ROYAL NORWEGIAN MINISTRY
OF HEALTH AND CARE SERVICES

EFTA Surveillance Authority
Rue Belliard 35
B-1040 Brussel

Your ref	Our ref	Date
72376-772442	16/155-	3 May 2016

Subject: Observations to the supplementary letter of formal notice to Norway concerning criteria for access to in-patient treatment in other EEA States

Dear Sir/Madam,

Reference is made to the Authority's supplementary letter of formal notice dated 3 February 2016 concerning criteria for access to in-patient treatment in other EEA States. The Authority's preliminary conclusion is that the Norwegian criteria for access to in-patient treatment are still not in line with EEA law, and that the Kingdom of Norway has failed to fulfil its obligations under Article 20 of Regulation No 883/2004 on social security coordination, 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 (Directive 2011/24/EU).

The Authority has in the said letter invited the Norwegian Government to submit its observations on the content within two months following receipt of the letter. The Ministry requested an extension of the deadline and the Authority decided to extend the deadline until 3 May 2016.

The Ministry of Health and Care Services will hereby provide its observations, limited to what seems appropriate at the present stage of the procedure.

Postal address	Visiting address	Telephone*	HelserettsavdelingenDepartment of Health Legislation	Our officer
Postboks 8011 DepPO Box 8011 Dep 0030 Oslo0030 Oslo postmottak@hod.dep.no	Teatergt. 9Teatergt. 9 www.hod.dep.no	22 24 90 90+47 22 24 90 90 Vat no. 983 887 406983 887 406		Pia Grude 22 24 84 16Pia Grude +47 22 24 84 16

1. Introductory remarks

As described in earlier letters there are three different legal grounds for publicly paid in-patient treatment abroad for patients in Norway:

1. Regulation 22 June 2012 No 585, incorporating Regulation (EC) No 883/2004 on social security coordination.
2. Regulation 22 November 2010 No 1466 on reimbursement of health care services received in another EEA State (Reimbursement Regulation)
3. Patient Rights Act (PRA) 2 July 1999 No 63 section 2-1b (4) and (5), with further provisions in Prioritization Regulation (PR) 1 December 2000 No 1208

The two first set of rules are incorporated into Norwegian legislation in order to fulfil our obligations according to EEA law.

The third set of rules (under the PRA and PR) has a different function and character. It provides additional right to access to health treatment abroad, but is not directed at the EEA in particular. It aims at fulfilling the general obligation to provide patients with necessary specialist health services within the time limit as required by PRA. It is a main goal to provide high quality health services in Norway. The costs of treatment abroad can nevertheless be covered under the PRA provisions if there are no adequate medical services in Norway for the individual patient (for instance because Norway, as a relatively small country, has not developed the particular treatment).

Two general points should be emphasized in this regard, to which we also return later.
First, the two first sets of rules are the important ones when assessing whether Norway has fulfilled its EEA obligations. It is therefore primarily these sets of rules that should be assessed. The third legal basis certainly gives additional rights to access to health care abroad. However, if the Authority should find, for instance, that one element of the EEA law requirements is not fully reflected in that third basis, there would indeed be no violation of EEA law if one of the first two sets of rules would provide for the necessary patient's right.

Second, Norwegian law rests on the general principle of interpretation in line with our international commitments. Moreover, should there be inconsistencies between more sets of legislation, the one implementing EEA law does prevail, cf. Act 27 November 1992 No. 109 on EEA. Hence, should there be an unclear implementation of an EEA law obligation or inconsistency between more sets of rules, the national provision providing for the correct and full EEA law implementation would prevail.

2. National legislation fulfilling obligations under EEA law

Regulation No 883/2004

Norway has incorporated Regulation No 883/2004 on social security coordination, as such, into Norwegian law, see Regulation 22 June 2012 No 585 on the incorporation of the social security into the EEA Agreement (forskrift 22. juni 2012 nr 585 om inkorporasjon av

trygdeforordningene I EØS-avtalen). The obligations with regard to the incorporation of the Regulation 883/2004 are therefore complied with. The Regulation provides an independent basis for in-patient treatment abroad. If the criteria in Article 20 of Regulation No 883/2004 are met, the patient will have a right to receive an authorisation or reimbursement in accordance with the Regulation.

