arsmeldinger. The number of incoming complaints to the AB ranged between 24 and 90 annually for the period 2000-2012, and the number of decided complaints by the AB ranged between 18 and 68 annually for the same period.

[75] See Section 3 of this letter

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

[77] 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.

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

[79] See *inter alia* Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*, cited above, paragraph 85.

[80] Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*, cited above, paragraph 84.

4.3.2 Complaints received by the Authority – the application of Section 2-1b(5) PRA in practice

Several complaint cases lodged with the Authority are exemplary to the actual application of the Norwegian legislation. The temporal aspect, as outlined under Section 4.2, is also an issue in several of these cases.

Case 71454 concerns an application for treatment abroad from a patient with *burning mouth syndrome* 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, [redacted], confirms that there is "*little resources on [burning mouth syndrome]*" in Norway.[81] A refusal of the authorisation for treatment abroad concerning the neck/jaw injury aspect of the case was appealed to the AB.[82]

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.[83] 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*".[84] 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.

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, 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.

The Authority has also received a complaint from a patient association.[85] 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.

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[81] [redacted]

[82] [redacted]

[83] Ibid.

[84] [redacted]

[85] Case 74734.

One of the issues highlighted in some of the abovementioned complaints/e-mails is a letter of 1 March 2012[86] 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 concerned 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 in situation type (b) had been approved by the AB even prior to this date,[87] even in a case where *the Norwegian Government had acknowledged that there was a need to strengthen the competence* nationally as concerned that specific disease (TMD). In such a situation one would at least presume that the admitted 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 in Norway* was not considered to be lacking.[88]

Complaint case no 74770 concerns an application for treatment abroad from a patient with TMD. Initially the complainant was considered a "*rights patient*" ("rettighetspasient") under Section 2-1(2) PRA, entailing that she would be entitled to treatment within the deadline set by the specialist health care services.[89] The initial decision to refuse the complainant's application for treatment abroad was provided by *Rikshospitalets Enhet for utenlandsbehandling*[90] ("the body") on , emphasized that the necessary competence to treat the complainant's condition exists in Norway. Furthermore the aforementioned body emphasized the following criteria applicable to the application for authorisation, and stated that these are cumulative: (i) a basic condition for reimbursement of treatment abroad is lacking medical competence in Norwegian hospitals; (ii) the patient must suffer from a life-threatening or very burdensome disease or condition; (iii) the treatment must be such that it cannot be conducted properly ("*forsvarlig*") in Norway; (iv) a statement from a Norwegian regional hospital or hospital with a regional function/responsibility ("regionsfunksjon") should be enclosed (this requirement may be waived if a statement from a hospital with competence centre for rare medical conditions is presented). In this regard the Authority notes that in some cases before the AB, a supporting argument for refusal of authorisation or reimbursement was that the patient in question had not been evaluated at the hospital with the nationwide responsibility for a given medical field.[91]

The aforementioned body's decision was appealed by the complainant by letter dated March 2009. In this letter the complainant highlights that her application for authorisation concerned diagnostics and treatment in a specialist facility for TMD *not* situated in the

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[87] 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 decision concern applications for authorisation or reimbursement for medical treatment outside of the EEA.

[88] UKN-2012-19, UKN-2011-95, UKN-2011-107, UKN-2011-38, UKN-2010-127, UKN-2008-30, UKN-2010-18.

[89] Letter from The Authority notes that the present distinction under Section 2-1(2) will be abolished upon the entry into force of the relevant part of Act of 21 June 2013 no 79.

[90]

[91] Cf. UKN-2011-90, UKN-2010-127,UKN-2012-35, UKN-2012-5, UKN-2011-102, UKN-2010-127, UKN-2010-124, UKN-2010-81, UKN-2010-54.

Nordic countries, such as the US (however the complainant did not limit the application to the US, and had consulted with *inter alia* UK specialists[92]).

In the AB's final decision in this complaint case,[93] which reaffirmed the abovementioned decision and the subsequent *original* decision of the AB in this case, the AB emphasized that it could not see that the (national) competence was lacking with regard to the complainant's condition in 2009.[94] The AB furthermore stated that it could not be considered that there is "*lack of competence*" within the meaning of the legislation, if there is competence in Norway to provide treatment and diagnostics in Norway when this has not been made use of.[95] EEA law requires EEA States to consider whether equally effective treatment can be obtained in the home State without undue delay, in *each specific case* and not generally speaking, taking due account of the patient's medical condition at the time 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.[96]

