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Patients' Rights in Cross-border Healthcare (Directive 2011/24/EU) and How It Applies to Turkey as a Negotiating Candidate Country

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Abstract

Cross-border healthcare and patient mobility across European Union Member States has been on the agenda of EU Commission for the last decade. Directive 2011/24/EU on the application of patients' rights in cross-border healthcare went into force in 2013. The Directive mainly addresses the responsibilities of Member States in cross-border healthcare, regulates reimbursement procedure, and coordinates European reference networks and health technology assessment in the EU. The Directive has direct and indirect implications on Turkish health system. In this article, first an overview of Directive 2011/24/EU is addressed with special attention to its relation to patient rights and other EU legislations. Then, Turkish citizens' position in the scope of EU legislation on patient rights is considered. Finally, the ethical implications of the Directive, conceptualisation of cross-border patient mobility, and Turkey's particular position among other candidate countries regarding cross-border healthcare is discussed.

Keywords

cross-border healthcare; patient rights; EU legislation; Turkey's accession to EU

1 Introduction

The European Union (EU) did not deal with health and healthcare until the Maastricht Treaty (1992). Maastricht is the first Treaty to address health as a part of EU legislation and to urge Member States (MS) and the European Economic Community (EEC) to act and co-operate in health-related issues. Article 129 of the Maastricht Treaty is dedicated to health with a particular emphasis on health protection and public health, stating that 'health protection requirements shall form a constituent part of the Community's other policies' and 'Community and the Member States shall foster co-operation with third countries and the competent international organizations in the sphere of public health'.¹

The Treaty of Amsterdam (1997) is the next legislation to address health and healthcare. In Article 152 (ex Article 129) of the Treaty deals with public health and demands 'a high level of health protection to be ensured in the definition and implementation of all Community policies and activities'. The article retains the subsidiary principle in public health, however, it extends the scope of health legislation in the responsibility of the Community.²

These two Treaties solidified public health as a policy and legislation area for EU. In 2000, the European Health Forum published a report and presented health policy recommendations to the EU Commission. Cross-border health services and patient mobility were addressed in this report. In 2002 a high level expert group started to work on patient mobility and cross-border health services and reported their work to the EU Commission in 2003. In the following years, cross-border healthcare and patient mobility has been on the agenda of working groups and EU Commission. Meanwhile, projects on cross-border health services and patients' mobility started to be financed by the EU Public Health Program. In 2008 a draft directive proposal was presented to the EU Parliament and Council by the EU Commission.³ After consultations, the amended and final version of the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare was approved by the EU Council in 28 February 2011.⁴

2 Content of Patients' Rights in Cross-border Healthcare (Directive 2011/24/EU)

The Directive consists of five chapters:

1. General provisions
 2. Responsibilities of Member States with regard to cross-border healthcare
 3. Reimbursement of costs of cross-border healthcare
 4. Cooperation in healthcare
 5. Implementing and provisions
1. General Provisions: The Directive provides rules 'for facilitating the access to safe and high-quality cross-border healthcare and promotes cooperation on healthcare between Member States' by maintaining the subsidiary principle of the MS in organizing and delivering healthcare services. In Article 3, definitions of healthcare, insured person, Member State of affiliation (MSA), Member State of treatment (MST), cross-border healthcare, health professional, healthcare provider, patient, medicinal product, prescription, health technology, medical records are given.

Healthcare is defined as health services provided by health professionals (a doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the directive 2005/36/EC) to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices.⁵ This definition is quite broad as it applies not only to health services by medical doctors but also to other healthcare staff, and to all treatment groups including preventive, curative and rehabilitative healthcare services.

The insured person's definition covers all persons and their family survivors with reference to Regulation EC No 883/2004 and third country nationals with reference to Regulation EC No 859/2003 and (EU) No 1231/2010. Thus the

insured person, who is subject to cross-border healthcare and patient mobility is either an EU citizen or a third country national and has right to access to a planned treatment (with or without prior authorization depending on the type of treatment) in another MS.