Article 36 EEA and the Patients' Rights Directive
Norway established 1 January 2011 a reimbursement scheme covering certain types of healthcare services received in the EEA, cf. Regulation 22 November 2010 No 1466 on reimbursement of health care services received in another EEA State (Reimbursement Regulation) to fulfil patients' rights to reimbursement according to case law. To complete our obligations according to the Patients' Rights Directive 2011/24/EU the reimbursement scheme was from 1 March 2015 extended to include expenses for in-patient treatment.

The main condition to get reimbursement is that the patient would have received benefits or contributions under the National Insurance Act (Act 1997-02-28-19) or the health care would be funded by the public, if the particular health care was received in Norway, cf. Section 2 of the Reimbursement Regulation. The cost is reimbursed up to the cost of the equivalent health care services in Norway, cf. Section 7.

Reimbursement is paid if the health service received abroad is equivalent to health services the patients would have received benefits or contributions to under Section 5-4 to 5-12, Section 5-14, section 5-22 and Section 5-25 in the National Insurance Act. Health services which patients receive (in the form of benefits or contributions) in accordance to the mentioned legislation are inter alia; medical examination or treatment by a general practitioner, laboratory research or tests, radiology research and treatment, treatment of some dental diseases, psychology examination or treatment, physical therapy, chiropractic, speech therapy, midwife examinations during pregnancies or help during birth, important medicaments and special medical equipment, hormonal medicaments in connection to infertility treatment. It is a condition that the provision of the healthcare services are necessary for medical reasons.

Dental treatment paid by the public in accordance with the Dental Health service Act and specialist health care paid by the public in accordance with the Specialist Health Service Act are also reimbursed, cf. Section 3 first paragraph c and d of the Reimbursement Regulation.

Prior authorisation is not required for the reimbursement of expenses for in-patient treatments.

The conditions for receiving reimbursement for healthcare abroad are as the main rule identical to the conditions for receiving the particular healthcare paid by the public in Norway, for example requirements of referral from a specialist etc. There are, however,

certain exceptions in Section 5 and 6 of the regulation which further facilitate the possibility to receive treatment abroad.

Furthermore, patients who are evaluated to have a right to receive necessary healthcare according to Section 2-1 b (2) PRA may apply for advance commitment (forhåndstilsagn). The commitment will clarify whether the patient is entitled to the particular healthcare that the patient would like to receive in another EEA country and the maximum reimbursable amount. This will further facilitate access to in-patient healthcare abroad, also on this point beyond what is required by EEA law.

The Ministry is of the opinion that the legislation here in Section 2 is fulfilling our obligations under Article 36 EEA and the Patients' Rights Directive.

3. Additional national legislation giving patients right to health care abroad

In addition to the mentioned legislation which fulfils the obligations according to EEA law, the Patients' Rights Act (PRA) section 2-1b (4) and (5) gives patients a right to go abroad (not limited to the EEA area) on certain conditions. One of the conditions is that the patient has a right to receive necessary healthcare, cf. Section 2-1b (2) PRA and Section 2 of the Prioritization Regulation (PR).

Section 2-1b (2) is recently amended and the amendments entered into force 1 November 2015. The paragraph reads as follows[1]:
"The patient is entitled to receive necessary healthcare from the specialist health service. The specialist health service shall within the period of evaluation, cf. section 2-2 first paragraph, set a time limit within which the patient shall receive necessary healthcare. The time limit shall be set in accordance with what is medically justifiable.[...]"

