Registered at the EFTA Court under N° E-15/23-12 on 19th of February 2024

ESA | EFTA Surveillance Authority

Brussels, 19 February 2024
Case No: 91511
Document No: 1429658

ORIGINAL

IN THE EFTA COURT

WRITTEN OBSERVATIONS

submitted, pursuant to Article 20 of the Statute of the EFTA Court, by

THE EFTA SURVEILLANCE AUTHORITY

represented by
Marte Brathovde, Ewa Gromnicka and Melpo-Menie Joséphidès,
Department of Legal & Executive Affairs,
acting as Agents,

IN CASE E-15/23

K

v

Nasjonalt klageorgan for helsetjenesten
(National Office for Health Service Appeals)

in which the National Insurance Court (*Trygderetten*) requests the EFTA Court to give an Advisory Opinion pursuant to Article 34 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice concerning the right to reimbursement of costs for dental treatment in another EEA State pursuant to Article 36 EEA, Directive 2011/24/EU and Directive 2005/36/EC.

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1. INTRODUCTION AND THE FACTS OF THE CASE

1. The present Request for an Advisory Opinion ("the Request") concerns the question of whether an application for the reimbursement of expenses incurred for dental treatment in another EEA State can be refused on the ground that the treating dental practitioner in the EEA State where the treatment took place does not have the specialisation required to be able to provide such treatment in the EEA State of affiliation ("**the Specialisation Requirement**").[1]

2. On 30 November 2017, the appellant in the main proceedings, "K", applied for reimbursement of costs relating to dental treatment in Poland in the period 16 August to 24 October 2017. The application concerned the second stage of treatment commenced in 2016 for severe marginal periodontitis. K has previously applied for, and been refused, reimbursement of the costs for the first stage of the treatment, on the ground that the treating dental practitioner lacked the necessary specialisation.[2]

3. By decision of 1 February 2018, the Norwegian Health Economics Administration (Helseøkonomiforvaltningen, "**HELFO**") rejected K's application for reimbursement for the second stage of the treatment. The rejection was based on the treating dental practitioner's lack of the specialisation required in Norway, similarly to the rejection of K's application for reimbursement of the costs for the first stage of treatment.[3]

4. Following a complaint by K, HELFO's decision was upheld by decision of 25 February 2021 by the National Office for Health Service Appeals ("**Helseklage**").

5. On 7 April 2021, K appealed the decision of Helseklage to the National Insurance Court ("**the Referring Court**").

6. As part of the preparations for the case before the Referring Court, Helseklage re-examined its decision. Following the re-examination, Helseklage upheld its decision, maintaining that reimbursement of expenses for dental treatment in

[1] In the Request referred to as the "*home EEA State*". ESA in the present written observations uses the terminology of the Patients' Rights Directive, which is "*EEA State of affiliation*", see Article 3(c).
[2] The Request, paragraph 1.
[3] The Request, paragraph 2.

another EEA State cannot be granted when the treating dental practitioner does not have the same specialisation as that required to perform the same treatment under Norwegian law.

7. Helseklage found that the conditions for benefits under section 5-24a of the National Insurance Act, read in conjunction with Section 5-6, were not fulfilled, both because the time of and background to the loss of teeth was not sufficiently documented and because the requirement of specialisation was not satisfied.[4]

8. In its submissions in the case pending before the Referring Court, Helseklage relies on Article 7(3) and 7(7) of the Patients' Rights Directive when it submits that:

> *"The Norwegian rules requiring that implant treatment must be performed by a dental practitioner having the necessary specialisation applies irrespective of where the dental treatment is received, be that in Norway or another EEA country. It also applies irrespective of the nationality of the treating dental practitioner",*

and furthermore, submits that the rules do not give rise to improper discrimination or an obstacle contrary to Norway's EEA law obligations.[5]

9. K submits that such a requirement is an unjustifiable restriction pursuant to Article 36 of the EEA Agreement and Article 7 of the Patients' Rights Directive. K further submits that Helseklage's use of the listing under Annex V of the Professional Qualifications Directive to determine what healthcare is reimbursed leads to arbitrary discrimination.[6]

10. On the basis of the submissions by the parties to the main proceedings, the Referring Court found it necessary to request an Advisory Opinion from the EFTA Court ("**the Court**") on the interpretation of Article 36 of the EEA Agreement ("**Article 36 EEA**"), Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare ("**the Patients' Rights Directive**") and Directive 2005/36/EC of the

[4] The Request, paragraph 13.
[5] The Request, paragraph 60.
[6] The Request, paragraphs 48 and 56.

European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications ("**the Professional Qualifications Directive**").

2. EEA LAW

11. Article 36 EEA provides:

> "*1. Within the framework of the provisions of this Agreement, there shall be no restrictions on freedom to provide services within the territory of the Contracting Parties in respect of nationals of EC Member States and EFTA States who are established in an EC Member State or an EFTA State other than that of the person for whom the services are intended.*
> *2. Annexes IX to XI contain specific provisions on the freedom to provide services.*"

12. The Patients' Rights Directive was incorporated into the EEA Agreement by Decision of the EEA Joint Committee No 153/2014 of 9 July 2014, adding it at point 2 of Annex X (Services in general) to the EEA Agreement.[7]

13. Recital 13 of the preamble to the Patients' Rights Directive states:

> "*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.*"

14. Recital 19 of the preamble states:

> *"When a patient receives cross-border healthcare, it is essential for the patient to know in advance which rules will be applicable. The rules applicable to cross-border healthcare should be those set out in the legislation of the Member State of treatment, given that, in accordance with Article 168(7) TFEU, the organisation and delivery of health services and medical care is the responsibility of the Member States. This should help the patient in making an informed choice, and should avoid misapprehension*

[7] OJ L 15, 22.1.2015, p. 78–79.

and misunderstanding. It should also establish a high level of trust between the patient and the healthcare provider."

15. Recital 20 of the preamble states:

> *"In order to help patients to make an informed choice when they seek to receive healthcare in another Member State, Member States of treatment should ensure that patients from other Member States receive on request the relevant information on safety and quality standards enforced on its territory as well as on which healthcare providers are subject to these standards. Furthermore, healthcare providers should provide patients on request with information on specific aspects of the healthcare services they offer and on the treatment options. To the extent that healthcare providers already provide patients resident in the Member State of treatment with relevant information on those specific aspects, this Directive should not oblige healthcare providers to provide more extensive information to patients from other Member States. Nothing should prevent the Member State of treatment from also obliging other actors than the healthcare providers, such as insurance providers or public authorities, to provide the information on specific aspects of the healthcare services offered, if that would be more appropriate with regard to the organisation of its healthcare system."*

16. Recital 26 of the preamble states:

> *"The right to reimbursement of the costs of healthcare provided in another Member State by the statutory social security system of patients as insured persons has been recognised by the Court of Justice in several judgements. The Court of Justice has held that the Treaty provisions on the freedom to provide services include the freedom for the recipients of healthcare, including persons in need of medical treatment, to go to another Member State in order to receive it there.* […]*"*

17. Recital 29 of the preamble states:

> "*It is appropriate to require that also patients who seek healthcare in another Member State in other circumstances than those provided for in Regulation (EC) No 883/2004 should be able to benefit from the principles of free*

movement of patients, services and goods in accordance with the TFEU and with this Directive. Patients should enjoy a guarantee of assumption of the costs of that healthcare at least at the level as would be provided for the same healthcare, had it been provided in the Member State of affiliation. This should fully respect the responsibility of the Member States to determine the extent of the sickness cover available to their citizens and prevent any significant effect on the financing of the national healthcare systems."