2. Responsibilities of MSA, MST and National Contact Points (NCP) for cross-border healthcare are addressed in three articles. MST is held responsible for providing clear and definite information about the healthcare providers, establishing transparent complaints procedures and mechanisms to seek remedies if patients suffer harm arising from healthcare they receive, personal data protection and medical records of treatments. MST is to provide these on the same basis as to domestic patients without any discrimination, MSA is responsible for the reimbursement of costs of healthcare received in MST, to supply clear and sufficient information regarding patient's rights and entitlements in terms of reimbursement, provide follow-up treatment and medical records. NCP's are the institutions designated for cross-border healthcare to provide information to the patients to make use of their rights in relation to cross-border healthcare.
3. Reimbursement of costs of cross-border healthcare is addressed in Article 7. The general rule holds MSA is responsible for the reimbursement of healthcare received by the insured person in another MS. However, the healthcare received should be among the benefits to which the insured person is entitled to in the MSA. MSA has the right to determine the healthcare which the insured person is entitled to and the amount of reimbursement is capped by the national tariff of the MSA. Travel, accommodation and other costs are not subject to reimbursement, hence MSA has the authorization to reimburse or not these related costs.

MSA may set a list of healthcare subject to pre-authorisation. This list is limited to healthcare which;

- a. is made subject to planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources
- b. involves treatments presenting a particular risk for the patient or the population; or
- c. is provided by a healthcare provider that, on a case-by-case basis, could give rise to serious and specific concerns relating to the quality or safety of the care, with the exception of healthcare which is subject to Union legislation ensuring a minimum level of safety and quality throughout the Union.

On the other hand, the situation in which the MSA must give pre-authorisation is also defined in the directive in Article 8;

Member State of affiliation may not refuse to grant prior authorization when this healthcare cannot be provided on its territory within a time limit which is medically justifiable, based on an objective medical assessment of the patient's medical condition, the history and probable course of the patient's illness, the degree of the patient's pain and/or the nature of the patient's disability at the time when the request for authorization was made or renewed.⁶

The pre-authorisation procedure should be publicly available and should be completed within a reasonable time with taking into consideration the specific medical condition and the urgency and individual circumstance.

Regulation EC No 883/2004 is also relevant in the reimbursement procedure. This regulation is on the coordination of social security institutions in the MS and regulates the social security provisions of insured people in EU. The Regulation aims to realise and ensure the free movement of workers and self-employed people in the EU. In practice, it applies to the person who travels to another MS (not for reasons of seeking healthcare, but to work), and needs healthcare; or a person traveling to another country for the purpose of receiving healthcare. No preauthorisation is required for the first person (worker), while countries may require pre-authorisation for the latter. The regulation provides healthcare only in public health institutions while Directive 2011/24/EC applies to both public and private healthcare services.⁷

4. Cooperation in healthcare focuses on mutual assistance as is necessary for the implementation of the Directive on standards and guidelines on quality and safety and the exchange of information. Within this context, this chapter addresses the recognition of prescriptions issued in MST, European reference networks (ERN) rare diseases, e-health and cooperation on health technology assessment.

The recognition of prescriptions is essential to ensure the continuity of treatment; hence MS are asked to enable measures to facilitate this process in line with Directive 2001/83/EC or Regulation (EC) No 726/2004 and maintaining the pharmacist's rights by virtue of national rules for ethical reasons. The Directive requires publishing guidelines to develop the interoperability of ePrescriptions, taking measures to address the correct identification of medicinal products or medical devices prescribed in one state and dispensed in another, and patient safety concerns in relation to their substitution in cross-border healthcare where the legislation of the dispensing MS permits such substitution.

European reference networks are to be established between healthcare providers and centres of expertise, in particular in the area of rare diseases, based on voluntary participation. The aim of the European reference networks is to realise the potential of EU MS regarding highly specialized healthcare services and healthcare systems, to contribute to the pooling of the knowledge on prevention, increase quality of expertise in rare diseases, and to promote the cost-effective use of resources.⁸

Rare diseases are addressed in the scope of extending the capability to diagnose and treat them, as expertise in this area is very limited. European reference networks are considered as a useful tool for extending the capacity in rare disease management. E-health and health technology assessment are addressed as areas in which more cooperation and coordination at EU level is encouraged by the Directive.