PR is amended in accordance with the amendments in PRA. The amendments entered into force 1 November 2015. Section 2 reads as follows[2]:

" The patient is entitled to receive necessary healthcare from the specialist health service pursuant to Section 2-1b second paragraph PRA when:

1. *The patient, with the exception mentioned in Section 3 second paragraph, has an expected benefit of the healthcare and*
2. *The expected costs are reasonable, taking due account to the effect of the measure.*

By "expected benefit of the health care" is meant that knowledge-based experience requires that active medical or multidisciplinary specialised health care can improve the patient's life expectancy or life quality with a certain duration, that the condition may worsen without healthcare or that treatment options are forfeited by postponing the health care."

[1] Unofficial translation by the Ministry
[2] Unofficial translation by the Ministry

Section 2a of the PR further provides[3]:

"The specialist health service shall prioritize patients with a right to necessary healthcare from the specialist health service based on degree of haste and seriousness. The prognosis of loss with regard to duration or quality of life if the healthcare is postponed, is to be emphasized in the priority of the patients."

The regional health enterprise has the obligation to provide for necessary specialist healthcare to patients residing in their region, cf. the Specialist Health Service Act Section 2-1a. This includes the obligation to plan, provide, evaluate and adjust their activity so that the supply and content of the specialist healthcare is in accordance with requirements of the legislation.

In Norway most of the in-patient treatment is provided by public hospitals. The regional health enterprise may also enter into agreements with private providers (in Norway or abroad) to fulfil its obligations to supply specialist health care to the patients residing in the region.

Section 2-1b (4) PRA provides[4]:

"If the regional health enterprise has not ensured that a patient who is entitled to necessary healthcare from the specialist health service receives such care within the time limit fixed pursuant to the second paragraph, the patient has the right to receive necessary healthcare immediately, if necessary from a private service provider or service provider outside the realm."

Section 2-1b (5) PRA provides[5]:

"If the regional health enterprise cannot provide healthcare 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 healthcare from a service provider outside Norway within the time limit."

Further criteria for healthcare abroad according section 2-1b (4) and (5) PRA follows from the PR. Section 6 of the PR is amended and entered into force 1 November 2015. Section 3 PR remains as described in the Supplementary letter dated 3 February 2016 at paragraph 19. We would like to inform the Authority that the new guidelines on Section 3 PR are made public on Lovdata and also sent to the foreign units and the Appeal Board.

The right to go abroad according to Section 2(4) and (5) PRA is intended to secure that the regional health enterprise fulfils its obligation to provide necessary specialist health services to patients within the time limit. When it is necessary for patients to go abroad in these cases, the expenses for travel and accommodation are, in addition to the treatment cost, fully

[3] Unofficial translation by the Ministry
[4] Unofficial translation by the Authority
[5] Unofficial translation by the Authority

covered. This right to access to health care services and full cost coverage does, in our view, go beyond our obligations under EEA law.

It is our opinion, that maintaining this legislation as a supplement to the provisions in the two EEA law pieces of legislation (cf. Section 2 above), will not constitute a breach of our obligations under EEA law.

4. The Ministry's observations

4.1 Introduction

The Ministry will structure its observations in line with the Authority's concluding remarks in the supplementary letter of formal notice of 3 February 2016.

4.2 The necessity test and international medicine

The first main point from the Authority relates to whether the necessity requirement must be based on international medicine.

The Authority claims that Norway has failed to fulfil our obligations under EEA law "*by maintaining in force legislation, such as Section 2-1b(2) PRA and Section 2 PR, which entails a necessity test as 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*[6]." .

The criteria used in the necessity test apply to the right to healthcare services in Norway as well as abroad. The Ministry can see no restriction on the free movement of services when patients are refused reimbursement of cost for treatment abroad, according to rules which apply in the same way to treatment in Norway.

Moreover, the necessity test is assessed according to international medicine. This is further illustrated below.

All health personnel must under the Health Personnel Act Section 4 conduct their work in accordance with the requirements to professional responsibility and diligent care that can be expected based on their qualifications, the nature of their work and the situation in general. The requirements to professional responsibility include the responsibility to conduct their work in accordance with sound professional practice. What would be considered sound practice will alter with time due to medical development, changes in ethical values and international knowledge of best practice.

