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PATIENT MOBILITY IN THE EUROPEAN UNION: CHALLENGES AND DEVELOPMENTS

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Anno Accademico 2019/2020

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INTRODUCTION

In this dissertation, we are going to delve into the history, developments and future of European cross-border healthcare. The whole discipline is derived from one of the four fundamental freedoms set in the Treaty of Rome, the freedom of movement of workers. Having the possibility to freely move from Member State to Member State in order to seek employment and to work was a revolutionary legal concept for the historical period in which the measures entered into force; the provisions relating to the freedom of movement of workers also have the historical merit of anticipating what the rights deriving from the EU citizenship are going to foresee later on in the development of the Union.

Since the very beginning of the Community, it became clear how an individual that sought to work abroad had to be protected from a social security standpoint. The individual, however, was only preserved in a limited manner, and still to this day, the level of coverage that a person may enjoy in the host Member State is not without its drawbacks.

Today, we find a European Union that is the result of an advanced process of integration: what started in the late 1950s as a blueprint for economic integration between European nations as a mean to avoid future military conflicts, ended up becoming something bigger thanks to developments on the social and political fronts, which further enhanced the level of coperation among the Member States. These advancements brought forth the need to protect the rights of the EU citizens to the highest degree possible. On this point, the role of the Court of Justice was, and still is, of the utmost importance due to the role it plays when it comes to its power of interpretation of EU law. Particularly in the field of European cross-border healthcare, the jurisprudence of the Court managed to expand the possibilities of patients that were seeking healthcare-related services in another Member State. Another important part is also played by the Charter of Fundamental Rights, whose provisions on healthcare (Articles 34 and 35 CFR), while being underused, still amount to a primary source of EU law, and as such, are to be held into high regard when implementing EU policies and actions.

Given the context that we have described, in which the mobility of people in Europe is not perceived as an exception anymore, we would expect that an individual seeking healthcare in any country would be treated in approximately the same way, - thus accomplishing the fundamental EU principle of non discrimination - but, unfortunately, this is not the case. As we are going to see in the future chapters, if a person wants to be treated abroad in a planned manner, they have to seek authorisation from the competent health institution of their country of affiliation. This authorisation is not a guarantee, however, since it is up to the competent organism to eventually grant it; still, the relevant legislation foresees two cases in which the authorisation cannot be denied: 1. when the necessary treatment cannot be provided in the Member State of residence and 2. when the aforementioned treatment cannot be delivered within a timeframe that is appropriate for the condition of the patient. The system that is in place is far from being perfect and poses a series of problems that are going to be analysed more in detail in the relevant chapters.

It is necessary to mention that the field of cross-border healthcare suffers from a lack of publicity that is particularly evident when studies are made on the topic. A 2015 Special Eurobarometer brought reported how the relevance of cross-border patient mobility is of 5% in the EU28, which is too little. The findings of the study also suggest that the European citizens are mostly unaware of their rights when it comes to the topic at issue. This could be tackled by the Union with the heavy use of advertising through mass media and social media in order to reach the largest population possible.

Another problem that presented itself during the time of writing is the COVID-19 pandemic, which brought with it a series of challenges not only for every individual affected but also for the European Union as a whole. Such a situation required a common European action; however, in reality, its Member States might have acted too independently from one another when dealing with the problem, an example of which is when the national governments decided to act regarding the quarantine period for their country. While there are tools at the disposal of the EU for dealing with a health crisis, there is the necessity to develop new ones that could make an even more significant difference. These tools are contact-tracing applications that

would help contain the spread of the virus thanks to the Bluetooth technology that is present in every smartphone.

Our work is going to be divided as follows: in Chapter 1, we are going to start with the introduction of the Treaty of Rome of 1957 and the implementing Regulation that allows us to flesh out the actual contents of the law when it comes to cross-border healthcare for workers. We will see how the relevant legislation changed up to 1971 and the news that it brought with it in the manifestation of the E-111 and E-112 forms. Finally, we will analyse two judgements of the Court of Justice that managed to undermine the territoriality principle that pervaded the providing of healthcare up to that point.

