

JUDGMENT OF THE COURT

5 December 2024*

(Social security law – Free movement of patients – Article 36 EEA – Directive 2011/24/EU – Article 7 – Patients' rights – Reimbursement of costs of cross-border healthcare – Article 129 EEA)

In Case E-15/23,

REQUEST to the Court under Article 34 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice by the National Insurance Court (*Trygderetten*), in the case between

K

and

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

concerning the interpretation 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, and in particular Article 7 thereof and Article 36 of the Agreement on the European Economic Area,

THE COURT,

composed of: Páll Hreinsson, President, Bernd Hammermann (Judge-Rapporteur) and Michael Reiertsen, Judges,

Registrar: Ólafur Jóhannes Einarsson,

^{*} Language of the request: Norwegian. Translations of national provisions are unofficial and based on those contained in the documents of the case.

having considered the written observations submitted on behalf of:

- the National Office for Health Service Appeals, represented by Andreas Runde, advocate;
- the Estonian Government, represented by Merili Kriisa, acting as Agent;
- the Polish Government, represented by Bogusław Majczyna, acting as Agent;
- the EFTA Surveillance Authority ("ESA"), represented by Marte Brathovde, Ewa Gromnicka, and Melpo-Menie Joséphidès, acting as Agents; and
- the European Commission ("the Commission"), represented by Lorna Armati,
 Sandrine Delaude and Esther Eva Schmidt, acting as Agents,

having regard to the Report for the Hearing,

having heard oral argument of K, represented by Lasse Nikolai Simonsen, counsel; the National Office for Health Service Appeals, represented by Andreas Runde; ESA, represented by Marte Brathovde; and the Commission, represented by Lorna Armati, at the hearing on 14 May 2024,

gives the following

JUDGMENT

I LEGAL BACKGROUND

EEA law

- 1 Article 36 of the Agreement on the European Economic Area ("the EEA Agreement" or "EEA") reads:
 - 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.

2 Article 129(1) EEA reads, in extract:

This Agreement is drawn up in a single original in the Danish, Dutch, English, Finnish, French, German, Greek, Icelandic, Italian, Norwegian, Portuguese, Spanish and Swedish languages, each of these texts being equally authentic.

• • •

The texts of the acts referred to in the Annexes are equally authentic in the Bulgarian, Croatian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish and Swedish languages as published in the Official Journal of the European Union and shall for the authentication thereof be drawn up in the Icelandic and Norwegian languages and published in the EEA Supplement to the Official Journal of the European Union.

- 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 (OJ 2011 L 88, p. 45; and Norwegian EEA Supplement 2018 No 27, p. 1) ("the Patients' Rights Directive") was incorporated into the EEA Agreement by Decision of the EEA Joint Committee No 153/2014 of 9 July 2014 (OJ 2015 L 15, p. 78; and Norwegian EEA Supplement 2015 No 5, p. 1) ("JCD 153/2014"). Patients' Rights Directive is referred to at point 2 of Annex X (Services in general) to the EEA Agreement. Constitutional requirements were indicated by Iceland and Norway. The requirements were fulfilled by 9 June 2015, and the decision entered into force on 1 August 2015.
- 4 Article 1 of JCD 153/2014 reads, in extract:

The following is added after point 1c (Commission Decision 2011/130/EU) of Annex X to the EEA Agreement:

'2. **32011** L **0024**: 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 (OJ L 88, 4.4.2011, p. 45).

The provisions of the Directive shall, for the purposes of this Agreement, be read with the following adaptations:

Without prejudice to future development by the EEA Joint Committee, it should be noted that the following acts are not incorporated into the EEA Agreement:

(a) Council Regulation (EC) No 859/2003 of 14 May 2003 extending the provisions of Regulation (EEC) No 1408/71 and Regulation (EEC) No 574/72 to nationals of

third countries who are not already covered by those provisions solely on the ground of their nationality,

(b) Regulation (EU) No 1231/2010 of the European Parliament and of the Council of 24 November 2010 extending Regulation (EC) No 883/2004 and Regulation (EC) No 987/2009 to nationals of third countries who are not already covered by these Regulations solely on the ground of their nationality.

Therefore all references to these acts shall not apply to the EFTA States.

, ...

- 5 Recitals 2 (in extract), 6, 8, 10, 11, 19, 20, 28, 29, 30, 31, 37 and 48 of the Patients' Rights Directive read as follows:
 - (2) Article 114 TFEU is the appropriate legal basis since the majority of the provisions of this Directive aim to improve the functioning of the internal market and the free movement of goods, persons and services. ...
 - (6) As confirmed by the Court of Justice of the European Union (hereinafter the 'Court of Justice') on several occasions, while recognising their specific nature, all types of medical care fall within the scope of the TFEU.
 - (8) Some issues relating to cross-border healthcare, in particular reimbursement of healthcare provided in a Member State other than that in which the recipient of the care is resident, have already been addressed by the Court of Justice. This Directive is intended to achieve a more general, and also effective, application of principles developed by the Court of Justice on a case-by-case basis.
 - (10) This Directive aims to establish rules for facilitating access to safe and high-quality cross-border healthcare in the Union and to ensure patient mobility in accordance with the principles established by the Court of Justice and to promote cooperation on healthcare between Member States, whilst fully respecting the responsibilities of the Member States for the definition of social security benefits relating to health and for the organisation and delivery of healthcare and medical care and social security benefits, in particular for sickness.
 - (11) This Directive should apply to individual patients who decide to seek healthcare in a Member State other than the Member State of affiliation. As confirmed by the Court of Justice, neither its special nature nor the way in which it is organised or financed removes healthcare from the ambit of the fundamental principle of the freedom to provide services. However, the Member State of affiliation may choose to limit the reimbursement of cross-border healthcare for reasons relating to the quality and safety of the healthcare provided, where this can

be justified by overriding reasons of general interest relating to public health. The Member State of affiliation may also take further measures on other grounds where this can be justified by such overriding reasons of general interest. Indeed, the Court of Justice has laid down that public health protection is among the overriding reasons of general interest that can justify restrictions to the freedom of movement envisaged in the Treaties.

- (19) 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 and misunderstanding. It should also establish a high level of trust between the patient and the healthcare provider.
- (20) 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.
- (28) This Directive should not affect an insured person's rights in respect of the assumption of costs of healthcare which becomes necessary on medical grounds during a temporary stay in another Member State according to Regulation (EC) No 883/2004. In addition, this Directive should not affect an insured person's right to be granted an authorisation for treatment in another Member State where the conditions provided for by Union regulations on the coordination of social security systems are met, in particular by Regulation (EC) No 883/2004 or Council Regulation (EEC) No 1408/71 of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community, which are applicable by virtue of Regulation (EU) No 1231/2010 of the European Parliament and of the Council of 24 November

- 2010 extending Regulation (EC) No 883/2004 and Regulation (EC) No 987/2009 to nationals of third countries who are not already covered by these Regulations solely on the ground of their nationality and Council Regulation (EC) No 859/2003 of 14 May 2003 extending the provisions of Regulation (EEC) No 1408/71 and Regulation (EEC) No 574/72 to nationals of third countries who are not already covered by those provisions solely on the ground of their nationality.
- (29) 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.
- (30) 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.
- (31) 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.
- (37) 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.