[6] Authority's conclusion, page 23

When a specialist is considering whether the individual patient has a right to necessary healthcare, he or she will normally base his or her consideration on national guidelines and his or her professional knowledge of treatments options available nationally or internationally.

The Norwegian Directorate of Health has a responsibility to make national guidelines and has adopted guidelines on several various conditions. The guidelines must be based on knowledge of evidence based practice and contribute to continuous improvement of the health care services, cf. the Specialist Health Service Act Section 7-3.

The guidelines include medical recommendations on examinations, treatments and follow-ups of the patients and are based on international knowledge of best practice. The main goal is to secure good quality health care and equal treatment across the country, the right use of resources and contribute to better interaction between health care professionals and providers. The guidelines are publicly available on the Directorate of Health's webpage https://helsedirektoratet.no/retningslinjer

To grade the quality of evidence and the strength of recommendations, and to improve communication with users of the guidelines, the Health Directorate uses international systems like GRADE*, see
http://handbook.cochrane.org/chapter_12/12_2_1_the_grade_approach.htm

which is also used by WHO and by many other international organizations.

The Knowledge Centre for the Health Services (as of 1 January 2016 incorporated in the Norwegian Institute of Public Health) contributes to quality improvement in the health services by summarising international research, promoting the use of research results, measuring the quality of health services, and working to improve patient safety.

The Center provides useful information for health professionals through the Norwegian Electronic Health Library; http://www.helsebiblioteket.no/ It is a publicly funded e-library that provides free access to many Norwegian and international sources. In addition, the e-library is a sharing platform for Norwegian clinical practice guidelines, clinical procedures, and other materials developed in the public health care system in Norway. The Knowledge Centre also provides free access to UpToDate®, an international evidence-based, physician-authored clinical decision support resource.

To enable sustainability and to increase quality and patient safety, Norway established in 2013 a national system for introduction of new health technologies within the specialist health service. The regional health authorities make common decisions to ensure that new technologies meet health needs for patients in all regions and secures sustainability of the specialist health care service. The system utilizes the Health Technology Assessment (HTA) tool to evaluate available international documentation on medicine efficacy, effectiveness and cost effectiveness. Also these assessments are therefore based on international medicine. The

decisions are justified by the following criteria; severity of the health condition, utility for the patients and cost effectiveness. Further, the system aims at contributing to greater transparency in the decision-making process and more knowledge-based decisions. The whole process from early assessments (horizon scanning approach), HTAs and decisions are available on the internet. The system has established a webpage where information is available: https://nyemetoder.no/

Many European countries use similar criteria for prioritization as Norway. In a study of health baskets in nine European countries, Velasco-Garrido et al (2006) reports that all nine countries included in the study, more or less, have defined explicit criteria governing decisions on the inclusion of specific services (or technologies) in the health basket: "*Overall, the most widespread criteria are need, effectiveness, cost and cost/effectiveness. Usually, these criteria are stated without further specification in the legal framework texts defining the benefit basket, and may apply to both the integration of broad areas of care and decisions related to specific technologies*." In a survey of 29 OECD countries, Paris, V., M. Devaux and L. Wei (2010) reports that 13 countries (9 EEA countries) do not explicitly define the benefit package for medical procedures, see http://www.oecd-ilibrary.org/docserver/download/5kmfxfq9qbnr.pdf?expires=1461845359&id=id&accname=guest&checksum=351426E0FC806F0048E4C6A4CE183C1F These countries rather use more general criteria for the right to health care as the ones used in Norway.

Finally, if the patient is not satisfied with the health care provider's assessment, he or she may make an administrative complaint. The administrative bodies, including the Appellate Body for Treatment Abroad (the Appeal Board) make their assessments according to international medicine.[7]

In the opinion of the Ministry the criteria used in the necessity test are transparent, objective and non-discriminatory. The criteria are, as set out, assessed on the basis of international medicine and applied in accordance with international standards. In our opinion Norway does not fail its obligation by maintaining such legislation.