In Chapter 2, we are going to dissect what happened in the early 2000s. The scandal of the Santer Commission that shook the Union at its core, and the introduction of the European Health Insurance Card (EHIC) are strongly linked to one another due to the historical and political circumstances of the time. Another essential piece of legislation that aimed to better coordinate the social security systems of the Member States is going to be analysed and discussed, along with another critical case of the Court of Justice, whose judgement introduced a series of news to the discourse around cross-border healthcare in the EU.

In Chapter 3, we will be arriving at the relevant legislation that is in force today when it comes to the providing of cross-border healthcare. We will see the relevant primary law that regulates the competences of the EU in the field, both in the TFEU and in the Charter of Fundamental Rights. We are also going to discuss a 2011 Directive that had the objective of both codifying the jurisprudence of the Court of Justice up to that point, as well as of clarifying the status of cross-border healthcare in the EU. One last critical case of the Court of Justice, however, came up in 2016, which managed to put doubts in the minds of experts around the world regarding the necessity of a Member State to provide minimum standards of quality when providing healthcare-related services.

Finally, in Chapter 4, we are going to analyse some statistics on the relevance of cross-border healthcare for the EU28 as well as how knowledgeable EU citizens are on their rights in the field. The importance of technology in the topic at issue is

going to be discussed twofold, both in relation to the eHealth Action Plan of 2012, and its interim assessment of 2014, and to the COVID-19 pandemic and the use of contact-tracing apps that aim to limit the spread of the virus.

CHAPTER I

CROSS-BORDER PATIENT MOBILITY: THE EC BEGINNINGS, THE LEGAL FRAMEWORK AND THE GUIDING PRINCIPLES OF THE ECJ

1. Cross-border patient mobility: introduction to the work

In this chapter we aim to paint a picture of the legislative beginnings and evolution of cross-border patient mobility. In order to understand how far we have come in this legal context, we need to analyse how it changed during the years. This is why a light will be cast on quite a large timeframe that spans around four decades; from the Treaty of Rome, where we will see what the relevant provisions mandate, passing through the 1970s up until the last breath of the 1990s.

More specifically, we are going to focus on Regulation 1408/71[1], which lays the groundwork for the mobility of patients in the Union, jointly with Regulation 574/72[2] (no longer in force).

Crucial to our discussion will also be the work done by the Court of Justice, whose *Kohll*[3] and *Decker*[4] judgements will be dissected in paragraphs 3 and 4.

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1 Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community. OJ L 149, 5.7.1971, p. 2–50.

2 Regulation (EEC) No 574/72 of the Council of 21 March 1972 fixing the procedure for implementing Regulation (EEC) No 1408/71 on the application of social security schemes to employed persons and their families moving within the Community. OJ L 74, 27.3.1972, p. 1–83.

3 Judgment of the Court of 28 April 1998. *Raymond Kohll v Union des caisses de maladie*. Reference for a preliminary ruling: *Cour de cassation* - Grand Duchy of Luxemburg. Case C-158/96. European Court Reports 1998 I-01931. ECLI identifier: ECLI:EU:C:1998:171.

4 Judgment of the Court of 28 April 1998. *Nicolas Decker v Caisse de maladie des employés privés*. Reference for a preliminary ruling: *Conseil arbitral des assurances sociales* - Grand Duchy of Luxemburg. Case C-120/95. European Court Reports 1998 I-01831. ECLI identifier: ECLI:EU:C:1998:167.

If there is an argument that has kept its relevance since the foundation of the European Community, all the way up to today, it is, without a doubt, the delicate balance of power between the Member States and the Community (now Union). Such a debate has been sparking up discussions since the foundation of the United States of America, a much older democracy, that still today struggles to find a final compromise on the powers of the States and of the federal government.

What differentiates the European dimension of this problem from its American counterpart is the vast heterogeneity of populations, ways of life, traditions and conceptions of what the State should do for its citizens. If some European Member States, namely the Scandinavian ones, have adopted a social-democratic regime where the government provides its residents with free healthcare at the cost of very high taxes, some others, for example, the Kingdom of the Netherlands have taken a more "liberal" path, having mandated for their citizens to be insured with private companies, while keeping taxes lower.

One sure thing is that there is not, nor there will ever be, a perfect recipe for how a healthcare system should work, but harmonisation measures at the European level have been tried over 50 years, and this is where our journey starts.