- (48) Appropriate information on all essential aspects of cross-border healthcare is necessary in order to enable patients to exercise their rights on cross-border healthcare in practice. For cross-border healthcare, one of the mechanisms for providing such information is to establish national contact points within each Member State. Information that has to be provided compulsorily to patients should be specified. However, the national contact points may provide more information voluntarily and also with the support of the Commission. Information should be provided by national contact points to patients in any of the official languages of the Member State in which the contact points are situated. Information may be provided in any other language.
- 6 Chapter I of the Patients' Rights Directive entitled "General provisions" contains Articles 1 to 3. Article 1(1), (2) and (4) of the Patients' Rights Directive, entitled "Subject matter and scope", reads:
 - 1. This Directive provides rules for facilitating the access to safe and high-quality cross-border healthcare and promotes cooperation on healthcare between Member States, in full respect of national competencies in organising and delivering healthcare. This Directive also aims at clarifying its relationship with the existing framework on the coordination of social security systems, Regulation (EC) No 883/2004, with a view to application of patients' rights.
 - 2. This Directive shall apply to the provision of healthcare to patients, regardless of how it is organised, delivered and financed.

- 4. This Directive shall not affect laws and regulations in Member States relating to the organisation and financing of healthcare in situations not related to cross-border healthcare. In particular, nothing in this Directive obliges a Member State to reimburse costs of healthcare provided by healthcare providers established on its own territory if those providers are not part of the social security system or public health system of that Member State.
- 7 Article 2 of the Patients' Rights Directive, entitled "Relationship with other Union provisions", reads, in extract:

This Directive shall apply without prejudice to:

...

- (m) Regulation (EC) No 883/2004 and Regulation (EC) No 987/2009 of the European Parliament and of the Council of 16 September 2009 laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems;
- (*n*) *Directive* 2005/36/EC;

...

8 Chapter II of the Patients' Rights Directive entitled "Responsibilities of Member States with regard to cross-border health care" contains Articles 4 to 6. Article 4(1) of the Patients' Rights Directive, entitled "Responsibilities of the Member State of treatment", reads:

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.
- 9 Article 5 of the Patients' Rights Directive, entitled "Responsibilities of the Member State of affiliation", reads, in extract:

The Member State of affiliation shall ensure that:

- (a) the cost of cross-border healthcare is reimbursed in accordance with Chapter III;
- (b) there are mechanisms in place to provide patients on request with information on their rights and entitlements in that Member State relating to receiving cross-border healthcare, in particular as regards the terms and conditions for reimbursement of costs in accordance with Article 7(6) and procedures for accessing and determining those entitlements and for appeal and redress if patients consider that their rights have not been respected, in accordance with Article 9. In information about cross-border healthcare, a clear distinction shall be made between the rights which patients have by virtue of this Directive and rights arising from Regulation (EC) No 883/2004;

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- 10 Chapter III of the Patients' Rights Directive entitled "Reimbursement of costs of cross-border healthcare" contains Articles 7 to 9. Article 7(1), (3), (4), (7) and (9) of the Patients' Rights Directive, entitled "General principles for reimbursement of costs", reads:
 - 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.
 - 4. The costs of cross-border healthcare shall be reimbursed or paid directly by the Member State of affiliation up to the level of costs that would have been assumed by the Member State of affiliation, had this healthcare been provided in its territory without exceeding the actual costs of healthcare received.

Where the full cost of cross-border healthcare exceeds the level of costs that would have been assumed had the healthcare been provided in its territory the Member State of affiliation may nevertheless decide to reimburse the full cost.

The Member State of affiliation may decide to reimburse other related costs, such as accommodation and travel costs, or extra costs which persons with disabilities might incur due to one or more disabilities when receiving cross-border healthcare,

in accordance with national legislation and on the condition that there be sufficient documentation setting out these costs.

- 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.
- Article 9(1), (2), (3) and (4) of the Patients' Rights Directive, entitled "Administrative procedures regarding cross-border healthcare", reads:
 - 1. The Member State of affiliation shall ensure that administrative procedures regarding the use of cross-border healthcare and reimbursement of costs of healthcare incurred in another Member State are based on objective, non-discriminatory criteria which are necessary and proportionate to the objective to be achieved.
 - 2. Any administrative procedure of the kind referred to in paragraph 1 shall be easily accessible and information relating to such a procedure shall be made publicly available at the appropriate level. Such a procedure shall be capable of ensuring that requests are dealt with objectively and impartially.

- 3. Member States shall set out reasonable periods of time within which requests for cross-border healthcare must be dealt with and make them public in advance. When considering a request for cross-border healthcare, Member States shall take into account:
- (a) the specific medical condition;
- (b) the urgency and individual circumstances.
- 4. Member States shall ensure that individual decisions regarding the use of cross-border healthcare and reimbursement of costs of healthcare incurred in another Member State are properly reasoned and subject, on a case-by-case basis, to review and are capable of being challenged in judicial proceedings, which include provision for interim measures.
- 12 Chapter IV of the Directive entitled "Cooperation in healthcare" contains Articles 10 to 15. Article 10(1) and (4) of the Patients' Rights Directive, entitled "Mutual assistance and cooperation", reads, in extract:
 - 1. Member States shall render such mutual assistance as is necessary for the implementation of this Directive, including cooperation on standards and guidelines on quality and safety and the exchange of information, especially between their national contact points in accordance with Article 6, including on provisions on supervision and mutual assistance to clarify the content of invoices.
 - 4. Member States of treatment shall ensure that information on the right to practise of health professionals listed in national or local registers established on their territory is, upon request, made available to the authorities of other Member States, for the purpose of cross-border healthcare, in accordance with Chapters II and III and with national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC, and the principle of presumption of innocence. ...
- Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (OJ 2005 L 255, p. 22; and Norwegian EEA Supplement 2011 No 71, p. 1322) ("the Professional Qualifications Directive") was incorporated into the EEA Agreement by Decision of the EEA Joint Committee No 142/2007 of 26 October 2007 (OJ 2008 L 100, p. 70; and Norwegian EEA Supplement 2008 No 19, p. 70). The Professional Qualifications Directive is referred to at point 1 of Annex VII (Recognition of professional qualifications) to the EEA Agreement. Constitutional requirements were indicated by Iceland, Liechtenstein and Norway. The

requirements were fulfilled by 14 May 2009 and the decision entered into force on 1 July 2009.

14 Recital 3 of the Professional Qualifications Directive reads:

The guarantee conferred by this Directive on persons having acquired their professional qualifications in a Member State to have access to the same profession and pursue it in another Member State with the same rights as nationals is without prejudice to compliance by the migrant professional with any non-discriminatory conditions of pursuit which might be laid down by the latter Member State, provided that these are objectively justified and proportionate.

15 Article 1 of the Professional Qualifications Directive, entitled "Purpose", at the material time, read:

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

- 16 Article 2 of the Professional Qualifications Directive, entitled "Scope", at the material time, read:
 - 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.
- 17 Article 10 of the Professional Qualifications Directive, entitled "Scope", reads, in extract:

This Chapter applies to all professions which are not covered by Chapters II and III of this Title and in the following cases in which the applicant, for specific and exceptional reasons, does not satisfy the conditions laid down in those Chapters:

...