4.3 Full cost coverage under Regulation 883/2004

Second, the Authority concludes that 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 been entitled to authorisation under Regulation No 883/2204, but for some reason did not receive it at all or in due time, Norway fails to fulfil its obligations under EEA law.

[7] For the sake of good order, it is noted that the Appeal Board, as an expert body, must make an assessment of the quality of the relevant expert opinions, and not decide the case on the basis of whether the experts are Norwegian or foreign or on the basis of the number of expert opinions received expressing their different views, see in this regard paragraph 52 of the Authority's supplementary letter of formal notice,

The Ministry disagrees as the patient, under the conditions set out by the Authority, does have the right to full cost coverage. If he or she fulfills the criteria for access to health care abroad under two or more of the relevant sets of legislation, the patient has the right to the best economic coverage.

Under the Reimbursement Regulation it is not required to have a prior authorisation and the patient may use health care providers which are not associated within the public health care system or national insurance system of the state of treatment. On the other hand, the reimbursement is limited to the cost of equivalent health care services delivered by the public in Norway.

This is different under the national regulation implementing the *Regulation 883/2004*. If the conditions set out in Article 20 of the Regulation are fulfilled, the patient has the right to be reimbursed in accordance to the regulation of reimbursement in the country where the treatment takes place, and not according to regulation of the Member State of affiliation.

The Authority points out that there is no legal base in the Reimbursement Regulation for reimbursing the patient in full, in cases where he or she would have been entitled to authorisation for treatment abroad at all or in good time. The Ministry would like to stress that in such cases the patients do have a right to reimbursement according to Regulation No 883/2004. The patients' right to refund under Regulation No 883/2004 is therefore explained in the guidelines to Regulation No 883/2004 rather than in the Reimbursement Regulation.

The Ministry has, however, incorporated an amendment in Article 7 of the Reimbursement Regulation to further clarify that the patient has a right to reimbursement according to the most beneficial legislation if the patient fulfils the conditions according to Regulation No 883/2004.

4.4 A case-by-case assessment and "equally effective" treatment

The third main issue raised by the Authority circles around issues related to the assessment of the effect of treatment in Norway and abroad, respectively. The Authority is of the opinion that by maintaining in force legislation, such as 2-1b(5) and Section 3 of the Prioritization Regulation, Norway 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 application for medical in-patient treatment in other EEA States.

As mentioned under Section 2, Norway has fulfilled its obligation according to the EEA law by implementing Regulation No 883/2004 into Norwegian law and by having established a reimbursement scheme providing for coverage of health care expenses as required by article 36 EEA, as interpreted by the EEA Courts, and by the Patients' Rights Directive, cf. the Reimbursement Regulation. The Reimbursement Regulation lets patients go abroad for in-

patient treatment without a prior authorisation to receive the same healthcare or healthcare equivalent to healthcare which would be offered by the public, had the healthcare been received in Norway. The conditions for receiving reimbursement for healthcare abroad are as the main rule identical to the conditions for receiving the particular healthcare paid by the public in Norway, such as the criteria under Section 2-1b (2) PRA and Section 2 of the Prioritization Regulation (PR).

In our opinion, it is not in breach of EEA law to have additional legislation which gives patients the right to go abroad as mentioned under Section 3 above. The right to go abroad according to PRA gives patients, who fulfil the set criteria, better cost coverage than would be the case under EEA law. It is also not limited to treatment in other EEA States. As pointed out above, this legislation aims to secure that the regional health enterprises on behalf of the State fulfil their obligation to provide patients with necessary healthcare, cf. the Specialized Health Services Act Section 2-1a(2) and Section 2-1.

The Authority states that 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 case law as regards Article 36 EEA.[8]

The basic rule emphasized by the Court of Justice of the European Union and by the EFTA Court is that the patient must be entitled to treatment in the home State before access to treatment abroad can be required. This was once again underlined by the Court of Justice in Case C-268/13 *Petru*.