18. Recital 30 of the preamble states:

"*For patients, therefore, the two systems should be coherent; either this Directive applies or the Union regulations on the coordination of social security systems apply.*"

19. Recital 31 of the preamble states:

"*Patients should not be deprived of the more beneficial rights guaranteed by the Union Regulations on the coordination of social security systems when the conditions are met. Therefore, any patient who requests an authorisation to receive treatment appropriate to his condition in another Member State should always be granted this authorisation under the conditions provided for in the Unions regulations when the treatment in question is among the benefits provided for by the legislation in the Member State where the patient resides and when the patient cannot be given such treatment within a time limit that is medically justifiable, taking account of his current state of health and the probable course of the condition. However, if a patient instead explicitly requests to seek treatment under the terms of this Directive, the benefits which apply to reimbursement should be limited to those which apply under this Directive. Where the patient is entitled to cross-border healthcare under both this Directive and Regulation (EC) No 883/2004, and the application of that Regulation is more advantageous to the patient, the patient's attention should be drawn to this by the Member State of affiliation*."

20. Recital 34 of the preamble states:

"*Member States of affiliation should give patients the right to receive at least the same benefits in another Member State as those provided for by the*

legislation of the Member State of affiliation. If the list of benefits does not specify precisely the treatment method applied but defines types of treatment, the Member State of affiliation should not refuse prior authorisation or reimbursement on the grounds that the treatment method is not available in its territory, but should assess if the cross-border treatment sought or received corresponds to benefits provided for in its legislation. The fact that the obligation to reimburse cross-border healthcare under this Directive is limited to such healthcare that is among the benefits to which the patient is entitled within its Member State of affiliation does not preclude Member States from reimbursing the cost of cross-border healthcare beyond those limits. Member States are free, for example, to reimburse extra costs, such as accommodation and travel costs, or extra costs incurred by persons with disabilities even where those costs are not reimbursed in the case of healthcare provided in their territory."

21. Recital 37 of the preamble states:

"*Member States may maintain general conditions, criteria for eligibility and regulatory and administrative formalities for receipt of healthcare and reimbursement of healthcare costs, such as the requirement to consult a general practitioner before consulting a specialist or before receiving hospital care, also in relation to patients seeking healthcare in another Member State, provided that such conditions are necessary, proportionate to the aim, not discretionary or discriminatory. This may include an assessment by a health professional or healthcare administrator providing services for the statutory social security system or national health system of the Member State of affiliation, such as the general practitioner or primary care practitioner with whom the patient is registered, if this is necessary for determining the individual patient's entitlement to healthcare. It is thus appropriate to require that these general conditions, criteria and formalities should be applied in an objective, transparent and non-discriminatory way and should be known in advance, based primarily on medical considerations, and that they should not impose any additional burden on patients seeking healthcare in another Member State in comparison with patients being treated in their Member State of affiliation, and that decisions should be made as quickly as possible.*

This should be without prejudice to the rights of the Member States to lay down criteria or conditions for prior authorisation in the case of patients seeking healthcare in their Member State of affiliation."

22. Recital 42 of the preamble states:

"*Given that the Member States are responsible for laying down rules as regards the management, requirements, quality and safety standards and organisation and delivery of healthcare and that the planning necessities differ from one Member State to another, it should therefore be for the Member States to decide whether there is a need to introduce a system of prior authorisation, and if so, to identify the healthcare requiring prior authorisation in the context of their system in accordance with the criteria defined by this Directive and in the light of the case-law of the Court of Justice. The information concerning this healthcare should be made publicly available in advance.*"

23. Article 2 of the Patients' Rights Directive, entitled "*Relationship with other Union provisions*" provides, in relevant parts, that:

"*This Directive shall apply without prejudice to* […]
(n) Directive 2005/36/EC;"

24. Article 3, entitled "*Definitions*" provides, in relevant parts:

"[…]
(f) 'health professional' means a doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC, or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC, or a person considered to be a health professional according to the legislation of the Member State of treatment;
(g) 'healthcare provider' means any natural or legal person or any other entity legally providing healthcare on the territory of a Member State;
[…]"

25. Article 4, entitled "*Responsibilities of the Member State of treatment*", provides, in the first paragraph:

> "*1. Taking into account the principles of universality, access to good quality care, equity and solidarity, cross-border healthcare shall be provided in accordance with:*
> *(a) the legislation of the Member State of treatment;*
> *(b) standards and guidelines on quality and safety laid down by the Member State of treatment; and*
> *(c) Union legislation on safety standards.*"

26. Article 7, entitled "*General principles for reimbursement of costs*", provides, in relevant parts:

> "*1. Without prejudice to Regulation (EC) No 883/2004 and subject to the provisions of Articles 8 and 9, the Member State of affiliation shall ensure the costs incurred by an insured person who receives cross-border healthcare are reimbursed, if the healthcare in question is among the benefits to which the insured person is entitled in the Member State of affiliation.*
> […]
> *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.*
> […]
> *7. The Member State of affiliation may impose on an insured person seeking reimbursement of the costs of cross-border healthcare, including healthcare received through means of telemedicine, the same conditions, criteria of eligibility and regulatory and administrative formalities, whether set at a local, regional or national level, as it would impose if this healthcare were provided in its territory. This may include an assessment by a health professional or healthcare administrator providing services for the statutory social security system or national health system of the Member State of affiliation, such as the general practitioner or primary care practitioner with whom the patient is registered, if this is necessary for determining the individual patient's*

entitlement to healthcare. However, no conditions, criteria of eligibility and regulatory and administrative formalities imposed according to this paragraph may be discriminatory or constitute an obstacle to the free movement of patients, services or goods, unless it is objectively justified by planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources.

[…]

9. The Member State of affiliation may limit the application of the rules on reimbursement for cross-border healthcare based on overriding reasons of general interest, such as planning requirements relating to the aim of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources.

[…]

11. The decision to limit the application of this Article pursuant to paragraph 9 shall be restricted to what is necessary and proportionate, and may not constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of goods, persons or services. Member States shall notify the Commission of any decisions to limit reimbursement on the grounds stated in paragraph 9."

27. Article 8, entitled "*Healthcare that may be subject to prior authorisation*" provides, in relevant parts:

"*1. The Member State of affiliation may provide for a system of prior authorisation for reimbursement of costs of crossborder healthcare, in accordance with this Article and Article 9. The system of prior authorisation, including the criteria and the application of those criteria, and individual decisions of refusal to grant prior authorisation, shall be restricted to what is necessary and proportionate to the objective to be achieved, and may not constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of patients.*

2. Healthcare that may be subject to prior authorisation shall be limited to healthcare which:

(a) is made subject to planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources and:

(i) involves overnight hospital accommodation of the patient in question for at least one night; or

(ii) requires use of highly specialised and cost-intensive medical infrastructure or medical equipment;

(b) involves treatments presenting a particular risk for the patient or the population; or

(c) is provided by a healthcare provider that, on a case-by-case basis, could give rise to serious and specific concerns relating to the quality or safety of the care, with the exception of healthcare which is subject to Union legislation ensuring a minimum level of safety and quality throughout the Union."