1.1 The Treaty of Rome and Regulation 3/1958[5]

In the year 1957 the Treaty of Rome was signed by the six founding Member States[6]. This revolutionary text brought forth a monumental shift in the political landscape of a divided Europe, since it instituted both the European Economic Community (EEC) and the European Atomic Energy Community (EAEC or Euratom).

The Treaty contained many provisions, of which are relevant to our discussion Articles 48-66, contained in Part Two, Title III, under the header 'Foundations of the Community'. These Articles contain dispositions that regulate the free

[5] Règlement n° 3 concernant la sécurité sociale des travailleurs migrants. OJ 30, 16.12.1958, p. 561–596.

[6] Belgium, France, Italy, Luxembourg, The Netherlands and West Germany.

movement of persons[7]. The beneficiaries must be nationals of a Member State, they must be workers and they must seek to exercise the right of free movement in a territory to which the EEC Treaty applies[8].

To put things into perspective, it can be useful to see where things are today in the context of social security and healthcare according to EU law. This is where we find the Charter of Fundamental Rights of the European Union (CFR), of which Articles 34[9] and 35[10] play a role in our discussion.

In the EEC we have observed very little margin of access to healthcare and social security since only workers were recognised as being the entitled category of individuals. In the landscape of today, Articles 34 and 35 CFR are very clear on how "*Everyone residing and moving legally within the European Union is entitled to social security benefits*", and "*Everyone has the right of access to preventive health care and the right to benefit from medical treatment*". These provisions, while massive in their idealistic aim, have a limited practical scope due to the nature of the CFR, whose effects may be observed only in the context of the

[7] Articles 48-51 are about workers, Articles 52-58 are about self-employed individuals, and articles 59-66 are about the providers of services.

[8] As derived from Article 48 EEC.

[9] "*The Union recognises and respects the entitlement to social security benefits and social services providing protection in cases such as maternity, illness, industrial accidents, dependency or old age, and in the case of loss of employment, in accordance with the rules laid down by Community law and national laws and practices.*

Everyone residing and moving legally within the European Union is entitled to social security benefits and social advantages in accordance with Community law and national laws and practices.

In order to combat social exclusion and poverty, the Union recognises and respects the right to social and housing assistance so as to ensure a decent existence for all those who lack sufficient resources, in accordance with the rules laid down by Community law and national laws and practices."

[10] "*Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.*"

implementation and application of EU law. We will discuss more in-depth in Chapter 3 the legal environment of today[11].

Regarding the context of patient mobility, already in the Treaty we can see a competence of the European Economic Community in the field of social security which is enshrined in Article 51 EEC[12] [now Article 48 TFEU].

The focus of the relevant provision, as already mentioned, was on migrant workers and did not cover patient-mobility in a strict sense.

In order to regulate "*a system which permits an assurance to be given to migrant workers and their beneficiaries*", as Article 51 EEC put it, the Council proceeded to legislate on the matter, producing Regulation 3/1958.

Considering the political environment in which the European nations found themselves during those years, it should not come to a surprise that the Contracting Parties had all the intentions of harmonising fields such as that of social security. It is precisely in 'Whereas' number 4 of the said Regulation that we find a crucial consideration, according to which a system that insures migrant workers and their beneficiaries constitutes an essential element for the setting-up of the freedom of movement of workers.

This Regulation was intended as the central piece of legislation that would implement what was foreseen in Article 51 EEC. It coordinated the social security systems of the Member States, with the effect of covering cross-border healthcare for all socially insured workers.

This piece of legislation was repealed and replaced by Regulation 1408/71, which carried forward 'the spirit' of the law of 1958, but expanded on the tools that allow for the recognition of the competent healthcare state to cover the costs of cross-

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[11] See paragraph 2 of Chapter III.

[12] "*The Council*, […] *shall, in the field of social security, adopt the measures necessary to effect the free movement of workers, in particular, by introducing a system which permits an assurance to be given to migrant workers and their beneficiaries:*

(a) that, for the purposes of qualifying for and retaining the right to benefits and of the calculation of these benefits, all periods taken into consideration by the respective municipal law of the countries concerned, shall be added together; and (b) that these benefits will be paid to persons resident in the territories of Member States."

border healthcare[13]. The reasons for the change in legislation may be found in 'Whereas' 1 and 3 of Regulation 1408/71, where the need for a revision of the preceding provision has made itself clearer with the passing of time, due to "*practical experience of its implementation*", as well as changes in the national legislations of the Member States. It is also stated how it was felt appropriate to "*bring together in a single legislative instrument all the basic provisions*" regarding the implementation of Article 51 EEC in order to benefit workers, frontier workers, seasonal workers and seamen.