The Court concluded[9]:

> *"It must be observed that the second subparagraph of Article 22(2) of Regulation No 1408/71 lays down two conditions which, if both are satisfied, render mandatory the grant by the competent institution of the prior authorisation applied for on the basis of Article 22(1)(c)(i). The first condition requires the treatment in question to be among the benefits provided for by the legislation of the Member State on whose territory the insured person resides. The second condition requires that the treatment which the latter plans to receive in a Member State other than that of residence cannot be given within the time normally necessary for obtaining the treatment in question in the Member State of residence, account being taken of his current state of health and the probable course of his disease (see, to that effect, Elchinov, C-173/09, EU:C:2010:581, paragraphs 53 and 54, and case-law cited).*
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> *As regards the second condition, with which the question in the present case is concerned, the Court has held that the authorisation required cannot be refused if the same or equally*

[8] Authority's decision, paragraph 71
[9] Jugdement of the Court C-268/13 Paragraph 30 and 31

effective treatment cannot be given in good time in the Member State of residence of the person concerned (see, to that effect, Inizan, C 56/01, EU:C:2003:578, paragraphs 45 and 60; Watts, C-372/04, EU:C:2006:325, paragraph 61, and Elchinov, EU:C:2010:581, paragraph 65)."

The Court hence underlines that there are two conditions laid down in Article 22(2) and both must be fulfilled. The first condition requires the treatment in question to be among the benefits provided for by the legislation. The second condition requires that that the treatment which the patient plans to receive in a Member State other than that of residence, cannot be given within the time normally necessary for obtaining the treatment in question in the Member State of residence.

It is the first and basic condition that seems relevant in relation to the Authority's concerns, and the Ministry will therefore comment further upon this condition. The cited paragraph concerns Regulation No 1408/71. This regulation has now been replaced by Regulation 883/2004, but the provisions relating to authorisation of appropriate treatment in another Member State remain effectively the same in Article 20 of Regulation No 883/2004.

Moreover, the same basic condition is set out in the Patients' Rights Directive as well as in consistent case law under the EU Treaty and EEA Agreement.

The Patients' Rights Directive codifies the rights under the Treaty on Functioning of the European Union and the principles confirmed by established case law. In the Preamble of the Patients' Rights Directive it is held:[10]

"This Directive respects and is without prejudice to the freedom of each Member State to decide what type of healthcare it considers appropriate. No provision of this Directive should be interpreted in such a way as to undermine the fundamental ethical choices of Member States."

Article 7(1) of the Patients' Rights Directive reads (emphasis added):

"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 cost 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.***"

Furthermore, it is held in the Preamble of the mentioned Directive[11]:

[10] Patients' Rights Directive No 2011/24/EU, Preamble (7)
[11] Patients' Rights Directive No 2011/24/EU, Preamble (13)

"It is clear that the obligation to reimburse costs of cross-border healthcare should be limited to healthcare to which the insured person is entitled according to the legislation of the Member State of affiliation."

Case law cannot be interpreted to the effect that the EEA States loose the fundamental freedom to organize their social security schemes. This is underscored by the Courts numerous times, also in Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*. It should be recalled that the basic rule is set out, inter alia, just before the term "equally effective" is used, cf. paragraphs 82 and 84, respectively. The EFTA Court held in paragraph 82:

"EEA law cannot in principle have the effect of requiring an EEA state to extend range of medical services paid for by its social security system. It follows that, even when striving for a high-quality health system, EEA States may decide that, given the need to prioritize within the overall resources available, certain treatments cannot be offered under the national health system, provided the exclusion of these treatments complies with requirements of EEA law as set out at paragraph 48 above".