Article 21(1) of the Professional Qualifications Directive, entitled "Principle of automatic recognition", reads:

Each Member State shall recognise evidence of formal qualifications as doctor giving access to the professional activities of doctor with basic training and specialised doctor, as nurse responsible for general care, as dental practitioner, as specialised dental practitioner, as veterinary surgeon, as pharmacist and as architect, listed in Annex V, points 5.1.1, 5.1.2, 5.2.2, 5.3.2, 5.3.3, 5.4.2, 5.6.2 and 5.7.1 respectively, which satisfy the minimum training conditions referred to in Articles 24, 25, 31, 34, 35, 38, 44 and 46 respectively, and shall, for the purposes of access to and pursuit of the professional activities, give such evidence the same effect on its territory as the evidence of formal qualifications which it itself issues.

Such evidence of formal qualifications must be issued by the competent bodies in the Member States and accompanied, where appropriate, by the certificates listed in Annex V, points 5.1.1, 5.1.2, 5.2.2, 5.3.2, 5.3.3, 5.4.2, 5.6.2 and 5.7.1 respectively.

The provisions of the first and second subparagraphs do not affect the acquired rights referred to in Articles 23, 27, 33, 37, 39 and 49.

Annex V to the Professional Qualifications Directive is entitled "Recognition on the basis of coordination of the minimum training conditions". Heading V.3 is entitled "DENTAL PRACTITIONER". At point 5.3.3 of Annex V entitled, "Evidence of formal qualifications of specialised dentists", the following is stated under "Orthodontics" as regards Poland:

| Country | Evidence of qualifications | formal | Body awarding the evidence of qualifications | Reference date |
|---------|--|--------|--|-------------------|
| Polska | Dyplom uzyskania specjalisty w dz ortodoncji | • | Centrum Egzaminów Medycznych | 1 May 2004 |

Further at point 5.3.3 of Annex V, the following is stated under "Oral surgery" as regards Poland:

| Country | Evidence of formal qualifications | Body awarding the evidence of qualifications | Reference date |
|---------|---|--|-------------------|
| Polska | Dyplom uzyskania tytułu specjalisty w dziedzinie chirurgii stomatologicznej | Centrum Egzaminów Medycznych | 1 May 2004 |

National law

- The National Insurance Act No 19 of 28 February 1997 (*lov 28. februar 1997 nr. 19 om folketrygd*) ("National Insurance Act") contains rules on reimbursement for treatment abroad.
- 22 Section 5-1 of the National Insurance Act, entitled "Purpose, etc.", read, at the material time:

The purpose of benefits under the present chapter is to provide total or partial compensation for insured persons' necessary expenses for healthcare in the event of sickness, injury, impairment, family planning, pregnancy, birth or termination of pregnancy.

No benefits shall be provided for interventions which are essentially carried out on cosmetic grounds, or for treatment of foreseeable consequences of such intervention.

In so far as public benefits are provided pursuant to other legislation, no benefits shall be provided under this chapter.

23 Section 5-1 a of the National Insurance Act, entitled "Relationship with provisions on international coordination of national social security", was enacted and entered into force after the material time, on 25 November 2022. It reads:

Benefits for healthcare are sickness benefits under the social security regulation. The provisions of this chapter shall be waived to the extent necessary to comply with relevant provisions of the Main Part of the EEA Agreement, the social security regulation, the implementation regulation and bilateral and multilateral social security agreements: see sections 1-3 a and 1-3 b.

24 Section 5-6 of the National Insurance Act, entitled "Dental practitioner care", reads:

The social security scheme shall provide benefits for coverage of expenses for sickness-related examination and treatment by a dental practitioner.

The benefits shall be provided according to pre-established rates.

The Ministry issues regulations on benefits pursuant to the present section, including on grants for common measures for dental practitioners.

25 Section 5-24 a of the National Insurance Act, entitled "Benefits for healthcare in another EEA State", reads:

Benefits shall be provided for coverage of expenses for healthcare incurred by the insured person in another EEA country 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 provided;
- b. who is entitled to benefits;
- c. conditions for benefits, including prior approval 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 countries.
- Section 1 of Regulation No 1702 of 16 December 2014 on benefits to cover expenses for sickness-related examination and treatment by dental practitioners and dental hygienists (forskrift 16. desember 2014 nr. 1702 om stønad til dekning av utgifter til undersøkelse og behandling hos tannlege og tannpleier for sykdom) ("the National Dental Regulation") entitled "Benefits-eligible examination and treatment", read, at the material time, in extract:

Under Section 5-6 of the National Insurance Act, benefits shall be provided 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 provided for coverage of expenses for examination and treatment of periodontitis performed by a dental hygienist pursuant to Nos 1, 4, 6 and 14 of the first paragraph.

The individual dental practitioner or dental hygienist shall be responsible for determining whether an insured person is entitled to benefits pursuant to section 5-6 or 5-6a of the National Insurance Act. The dental practitioner/dental hygienist shall also 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 determinations, and the patient log 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.

27 Section 3 of the National Dental Regulation, entitled "The dental practitioner's and the dental hygienist's competence", reads:

Benefits shall be provided only if the examination or treatment is performed by a dental practitioner or dental hygienist who is permitted to perform dental treatment pursuant to Act No 64 of 2 July 1999 on healthcare professionals, etc. (the Healthcare Professionals Act) (lov 2. juli 1999 nr. 64 om helsepersonell m.v. (helsepersonelloven)), including dental practitioners or dental hygienists from other EEA States providing temporary services in Norway: see Section 16 of Regulation of 8 October 2008 No 1130 on authorisation, licensing and specialist approval for healthcare professionals having professional qualifications from other EEA countries and Switzerland (forskrift 8. oktober 2008 nr. 1130 om autorisasjon, lisens og spesialistgodkjenning for helsepersonell med yrkeskvalifikasjoner fra andre EØS-land og Sveits).

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 Professionals Act (helsepersonelloven), 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 shall be covered only 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 tasks requiring specialist competence, or particular competence approved by the Directorate of Health, may not be delegated to another healthcare professional where reimbursement for treatment is claimed pursuant to the present provision.

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

Section 1 of Regulation No 1466 of 22 November 2010 on benefits for healthcare received in another EEA State (forskrift 22. november 2010 nr. 1466 om stønad til helsetjenester mottatt i et annet EØS-land) ("the National Reimbursement Regulation"), entitled "General scope", read, at the material time:

The Regulation shall apply to benefits for coverage of expenses for healthcare received in another country in the European Economic Area (EEA), hereinafter called EEA countries.

Where telemedicine is used, the healthcare shall be deemed to be received in the country where the service provider is established.

29 Section 2 of the National Reimbursement Regulation, entitled "Main conditions", reads:

Benefits shall be provided 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.

30 Section 3 of the National Reimbursement Regulation, entitled "Which types of healthcare for which benefits are provided", at the material time, read:

Benefits shall be paid to cover expenses for healthcare equivalent to healthcare:

a. for which benefits are provided 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. which is given totally or partially free of charge under the first paragraph of Section 1-3 of the Dental Health Services Act (tannhelsetjenesteloven), read in conjunction with Section 2-2 thereof;

d. which is provided totally or partially free of charge under the Specialist Healthcare Act (spesialisthelsetjenesteloven).

Benefits shall not be provided for substitution treatment for opioid dependency. This applies even if the insured person is undergoing medicinal product-assisted rehabilitation in Norway.