It should, additionally, be noted that at a later stage, this complainant's status as a "rights patient"[97] within the meaning of Section 2-1b(2) PRA was revoked on appeal under the PRA.[98] 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,[99] contrary to what this patient was informed of originally. Similarly, in 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.[100] In both of these cases, it is not clear what these assumptions 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 based on what has been established according to international medicine. In this regard the Authority would like to stress that the evaluation of the expected benefits of the patient, as part of the necessity assessment addressed under Section 4.1 of this letter, should be conducted considering expected benefits in accordance with what has been established by international medical science, in applying the usual principles of interpretation and on the basis of objective and non-discriminatory criteria, taking into consideration all the relevant medical factors and available scientific data.[101]

Case 66927 concerns an application for treatment abroad from a patient with the rare eye disease *aniridia*. A letter of formal notice was sent to Norway concerning the initial refusal of the complainant's application to the relevant Board of Health (*utenlandskontor*) of a regional health enterprise concerning the reasoning therein, which in the Authority's opinion did not adequately take into consideration foreign medical opinions, before the case was appealed to the AB. Additionally, the Authority highlighted that the application

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[92] See UK expert opinion and treatment plan outlined for this complainant in the context of the ongoing application for treatment abroad dated

[93]

[94] Ibid on page

[95] Ibid on page

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

[97] Letter from

[98] See letter from

[99] Letter from

[100]

[101] 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.

was refused even if *equally effective treatment* which could be provided *without undue delay* had not been proven to exist in Norway.[102]

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, would be required in order to successfully treat (surgically) the complainant's condition.[103] 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 also 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 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.[104]

In the Authority's view, the decision delivered by the AB in this case illustrates that the criteria applicable to applications for authorisation for in-patient treatment abroad, and the *methods for evaluating the evidence* put forth in relation thereto, are not sufficiently clear and precise. The complainant had collected significant evidence indicating that more effective treatment would be available abroad,[105] in the form of *inter alia* numerous expert opinions from experts with extensive experience and familiarity with his specific medical condition. The expert opinions put forth by the complainant in this case outnumbered the *general* expert witness opinions in the field which were consulted by the AB in Norway and Sweden in the context of the appeal, and whose opinions emphasized the general competence existing in Norway but did not otherwise provide any proof of specific competence and familiarity with the complainant's rare disease; yet the AB did not conclude in favour of the complainant, even in a case where precisely *sufficiently specialised competence*, as an (alleged) prerequisite for effective treatment was at stake. In the AB's opinion, there was sufficient competence in Norway to evaluate and treat the complainant's condition because there was general competence in Norway to evaluate and treat *complex* cataract conditions, even if the AB acknowledged that there had been few cataract operations on patients with *aniridia* in Norway.[106]

Whereas the foreign experts consulted in the aforementioned appeal case stated that familiarity and knowledge of the specific condition (*aniridia*) would be recommendable in order to ensure that the sought treatment could be performed successfully, the AB focused on evaluating whether there was a *lack of competence* on a more general basis, and eventually concluded that the *general* treatment methods and diagnostics for this disease or other similar eye conditions and variations of complex cataract were not lacking in Norway, and highlighted this as the basis for its decision to refuse the application. The Authority does not consider this conclusion to be sufficiently supported by empirical evidence, such as statistics on successful operations performed or any academic publications. It should be recalled that such evidence is required by the jurisprudence of

[102] See Event No 593374, letter of formal notice dated 1 June 2011.

[103]

[104]

[105] Case C-157/99 *Smits and Peerbooms*, cited above, paragraphs 103-104 and 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.

[106]

the Court of Justice and the EFTA Court in assessing whether a treatment is experimental or not; national authorities called on to decide whether hospital treatment provided in another EEA State has been sufficiently tried and tested must thus 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.[107] Furthermore, the EFTA Court has specified that the assessment of whether the patient in the home State can receive an offer of adequate treatment, in the sense of being equally effective treatment, has to be carried out according to accepted international methods within a medically justifiable time-limit.[108]

The above complaint cases and inquiry cases 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.[109] The temporal aspect, as outlined under Section 4.2, is also an issue in several of the aforementioned cases.

In light of the above, the Authority does not consider that the Norwegian criterion established in Section 2-1b(5) adequately ensures that Norway's obligations under Article 20 of Regulation 883/2004 and Article 36 EEA are met in relation to treatment abroad. The Authority does not consider that the criterion laid down in Section 2-1b(5) PRA ensures 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 the more effective in-patient medical treatment for the concerned patient who is entitled to treatment under the Norwegian legislation.[110] Rather, as also emphasized in the preparatory works and in the relevant *rundskriv* to Section 2-1b(5) PRA,[111] and as reflected in several cases before the AB cited in the above paragraphs, the criterion in Section 2-1b(5) PRA appears to focus on the general competence in Norway, and does not appear to adequately ensure an overall medical assessment of whether *equally effective treatment* can be provided to the individual patient *within a medically justifiable deadline*.

In order to give full effect to this criterion established under Article 20 of Regulation 883/2004 and 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.

4.3.3 Legal certainty

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.

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[107] 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.

[108] Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*, cited above, paragraph 85.