Indeed, the EFTA Court held in *Rindal and Slinning* that the further assessments made in paragraphs 83 and 84 are made under the condition that the patient "fulfils the criteria for entitlement to treatment" under national law. The EFTA Court held in paragraph 83 (emphasis added):

*"However, **where no such limitations apply and a patient**, under the social security system of his or her home State, **fulfils the criteria for entitlement to treatment**, prioritization of the home State treatment, such as in the case at hand, cannot be justified unless the home State itself can provide treatment which is the same or equally effective for the patient as the treatment abroad within a medically justifiable time limit, compare Smits and Peerbooms, at paragraphs 103-104."*

We would like to point out that there are limitations on what kind of healthcare a patient is entitled to under Norwegian social security scheme. Entitlement to in-patient treatment in Norway depends, as mentioned above, on whether the patient fulfils the criteria for "entitlement to receive necessary health care" pursuant to Section 2-1 b(2) PRA and Section 2 PR. This warrants a concrete assessment of the expected benefits of the health care in question seen in light of the medical condition of the patient as well as the expected costs of the treatment. There must be solid documentation that the treatment may be effective. Internationally available clinical evidence is taken into account, as described above.

Under Norwegian legislation a patient is entitled to health care if the health care is assessed to be necessary, according to an individual medical assessment in each case. There must be an expected benefit of the particular treatment for the particular patient and the expected cost of the particular health care must be reasonable, taking into account the effect of the health care.

Hence, if a treatment is too costly compared to expected benefits, there is no entitlement to such treatment, whether it is regarded as more or less "effective" compared with the treatment available in Norway. This seems to be confirmed by the EFTA Court in *Rindal and Slinning*, see for instance paragraph 105:

> *"As pointed out at paragraph 82 above, EEA law cannot in principle have the effect of requiring an EEA State to extend the range of treatments paid for by its social security system. Consequently, an EEA State may decide that certain treatments, despite being recognised, cannot be offered under the national system, provided that the exclusion of these treatments complies with the requirements of EEA law as set out in paragraph 48 above. This must be so even if the home State has no adequate alternative to the more advanced treatment on offer abroad."*

As described above there are national guidelines which describe recommendations on examinations, treatments and follow-ups of patients with different diagnoses made by the Norwegian Directorate of Health. The guidelines are available on their website. Furthermore, there is a national system for the introduction of new health technologies within the specialist health service. The guidelines and the decisions taken by the National System for Introduction of New Health Technologies will further clarify what a patient would be entitled to according to the national social security scheme and are all available on a website.

Moreover, as described above, patients who are evaluated to have a right to necessary healthcare according to Section 2-1 b (2) PRA may apply for advance commitment (forhåndstilsagn) from HELFO if they consider receiving healthcare in another EEA country. The commitment will clarify whether the patient is entitled to the particular healthcare that the patient would like to receive in another EEA country and the maximum amount the patient will get reimbursed. This will further facilitate access to in-patient healthcare abroad.

The Ministry is of the opinion that case law does not give patients a legal claim for reimbursement for any treatment abroad only because this treatment is indeed more effective than the treatment provided in Norway. The condition is that the patient is entitled to the treatment in the home State before access to treatment abroad can be required. As described above there are limitations to what kind of in-patient treatment a patient is entitled to under the Norwegian social security scheme.

4.5 Objectivity, transparency, clarity and precision

Finally, the Authority is of the opinion that Norway is failing to ensure that the criteria applicable to applications for authorisations or reimbursement for of in-patient medical treatment abroad in Norway, such as Section 2-1 b(2) PRA and Section 2 PR, Section 7(2) of the Reimbursement Regulation, Section 3 PR and Section 2-1b(5), as well as Section 6 PR, meet the requirements established in the case law concerning objectivity, clarity, transparency and precision, as also required by Articles 7(6), 7(9)-7(11), 8(1), 8(3)-(5) and 9(1)of the Patients' Rights Directive

The Ministry finds, for its part, that the criteria are sufficiently objective and precise etc. to comply with the standards set out in relevant case law.