28. The Professional Qualifications Directive was incorporated into the EEA Agreement by Decision of the EEA Joint Committee No 142/2007 of 26 October 2007 adding it at point 1 of Annex VII (Recognition of professional qualifications) to the EEA Agreement.[8]

29. Article 1 of the Professional Qualifications Directive, entitled "*Purpose*", provides:

"This Directive establishes rules according to which a Member State which makes access to or pursuit of a regulated profession in its territory contingent upon possession of specific professional qualifications (referred to hereinafter as the host Member State) shall recognise professional qualifications obtained in one or more other Member States (referred to hereinafter as the home Member State) and which allow the holder of the

[8] OJ L 100, 10.4.2008, p. 70–83.

said qualifications to pursue the same profession there, for access to and pursuit of that profession."

30. Article 2, entitled "*Scope*", provides:

> "*1. This Directive shall apply to all nationals of a Member State wishing to pursue a regulated profession in a Member State, including those belonging to the liberal professions, other than that in which they obtained their professional qualifications, on either a self-employed or employed basis.*
> *2. Each Member State may permit Member State nationals in possession of evidence of professional qualifications not obtained in a Member State to pursue a regulated profession within the meaning of Article 3(1)(a) on its territory in accordance with its rules. In the case of professions covered by Title III, Chapter III, this initial recognition shall respect the minimum training conditions laid down in that Chapter.*
> *3. Where, for a given regulated profession, other specific arrangements directly related to the recognition of professional qualifications are established in a separate instrument of Community law, the corresponding provisions of this Directive shall not apply.*"

3. NATIONAL LAW

31. Chapter 5 of the National Insurance Act is entitled "*Benefits for healthcare*", and is part of Part IV of the Act, entitled "*Sickness benefits, etc.*"[9]

32. Section 5-6, entitled "*Dental care*", sets out the coverage of examination and treatment for dental care:

> "*The social security scheme shall pay benefits for coverage of expenses for sickness-related examination and treatment by a dental practitioner.*
> *The benefits shall be provided according to fixed rates.*
> *The Ministry shall issue regulations on benefits pursuant to the present paragraph, including on grants for common measures for dental practitioners*."

[9] In Norwegian: *Lov 28. februar 1997 nr. 19 om folketrygd*.

33. Rules referred to in Section 5-6 are laid down in Regulation of 16 December 2014 No 1702 *on benefits to cover expenses for sickness-related examination and treatment by dental practitioners and dental hygienists* ("**the Dental Regulation**").[10]

34. Section 1 of the Dental Regulation, entitled "*Benefits-eligible examination and treatment*", provides:

> "*Under Section 5-6 of the National Insurance Act, benefits shall be paid for coverage of expenses for examination and treatment performed by a dental practitioner in the event of the following conditions/cases:*
> […]
> *6. Periodontitis*
> […]
> *Under Section 5-6a of the National Insurance Act, benefits shall be paid for coverage of expenses for examination and treatment of periodontitis performed by a dental hygienist pursuant to first paragraph Nos 1, 4, 6 and 14.*
> *The individual dental practitioner or dental hygienist shall be responsible for determining whether an insured person is entitled to benefits pursuant to Sections 5-6 or 5-6a of the National Insurance Act. The dental practitioner/dental hygienist shall furthermore determine whether the treatment is within the parameters of necessary and appropriate dental treatment. The dental practitioner/dental hygienist must be able to document their assessments, and the patient record shall contain all relevant and necessary information: see the Healthcare Professionals Act with accompanying regulations.*
> *The Directorate of Health* (Helsedirektoratet) *shall lay down comprehensive provisions and detailed guidelines for which treatments and conditions are covered by the scheme under Section 1.*
> *It is a condition for benefits under the present Regulation that the person in question is an insured person under the national insurance scheme: see Section 5-2 of the National Insurance Act*."

[10] In Norwegian: *Forskrift 16. desember 2014 nr. 1702 om stønad til dekning av utgifter til undersøkelse og behandling hos tannlege og tannpleier for sykdom*.

35. Section 3, entitled "*The dental practitioner's and the dental hygienist's competence*", provides:

> "*Benefits shall be paid only if the examination or treatment is performed by a dental practitioner or dental hygienist who is allowed to perform dental treatment pursuant to Act No 64 of 2 July 1999 on healthcare personnel, etc. (the Healthcare Personnel Act),*[11] *including dental practitioners or dental hygienists from other EEA States providing temporary services in Norway, see Section 16 of Regulation 8 October 2008 No 1130 on authorisation, licensing and specialist approval for healthcare personnel having professional qualifications from other EEA States and Switzerland.*[12]
> *In the event of examination and possible start of orthodontics treatment, a referral is required from another dental practitioner or dental hygienist before treatment with the orthodontist may begin. A referral for insured persons covered by Section 1(8) group (b) or (c) shall be valid for 24 months from the date of the referral. The treatment must be performed by an orthodontist or by a dental practitioner undergoing specialist education in orthodontics. If the treatment is performed by a dental practitioner undergoing specialist education in orthodontics, the treatment must be performed as part of the training. If tasks are delegated to other professionals, see Sections 4 and 5 of the Healthcare Personnel Act, it is assumed that delegated tasks are performed under the responsibility, presence and full attention of the orthodontist.*
> *Expenses for implant-anchored dental prosthetics treatment is only covered if the surgical placement of dental implants is performed by a specialist in oral surgery and oral medicine, specialist in maxillofacial surgery or specialist in periodontics. In addition, the prosthetics-related part of the treatment must be performed by a specialist in oral prosthetics or by a dental practitioner having the necessary competence approved by the Directorate of Health. Treatment requiring specialist competence, or particular competence approved by the Directorate of Health, may not be delegated to another*

[11] In Norwegian: *Lov 2. juli 1999 nr. 64 om helsepersonell m.v.*
[12] In Norwegian: *Forskrift 8. oktober 2008 nr. 1130 om autorisasjon, lisens og spesialistgodkjenning for helsepersonell med yrkeskvalifikasjoner fra andre EØS-land og Sveits.*

healthcare professional where reimbursement for treatment is claimed pursuant to this present provision.

Expenses for maxillofacial radiology examinations done using CT/MR is covered only if the examinations are performed by a specialist in maxillofacial radiology."