3 Patient Rights in EU Legislation

In the Treaty on the Functioning of the European Union (TFEU), public health is among the policy areas in which EU and the MS have shared competency.⁹ Pharmaceuticals, mutual recognition of diplomas, and special health areas such as blood and blood products, tissues and cells have been areas on which the EU had impact. On the other hand, healthcare services have been considered as a policy area which is out of the TFEU's scope, and under the full competence of the MS. However, people who seek cross-border healthcare either as a worker subject to the free movement of workers, or as an individual subject to the free movement of people have challenged this understanding. A series of cases have been thrown to the European Court of Justice (ECJ) since 1998, of which the *Kohll* and *Decker* cases are the best-known, with a huge impact on patient rights in cross-border healthcare. The ruling of the ECJ in these cases changed the existing perception on healthcare services, and altered it to a policy area subject to internal market rules governing the free movement of goods and services.¹⁰ The ECJ interpreted access to health services subject to Article 56 paragraph 1 of TFEU which follows: '... restrictions on freedom to provide services within the Union shall be prohibited in respect of nationals of Member States (MS) who are established in a MS other than that of the person for whom the services are intended'.

This interpretation implies that all regulations to restrict the right to access to cross-border healthcare impede the freedom to provide and receive services, and hence hinder the creation of the internal market. These rulings extended patient rights and challenged the implementations such as pre-authorisation procedure and secured them in primary EU law. Directive 2011/24/EC solidifies the case law on cross-border healthcare under TFEU by regulating the patients' rights in this context.

The patients' have rights to access the following by Directive 2011/24/EU;

1. Healthcare services which they do not have in their countries.
2. High quality and safe treatment in another MS.
3. Information regarding a transparent mechanism for the calculation of costs of cross-border healthcare.
4. Reimbursement of healthcare costs delivered in another MS (as specified in the Directive, the provisions of Regulation EC No 883/2004 also applies).
5. Information on their rights, entitlements, and service providers in the MS in which they have cross-border healthcare.
6. Medical follow-up in MSA after the treatment.

7. A copy of their medical records.
8. Recognition of their prescriptions in their home country.
9. Complaint mechanisms regarding the received cross-border healthcare service.

4 State of Play of the Operation of Directive 2011/24/EU

The Article 20(1) of the Directive requires the EU Commission to report on the operation of this Directive by October 2015 and every three years thereafter. Due to this article the first report of the Commission is published and submitted to the Council and the Parliament by October 2015.¹¹ In this report, the main issues regarding the operation of the directive are addressed as follows:

1. As of July 2015 only four infringement proceedings against four MS on the grounds of incompleteness of transposition measures were open; and all four MS concerned made commitments to address the infringements.
2. Fourteen MS have introduced prior authorisation for highly specialized healthcare services or healthcare requiring overnight stays at hospital. However, only nine of these fourteen MS have identified which treatments they consider to meet 'highly specialized' criterion, while five have not.
3. Three MS have introduced reimbursement practices for cross-border healthcare in which the tariffs for reimbursement are based on the costs that would be borne by MSA for healthcare received from a private or non-contracted provider, which is lower than the rate for public or contracted providers. Three MS require any patient seeking reimbursement for cross-border healthcare to prove that the particular healthcare episode was necessary to be received in another country. Four MS require the patients to provide a sworn translation of invoices, despite Article 10 of the Decision that obliges the NCP to assist each other in understanding the invoices.
4. Twelve MS have used the provision that allows the MS to impose the same conditions and formalities on patients seeking cross-border healthcare as they would impose if the healthcare was to be provided in their territory, such as a referral from a family physician. Although MS are to recognize the decisions about the clinical need provided by an equivalent medical professional in any MS, five of these twelve MS insist that the referral should be given by a medical professional in their country.
5. The structures of NCPS' vary widely among MS. Some MS have different NCPS for incoming and outgoing patients, while others have regional NCPS dealing with both incoming and outgoing patients. Some MS have launched their NCP in the Ministry of Health, others in healthcare insurance institutions or in independent bodies. Regarding the information provided by the NCPS, some MS give links to different legal documents or general description of quality assurance strategies, while a few MS provide detailed information about hospitals including mortality rates and number of patients treated with complications.¹²