2 Regulations 1408/71 and 574/72

Regulation 1408/71 is the bedrock for our discussion on Cross-border healthcare in the European Union; what it did was give the citizens of the other Member States the possibility to receive the same emergency treatment that residents of the host State had the right to.

The Regulation finds its legal basis in Article 2[14] [now Article 26 TFEU], 7[15] [now Article 18 TFEU] and 51 of the Treaty Establishing the European Community. As it is clear, the legislator wanted to update a fundamental provision whose function was fundamental for a concrete enforcement of the freedom of movement of workers.

Another relevant piece of legislation to our discussion is Regulation 574/72, which finds the same legal basis in the Treaty as Regulation 1408/71, plus, as mentioned in its 'Whereas' number 2, it also finds one in Article 97 of Regulation 1408/71[16].

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[13] Hans Vollaard. 2007. *The challenge of patient mobility to healthcare states in the EU*, p. 5

[14] "*It shall be the aim of the Community, by establishing a Common Market and progressively approximating the economic policies of Member States, to promote throughout the Community a harmonious development of economic activities, a continuous and balanced expansion, an increased stability, an accelerated raising of the standard of living and closer relations between its Member States."*

[15] "*Within the field of application of this Treaty and without prejudice to the special provisions mentioned therein, any discrimination on the grounds of nationality shall hereby be prohibited*."

[16] "*A further regulation shall lay down the procedure for implementing this Regulation.*"

This Regulation was adopted, as stated in its 'Whereas' number 7, in order to make clarity on which is the competent institution of each Member State, as well as the relevant documents and formalities that are necessary for a correct use of the procedures that are also provided for in said Regulation.

The two Regulations must be read together. They made it so that European citizens that are publicly insured for health care could, when moving to other Member States, continue to be insured at the expense of the institution they were already insured with.
Two tools in particular were available to patients according to the Regulations: the E-111[17] and the E-112[18] forms.

2.1 The E-111 form

The E-111 form was the mechanism that provided for the coverage of costs of immediately necessary care during a temporary stay abroad for professional or private purposes; the system of the State of residence would then be charged for the costs sustained by the host State.
The form stated: 1. That the person in question was entitled to receive health care services in another Member State; 2. That the medical treatment could not have been postponed without endangering their life or health[19]; 3. How long the emergency treatment could have been obtained for at the expense of the competent institution.
The moment that the situation of emergency was over[20] the providing State seemed to have the right to send the patient back to his or her home State for further treatment[79].

[17] As provided for in Article 22(1) letter a) of Regulation 1408/71.

[18] As provided for in Article 22(1) letter c) of Regulation 1408/71.

[19] Decision Nr. 135 of the Administrative Commission, point 4 and 5.

[20] The assessment on the duration of the situation of emergency was to be made by the health institution or provider in the "providing" State. See also Y. Jorens, *Wegwiys in het Europees Sociale Zekerheidsrecht,* (de Keure, 1992), 96-97.

The form received widespread use from tourists since the late 1970s, but it was quite burdensome: it had to be requested from a domestic health insurance institution before departure, and many tourists were uninformed about its existence[21]. To make matters worse, in certain countries, the foreign health insurance institution wished to approve the form in advance in order to obtain reimbursement for yet unforeseen emergency cases[76]. The formalities that needed to be fulfilled differed from Member State to Member State; in the case of non-compliance the patient would have lost his or her right to reimbursement and had, therefore, to pay out of his pocket for the providing of health services[22].

The scope of the form was expanded in 2004[23], wherein the notion of emergency care was included the medical treatment that was necessary during the stay in the host State, therefore, a chronic kidney patient can still receive renal dialysis, even though he or she knows in advance that treatment will be necessary during the stay abroad[76].

Since June 2004 the form was gradually replaced by the European health insurance card, which we will talk about in Chapter 2.