36. Section 5-24a, entitled "*Benefits for healthcare in another EEA State*", provides:

> "*Benefits shall be paid for coverage of expenses for healthcare incurred by the insured person in another EEA State under rules laid down by the Ministry by regulation.*
>
> *The Regulation may contain more detailed provisions on inter alia:*
>
> *a. which healthcare services and goods for which benefits are to be paid;*
>
> *b. who is entitled to benefits;*
>
> *c. conditions for benefits, including prior authorisation and requirements in respect of the service provider;*
>
> *d. calculation of the benefits;*
>
> *e. coverage of travel and subsistence expenses;*
>
> *f. requirements in respect of documentation and translation of documents;*
>
> *g. relationship to other rules on benefits for healthcare received in other States.*"

37. Rules referred to in Section 5-24a have been laid down in Regulation of 22 November 2010 No 1466 *on reimbursement of health care received in another EEA State* ("**the Reimbursement Regulation**").[13]

38. Section 1 of the Reimbursement Regulation, entitled "*General scope*", provides:

> "*The Regulation shall apply to benefits for coverage of expenses for healthcare received in another State in the European Economic Area (EEA), hereinafter referred to as EEA States.*
>
> *Where telemedicine is used, the healthcare shall be deemed to be received in the country where the service provider is established.*"

[13] In Norwegian: *Forskrift 22. november 2010 nr. 1466 om stønad til helsetjenester mottatt i et annet EØS-land*.

39. Section 2, entitled "*Main conditions*", provides:

> "*Benefits shall be paid only for healthcare for which the insured person would have received benefits or a contribution under the National Insurance Act or had covered by the public health and care service had the healthcare in question been received in Norway.*
> *Unless exceptions or adaptations are provided for in the present Regulation, the same conditions shall apply as for equivalent healthcare at public expense in Norway*."

40. Section 3, entitled "*Which types of healthcare for which benefits are paid*", provides:

> "*Benefits shall be paid to cover expenses for healthcare equivalent to healthcare:*
> *a. for which benefits are paid under for under sections 5-4 to 5-12, 5-14 and 5-25 of the National Insurance Act;*
> *b. for which contributions are made under Section 5-22 of the National Insurance Act, limited to the contribution-related purposes hormonal contraceptives and medicinal products in connection with fertility treatment;*
> *c. is provided totally or partially free of charge under Section 1-3(1) of the Dental Health Services Act,*[14] *read in conjunction with Section 2-2 thereof;*
> *d. is provided totally or partially free of charge under the Specialist Healthcare Act*.[15]
> *Benefits shall not be paid for substitution treatment for opioid dependency, even if the insured person is undergoing medicinal product-assisted rehabilitation in Norway*."

41. Article 6, entitled "*Authorisation and other requirements to the service provider*", provides:

> "*The healthcare must be performed by healthcare personnel having official authorisation in the profession in question which is valid in the State where the healthcare is received.*

[14] In Norwegian: *Lov 3. juni 1983 nr. 54 om tannhelsetjenesten.*
[15] In Norwegian: *Lov 2. juli 1999 nr. 61 om spesialisthelsetjenesten m.m.*

When specialist approval is a condition for entitlement to benefits or healthcare at public expense in Norway, the healthcare must be performed by healthcare personnel having equivalent specialist approval that is valid in the State where the healthcare is received. The same applies to other particular competence requirements. Exceptions can be made to this condition if the speciality in question or equivalent formal competence does not exist in the State where the healthcare is received. It is a condition that, instead, it must be documented that the service provider actually has equivalent substantive competence or other doctor specialisation in medicine which is clearly comparable to the speciality required in Norway.

The healthcare personnel must have permission to practise lawfully in the State where the healthcare is received.

It is not a condition that the healthcare must be performed by healthcare personnel who is part of the public health service, although this is a condition for equivalent healthcare at public expense in Norway."

42. In addition to the Reimbursement Regulation, there is an administrative circular accompanying Section 5-24a of the National Insurance Act ("**the Administrative Circular**").[16]

43. Part 6 of the Administrative Circular relating to Section 6 of the Reimbursement Regulation, states in relevant parts:

"***Specialist approval and other particular competence requirements***

Where specialist approval is a requirement for receiving benefits for healthcare in Norway, the treatment abroad must be performed by a healthcare professional having equivalent specialist approval. The specialist approval must be valid in the country where the healthcare is received. Norwegian specialist approval is not required.

For specialist doctors in medicine, approved specialities are largely harmonised through the Professional Qualifications Directive, 2005/36/EC.

Thus, the requirement of doctor speciality in medicine will generally be satisfied in most cases. For a more detailed description of qualification

[16] In Norwegian: *Rundskriv til folketrygdloven § 5-24a – Stønad til helsetjenester mottatt i et annet EØS-land*.

requirements, see Annex V – approval of harmonised courses of education. Where particular competence requirements are imposed with respect to the service provider for entitlement to benefits under Norwegian rules, they shall apply accordingly to treatment received abroad. Examples include additional courses/education for certain rates for care by a doctor in medicine, manual therapy and psychomotor physiotherapy, and psychological care. The Reimbursement Regulation allows for exceptions to be made from the condition on equivalent specialist approval or particular competence. Two conditions must be satisfied in order for an exception to be made. First, the speciality in question or equivalent formal competence must not exist in the country where the healthcare is received. Second, it must be documented that the service provider instead actually has equivalent substantive competence or other doctor specialisation in medicine which is clearly comparable to the speciality required in Norway. Exceptions may not be made if the specialisation in question exists in the country where the healthcare is received.

Specific remarks on specialist approval for implant-based prosthetics

Pursuant to the rules on benefits for dental treatment under Section 5-6 of the National Insurance Act, for reimbursement for implant-based prosthetics and implant surgery, particular competence requirements are set out for the dental practitioner who performs the treatment. In order to receive benefits for implant-based prosthetics in Norway, both the dental practitioner who places the implants (the surgeon) and the dental practitioner who performs the prosthetics-related work must have a specified specialist approval. Dental/oral surgery is referred to in Annex V to the Professional Qualifications Directive. Hence documentation may be required showing that the dental practitioner who performed the surgical placement of implants in another EEA State is in possession of the relevant specialities.

In Norway, a specialty in oral prosthetics is required, or that the dentist has the necessary expertise approved by the Norwegian Directorate of Health, for reimbursement to be given for prosthetic treatment, in accordance with Section 3 of the Dental Regulation.

The speciality in oral prosthetics is not, however, referred to in the Professional Qualifications Directive, and not all EEA countries have such

specialist approval. Nevertheless, allowance is made for reimbursement for the prosthetics-related part of the treatment in countries where an oral prosthetics speciality does not exist. In such cases, a specific assessment must be made of whether the service provider's competence can be deemed to be almost the same as the specialist competence required in Norway."

4. THE QUESTIONS REFERRED

44. The Referring Court has asked the EFTA Court the following questions:

1. Is it compatible with Article 36 of the EEA Agreement and Article 7 of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare to refuse reimbursement of costs for dental treatment in another EEA State on the ground that the treating dental practitioner does not possess the required specialisation in order to have equivalent treatment reimbursed in the service recipient's home State?

2. Does it affect the answer to question 1 if the specialisation required in the service recipient's home State is included in Annex V to Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications?

3. If the specialisation is not included in Annex V to Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications, must the competent authorities in the service recipient's home State also conduct an assessment under Article 36 of the EEA Agreement in order to determine whether the treating dental practitioner has equivalent competence to that required under national law?

5. LEGAL ANALYSIS

5.1. Introductory remarks. The various schemes for reimbursement of costs for healthcare received in another EEA State

45. Within the EEA legal order, there are a number of different legal bases for access to planned cross-border healthcare, and the reimbursement thereof: Article 36 EEA, the Patients' Rights Directive and Article 20 of Regulation 883/2004. The conditions for and the level of reimbursement depends on the legal basis relied on.