6. The mutual recognition of prescriptions was addressed in Implementing Directive 2012/52/EU.¹³ The deadline for the transposition of the Implementing Directive was 25 October 2013. Twenty-one MS either did not transpose by the due date or transposed incompletely, leading to infringement procedures. Two of these infringements were pending by 1 July 2015, and the MS have committed to address the infringements to fully transpose the Implementing Directive.
7. The legal framework for the establishment and evaluation of ERNS was adopted.¹⁴ The first call for the establishment for ERNS took place in March 2016 and the first networks are expected to be approved in the course of 2016.
8. There is some progress regarding e-Health and health technology assessment (HTA). Implementing Decision 2011/890/EU concerning e-health network was adopted by 2011 to support cooperation between national authorities in compliance with e-health action plan 2012–2020. The network for HTA adopted a strategy for EU cooperation on HTA in October 2014 and a reflection paper on reuse of joint HTA work in national activities in April 2015. MS have asked the Commission to propose measures to ensure long term sustainability of strong and efficient HTA network.

5 The Position of Turkey as a Negotiating Candidate Country

Turkey has been a candidate country to the EU since 1999.¹⁵ Since then, alignment of Turkish legislation with that of EU is being carried on. Three national programs for the adoption of *acquis* (NPAA) have been published in 2011, 2003, and 2008. NPAA's contained the list of EU *acquis* to be adopted and implemented within a time limit.

TFEU applies to 28 Member States of EU and 3 European Economic Area Countries (Norway, Iceland, and Liechtenstein-EEA). Turkey, as a candidate country is not subject to TFEU. As stated before, patients' rights to receive cross-border healthcare emerges from Article 56 of TFEU. Hence, no freedom for Turkish citizens who are the recipient of services to visit a MS in order to obtain services exists in this context. This was stated clearly in the judgment of the *Demirkan* case by the ECJ; '... the protection of passive freedom to provide services does not encompass ... the mere possibility of obtaining services'.¹⁶ Furthermore, Regulation EC No 883/2004 covers MS, EEA and Switzerland. The case law of ECJ clearly states that fact; 'EEC-Turkey Agreement does not establish between the contracting parties a regime coordinating social security systems such as that established by Regulation No 1408/71'.¹⁷ Regulation 1408/71 is the former legislation to Regulation 883/2004/EC.

In 2014, a national action plan for the accession to EU was published. This program states that Turkey will adopt Regulation EC No 883/2004 by the end of 2017. However, the Turkish Social Security Institute limits the implementation of the Regulation to the bilateral agreements on coordination and cooperation of social security institutions with Italy, Hungary, Spain and Poland. Thus, the provisions of the adopted legislation will only apply to patients and citizens from these countries and Turkey.

Directive 2011/24/EC is relatively new as it went into force by 2013. Turkey did not include the Directive in the 2014 national action plan for accession to EU after comprehensive discussions with the involved parties. Hence Directive 2011/24/EU is not subject to adoption by Turkish legislation until 2019.

6 Discussion

Patient mobility and cross-border healthcare is a vastly growing health concern in Europe and Turkey. According to the Eurobarometer Flash Report 2007, 54% of EU citizens are open to travel to another country, and 4% of Europeans did travel to receive cross-border healthcare. The main motive behind patient mobility was found to be the unavailability of necessary treatment in home country and the expectation of getting higher quality healthcare. Patient mobility is greater for relatively small EU MS such as Luxemburg where every fifth citizen received cross-border healthcare in 2007.¹⁸

In the EU commission report on the implementation and impact of Directive 2014/24/EU, patient mobility for planned healthcare under both the Directive and social security regulations are found to be far below the potential levels suggested by the Eurobarometer report.¹⁹ According to EU Commission report and Eurobarometer, the number of EU citizens who are aware of their rights to cross-border healthcare services is 'extremely low'.²⁰ Interviews with 20 health insurers showed that 15 of them thought that patients in their country do not know whether a treatment is subject to prior authorisation or not. The other reasons for low patient flow for healthcare abroad under the Directive are language barriers, unwillingness of patients to travel, price differentials between MS, and acceptable waiting times in MSA.