2.2 The E-112 form

The E-112 form regarded the authorised treatments: according to Article 22(1) letter c) of Regulation 1408/71, EU citizens could obtain medical benefits in other Member States when they had received the prior authorisation of the competent institution[24]. Insured persons who wished to go to another State with the intention to obtain medical care there were invested of this right.

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[21] Hermans, H.E.G.M. & Berman, P.C. (1998), 'Access to health care and health services in the European Union: Regulation 1408/71 and the E111 process', in R. Leidl (ed.), *Health care and its financing in the single European market*. Amsterdam: IOS Press. 324- 343.

[22] H. Hermans, 'Access to Health Care and Health Services in the European Union: Regulation 1408/71 and the E 111 Process', in: R. Leidl (ed.), *Health Careand its Financing in the Single EuropeanMarket*, (IOS Press, 1998), 324.

[23] The part of the Regulation which is the basis for the E-111 form has not received any change in the 33 year gap between its introduction and its repeal.

[24] "*A worker who satisfies the conditions of the legislation of the competent State for entitlement to benefits, taking account where appropriate of the provisions of Article 18, and:*

The authorisation may have been given for any type of treatment that could have been considered as effective for the situation of the person in question; it should also be noted that whether the type of treatment was covered by the insurance administered by the competent organ was to be deemed of little importance[25].

According to Article 22(2) of the Regulation, the authorisation had to be presented to the competent health insurance institution, and could not be refused in the case two conditions were met: 1. The treatment that was sought was part of the healthcare package of the employee, and 2. The treatment could not be given within the period usually necessary, having considered his or her current state of health and the probable course of his or her illness.

Moreover, the interpretation of Article 22(2) given by the Court made it so that patients had the right to obtain authorisation for treatments that were deliberately excluded from the national insurance package on medical, medical-ethical or financial grounds. This was specifically said in the *Pierik II* case, where the Court said:

"[...] it emerges from the provisions and the essential aims of Article 22 that it was the intention of the regulation to give medical requirements a decisive role in the decision of the competent institution to grant or refuse the aforesaid authorization by providing generally and unreservedly in the second subparagraph of Article 22(2) that authorization may not be refused 'where the treatment in question cannot be provided for the person concerned within the territory of the Member State in

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(c) who is authorised by the competent institution to go to the territory of another Member State to receive there the treatment appropriate to his condition, shall be entitled:

(i) to benefits in kind provided on behalf of the competent institution by the institution of the place of stay or residence in accordance with the legislation which it administers, as though he were insured with it; the length of the period during which benefits are provided shall be governed however by the legislation of the competent State;

(ii) to cash benefits provided by the competent institution in accordance with the legislation which it administers. However, by agreement between the competent institution and the institution of the place of stay or residence, such benefits may be provided by the latter institution on behalf of the former, in accordance with the legislation of the competent State."

[25] Case 117/77 *Pierik I* [1978] ECR 825, at 15-16.

which he resides.' (..) Thus ... when the competent institution acknowledges that the treatment in question constitutes a necessary and effective treatment of sickness or disease from which the person concerned suffers, the conditions for the application of the second subparagraph of Article 22(2) of Regulation No 1408/71 are fulfilled and the competent institution may not in that case refuse the authorisation referred to by that provision and required under Article 22(1)(c)."[26]

Looking at the *Pierik* judgements from the point of view of the patients, they certainly were to be considered positively. In principle patients are supposed to obtain medical treatment in the Member State where they reside; however in the case of better or different treatment that became available in another Member State, they had the possibility to obtain authorisation and to receive them at the expense of the competent institution. The Court had virtually recognised a free movement of patients[79].

What happened after the *Pierik II* case was that, within just two years, the Member States exerted pressure in order to amend Article 22(2) and replace it with a new version that was much more consistent with their interests (i.e. less costs for the running of the healthcare system).

The amendment of the article brought forth a change which clarified that patients did not have the right to obtain in other States forms of treatment which were excluded in their own insurance package; it was then left to the Member State whether or not to give the authorisation, which in turn usually ended with a refusal.