31 Section 6 of the National Reimbursement Regulation, entitled "Authorisation and other requirements for the service provider", read, at the material time:

The healthcare must be performed by a healthcare professional having official authorisation in the profession in question which is valid in the country where the healthcare is received.

When specialist approval is a condition for entitlement to benefits or healthcare at public expense in Norway, the healthcare must be performed by a healthcare professional having equivalent specialist approval that is valid in the country where the healthcare is received. The same applies to other particular competence requirements. Exceptions may be made to this condition if the speciality in question or equivalent formal competence does not exist in the country 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 it is natural to compare with the speciality required in Norway.

The healthcare professional must have permission to practise lawfully in the country where the healthcare is received.

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

- 32 There is an administrative circular which accompanies Section 5-24a of the National Insurance Act (*Rundskriv til folketrygdloven § 5-24 a Stønad til helsetjenester mottatt i et annet EØS-land*) (the "Administrative Circular"). The following paragraphs reproduce the Administrative Circular as it read at the material time.
- 33 In the part entitled "Introduction" of the Administrative Circular, the following is stated:

Section 5-24a confers entitlement to benefits for healthcare received in another EEA country. Detailed provisions are laid down by regulation.

The reimbursement scheme provides an option to choose to receive treatment to which a person is entitled in Norway also in other EEA countries. Thus, Section 5-24a does not broaden which types of healthcare services a person is entitled to receive but does entail greater freedom of choice in terms of place of treatment.

In order to assess a claim for reimbursement under Section 5-24a, regard is had to the national conditions applicable to the healthcare in question (medicinal products, dental health, medical care, etc.). The general rule is that treatment should take place as if the healthcare was received in Norway. The patient may, however, make use of private healthcare providers. Which conditions apply in respect of the healthcare in question will not be discussed in the administrative circular, unless there are particular matters which should be commented on.

In the part "Background to the scheme", the following is stated:

The ECJ has held that the EU Treaty's principle of freedom to provide services encompasses healthcare services. Thus, the principle of freedom to provide services entails that patients have rights as recipients of services.

The Patients' Rights Directive was implemented in the EU in October 2013, and is a codification of the ECJ's case law. Section 5-24a implements the Patients' Rights Directive in Norwegian law.

Part 6 of the Administrative Circular, entitled "Authorisation and other requirements for the service provider", reads:

In order for the healthcare to be eligible for reimbursement, the service provider must, as a main rule, have authorisation and, as the case may be, specialist

approval, etc., in an equivalent manner as if the treatment had been performed in Norway.

Part 6.1 of the Administrative Circular, entitled "Requirement of official authorisation", reads:

An authorisation is a confirmation that a person fulfils the formal and professional requirements for the applicable professional title in question.

It follows from the first paragraph of Section 6 that the healthcare must be provided by a healthcare professional having official authorisation. The authorisation must be valid in the country where the healthcare is received. Norwegian authorisation is not required.

Part 6.2 of the Administrative Circular, entitled "Specialist approval and other particular competence requirements", reads:

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 medical speciality will generally be satisfied in most cases. For a more detailed description of qualification 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. Examples include additional courses/education for certain rates for care by a doctor in medicine, manual therapy and psychomotor physiotherapy, and psychological care.

The 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

In the regulation for 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 country is in possession of the relevant specialities.

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.

Annex 2 accompanying the Regulation on authorisation, licensing and specialist approval for healthcare professionals having professional qualifications from other EEA countries can offer some guidance for the assessment of confirmation of authorisation and the like from other EEA countries. The Annex contains a list of names of diplomas, levels of education, etc., for different groups of healthcare professionals.

Part 6.4 of the Administrative Circular, entitled "No requirement that treatment provider must be part of the public health service", reads:

It is not a requirement for benefits under this reimbursement scheme that the treatment received is performed by a healthcare professional who is part of the public health service.

II FACTS AND PROCEDURE

- On 30 November 2017, K applied for benefits to cover dental treatment received in Poland in the period 16 August to 24 October 2017. The application related to stage two of treatment for severe marginal periodontitis that had been commenced in 2016. K had previously applied for, and been refused, reimbursement for the first stage of the treatment, also on the ground that the treating dental practitioner lacked the necessary specialisation. The refusal of reimbursement for the first stage of the treatment was upheld by the National Insurance Court's ruling in Appeal Case No 20/00406 delivered on 9 April 2021.
- 40 By decision of 1 February 2018, the Norwegian Health Economics Administration (*Helseøkonomiforvaltningen* ("Helfo")) rejected K's application for reimbursement for that portion of the treatment at issue in the present case. The grounds given for the rejection were the treating dental practitioner's lack of specialisation.
- 41 Following a complaint by K, Helfo's decision was upheld by decision of 25 February 2021 of the National Office for Health Service Appeals ("Helseklage").
- On 7 April 2021, K appealed against the decision of Helseklage to the National Insurance Court. As part of the preparation of the appeals case, Helseklage re-examined the decision under appeal in accordance with Section 13(1) of the National Insurance Court Act. Following the re-examination, Helseklage arrived at the same conclusion as in the decision appealed. In the cover letter dated 10 September 2021, the following was stated with regard to the requirement of specialisation:

As mentioned, it follows from the third paragraph of Section 3 of the Dental Regulation that expenses for implant-anchored dental prosthetics treatment are covered only if the surgical placement of dental implants is performed by a specialist in oral surgery and oral medicine, specialist in maxillofacial surgery or a specialist in periodontics. In the present case, the surgical part of the treatment was not performed by a specialist in oral surgery and oral medicine, a specialist in maxillofacial surgery or a specialist in periodontics (see ruling 20/00406 of the National Insurance Court). Nor, accordingly, can the prosthetics part of the treatment be covered.

The appellant submits that the requirement of specialisation in order to be able to claim reimbursement is contrary to the EU rules on non-discrimination. In that respect, reference is made, *inter alia*, to Case 205/84 *Commission* v *Germany* and Case C-398/95 *Symvoulio Epikrateias - Greece*.

The National Office for Health Service Appeals wishes to point out that it is not the right to place implants that is restricted under section 3 of the Regulation, but rather the right to claim reimbursement for the placed implants. There is nothing preventing a person from receiving treatment from a dental practitioner not in possession of the necessary specialisation. The regulations concern only the right to claim reimbursement for the treatment in question, and in no way regulate who has a right to perform dental treatment. Since the judgments referred to concern the requirements for providing services in another EEA country, and not which national requirements that may be imposed for awarding reimbursement, those judgments are not relevant in the present case.

In its ruling 20/00406, the National Insurance Court held that the regulation on the requirement of specialisation in order to claim reimbursement was not contrary to EEA law. The National Office for Health Service Appeals also refers to Article 7 of the Patients' Rights Directive, which regulates the right to receive reimbursement for healthcare received in another EEA/EU country than the state of affiliation.

Article 7(3) of the Directive provides that it is the Member State of affiliation itself that 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. [...]

This means that it is the State itself that determines which healthcare services can be covered and how much is to be covered. It further follows from Article 7(7) that the Member State of affiliation may impose on an insured person seeking reimbursement of the costs of 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 that healthcare were provided in its territory.