In ethical perspective, the reimbursement procedure established by the Directive 2014/24 EC is problematic, since it demands the patient to pay for the costs of his/her medical treatment first and then get reimbursed. This requires the patients to have the necessary money before the treatment, limiting the patients who can realise their rights to cross-border healthcare to a group of people with a higher economic status. The ones who live under this economic level would need to take out loans or raise funds to afford cross-border healthcare *si opus sit*. This damages the principle of justice and equality.

Having said this, the position of Turkey requires further discussion. Although Turkey did not commit to adopt Directive 2014/24/EU, the adoption of Regulation EC No 883/2004 is on the agenda. As stated before, Regulation EC No 883/2004 will be adopted and implemented within the scope of bilateral agreements on coordination and cooperation of social security institutions with Poland, Hungary, Spain and Italy. This is a good start for the Turkish social security system to be in compliance with that of EU MS countries. Furthermore, Turkey has bilateral agreements with 13 EU MS countries (UK, France, Sweden, Austria, Belgium, Netherlands, Germany, Denmark, Check Republic, Romania, Luxemburg, Slovakia and Croatia). In the context of these bilateral agreements, costs of medical treatments are reimbursed mutually by parities.

In Turkey, cross-border patient mobility is widely conceptualised in the context of health tourism, and has attracted attention from both the public and private health sectors. With the support from government and the private sector Turkey has become a centre of attraction for health tourism in recent years. Lately, the International Patient Portal has been established to provide information to cross-border patients. This portal contains information regarding health services, medical treatments, centres of expertise on special services, prices and public and private hospitals. Cross-border patients can receive information from this portal via a call centre. However, this portal is far from a NCP as described in the Directive 2014/24/EU. The portal lacks information about clear and definite data about the healthcare providers, transparent complaints procedures and mechanisms to seek remedies if patients suffer harm arising from healthcare they receive, personal data protection and medical records of treatments. Hence there is still a lot to be done about providing information to international patients.

Personal data protection is still an issue in Turkey as Directive 95/46/EC on protection of personal data is not adopted yet.²¹ This creates a serious concern about the security of the medical records of cross-border healthcare patients who receive healthcare in Turkey. Hence apart from particular EU legislations related to health, all other EU legislations on fundamental human rights such as personal data protection should be on the agenda of Turkey to adopt.

Turkey has a particular position among other candidate countries. There are 1, 983, 240 Turkish people residing in the EU MS. With this number Turkey is on the top of the list of countries of origin of non-EU nationals residing in the EU.²² Most of these people have been living in EU countries for more than one generation, and thus are covered by definitions such as 'insured person' or 'patient' in Directive 2014/24/EU which makes these people eligible for having cross-border healthcare. In case of being diseased, these people may be prone to seek health services in their home country; Turkey, especially if the health issue is a serious one requiring long-term care or rehabilitation. Adopting Regulation EC No 883/2004 and Directive 2014/24/EU would facilitate the process for Turkish people residing in EU. Therefore, having these two legislations as a template for bilateral agreements with EU countries is a rational approach which requires the further attention of the Turkish parliaments. Keeping in mind that Turkey has the obligation to adopt all EU legislation to national legislation by the time of full membership, aligning Directive 2014/24/EU and Regulation EC No 883/2004 in the near future should be considered and put on the agenda for the national action plan for accession to EU.

7 Conclusion

Turkish citizens are not within the scope of TFEU Article 56 from which the right to have access to services arises. Hence Directive 2014/24/EC on patients' rights on cross-border healthcare does not cover Turkish patients until Turkey attains full membership in the EU. However, as a negotiating candidate country Turkey has the obligation to adopt EU legislation by the time of membership. The 2014 National action plan for the accession to EU includes all EU legislation to be adopted until 2019, but Directive 2014/24/EC does not exist in that plan. On the other hand, Turkey has an increasing number of international

patients and health tourism is becoming a bigger sector. Regulation EC No 883/2004 is the EU legislation for the coordination of social security systems in the EU. Turkey has committed to adopt this regulation in the scope of bilateral agreements with some EU MS. In this perspective adoption of Directive 2014/24/EC would facilitate the alignment of Turkish health and social security system with that of EU MS and improve Turkish health sector by establishment of HTA institute and centres of expertise of rare diseases.

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