The regime of prior authorisation that was provided for in Article 22 of Regulation 1408/71 has been analysed by the Court in the context of the Treaty provisions on the free movement of services in a 2001 case[27]: what came out of the judgement was that the authorisation regime was not to be considered as a restriction to the movement of services; on the contrary, it bestowed upon patients a right to seek cross-border healthcare that they would not be entitled to without it under the national health insurance package.

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[26] Case 182/78 *Pierik II* [1979] ECR 1977, at 12-13

[27] Case C-56/01 *Inizan*, para.[14].

Article 22 of Regulation 1408/71 was later only amended by Regulation 631/2004[28] in the context of the introduction of the European Health Insurance Card (EHIC). This change made it so that the provisions on social security were ready with the shift that was about to happen to the way social security was enforced in the context of the freedom of movement. We will see more on the EHIC in Chapter 2.

As we have seen, these forms were provided in order to identify the competent healthcare state that would cover the costs; however they did not arrange for as simple of a framework as intra-national provisions offer, having the unfortunate effect of stimulating a process that was already enshrined in the minds of the citizens, that is to look for treatment only within the boundaries of the State of residence.

The impact of this provision cannot be understated: it has overruled the principle of territoriality of national healthcare systems, as it "deterritorialises the national systems in order to ensure that migrants are entitled to benefits on the basis of their own insurance record"[29]; insurance rights follow the worker within the EU, with the consequence of a "personalisation" of previously territorially restricted rights[30]; it also gave leeway for a revolution that, while numerically is very small (as we will see), it is nonetheless massive in the context of a deeper European integration: it was originally aimed at the freedom of movement of workers, but it expanded such

[28] Regulation (EC) No 631/2004 of the European Parliament and of the Council of 31 March 2004 amending Council Regulation (EEC) No 1408/71 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community, and Council Regulation (EEC) No 574/72 laying down the procedure for implementing Regulation (EEC) No 1408/71, in respect of the alignment of rights and the simplification of procedures (Text with relevance for the EEA and for Switzerland) OJ L 100, 6.4.2004, p. 1–5

[29] Van der Mei, A.P. (2001), *Free movement of persons within the European Community: cross-border access to public benefits* (dissertation Maastricht University). Maastricht: Maastricht University. 75.

[30] Watson, 1980 as cited in Hans Vollaard. 2007. *The challenge of patient mobility to healthcare states in the EU*, p. 7

that, under certain circumstances, a person was entitled to medical care abroad even without having ever worked or resided in another Member State[31].

Having read the two Regulations, we can establish a relatively simple set of principles.

- In all instances where an individual receives medical care outside of the competent State (i.e. the State of residence of the patient), it will be the competent institution of said State that will bear the costs; The "providing" State (i.e. the host State) is entitled to be fully reimbursed by the competent institution of the State of residence[32];
- Medical care is to be offered according to the legislation of the providing State, not of the competent State;
- The patient is to be treated by the providing State as if he/she was one of its residents.

It is now appropriate to discuss the work of the Court of Justice in this field. As we know, the legal system of European law is heavily influenced by said Court, since it is the only institution that has the authority to interpret both primary and secondary EU law.
We will analyse two cases specifically, the *Kohll* case and the *Decker* case: both of these judgements took place in 1998, almost thirty years after the first implementation of the Regulations that we dissected previously. These cases had serious effects in the field of cross-border patient mobility, as we will see later in this chapter, and, therefore, deserve to be scrutinised thoroughly.

[31] Cornelissen, R. (1996), 'The principle of territoriality and the Community Regulations on social security (Regulation 1408/71 and 574/72)', *CML Rev*. 33, 439-471.

[32] For the details regarding the refunding of the "providing" institution by the competent institution see Articles 93-95 of Regulation 574/72.

3. The *Kohll* case: patients should not be subjected to a mechanism of prior authorisation to obtain the reimbursement of medical services

3.1 The facts

Mr Kohll is a Luxembourg national which is insured with the *Union des Caisses de Maladie* (UCM). A doctor established in Luxembourg requested an authorisation for his daughter to be treated by an orthodontist established in Germany. In essence the problem arose when such a request was turned down by the social security medical supervisors because the treatment was deemed as not urgent, and, therefore, it could be provided in Luxembourg.

The request was presented by the doctor because of Article 20(1) of the *Code des Assurances Sociales*, which prescribed that "*with the exception of emergency treatment received in the event of illness or accident abroad, insured persons may be treated abroad […] only after obtaining the prior authorisation of the competent social security institution*".