This means that it is possible to impose the same conditions for reimbursement in Norway as for treatment abroad. This is also in keeping with the EU principle of non-discrimination, because if less stringent requirements were to be imposed for reimbursement for dental treatment received in another EEA country, that would amount to a discriminatory scheme towards those who receive dental treatment in Norway.

The requirement that implant-anchored dental prosthetics treatment must be performed by a dental practitioner with a given specialisation in order for reimbursement to be granted applies irrespective of where you receive the treatment. Accordingly, it makes no difference if you visit your dental practitioner in Norway or if you travel to Poland. The requirement imposed for reimbursement is the same.

In the light of the foregoing, the National Office for Health Service Appeals finds that the conditions for benefits under Section 5-24a of the National Insurance Act (*folketrygdloven*), read in conjunction with Section 5-6, are not

fulfilled, both because the time of and background to the loss of teeth is not sufficiently documented and the requirement of specialisation is not satisfied.

- According to the request, the parties disagree as to whether a requirement may be imposed to the effect that the treating dental practitioner must have the same specialisation as what is required for reimbursement under the third paragraph of Section 3 of the National Dental Regulation.
- 44 Against this background, on 1 December 2023, the National Insurance Court decided to request an advisory opinion, registered at the Court on the same day, referring the following questions to the Court:
 - 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?
- Reference is made to the Report for the Hearing for a fuller account of the legal framework, the facts, the procedure and the proposed answers submitted to the Court. Arguments of the parties are mentioned or discussed hereinafter only insofar as is necessary for the reasoning of the Court.

III ANSWER OF THE COURT

By its first question, the referring court asks, in essence, whether a national measure imposing, for the purposes of reimbursement of national and cross-border healthcare, a requirement of specialisation of the practitioner delivering the healthcare is compatible with Article 36 EEA and Article 7 of the Patients' Rights Directive. The second and third

questions, in essence, enquire whether it is of relevance if the required specialisation is included in Annex V to the Professional Qualifications Directive, and whether the competent authorities in the State of affiliation must also conduct an assessment under Article 36 EEA in order to determine whether the treating healthcare practitioner has equivalent competence to that required under national law. The Court finds it appropriate to answer these questions together.

- It should be observed from the outset that EEA law does not detract from the power of the EEA States to organise their social security systems. In the absence of harmonisation at EEA level, it is for the legislature of each EEA State to determine the conditions on which social security benefits are granted. Nevertheless, when exercising that power, the EEA States must comply with EEA law (see the judgment of 18 April 2024 in *A v Arbeids- og velferdsdirektoratet*, E-3/23, paragraph 55 and case law cited).
- The Court recalls that Article 36 EEA provides for the freedom to provide services, which covers both providers and recipients of services within the framework of the EEA Agreement. It follows from settled case law that medical services provided for consideration fall within the scope of the provisions on the freedom to provide services. Medical services are neither by their special nature nor the way in which they are organised or financed removed from the ambit of the freedom to provide services (see the judgment of 28 March 2023 in *Stendi AS & Norlandia Care Norge AS v Oslo kommune*, E-4/22, paragraph 44 and case law cited). This is also reflected in recitals 6 and 11 of the Patients' Rights Directive. As is apparent from recital 8 of the Patients' Rights Directive, that directive has codified case law relating to the freedom to provide services guaranteed by Article 36 EEA in the field of healthcare, while intending to achieve a more general, and also effective, application of principles developed on a case-by-case basis in that case law (compare the judgment of 29 October 2020 in *Veselības ministrija*, C-243/19, EU:C:2020:872, paragraph 66).
- The Patients' Rights Directive, as set out in Article 1(1) and recital 10 thereof, lays down rules for the facilitation of access to safe and high-quality cross-border healthcare and promotes cooperation on healthcare between EEA States, in full respect of national competencies in organising and delivering healthcare. As noted in recital 2 of the Patients' Rights Directive, it further aims to improve the functioning of the internal market and the free movement of goods, persons and services. It follows from Article 1(2) and (4) that the Patients' Rights Directive applies, without prejudice to the provisions set out in Article 2, for the reasons provided in recitals 28 to 31, to the provision of healthcare to patients in situations related to cross-border healthcare, and therefore, as stated in recital 11, to individual patients who decide to seek healthcare in an EEA State other than the State of affiliation. Hence the Patients' Rights Directive applies to situations such as those of the main proceedings.

- The responsibilities of the State of treatment and State of affiliation with regard to cross-border healthcare, as defined in Article 3(c) and (d) of the Patients' Rights Directive respectively, are set out in Chapter II of the Patients' Rights Directive. As noted by ESA, Article 4(1)(a) and (b) thereof, sets out that cross-border healthcare must be provided in accordance with the legislation of, and in accordance with standards and guidelines on quality and safety laid down by, the State of treatment. Conversely, Article 5 sets out the responsibilities of the State of affiliation. The State of affiliation must, inter alia, ensure that the cost of cross-border healthcare is reimbursed in accordance with Chapter III and must provide patients on request with information on their rights and entitlements relating to receiving cross-border healthcare, in particular as regards the terms and conditions for reimbursement of costs.
- The general principles of reimbursement are laid down in Article 7 of the Patients' Rights Directive. According to Article 7(1), without prejudice to Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems and subject to the provisions of Articles 8 and 9 of the Patients' Rights Directive, the 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 State of affiliation. It is for the State of affiliation, pursuant to Article 7(3), 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. Article 7(7) further allows, subject to specified conditions, for the State of affiliation to impose the same conditions, criteria of eligibility and regulatory and administrative formalities on an insured person seeking reimbursement of the costs of cross-border healthcare as it would impose if the healthcare in question were provided in its territory.
- It appears from the request that K's dental treatment is among the benefits to which he may be entitled in Norway for the purpose of Article 7(1) of the Patients' Rights Directive, provided he meets the other eligibility conditions laid down in Norwegian law. According to Helseklage's submission, as set out in the request, the national measure at issue only restricts the right to claim reimbursement for K's dental implants and does not regulate who may perform dental treatment. Therefore, the requirement that a specialised practitioner delivers such healthcare appears to be a condition for reimbursement within the meaning of Article 7(7).
- In this respect, ESA's argument that Article 7(7) of the Patients' Rights Directive cannot serve as a basis for the disputed specialisation requirement because that provision is said to cover only administrative conditions and formalities, and not qualification requirements imposed on the healthcare practitioner, must be rejected. It follows from the wording of that provision that "criteria of eligibility" are also covered. This is further supported by a contextual interpretation: while the responsibilities of the State of treatment are set out in Article 4, the duty placed upon the State of affiliation to reimburse costs is governed by