46. First, patients who have received prior authorisation from their EEA State of affiliation can travel to another EEA State with the purpose of receiving benefits in kind in accordance with Article 20 of Regulation 883/2004. Furthermore, if the treatment in question is amongst the benefits provided for by the legislation of the EEA State of affiliation, and the same or equally effective treatment compared with the treatment abroad cannot be provided in the EEA State of affiliation within a time-limit which is medically justifiable, the patient must be permitted to travel abroad for treatment in accordance with Article 20 of Regulation 883/2004.[17] The level of reimbursement pursuant to Regulation 883/2004 is defined by the legislation of the EEA State providing the treatment – i.e. the costs of the treatment in the EEA State of treatment.

47. Second, patients can seek such reimbursement pursuant to the Patients' Rights Directive, which seeks to codify the case law of the Court of Justice of the European Union ("**the CJEU**") relating to the freedom to provide services guaranteed by Article 56 TFEU, and, correspondingly, Article 36 EEA, in the field of healthcare.[18] Pursuant to the Patients' Rights Directive, the treatment in question must be among the benefits provided for by the legislation of the EEA State of affiliation, and the patient is entitled to reimbursement equal to that of the legislation of the EEA State of affiliation – i.e. how much the treatment costs in that State.

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[17] See, e.g., Case C-777/18 *WO*, EU:C:2020:745, paragraph 43. It is for the legislation of the EEA State of affiliation to decide whether it wants to provide for a system of prior authorisation under Article 20. It is not clear to ESA whether there is a prior authorisation requirement pursuant to Norwegian law for the treatment in question in the present case. Independently of whether an EEA State introduces a system of prior authorisation, Article 20 provides for a right to be reimbursed for treatment received abroad if the additional criteria are met.

[18] Recital 8 to the Patients' Rights Directive and Cases C-777/18 *WO*, paragraph 65 and C-243/19 *Veselības ministrija*, EU:C:2020:872, paragraph 66.

48. Third, patients can seek reimbursement of the costs related to healthcare received in another EEA State pursuant to Article 36 EEA.[19]

49. The Referring Court's questions in the present case are limited to Article 36 EEA and the Patients' Rights Directive, and it notes in the Request that the parties to the domestic proceedings agree that Article 20 of Regulation 883/2004 "*is not relevant in the present case*".[20] The Request does not elaborate on why Regulation 883/2004 is not relevant.

50. ESA recalls that the Patients' Rights Directive does not affect the EEA States' obligations under Regulation 883/2004.[21] In instances where the patient is entitled to cross-border healthcare under both the Patients' Rights Directive and Regulation 883/2004 and the application of that Regulation is more advantageous to the patient, it is incumbent on the EEA State of affiliation to draw this to the patient's attention.[22] In any case, ESA observes that a specialisation requirement such as that in Section 3(3) of the Dental Regulation and Section 6(2) of the Reimbursement Regulation could not be maintained under Regulation 883/2004, pursuant to which both the treatment as well as its costs are established on the basis of the legislation of the EEA State of treatment. Taking into account the financial consequences and planning necessities in the health sector, the prior authorisation requirement embedded in Article 20 of the Regulation was therefore designed to allow the EEA State of affiliation a measure of control.

51. On the basis of the parties' submissions that Article 20 of Regulation 883/2004 is not relevant in the present case, ESA assumes that the relevance of that provision has been assessed and will answer the questions raised by the Referring Court on the basis of Article 36 EEA and the Patients' Rights Directive.

52. ESA notes, for the sake of completeness, that the effectiveness of Article 20 of Regulation 883/2004 in the Norwegian legal order is being addressed in a separate infringement action brought by ESA against Norway.[23] In that case, ESA addresses exactly the concern that patients who are seeking authorisation or reimbursement

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[19] See, e.g., Case C-372/04 *Watts*, EU:C:2006:325, paragraphs 86–87, and Joined Cases E-11/07 and E-1/08 *Rindal and Slinning*, paragraph 42.
[20] The Request, paragraph 6.
[21] See, *inter alia*, recital 28 and Article 2(m) of the Patients' Rights Directive.
[22] See, *inter alia*, recital 31 of the Patients' Rights Directive.
[23] Case E-9/23 *EFTA Surveillance Authority v Norway*, lodged with the EFTA Court on 26 July 2023.

for treatment in another EEA State fail to be assessed under Regulation 883/2004, even though they could have a right to reimbursement of costs for healthcare abroad pursuant to that provision. The present written observations are without prejudice to ESA's submissions in Case E-9/23.

53. ESA notes that the Court is not precluded from providing the Referring Court with all the elements of interpretation of EEA law which may be of assistance in adjudicating in the case pending before it, whether or not the Referring Court has referred to them in the wording of its questions.[24]

54. ESA therefore submits that the first question from the Referring Court cannot be considered without referring to Article 4 of the Patients' Rights Directive concerning the responsibilities of the EEA State of treatment, as interpreted in light of the fundamental freedom to receive services pursuant to Article 36 EEA.

55. In part 5.2 of these written observations, the specialisation requirement pursuant to Section 3(3) of the Dental Regulation and Section 6(2) of the Reimbursement Regulation is therefore assessed in view of Article 4 of the Patients' Rights Directive and Article 36 EEA. There, ESA submits that Article 36 EEA and Articles 4 and 7(1) of the Patient's Rights Directive must be interpreted as precluding a national provision which excludes reimbursement of costs for dental treatment in another EEA State on the ground that the treating dental practitioner does not possess the required specialisation in order to have equivalent treatment reimbursed in the EEA State of affiliation.

56. In part 5.3, ESA addresses Articles 7(3) and 7(7) of the Patients' Rights Directive and the Professional Qualifications Directive for the questions at issue in the present case, as asked by the Referring Court, concluding that these provisions are not relevant or applicable to the facts at stake.

[24] See, e.g., Case E-16/20 *Q and Others*, paragraph 35.

5.2. Articles 4 and 7(1) of the Patients' Rights Directive and Article 36 EEA: Imposing Norwegian Specialisation Requirement on treatment provided in another EEA State is contrary to the principle that the delivery of healthcare is the responsibility of the EEA State of treatment

57. Article 7(1) of the Directive guarantees reimbursement of costs of cross-border healthcare. It provides that the EEA State of affiliation shall ensure that the costs incurred by an insured person who receives cross-border healthcare are reimbursed, if the healthcare in question is among the benefits to which the insured person is entitled in the Member State of affiliation.

58. In accordance with Articles 4(1)(a) and 4(1)(b) of the Patients' Rights Directive, respectively, cross-border healthcare must be provided in accordance with the legislation of the EEA State of treatment, and in accordance with standards and guidelines on quality and safety laid down by the EEA State of treatment.