Moreover, according to Article 27 of the UCM statutes "*authorisation will be granted only after a medical assessment and on production of a written request from a doctor established in Luxembourg indicating the doctor or hospital centre recommended and the facts and criteria which make it impossible for the treatment in question to be carried out in Luxembourg*".

The decision made by the social security medical supervisors was later confirmed by a decision of the UCM board.

Mr Kohll appealed against the decision of the board to the *Conseil Arbitral des Assurances Sociales* (Social Insurance Arbitration Council) arguing that the provisions relied on were contrary to Article 59[33] [now Article 66 TFEU] of the Treaty.

[33] "*Within the framework of the provisions set out below, restrictions on the free supply of services within the Community shall be progressively abolished in the course of the transitional period in respect of nationals of Member States who are established in a State of the Community other than that of the person to whom the services are supplied.*

The appeal was dismissed, but Mr Kohll appealed once again to the *Conseil Supérieur des Assurances Sociales* (Higher Social Insurance Council), which in turn upheld the contested decision because Article 20 of the *Code des Assurance Sociales* and Article 27 of the UCM statues were consistent with Regulation 1408/71.

One last time Mr Kohll appealed in front of the *Cour de Cassation*. In essence the argument brought forward was that the *Conseil Supérieur des Assurances Sociales* only verified the consistency of the national rule with Regulation 1408/71, while ignoring its coherency with the provisions set in Article 59 [now Article 66 TFEU] and Article 60[34] [now Article 57 TFEU] of the Treaty establishing the EEC.

3.2 The questions raised and the answer of the Court

Since the argument raised a problem concerning the interpretation of the Treaty, the Court referred two questions for a preliminary ruling.

Question 1 asked whether Articles 59 and 60 EEC precluded rules which subjected reimbursement of the cost of benefits to an authorisation by the social security institution relevant for the insured person when the benefits are provided in a Member State that is different from the one of residence of the patient.

The Council, acting by means of a unanimous vote on a proposal of the Commission, may extend the benefit of the provisions of this Chapter to cover services supplied by nationals of any third country who are established within the Community."

[34] "*Services within the meaning of this Treaty shall be deemed to be services normally supplied for remuneration, to the extent that they are not governed by the provisions relating to the free movement of goods, capital and persons.*

Services shall include in particular:

(a) activities of an industrial character;

(b) activities of a commercial character;

(c) artisan activities; and

(d) activities of the liberal professions.

Without prejudice to the provisions of the Chapter relating to the right of establishment, a person supplying a service may, in order to carry out that service, temporarily exercise his activity in the State where the service is supplied, under the same conditions as are imposed by that State on its own nationals."

Question 2 proceeds to ask if the answer to Question 1 would change if the rules at issue were in place in order to "*maintain a balanced medical and hospital service accessible to everyone in a given region*"[35].

In essence, these questions ask whether Articles 59 and 60 of the Treaty prevent social security rules such as those at issue to be applied in the main proceeding.

It first must be established that the organisation of the social security system of a Member State is left to its competence. Therefore Community law does not take away any power from any one nation[36][37]. However, notwithstanding the unique nature of the services that are provided in the context of the social security system, their peculiar identity does not exclude them from the application of the fundamental principle of freedom of movement. Therefore, the fact that national rules fall within the social security sphere does not prevent the use of Articles 59 and 60 of the Treaty[38].

In the words of the Court: "*Article 59 of the Treaty precludes the application of any national rules which have the effect of making the provision of services between*

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[35] Case C-158/96 *Raymond Kohll v Union des caisses de maladie*, para[10]

[36] See notably Case 238/82 *Duphar v Netherlands* [1984] ECR 523, para.[16] and Case C-70/95 *Sodemare v Regione Lombardia* [1997] E.C.R. I-3395, para.[27].

[37] This is consistent with Article 137(4) EC [Today Article 153(4) TFEU], which states that the provisions adopted in the social field "*shall not affect the right of Member States to define the fundamental principles of their social security systems and must not significantly affect the financial equilibrium thereof*"; and with Article 152(5) EC [Today Article 168(7) TFEU], which provides that "*Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care*".