- Article 7. The compatibility of conditions for reimbursement provided for in the legislation of the State of affiliation must thus be examined under the latter provision.
- According to Article 7(7) of the Patients' Rights Directive, it must be established that the requirement of specialisation, and the conditions to prove that the requirement is fulfilled, are neither discriminatory nor constitute an obstacle to the free movement of patients unless 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 EEA State concerned, or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources.
- It appears from the request that the national measure in question accepts the same specialisation obtained in other EEA States. Furthermore, the national law permits exceptions from the requirement of equivalent specialist approval or particular competence to be made. 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 EEA State in which the healthcare is received. Second, it must be documented that the service provider has equivalent substantive competence or other specialisation in medicine which is clearly comparable to the required speciality in Norway. Therefore, subject to verification by the requesting court, the national measure does not appear to be discriminatory within the meaning of Article 7(7) of the Patients' Rights Directive. Nevertheless, the national measure may constitute an obstacle to the free movement of patients.
- With regard to the question as to whether the application of national legislation such as that at issue in the main proceedings constitutes an obstacle to free movement under Article 36 EEA and the Patients' Rights Directive, it should be observed, first of all, that all measures which prohibit, impede or render less attractive the exercise of the free movement of services must be regarded as restrictions (see the judgment of 5 May 2021 in *Criminal proceedings against N*, E-8/20, paragraph 79 and case law cited).
- Furthermore, it is of no relevance whether restrictions are imposed by the home State or by the host State. Article 36 EEA also applies to any national rules that render the provision of services between EEA States more difficult than the provision of services purely within an EEA State (see the judgment in *Criminal proceedings against N*, E-8/20, cited above, paragraph 80 and case law cited).
- The Court notes that administrative procedures may in themselves constitute an obstacle if they make the use of free movement less attractive for patients. This is so even if the conditions for reimbursement are the same for treatment received within and outside of Norway if, as a matter of practice, they make it more difficult for patients to seek treatment abroad (see, to that effect, the judgment of 19 December 2008 in *Rindal and Slinning*, Joined Cases E-11/07 and E-1/08, paragraphs 47 and 54). This may be the case, for example, if the rules in question make it more difficult for patients to seek reimbursement

for treatment received abroad than would have been the case had the treatment been administered in their home EEA State.

- Notwithstanding the foregoing, the Court observes that in any system of reimbursement, such as that regulated by the Patients' Rights Directive, an administrative procedure and a certain amount of paperwork will be required in order for the patient to successfully claim reimbursement. The decisive factor is hence whether the effect of the specialisation requirement represents an unjustified additional burden for individuals choosing to receive treatment in another EEA State compared to patients seeking treatment in Norway (see, to that effect, the judgment in *Criminal proceedings against N*, E-8/20, cited above, paragraph 86).
- The existence of an obstacle under Article 7(7) of the Patients' Rights Directive must thus 60 be subject to an overall assessment of both the substantive and procedural aspects of the legislation at issue. As noted by the Commission, conditions, criteria and formalities for reimbursement have significant potential to undermine the very purpose of the Patients' Rights Directive, namely to facilitate the access to cross-border healthcare and to improve the functioning of the internal market and the free movement of goods, persons and services. Recital 37 states that such general conditions, criteria and formalities should be applied in an objective, transparent and non-discriminatory way, and should not impose any additional burden on patients seeking healthcare in another EEA State when compared to the situation faced by patients receiving healthcare in their State of affiliation. Moreover, decisions should be based primarily on medical considerations, and should be made as quickly as possible. As such, if patients receiving treatment in another EEA State are required to provide extensive documentation of the practitioner's qualifications, and the burden of proof for the acceptance of these qualifications falls on the patient, this could discourage them from seeking cross-border healthcare to the extent that it will amount to an obstacle under Article 7(7) of the Patients' Rights Directive.
- In assessing whether such an obstacle exists, it must also be considered whether other national measures have been put in place to mitigate such restrictive effects. These may include, but are not limited to, the availability of information to patients, assistance provided by competent authorities, any agreements between authorities and healthcare providers, and exchanges of information between competent authorities.
- Hence, it is for the referring court to establish whether the conditions to prove the required qualification of the practitioner delivering healthcare are more difficult and burdensome to fulfil in cross-border situations than when the treatment is received in the State of affiliation, considering also the information provided in accordance with Article 5(b) of the Patients' Rights Directive.
- As set out in recitals 19 and 20 of the Patients' Rights Directive, it is essential for patients to know in advance which rules are applicable in order make an informed choice when they

seek to receive healthcare in another EEA State. In addition, as stated in recital 48, appropriate information on all essential aspects of cross-border healthcare is necessary in order to enable patients to exercise their rights in practice. Therefore, the Patients' Rights Directive establishes requirements for the administrative procedures regarding cross-border healthcare in Article 9. That provision requires, inter alia, that such administrative procedures are based on objective, non-discriminatory criteria which are necessary and proportionate to the objective to be achieved and that they are easily accessible, and that information relating to such a procedure is made publicly available at the appropriate level.

- Since uncertainty for the patient as to whether the conditions for reimbursement will be met is a strong disincentive to the use of cross-border healthcare, the referring court must consider the possibilities for the patient to verify and prove whether the dentist providing treatment meets the national qualification requirements.
- The Court notes that Article 10 of the Patients' Rights Directive establishes procedures for mutual assistance and cooperation, inter alia, for the exchange of information. According to Article 10(4), the State of treatment shall ensure that information on the right to practise of health professionals established on their territory is, upon request, made available to the authorities of other EEA States, for the purpose of cross-border healthcare, in accordance with Chapters II and III. Hence, these possibilities for the State of affiliation must be taken into account when assessing the burden of proof concerning the specific qualification requirement in question.
- The Court notes that further information in this regard, especially concerning the reimbursement procedure, the requested documents and the assessment made by Helfo and Helseklage as well as their assessment criteria, is not in the Court's case file, but is to be considered by the referring court in order to establish, whether the national measure constitutes an obstacle to the free movement of patients.
- In this context, and having regard to this additional information, it has to be assessed by the referring court whether the fact that the required specialisation is included in Annex V to the Professional Qualifications Directive may alleviate any additional burden and whether there is a requirement under national law for the competent authorities to assess, in addition, whether the treating healthcare practitioner has equivalent competence to that required under Norwegian law.
- Nevertheless, based on the information provided in the request, the Court can provide some guidance for this assessment. It appears from the request that the rules in question in the main proceedings require that the healthcare practitioner holds one of the following qualifications: specialist in oral surgery and oral medicine, specialist in maxillofacial surgery or specialist in periodontics. Of the three types of specialist referred to in the rule in question, the first is listed in point 5.3.3 of Annex V to the Professional Qualifications Directive concerning specialist dentists. The second is listed in point 5.1.3 of Annex V to

the Professional Qualifications Directive concerning specialist doctors. Point 1 in Annex VII to the EEA Agreement refers to the corresponding Norwegian qualifications for both these categories of specialists.