59. ESA submits that the Specialisation Requirement pursuant to Section 3(3) of the Dental Regulation and Section 6(2) of the Reimbursement Regulation, according to which the health professional in the EEA State of treatment must possess the required specialisation in order to have equivalent treatment reimbursed in Norway is a requirement relating to the *provision or delivery of healthcare*, therefore falling within the scope of Article 4 of the Patients' Rights Directive. Helseklage also acknowledges in their submissions that the Specialisation Requirement set out in Section 3(3) of the Dental Regulation and Section 6(2) of the Reimbursement Regulation is a requirement linked to, in their own words, "*the competence held by the treatment provider*".[25]

60. It is clear from the legislative history of Article 4 that the purpose of the provision is exactly to make sure that the provision of healthcare is decided by the EEA State of treatment. As noted by the Commission in its proposal for the Patients' Rights Directive:

[25] The Request, paragraph 62.

"*the rules applicable to* ***the actual provision of healthcare*** *(as defined in Art.4 a)) of the Directive has to be governed by the rules of the Member State of treatment.*"[26]

61. Articles 4(1)(a) and 4(1)(b) of the Patients' Rights Directive as such reflects the principle that EEA law does not detract from the power of the EEA States to organise the provision of health care, in this instance the way in which Poland treats periodontitis.

62. The principle that cross-border healthcare must be provided in accordance with the legislation of the EEA State of treatment permeates the Patients' Rights Directive. In recital 19 of the preamble it is stated that "[t]*he rules applicable to cross-border healthcare should be those set out in the legislation of the* [EEA] *State of treatment*", whilst "*health professional*" is defined in Article 3(f) of the Patients' Rights Directive as "*… or any person considered to be a health professional according to the legislation of the* [EEA] *State of treatment",* making clear that any matter relating to the provision of healthcare is decided by the EEA State of treatment. This is also confirmed by recital 20 of the preamble, which explains that is the EEA State of treatment that provides the patient with "*the relevant information on safety and quality standards enforced on its territory.*"

63. Furthermore, as noted in Part 5.1 above, the Patients' Rights Directive seeks to codify the case law of the CJEU relating to the freedom to provide services guaranteed by Article 56 TFEU, and, correspondingly, Article 36 EEA, in the field of healthcare. The Patients' Rights Directive must therefore be interpreted in light of Article 36 EEA and related case law.

64. Helseklage does not seem to dispute that the requirement that the treating dental practitioner in the EEA State of treatment must possess the required specialisation in the EEA State of affiliation in order to have equivalent treatment reimbursed in the service recipient's home State constitutes a restriction on the service recipient's

[26] See the Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare, COM(2008) 414 final, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52008PC0414, on p. 18. Emphasis by ESA.

freedom to receive services in another EEA State in accordance with Article 36 EEA.[27]

65. As noted by the Court in *Criminal Proceedings against N*, the freedom to provide services conferred by Article 36 EEA also includes the "*passive*" freedom to provide services, that is, the freedom for recipients of services to go to another EEA State in order to receive a service there, without being hindered by restrictions, such as in the present case.[28]

66. In *Criminal Proceedings against N*, the Court furthermore noted that *all measures* which prohibit, impede or render less attractive the exercise of the free movement of services must be regarded as restrictions,[29] in line with the Court's settled case law that no form of *de minimis* rule exists in that regard.[30] This does also not seem to be disputed by Helseklage, having submitted that "*each and every potential obstacle to freedom to provide services must be assessed in the light of Article 36 of the EEA Agreement*".[31]

67. It is clear that the Specialisation Requirement pursuant to Section 3(3) of the Dental Regulation and Section 6(2) of the Reimbursement Regulation prohibit, impede and render less attractive the freedom to receive services abroad in all instances, such as the present, where the legislation of the EEA State of treatment does not require the same specialisation as that required in Norway.

68. In *Stamatelaki*, the CJEU noted that the fact remains that the treating institutions in other EEA States are subject, in those States, to quality controls and requirements as to their professional qualifications set out by the legislation of that State.[32] The CJEU therefore concluded that the lack of verification as to whether the treating institutions in another EEA State are able to provide appropriate, as in identical or

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[27] See paragraph 62 of the corrected Request.
[28] Case E-8/20 *Criminal proceedings against N*, paragraph 75.
[29] *Ibidem*, paragraph 79.
[30] See, e.g. E-9/20 *ESA v Norway*, paragraph 77. From the CJEU, see e.g., Case C-49/89 *Corsica Ferries France v Direction générale des douanes*, EU:C:1989:649, paragraph 8.
[31] The Request, paragraph 62. In the Request first received, the English translation read that Helseklage *disagreed* each and every potential obstacle to the freedom to provide services must be assessed in the light of Article 36 EEA. This has been corrected in the second version of the Request.
[32] Case C-444/05 *Stamatelaki,* EU:C:2007:231, paragraph 37.

equivalent, medical treatment, as that in the EEA State of affiliation could not justify a restriction on the freedom to receive services in other States.[33]

69. ESA on the basis of the above submits that the requirement that the treating practitioner in the EEA State of treatment must possess the required specialisation in order to have equivalent treatment reimbursed in Norway is contrary to Articles 4 and 7(1) of the Patients' Rights Directive and Article 36 EEA.

70. Having submitted that imposing Norwegian requirements of specialisation on treatment provided in another EEA State is contrary to the principle that the delivery of healthcare is the responsibility of the EEA State of treatment pursuant to Articles 4 and 7(1) of the Patients' Rights Directive and constitutes an unjustifiable restriction under Article 36 EEA, ESA does not consider it necessary to answer the second and third questions from the Referring Court.

71. With reference to Helseklage's submission that it would lead to improper discrimination if the Specialisation Requirement applied only to those receiving dental treatment in Norway,[34] ESA notes that such reverse discrimination is not prohibited under EEA law.

5.3. The relevance of Articles 7(3) and 7(7) of the Patients' Rights Directive for the assessment of the Norwegian Specialisation Requirement. The distinction between entitlement to a treatment under the legislation of the EEA State of affiliation and the provision of that treatment in the EEA State of treatment

5.3.1. Introductory remarks

72. Helseklage in its decision of 25 February 2021 and in its submissions before the Referring Court relies on Articles 7(3) and Article 7(7) of the Patients' Rights Directive to justify the requirement that the treating practitioner in the EEA State of treatment must possess the required specialisation in order to have equivalent treatment reimbursed in Norway pursuant to Section 3(3) of the Dental Regulation and Section 6(2) of the Reimbursement Regulation. ESA for the sake of completeness notes that this also seems to be the practice of the Referring Court

[33] *Ibidem,* paragraph 36.
[34] The Request, paragraph 63.

itself, which has previously ruled that imposing the specialisation requirement on dental practitioners in other EEA States is not contrary to EEA law.[35]

73. ESA submits that neither Article 7(3) nor Article 7(7) of the Patients' Rights Directive can justify the introduction of the Specialisation Requirement pursuant to Section 3(3) of the Dental Regulation and Section 6(2) of the Reimbursement Regulation.

5.3.2. Article 7(3) of the Patients' Rights Directive

74. Recital 29 of the Patients' Rights Directive recalls that patients can seek access to healthcare in other EEA States in circumstances such as those provided in Regulation 883/2004, but that they also benefit from the principles of free movement of patients in accordance with the EEA Agreement and the Patients' Rights Directive.