[109] See *inter alia* Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*, cited above, paragraph 85.

[110] 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.

[111] Cited in Section 2 of this letter.

As the EFTA Court has held, *inter alia* in Case E-9/11 *EFTA Surveillance Authority v The Kingdom of Norway,*[112] 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,[113] 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,[114] and therefore is not in line with EEA law.

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 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).*"[115]

Firstly, it is not necessarily immediately clear to concerned patients what is encompassed by the term "*no adequate medical services*" within the meaning of the PRA and the PR, as the actual interpretation thereof appears to be primarily "*when the necessary competence in Norway is lacking*," as illustrated *inter alia* by the aforementioned relevant preparatory works and *rundskriv*, as well as the decisions directed to the complainants in *inter alia* complaint cases 66927, 71454 and 74770.

Secondly, as the relevant criteria under Section 2-1b(5) primarily appear to entail an assessment of whether there is a *lack of competence* in Norway, the criteria may give rise to subjective and potentially discriminatory considerations. This is particularly so because all medical specializations 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.

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[112] 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.

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

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

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

The criteria should ensure that the assessment which EEA law requires, namely whether *equally effective treatment* can be provided to the individual patient *within a medically justifiable deadline*, is conducted.

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 for individuals to determine the full scope of their rights. The Norwegian rules restricting patients access' to in-patient treatment abroad under Section 2-1b(5) must therefore be considered disproportionate in themselves, rendering them *as such* incompatible with Article 36 EEA and Article 20 of Regulation 883/2004.[116]

5 Action to be taken by the Norwegian authorities

It seems to the Authority that ensuring legal certainty, clarity and precision for patients that want to make use of their rights under Article 36 EEA and Article 20 of Regulation 883/2004 requires legislative change in Norway. The necessary changes should be adopted without undue delay.

Still, the legislative process may take some time, and it is therefore important that appropriate action is taken so that patients are not deprived of their rights under Article 36 EEA and Article 20 of Regulation 883/2004 in the meantime. Thus, as required by the EEA law principle of conforming interpretation, Norwegian authorities should make every effort to interpret the Patients' Rights Act and the Prioritisation Regulation in accordance with Article 36 EEA and Article 20 of Regulation 883/2004.

The Authority notes that in case such conforming interpretation proves impossible, patients must be allowed to rely directly on Article 36 EEA, respectively Regulation 883/2004, as incorporated into Norwegian law by the EEA Act, respectively *Forskrift 22. juni 2012 nr. 585 om inkorporasjon av trygdeforordningene i EØS-avtalen* ("the 2012 Incorporating Regulation"). The Authority notes also that it follows from Section 2 of the EEA Act, which is intended to implement Protocol 35 EEA, that EEA rules incorporated into Norwegian law must take precedence over other Norwegian legislation. Section 2 of the EEA Act clearly ensures that Article 36 EEA takes precedence over the Patients' Rights Act and the Prioritisation Regulation. Moreover, Regulation 883/2004 also takes precedence over the Prioritisation Regulation, but it seems *not* over the Patients' Rights Act. Indeed, Section 2 of the EEA Act would seem to give the Patients' Rights Act of 1999 precedence over Regulation 883/2004 because the Act is older than the 2012 Incorporating Regulation. Such failure to give precedence to the incorporation into Norwegian law of Regulation 883/2004 is not only difficult to reconcile with Protocol 35 EEA. More importantly, it may deprive patients of their rights under EEA law and refuse them medical treatment or coverage of medical treatment to which they are entitled. Hence, it is all the more important in the present case that the Patients Rights Act is interpreted in accordance with Regulation 883/2004.

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

6 Conclusion

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

- By maintaining in force legislation, such as Section 2-1b(4) of the Patients' Rights Act and Section 6 of the Prioritisation Regulation, 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, the Kingdom of Norway has failed to fulfil its obligations under Article 20 of Regulation 883/2004[117] and/or Article 36 of the EEA Agreement;

- By failing to ensure, if it has been established that a patient cannot be given the medical treatment to which he is entitled under the Prioritisation Regulation and/or the Patients' Rights Act *within a medically justifiable time limit*, 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, to turn to an EEA medical service provider, the Kingdom of Norway has failed to fulfil its obligations under those provisions;

- 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 of the EEA Agreement;

- By failing to ensure that the required overall 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, *inter alia* by maintaining in force legislation, such as Section 3 fourth paragraph of the Prioritisation Regulation, which *precludes* such an overall assessment, the Kingdom of Norway has failed to fulfil its obligations under Article 20 of Regulation 883/2004 and/or Article 36 of the EEA Agreement.

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

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 invites the Kingdom of Norway to submit its observations on the content of this letter *within two months* following receipt thereof.

After the time limit has expired, the Authority will consider, in the light of any observations received from the Kingdom of Norway, 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