- It appears from the request that the healthcare practitioner providing the dental treatment was neither a specialist in oral surgery and oral medicine, nor a specialist in maxillofacial surgery nor a specialist in periodontics. As submitted by ESA, it appears to follow from the second paragraph of Section 6 of the National Reimbursement Regulation, as interpreted in accordance with Part 6 of the Administrative Circular and subject to the referring court's verification, that the subsequent assessment of the treating healthcare practitioner's qualifications is not undertaken on a case-by-case basis with regard to equivalent substantive competence or a comparable specialisation in medicine when the required specialisation exists in the State of treatment. Rather it is decided on the basis of whether the healthcare practitioner possesses evidence of the specialisation listed in Annex V to the Professional Qualifications Directive.
- The Court notes in this respect that the Professional Qualifications Directive, as is apparent from its recital 3 and Articles 1 and 2 thereof, concerns the access to or pursuit of a regulated profession in an EEA State other than where the professional qualification was obtained and is therefore not directly applicable to the situation at issue in the main proceedings. However, it is relevant to observe, as noted by ESA and the Commission, that case law has explicitly taken into account the system of mutual recognition of professional qualifications and the resulting trust that could be placed in the professional ability of healthcare practitioners from another EEA State, in the context of the free movement of healthcare services (compare the judgment of 19 April 2007, *Stamatelaki*, C-444/05, EU:C:2007:231, paragraph 37).
- Article 21 of the Professional Qualifications Directive provides for a system of automatic recognition for evidence of professional qualifications for certain professions on the basis of coordinated minimum conditions for training, including those for dental practitioners. The system of automatic recognition is based on automatic and unconditional recognition which does not involve any substantive examination by the host State of the evidence of formal qualifications being recognised (see the judgment of 25 March 2021 in *Lindberg*, E-3/20, paragraphs 40 and 45).
- Those who cannot avail themselves of the system of automatic recognition must, under the specific conditions of Article 10 of the Professional Qualifications Directive, be assessed under the general system of recognition. This provision is intended to facilitate and simplify the recognition of professional qualifications in the specific cases listed therein (see the judgment in *Lindberg*, E-3/20, cited above, paragraph 60). Both Articles 10 and 21 refer to Annex V. However, Annex V does not contain an exhaustive list of all qualifications that are available in each EEA State with regard to substantive competences.

- The objective of the Professional Qualifications Directive is, as is apparent from Article 1 thereof and Article 30 EEA, to facilitate the mutual recognition of diplomas, certificates, and other evidence of formal qualifications by laying down rules and common criteria which result, as far as possible, in automatic recognition of those professional qualifications and, thus, make the process of recognition more predictable and efficient for the applicant. It is not the purpose of the Professional Qualifications Directive to make recognition of professional qualifications more difficult in situations falling outside its scope, nor may it have such an effect. The system of automatic recognition under this directive thus complements the rights guaranteed under the main part of the EEA Agreement but does not displace an assessment under those provisions (see the judgment in *Lindberg*, E-3/20, cited above, paragraph 59 and case law cited).
- In light of the above, in circumstances where the conditions for the recognition of professional qualifications under the Professional Qualifications Directive are not met, the right to recognition of professional qualifications may be derived from Articles 28 and 31 EEA. This also applies where a directive for the mutual recognition of diplomas has been adopted for the profession in question, but the applicant does not satisfy the conditions for recognition of qualifications (see the judgment in *Lindberg*, E-3/20, cited above, paragraph 61 and case law cited). The same applies with regard to Article 36 EEA.
- It follows from established case law that the authorities of the host State must take into account all of an applicant's diplomas, certificates, other evidence of qualifications, and relevant experience, when they compare the qualifications and experience held by an applicant with the knowledge and qualifications required by the national legislation for access to the relevant profession. The host State must therefore examine the qualification and the specific content of the training. The assessment must enable the authorities of the host State to assure themselves on an objective basis that a foreign diploma certifies that the knowledge and qualifications are, if not identical, at least equivalent to those attested by the national diploma. That assessment must be based exclusively on the level of knowledge and qualifications which its holder can be assumed to possess, having regard to the nature and duration of the studies and practical training to which the diploma relates (see the judgment in *Lindberg*, E-3/20, cited above, paragraph 64 and 65 and case law cited).
- Accordingly, in order to establish whether the healthcare practitioner in another EEA State has an equivalent specialisation or substantive competence, a specialisation listed in Annex V to the Professional Qualifications Directive may be deemed sufficient proof of substantive competence, since that person has a right to automatic recognition. However, a specialisation listed in Annex V cannot be considered necessary to prove substantive competence. Therefore, an assessment in order to determine whether the treating healthcare practitioner has equivalent competence to that required for reimbursement purposes must not be limited to cases in which the speciality in question or equivalent formal qualification is not listed in Annex V.

- It is important to emphasise, however, that even if the specialisation requirement allows for an assessment in accordance with the interpretation of the Professional Qualifications Directive provided for above, meaning that it does not in fact discriminate towards service providers in other EEA States, the specialisation requirement may still amount to an obstacle to the free movement of patients if it represents an unjustified additional burden for individuals choosing to receive treatment in another EEA State compared to patients seeking treatment in Norway. The Court recalls that requiring patients to provide sufficient documentation relating to the healthcare practitioner's qualifications and training to enable an assessment of equivalence by the competent authorities, with the burden of proof resting on the patient, could discourage patients from seeking cross-border healthcare, thus constituting an obstacle to the freedom of movement of patients under Article 7(7) of the Patients' Rights Directive.
- In addition, the formalities imposed will be discriminatory if, in a situation such as in the case at hand in which the non-Norwegian qualification of the healthcare practitioner is listed in Annex V to the Professional Qualifications Directive or Annex VII to the EEA Agreement for a specialisation for which Norway also has an entry in the latter, the patient is required to supply a greater volume of information pertaining to the healthcare practitioner's credentials than would be the case had the healthcare been supplied in Norway. Conversely, however, if the procedure for such situations is identical in form and in effect to that applicable in a purely internal situation, also taking into account the burden placed on the patient in both scenarios, it will not constitute an obstacle to the freedom of movement of patients, nor can it be viewed as discriminatory. It is for the referring court to determine, in accordance with the interpretation set out above along with any additional national measures aimed at reducing the administrative burden and legal uncertainty for patients, whether the contested specialisation requirement, in practice, makes it more difficult for patients to receive treatment in another EEA State than in Norway.
- If the national measure is discriminatory or constitutes an obstacle to the free movement of patients, it can only be 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 EEA State concerned, or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources within the meaning of Article 7(7) of the Patients' Rights Directive.
- With regard to a justification of the specialisation requirement, Helseklage submitted that by requiring the relevant specialisation, the risk of unsuccessful treatment is reduced to a minimum, which will further reduce the risk of waste of financial and human resources. In this regard, Helseklage submitted that unsuccessful treatment is likely to be very difficult and expensive to rectify.
- 81 The Court observes that the justification of the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources, cannot be interpreted so

as to allow a justification based on a need to control or ensure the quality or safety of the provided healthcare in question. It is established case law that restrictions of the free movement of patients cannot be justified on grounds of public health in order to protect the quality of medical services provided in other EEA States (compare, inter alia, the judgment of 28 April 1998 in *Kohll*, C-158/96, EU:C:1998:171, paragraphs 49 to 52, the judgment of 28 April 1998 in *Decker*, C-120/95, EU:C:1998:167, paragraph 45, and the judgment in *Stamatelaki*, C-444/05, cited above, paragraphs 36 and 37). Furthermore, it is apparent from Article 4 of the Patients' Rights Directive that it is the responsibility of the State of treatment to ensure the quality and safety requirements of the cross-border healthcare provided.