75. As expressed in recital 26 of the preamble to the Directive "*The right to reimbursement of the costs of healthcare provided in another Member State by the statutory social security system of patients as insured persons has been recognised by the Court of Justice in several judgements. The Court of Justice has held that the Treaty provisions on the freedom to provide services include the freedom for the recipients of healthcare, including persons in need of medical treatment, to go to another Member State in order to receive it there.* […]"

76. Article 7(3) of the Patients' Rights Directive establishes that the EEA State of affiliation has the right to determine 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.

77. As regards the relevance of Article 7(3) of the Patients' Rights Directive, a fundamental distinction must be drawn between the *entitlement to* a specific treatment, on the one hand, and the *provision of* that healthcare in another EEA State, on the other. The entitlement to a specific treatment and the corresponding

[35] See Appeal Case No 20/00406, referred to at paragraph 10 of the Request, where it is stated on page 4 that "*Ap's statement that the requirement concerning the dentist's competence is contrary to EEA law, can in the Court's view clearly not be upheld. It is clear, as the Court sees it, from the above that there cannot be different requirements for dentists within the EEA than there are in Norway*" (translation by ESA). The decision in Appeal Case No 20/00406 is not publicly available, and was retrieved by ESA upon direct request to the National Insurance Court.

right to reimbursement of the costs for such treatment in another EEA State is, in accordance with Article 7(3) of the Patients' Rights Directive, decided by the legislation of the EEA State of affiliation, whilst the organisation and delivery of healthcare remains the responsibility of the individual EEA State providing that healthcare.

78. Periodontitis is listed in point 6 of Article 1(1) of the Dental Regulation as a condition for which examination and treatment is covered by the national insurance scheme in Norway pursuant to Section 5-6 of the National Insurance Act. Treatment for periodontitis is therefore a type of healthcare for which members of the Norwegian national insurance scheme can be *entitled to* under Norwegian law.

79. As K has not claimed to be entitled to a treatment that is not provided for by the national insurance scheme in Norway, ESA submits that Article 7(3) of the Patients' Rights Directive is not relevant for the questions at issue in the present case.

5.3.3. Article 7(7) of the Patients' Rights Directive

80. Helseklage furthermore relies on Article 7(7) of the Patients' Rights Directive, which allows the EEA State of affiliation to "*impose on an insured person seeking reimbursement of the costs for cross-border healthcare* […] *the same conditions, criteria of eligibility and regulatory and administrative formalities, whether set at a local, regional or national level, as it would impose if this healthcare were provided in its territory.*"

81. Under settled case law, the meaning and scope of terms for which EEA law provides no definition must be determined by considering their usual meaning in everyday language, while also taking into account the context in which they occur and the purposes of the rules of which they are part.[36]

82. Taking into account the wording of Article 7(7) and its usual meaning and the context in which it occurs and the purpose of the Patients' Rights Directive, ESA submits that Article 7(7) cannot serve as basis for the Specialisation Requirement in Section 3(3) of the Dental Regulation and Section 6(2) of the Reimbursement Regulation for a number of reasons.

[36] See, e.g., Case E-2/21 *Norep AS v Haugen Gruppen AS*, paragraph 31.

83. It follows from the wording of Article 7(7) that it concerns conditions, criteria and formalities imposed on *the insured person*, and not, as the Specialisation Requirement in Section 3(3) of the Dental Regulation and Section 6(2) of the Reimbursement Regulation, imposed on *the healthcare provider* and relating to their professional qualifications. ESA notes that "*Healthcare provider*" is defined in Article 3(g) of the Patients' Rights Directive as any natural or legal person or any other entity legally providing healthcare on the territory of an EEA State, and defined by the rules of *the EEA State of treatment*.

84. That the Specialisation Requirement is imposed on the healthcare provider is evident also from the titles of Section 3(3) of the Dental Regulation and Section 6(2) of the Reimbursement Regulation – "*The dental practitioner's and the dental hygienist's competence*" and "*Authorisation and other requirements to the service provider*", respectively.[37]

85. Recital 37 of the Patients' Rights Directive makes specific reference to the possibility for the EEA State of affiliation to maintain "*general conditions, criteria for eligibility and regulatory and administrative formalities for receipt of healthcare and reimbursement of healthcare costs*", and provides an example of such conditions, criteria and administrative formalities. The example provided in the recital is "*the requirement to consult a general practitioner before consulting a specialist or before receiving hospital care*". This example clearly supports the interpretation that Article 7(7) concerns *administrative conditions criteria and formalities*, and not qualification requirements imposed on the healthcare provider.

86. An example of such an administrative procedure that can be imposed on the patient in the same way as if the treatment had been provided in the EEA State of affiliation, is the requirement pursuant to Article 1(3) of the Dental Regulation that the patient must have undergone an assessment by a dentist or dental hygienist concluding that they are entitled to the treatment in question.

87. This is also evident in view of the Commission's report to the European Parliament and the Council on the operation of the Patients' Rights Directive, where the

[37] Translations by ESA. In Norwegian, Section 3(3) of the Dental Regulation is entitled "*Tannlegens og tannpleierens kompetanse*", whilst Section 6(2) of the Reimbursement Regulation is entitled "*Autorisasjon og andre krav til tjenesteyteren*".

application of Article 7(7) is considered under the heading "*Administrative procedures*".[38] When elaborating on the outcome of the assessment, it is *inter alia* noted that:

> "*Evidence gathered for the evaluation confirms that cumbersome and disproportionate* ***administrative procedures*** *undermine citizens' rights to cross-border healthcare in some Member States*."[39]

88. ESA's position is therefore that Article 7(7) of the Patients' Rights Directive is not applicable in the present case. However, should the Court consider that it is applicable, ESA submits that the Specialisation Requirement pursuant to Section 3(3) of the Dental Regulation and Section 6(2) of the Reimbursement Regulation would in any case not be justifiable.

89. Imposing the Norwegian Specialisation Requirement on treatment provided in other EEA States is discriminatory. As the Specialisation Requirement is set according to Norwegian rules, patients that have received the treatment in another EEA State are *per se* put in a disadvantageous situation compared to those who have received the treatment in Norway, as treatment received in Norway by its very nature of having been performed in Norway will fulfil the Specialisation Requirement, whilst treatment received abroad is less likely to.

90. As follows from the wording of Article 7(7) of the Patients' Rights Directive, any conditions, criteria of eligibility and regulatory and administrative formalities imposed according to that paragraph must be "*objectively justified by planning requirements*". Helseklage has submitted no arguments to the effect that the Specialisation Requirement pursuant to Section 3(3) of the Dental Regulation and Section 6(2) of the Reimbursement Regulation is necessitated due to planning requirements. Since *Helseklage* has not brought forward any planning justifications, the measure cannot be justified under Article 7(7) of the Patients' Rights Directive.

91. The only justification provided by Helseklage – that a removal of the Specialisation Requirement pursuant to Section 3(3) of the Dental Regulation and Section 6(2) of

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[38] Commission's report to the European Parliament and the Council on the operation of the Patients' Rights Directive, COM/2022/210 final, p. 4, available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022DC0210

[39] *Ibidem*, p. 4. Emphasis by ESA.

the Reimbursement Regulation would "*lead to a situation where the quality of healthcare worsens and Norway will incur greater expenditure related to reimbursement of healthcare that has not been performed sufficiently well because the treatment provider lacks sufficient competence*"[40] – is not a relevant consideration under Article 7(7) of the Patients' Rights Directive.