The criteria for access to health care under Regulation No 883/2004 are as such made part of national legislation by Regulation 22 June 2012 No 585. Common to the criteria under the Reimbursement Regulation and the PRA/PR is that they are set out in the relevant legislation and they are further explained in the guidelines described above. The criteria are, the Ministry submits, sufficiently clear, precise and accessible. All criteria are based on international medicine, and all relevant decisions are subject to administrative and judicial control.

In sum, this implies that the requirements regarding objectivity, transparency, non-discrimination, clarity and precision (i.e. legal certainty) are complied with.

This can be exemplified with the criterion "necessary health care" under the PRA Section 2-1b(2). As mentioned above Section 2 of the Prioritization Regulation provides further criteria for entitlement to receive "necessary health care" pursuant to PRA. The guidelines for PRA give additional information regarding the interpretation of the criteria. The Norwegian Directorate of Health is at the moment updating the guidelines for chapter 2 PRA and the new guidelines is expected to be published before summer. The general guideline on priority of patients is recently updated, see https://helsedirektoratet.no/retningslinjer/aktuell-informasjon-om-lov-og-forskrift-for-prioriteringsveilederne

As described above the Norwegian Directorate of Health has also adopted guidelines on several various conditions, which gives recommendations on examinations, treatments and follow-ups of the patients and are based on international knowledge of best practise. The national system for introduction of new health technologies within the specialist health service does moreover make common decisions on introduction of new medical procedures and pharmaceutical treatment.

It must be appreciated that the EEA States may choose different types of regulations of access to health care that are equally legitimate. Some states provide for a basket of benefits that is available to patients, whereas others – like Norway – provide more general criteria that must be assessed individually in each case, see Section 4.2 above. Moreover, the legislative task in this field of law is particularly challenging in that all patients are different, there are countless numbers of possible treatments that should be adapted individually in each case, and the field is very dynamic in the sense that new treatments are constantly available.

The EEA requirements cannot, under such circumstances, be interpreted to the effect that more general criteria as for instance "necessary health care" cannot effectively be applied.

5. Concluding remarks

In Norway we have for several years had a debate on how to prioritize the resources available and criteria for prioritizing, cf. PRA Section 2-1 b and PR Section 2. This is a difficult and an ongoing debate and there have been several green papers on the matter. NOU 2014:12 "Åpent og rettferdig – prioritering i helsetjenesten" is the latest green paper, see https://www.regjeringen.no/no/dokumenter/NOU-2014-12/id2076730/?ch=1&q= . A working group was appointed to follow up the paper. The working group has published a report "På ramme alvor - Alvorlighet og prioritering", see https://www.regjeringen.no/contentassets/d5da48ca5d1a4b128c72fc5daa3b4fd8/paa_ramme_alvor.pdf
The Ministry is planning to submit in June 2016 a white paper discussing principles for prioritization in the health care service.

In our opinion the Authority's interpretation would risk undermining the essential work on prioritizing the resources that any state has to do. If the national system for introduction of new health technologies within the specialist health service has decided, for instance, that Norway will not include a very expensive medicinal product in the public healthcare, because it is too costly balanced with the expected benefits, it would undermine the national prioritizing if the patient can go abroad and get it reimbursed. The same principles must apply whether the assessment is made in a state with a "basket-of-care" system or in a state with more general criteria for access to health care. The overall concern for the Ministry is that the Authority interprets EEA law to the effect that the states *de facto* lose the ability to decide which treatments should be offered to residents and maintain control over the healthcare expenses. This would be contrary to, for instance, the case law cited in Section 4.4 above.

The Ministry is of the opinion that the presently applicable legislation is compatible with EEA law requirements under Article 36 EEA, the Patients' Rights Directive and Regulation No 883/2004. In that respect it is also noted that all relevant criteria are assessed on basis of international medicine and applied in accordance with international standards. The criteria are objective and non-discriminatory and subject to administrative as well as judicial control. The principle of legal certainty is hence also complied with.

Yours sincerely,

Kari Sønderland
Director General

This document has been signed electronically and therefore it is not signed by hand.