- The Court notes that the justification of conditions, criteria of eligibility and regulatory and administrative formalities of reimbursement, which are discriminatory or which constitute an obstacle to the free movement of patients is limited to the grounds listed in Article 7(7) of the Patients' Rights Directive. According to the wording of this provision, restrictions on patients' right to free movement may only be justified by "planning requirements".
- The Court observes that the Norwegian translation of Article 7(7) of the Patients' Rights Directive, in contrast to other language versions such as the English, French, and Italian versions, is ambiguous, as it seems to place the wish to control costs on an equal footing with planning and rationalisation efforts.
- The Court recalls that the purpose of Article 129(1) EEA, by providing for the translation and publication of the acts referred to in the Annexes to the Agreement beyond the EU official languages and into the Norwegian and Icelandic languages, is to ensure the uniform interpretation of those rules across the EEA, in light of the versions existing in all EEA languages (see the judgment of 28 September 2012 in *Irish Bank*, E-18/11, paragraph 87).
- As such, the wording used in one language version of an EEA provision cannot serve as the sole basis for the interpretation of that provision, or be made to override the other language versions in that regard. Such an approach would be incompatible with the principle of homogeneity and the requirement of the uniform application of EEA law (see the judgment in *Irish Bank*, E-18/11, cited above, paragraph 88).
- Further, it follows from settled case law that in the case of divergence between the language versions of a legal act, a provision must be interpreted by reference to the purpose and general scheme of the rules of which it forms a part (see the judgment of 25 January 2024 in *A Ltd*, E-2/23, paragraph 42 and case law cited).
- Article 7(7) of the Patients' Rights Directive must therefore be interpreted in the context of the other provisions of that directive. The Court notes at the outset that Article 7(7) constitutes an exception to the general principle of reimbursement as laid down in Article 7(1). Since the freedom of movement for patients is one of the foundations of that directive, any limitations to that freedom must be interpreted strictly (see, by analogy, the judgment

of 21 March 2024 in *Criminal proceedings against LDL*, E-5/23, paragraph 51 and case law cited).

- In this context, it is relevant to note that Article 7(9) of the Patients' Rights Directive refers to "overriding reasons of general interest, such as planning requirements ...". This suggests that other overriding reasons must be assessed separately from planning requirements. A justification under Article 7(7) therefore cannot be based on other overriding reasons of general interest as stated in Article 7(9), since that provision rather concerns a limitation of the application of the rules on reimbursement for cross-border healthcare, which is not applicable to a situation such as that at issue in the main proceedings. The language of the latter suggests that planning requirements, the sole available ground of justification under Article 7(7), form part of a larger set of potential justification grounds available under Article 7(9), and applicable solely in the context to which the latter pertains. This mitigates in favour of an interpretation whereby planning requirements represent the sole available ground of justification under Article 7(7).
- 89 This interpretation is further reinforced by case law under Article 36 EEA, which the Patients' Rights Directive aims to codify. While reasons of a purely economic nature cannot constitute overriding reasons in the public interest justifying a restriction on a fundamental freedom guaranteed by the Agreement (see the judgment of 16 November 2018 in Kristoffersen, E-8/17, paragraph 115 and case law cited), the Court has recognised that the aim of ensuring sufficient and permanent access to a balanced range of high-quality hospital treatment in the EEA State concerned, and the desire to control costs and prevent wastage of financial, technical and human resources, are aims which may justify restrictions on the free movement of hospital services. The objective of maintaining a balanced medical and hospital service open to all is inextricably linked to the way in which the social security system is financed and to the control of expenditure. Thus, the risk of seriously undermining the financial balance of the social security system may also constitute an overriding general-interest reason capable of justifying a restriction on the free movement of services and patients in so far as it could have consequences for the overall level of public-health protection (see the judgment in Rindal and Slinning, Joined Cases E-11/07 and E-1/08, cited above, paragraph 55 and case law cited).
- However, since assuming the costs of one isolated case of treatment, carried out in another EEA State, can never make any significant impact on the financing of the social security system in the home State, an overall approach must be adopted in relation to the consequences of freedom to provide health-related services (see the judgment in *Rindal and Slinning*, Joined Cases E-11/07 and E-1/08, cited above, paragraph 56 and case law cited).
- The relevant test for the justification of such measures, which is for the referring court to perform, will, as noted by the Commission, broadly reflect that related to any of the fundamental freedoms of EEA law. As such, it is for the EEA State concerned to

demonstrate, firstly, that the measure is justified on the grounds listed exhaustively in Article 7(7) of the Patients' Rights Directive and, secondly, that it observes the principle of proportionality, which entails that it is suitable for securing, in a consistent and systematic manner, the attainment of the objective pursued and does not go beyond what is necessary in order to attain it.

- Therefore, the answer to the first question referred must be that a national measure imposing, for purposes of reimbursement of national and cross-border healthcare, a requirement of specialisation of the practitioner delivering the healthcare is compatible with Article 36 EEA and Article 7 of the Patients' Rights Directive only if the conditions to prove the required qualification of the practitioner delivering the healthcare are neither discriminatory nor constitute an obstacle to the free movement of patients, unless they are 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 EEA State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources.
- 93 The answer to the second question must be that, in order to establish whether the healthcare practitioner in another EEA State has an equivalent specialisation or substantive competence, a specialisation listed in Annex V to the Professional Qualifications Directive may be deemed sufficient proof of substantive competence, but cannot be considered necessary to prove substantive competence. Any assessment undertaken by an EEA State's authorities under Article 7(7) of the Patients' Rights Directive to determine whether the treating healthcare practitioner has equivalent competence to that required for reimbursement purposes must not be limited to cases in which the speciality in question or equivalent formal competence is not listed in Annex V.
- The answer to the third question must be that the competent authorities in the State of affiliation must also conduct an assessment in order to determine whether the treating healthcare practitioner has equivalent competence to that required under national law, even if the specialisation is included by the State of treatment in Annex V to the Professional Qualifications Directive but is not possessed by the healthcare practitioner. The administrative procedures connected with the equivalence assessment must not, however, represent an unjustified additional burden for patients choosing to receive treatment in another EEA State compared to patients seeking treatment in Norway.

IV COSTS

Since these proceedings are a step in the proceedings pending before the national court, any decision on costs for the parties to those proceedings is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds,

THE COURT

in answer to the questions referred to it by the National Insurance Court hereby gives the following Advisory Opinion:

- 1. A national measure imposing, for purposes of reimbursement of national and cross-border healthcare, a requirement of specialisation of the practitioner delivering the healthcare is compatible with Article 36 EEA 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 only if the conditions to prove the required qualification of the practitioner delivering the healthcare are neither discriminatory nor constitute an obstacle to the free movement of patients, unless they are 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 EEA State concerned, or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources.
- 2. In order to establish whether the healthcare practitioner in another EEA State has an equivalent specialisation or substantive competence, a specialisation listed 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 may be deemed sufficient proof of substantive competence but cannot be considered necessary to prove substantive competence. Any assessment undertaken by an EEA State's authorities under Article 7(7) of Directive 2011/24/EU to determine whether the treating dental practitioner has equivalent competence to that required for reimbursement purposes must not be limited to cases in which the speciality in question or equivalent formal competence is not listed in Annex V.
- 3. The competent authorities in the State of affiliation must also conduct an assessment in order to determine whether the treating healthcare practitioner has equivalent competence to that required under national law, even if the specialisation is included by the State of treatment in Annex V to Directive 2005/36/EC but is not possessed by the healthcare practitioner. The administrative procedures connected with the equivalence assessment must not, however, represent an unjustified additional burden for patients choosing to receive treatment in another EEA State compared to patients seeking treatment in Norway.

Páll Hreinsson Bernd Hammermann Michael Reiertsen

Delivered in open court in Luxembourg on 5 December 2024.

Ólafur Jóhannes Einarsson Registrar Páll Hreinsson President