92. As referred to in Part 5.2 above, the CJEU in *Stamatelaki* noted that the treating institutions in other EEA States are subject, in those States, to quality controls and requirements as to their professional qualifications set out by the legislation of that State.[41] That case concerned a rule in national legislation excluding all reimbursement of costs for treatment in private hospitals in other States. The rule was sought to be justified by the fact that the social security institutions of the EEA State of affiliation did not check the quality of treatment in the EEA State of treatment, and the lack the lack of verification as to whether the treating institutions in the other EEA State are able to provide identical or equivalent treatment to that in the EEA State of affiliation. The CJEU dismissed these reasons as relevant justifications for the national rule in question.[42]

93. The consideration put forth by Helseklage could, if properly documented, be relevant under *Article 8(1)(c)* of the Patients' Rights Directive, according to which the EEA State of affiliation may provide for a system of prior authorisation for reimbursement of costs of cross-border healthcare which is *"provided by a healthcare provider that, on a case-by-case basis, could give rise to serious and specific concerns relating to the quality or safety of the care*". This is recognised in recital 42 of the preamble to the Patients' Rights Directive, which specifically mentions rules concerning, amongst others, quality and safety standards.

94. The possibility for the State of affiliation to adopt a system of prior authorisation was also a consideration used by the CJEU when finding that a restriction on the right to be reimbursed for healthcare received abroad was not justifiable in *Stamatelaki*.[43]

[40] The Request, paragraph 64.
[41] Case C-444/05 *Stamatelaki,* paragraph 37.
[42] *Ibidem,* paragraph 36.
[43] *Ibidem,* paragraph 35.

Norway has, however, consistently maintained to ESA that it does not have a system of prior authorisation pursuant to the Patients' Rights Directive.[44]

95. As regards the suitability of the measure, it follows from Section 6(2) of the Reimbursement Regulation, as interpreted in accordance with Part 6 of the Administrative Circular, that the assessment of the treating healthcare provider's qualifications is not done on an individual case-by-case basis when the equivalent formal competence exists in the EEA State of treatment, but schematically decided on the basis of the States' reporting under Annex V to the Professional Qualifications Directive.[45]

96. With regard to the relevance of the Professional Qualifications Directive to the first question raised by the Referring Court, ESA notes that the Professional Qualifications Directive is *as such* not applicable in the present case. In accordance with Article 2(1) of the Professional Qualifications Directive it applies, in essence, to all nationals of an EEA State wishing to pursue a regulated profession in another EEA State. The present case, however, does not concern a dental practitioner wishing to pursue the profession of dental practitioner in an EEA State other than that in which they obtained their professional qualifications.

97. ESA furthermore recalls that the existence of Annex V, point 5.3.3 on medical specialisation, does not oblige EEA States to create dental specialisations. This means that the reporting to introduce a dental specialisation into Annex V to the Professional Qualifications Directive is at the discretion of the States. This goes so far that even when a specialisation compliant with the minimum harmonisation requirements existed in a State, it would not be obliged to list it in Annex V. For

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[44] See Norway's Reply of 18 June 2021 to a Request for information from ESA, where it is stated in the second sentence of page 19 that "*Norway has not adopted a system of prior authorisation in accordance with the Patients' Rights Directive.*" Available at: https://www.eftasurv.int/cms/sites/default/files/documents/gopro/21-2317-Request%20for%20information%20concerning%20thecriteria%20for%20access%20to%20inpatien%20reatment%20in%20ot%20%28L%29%281954764%29.pdf.

[45] Part 6.2 of the Administrative circular titled "Specialist approval and other particular competence requirements" provides in relevant parts: *"The Reimbursement Regulation allows for exceptions to be made from the condition on equivalent specialist approval or particular competence. Two conditions must be satisfied in order for an exception to be made. First, the speciality in question or equivalent formal competence must not exist in the country where the healthcare is received. Second, it must be documented that the service provider instead actually has equivalent substantive competence or other doctor specialisation in medicine which is clearly comparable to the speciality required in Norway.* ***Exceptions may not be made if the specialisation in question exists in the country where the healthcare is received****."* Emphasis by ESA.

instance, Austria, Belgium, Estonia, Luxembourg and Spain have not listed any titles under point 5.3.3 of Annex V. One reason for not listing a specialisation in Annex V, and thus including it in the automatic recognition procedure under the Professional Qualifications Directive, could also be that the training in the EEA State in question goes *beyond the minimum requirements* and therefore would not want to automatically recognise dentists only fulfilling the minimum requirements.

98. Furthermore, the Professional Qualifications Directive does not guarantee that a dental specialist, e.g. a qualified oral surgeon in another EEA State, has access to and is able to pursue the same activities in Norway. The Directive is silent about the content of dental specialist training and which activities these specialists are allowed to perform, including, for the purposes of the present case, the activity of placing implants and implant surgery, as a qualified oral surgeon.[46] The explanation in Section 6 of the Circular that "[s]*ince this is a harmonized specialty, documentation may be required that the dentist who has carried out the surgical insertion of implants in another EEA State, holds one of the specialties in question*" cannot therefore be upheld.

99. Applying the States' listing pursuant to Annex V to the Professional Qualifications Directive in instances where the same specialisation as required in Norway exists in the EEA State of treatment is also contrary to the provisions of the Patients' Rights Directive, as the definitions of "*health professional*" and "*healthcare provider*" in Article 3(f) and Article 3(g), respectively, makes clear that those concepts are determined on the basis of the legislation of the EEA State of treatment.

100. ESA on this basis submits that the listing of specialist qualifications in Annex V, point 5.3.3, of the Professional Qualifications Directive is not a criterion suitable to fulfil the objective of the Specialisation Requirement in ensuring that the treatment abroad is provided by someone who possesses the same professional qualifications as those required in Norway.

101. With regard to Section 6(2) of the Reimbursement Regulation and the requirement to document that the health professional in the EEA State of treatment has

[46] See, to the contrary, Articles 42(2) and 45(2) of the Professional Qualifications Directive which sets out a minimum list of special activities midwifes and pharmacists, respectively, must be allowed to pursue in every EEA State.

equivalent substantive competence clearly comparable to the speciality required in Norway, in instances where the specialisation in question does not exist in the EEA State of treatment, ESA assumes that it is the patient that has to provide this documentation. The requirement seems to entail that the patient must obtain detailed documentation of the health professional's qualifications, which would disproportionately affect the patient's possibility to get reimbursement for treatment received abroad.

102. In conclusion, ESA submits that the Specialisation Requirement does not fall within the scope of Article 7(7) of the Patients' Rights Directive and, even if it came within its scope, it would constitute an unjustified restriction.

6. CONCLUSION

Accordingly, ESA respectfully requests the Court to answer the first question from the Referring Court as follows:

> **Article 36 EEA and Articles 4 and 7(1) of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare must be interpreted as precluding a national provision which excludes reimbursement of costs for dental treatment in another EEA State on the ground that the treating dental practitioner does not possess the required specialisation in order to have equivalent treatment reimbursed in the EEA State of affiliation.**

Marte Brathovde Ewa Gromnicka

Melpo-Menie Joséphidès

Agents of the EFTA Surveillance Authority