



ROYAL NORWEGIAN MINISTRY
OF HEALTH AND CARE SERVICES

EFTA Surveillance Authority
Rue Belliard 35
B-1040 Brussel
BELGIUM

Your ref

Our ref

Date

16/155-

15 June 2018

Response to reasoned opinion – Norwegian rules concerning access to in-patient treatment in other EEA States

Dear Sir/Madam,

Reference is made to the Authority's letter dated 26 February 2018 and our response dated 11 April 2018. As pointed out in our previous letters, 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.

Nevertheless, to make the Norwegian regulation regarding access to healthcare abroad more transparent and more easily accessible for the patients, the Ministry has in the attached consultation paper proposed several changes in the legal framework for access to healthcare in other EEA States which we believe will accommodate concerns from the Authority.

Firstly, the Ministry has proposed a new provision in the Act of 2 July 1999 No 63 relating to patients' rights (PRA). The new provision gather the various schemes for access to healthcare abroad. The provision will make the regulation more transparent and give patients a better overview of existing schemes.

Furthermore, the Ministry has proposed changes in the legislative framework for access to specialist healthcare abroad in situations where there are no adequate medical services in Norway. It is clarified that the right to access specialist healthcare abroad also applies in situations where the healthcare abroad is more effective than the healthcare provided by the public specialist health service in Norway. The right to more effective healthcare abroad is limited by the same terms as apply within Norway, hereby the criteria in Section 2 in the

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Prioritization Regulation (PR). In the consultation paper there is also proposed some changes in the wording used in Section 2 PR to ensure the same term usage in the regulations, guidelines and other material regarding prioritization.

In accordance with the Patients' Rights Directive Article 7(3) it "is for the Member State of affiliation to determine whether at a local, regional or national level, the healthcare for which an insured person is entitled to assumption of costs and the level of assumption of those costs, regardless of where the healthcare is provided".

As explained in our letter 3 May 2016, Norway has established 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 secure sustainability of the specialist healthcare service. The system utilize the health Technology Assessment (HTA) tool to evaluate available international documentation on medicine efficacy, effectiveness and cost effectiveness. These assessments are based on international medicine. The decisions are justified by the following criteria; severity of the health condition, utility for the patients and cost effectiveness. 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 is further explained in the consultation paper and on this webpage:

<https://nyemetoder.no/>

The same terms for public assumption of cost must apply for healthcare received abroad as within Norway. In the new provision regarding healthcare abroad, it is therefore proposed to clarify that expenditure on healthcare abroad will not be covered if The National System for Managed Introduction of New Health Technologies has decided that the healthcare in question is not among the benefits covered by the public specialist health service in Norway. These decisions are available for patients on the webpage as mentioned above.

The Ministry has furthermore proposed to make changes in the right to receive treatment from a private healthcare provider or 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. Since 2013 there has not been patients going abroad in accordance to this provision. Patients will in such situations have a right to obtain authorisation in accordance to Article 20 (2) of Regulation 883/2004 and will also have a right to reimbursement in accordance with the Reimbursement Regulation. It is therefore proposed that the provision is limited to regulate the right to go to a private healthcare provider in Norway.

In the attached consultation paper the proposals are explained in more detail. Should there be any questions regarding the proposals, do not hesitate to contact us.

Yours sincerely

Kari Søndersland
Director General

This document is signed electronically and has therefore no handwritten signature