ROYAL NORWEGIAN MINISTRY
OF HEALTH AND CARE SERVICES

EFTA Surveillance Authority
Rue Belliard 35
B-1040 Brussel

| Your ref | Our ref | Date |
|---|---|---|
| 72376-828764 | 16/155- piag | 19. January 2018 |

**Reply to reasoned opinion concerning Norway's criteria for access to in-patient treatment in other EEA States**

Dear Sir/Madam,

Reference is made to the Authority's reasoned opinion dated 20 September 2017 concerning Norway's criteria for access to in-patient treatment in other EEA States, and their compliance with Article 20 of Regulation 883/2004 and/or Article 36 EEA and/or Articles 7(6), 7(9)-(11), 8(1), 8(3)-(5) and 9(1) of Directive 2011/24.

In the reasoned opinion the Authority addresses four main issues which are, in the opinion of the Authority, not in line with EEA law. The Ministry does not share the view of the Authority and maintains the conclusion that the applicable Norwegian 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, as the Ministry sees it, hence also complied with. This is further addressed in the Ministry's letter of 3 May 2016.


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

One of the main points of the Authority is that the applicable Norwegian legislation does not ensure that international medical science is taken into account when the expected benefit of treatment is evaluated. As already mentioned above, the Ministry is of a different opinion as the necessity test shall be assessed on the basis of international medicine and applied in accordance with international standards. The Ministry is not aware of circumstances demonstrating that this rule is not generally followed by the relevant authorities, and cannot see that the arguments presented by the Authority call for a different conclusion. Nevertheless, to remove any doubt in this regard, the Ministry has made a clarification in Section 3 (3) PR. The amended wording came into force the 1st of January 2018:

"*Vurderingen av pasientens nytte av behandlingen skal være individuell og ta utgangspunkt i internasjonal medisinsk vitenskap.*"
(The evaluation of the patient's benefits of treatment must be individual and based on international medical science.)

The Authority takes, as another main point, the view that Section 6 PR, which prohibits patients whose justifiable deadlines for medical treatment set under the Prioritisation Regulation 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, is failing to ensure that such a patient will obtain the necessary authorisation under Article 20(2) of Regulation 883/2004 and/or that such a patient will obtain reimbursement under Article 36 of the EEA Agreement.

The Ministry wants to emphasize that Section 6 PR does not prevent patients from obtaining authorisation under Article 20(2) of Regulation 883/2004, or reimbursement in accordance with the Reimbursement Regulation (which implements the right to reimbursement in accordance with Article 36 of the EEA Agreement and the Patients' Rights Directive). However, to avoid any doubt in this regard, the Ministry has made some amendments to further clarify Section 6 PR. The amended wording came into force the 1st of January 2018:

"*Uavhengig av om det foreligger fristbrudd kan pasienten søke om å få refundert utgifter til helsetjenester mottatt i et annet EØS-land i samsvar med forskrift om stønad til helsetjenester mottatt i et annet EØS-land. Pasienten kan også ha rett til å få dekket utgifter til helsetjenester i andre EØS-land etter vilkårene i rådsforordning (EF) nr.*

*883/2004. Søknad om refusjon etter forskrift om stønad mottatt i et annet EØS-land eller forhåndsgodkjenning etter rådsforordning (EF) nr. 883/2004 behandles av HELFO.*"
(Regardless of whether the deadline is overdue, the patient may apply for reimbursement of expenses for healthcare received in another EEA State in accordance with the Regulation on reimbursement of healthcare services received in another EEA State. The patient may also be entitled to get their healthcare expenses in another EEA State covered according to the terms of Regulation 883/2004. Application for reimbursement according to the Regulation on reimbursement of healthcare services received in another EEA State or prior authorisation according to the Regulation 883/2004 are handled by HELFO.)

In the opinion of the Ministry, the above two changes will make the regulation clearer, more precise and more transparent.

The Authority argues, as a third main point, that the applicable Norwegian legislation 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, and that Norway thereby fails to fulfil its obligations under the EEA agreement. The Ministry is of the opinion that the present legislation is compatible with EEA law requirements under Article 36 EEA, the Patients' Rights Directive and Regulation No 883/2004 as further addressed in the Ministry's letter of 3 May 2016.

Nevertheless, in order to make the regulation more transparent and more easily accessible for the patients, the Ministry has started to consider several possible changes in the legal framework.

There are different provisions in the Norwegian legislation which give patients access to health care abroad with public funding. To give the patients a better overview of the different legal bases and schemes for access to healthcare abroad and make the regulation more transparent, the Ministry is considering to gather the different provisions regarding access to healthcare abroad in one new provision.

Furthermore, the Ministry has started to look into possible adjustments in the legislative framework for access to specialist healthcare in other EEA State, applicable in situations where there are no adequate medical services in Norway. We are inter alia considering a wording which gives a more transparent right to more effective treatment

in other EEA states – limited by the same terms as apply within Norway, hereby the cost-benefit criterion cf. Section 2 PR. The Ministry will also look into possible changes in the right to receive treatment abroad in accordance with Section 2-1 b (4) PRA when the patient has not received specialist health care within the deadline because of lack of capacity.

The Ministry will in addition investigate possible improvements in the administration of these cases, in order to ensure an easily accessible system which is capable to make objective and professionally well-founded decisions within a reasonable time.

The Ministry has informed HELFO and the offices for treatment abroad about the change in Section 3 (3) PR which further reminds all parties that evaluation of the patient's benefits of treatment must be individual and based on international medical science. Equally, the Ministry has informed about the clarification in Section 6 PR. HELFO and the offices for treatment abroad are also instructed to give patients information on the different schemes for access to healthcare abroad to further ensure that lack of information does not result in patients not seeking their rights under the different schemes.

The Ministry will give the revision of the legislation high priority in the time to come, also with regards to progress. We stress, however, the importance of conducting thorough work in order to ensure that the new legislative framework is safeguarding the patients' rights to access health care in other EEA State, but also maintaining the criteria which must be fulfilled for entitlement to receive specialist health care funded by the public within Norway, hereby the cost-benefit criterion cf. Section 2 PR that is vital to ensure a balanced health care service.

The Ministry will keep the Authority updated on the further progress in the work with possible changes in the legal framework.

Yours sincerely,

Kari Sønderland
**Director General**

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