[38] "The social security sector does not constitute an island beyond the reach of Community law" – Joined Opinion of Advocate General Tesauro on Case C-120/95 *Nicolas Decker v Caisse de maladie des employés privés*, [1998] ECR I-1831 and Cace C-158/96, *Raymond Kohll v Union des caisses de maladie* [1998] ECR I-1931.

Member States more difficult than the provision of services purely within one Member State".

While the national rules at issue do not prevent insured persons from approaching a provider of services that is established in another Member State, they make reimbursement of the costs sustained in that Member State subject to prior authorisation and do not allow for any compensation when the approval is not obtained. The consequence is that such rules discourage individuals who are insured from approaching providers of medical services that are established in another Member State, and therefore amount to a barrier to the freedom to provide services. Such a barrier could, in theory, be justified in front of a real risk of a severe undermining of the financial balance of the social security system since it would constitute an overriding reason in the general interest. However, the reimbursement of the costs of dental treatment has no significant effect on the financing of the social security system.

Another ground that could limit the aforementioned fundamental freedom would be prevailing reasons of public health; however, this would not allow the exclusion of the public health sector (intended as one of economic activity from the point of view of the freedom to provide services) from the application of the fundamental principle of freedom of movement. Instead, what is allowed under Article 56 of the Treaty [now Article 52 TFEU], is the limiting of the freedom to provide medical and hospital services "*in so far as the maintenance of a treatment facility or medical service on national territory is essential for the public health and even the survival of the population*"[39]. However, none of the observations submitted have shown that the rules at issue were necessary for these reasons. What must then be concluded is that the provisions at issue are not justified on the grounds of public health.

The answer of the Court to the questions at issue is that Articles 59 and 60 of the Treaty preclude national rules under which reimbursement of the cost of dental

[39] Case C-158/96, *Raymond Kohll v Union des caisses de maladie* [1998] ECR I-1931, para[51]

treatment provided by an orthodontist established in another Member State is subject to authorisation by the insured person's social security institution.

To sum up, the Court has concluded that, to obtain the reimbursement of the cost of medical services, Member States may not subject the patient to a mechanism of prior authorisation of the competent organ; they have however the possibility to limit reimbursement up to the rates applied in the territory of their State. The consequence of this is that a patient may not be reimbursed fully for the costs deriving from medical care obtained abroad. In essence the individual could ask for the authorisation of the competent insurance organ. However there is no right in place for the individual to obtain it. The same problem presents itself in the case of medical services that are not included in the insurance package of the patient; an authorisation is necessary. Still, there is not a right that ensures its receiving.

3.3 Open questions after the judgement and later clarifications of the Court

The judgement, however, left open two crucial questions: 1. Because the medical care at issue in the case was only ambulatory care, does hospital care qualify as a medical activity service as well?[40] And 2. Is a framework of a benefits-in-kind system[41] or of a national health system[42] to be subject to the Treaty provisions on the free movement of services?

After more than three years from the conclusion of the case at issue, the Court gave answers to these questions. First and foremost, the Court stated how hospital care should be treated no differently than ambulatory care, "medical activities fall within the scope of Article 60 of the Treaty [now Article 57 TFEU[34]], there being no need

[40] Advocate General Tesauro suggested in his Opinion on *Decker* and *Kohll* that this question be answered affirmatively. He also added that due to the specific characteristics of medical care provided in hospitals, prior authorisation rules could, at least in principle, be justified. See paras. [59-60] of the Opinion.

[41] In benefits-in-kind systems, patients are, in principle, entitled to obtain medical care from any contracted provider. Health care providers are paid directly by the health insurance institutions on the basis of agreements previously concluded between both parties. - Pedro Cabral. 2004. *The internal market and the right to cross border medical care.*

[42] National health systems generally offer a universal right to (quasi) free health care. This is funded (essentially) through tax revenues.

to distinguish in that regard between care provided in a hospital environment and care provided outside such an environment"[43].

On the second question, the Court decided that the distinction between a healthcare provided in the framework of a benefits-in-kind system or in the context of a reimbursement system is irrelevant for the application of the Treaty provisions on the freedom of movement of services, since "*the fact that hospital medical treatment is financed directly by the sickness insurance based on agreements and pre-set scales of fees is not in any event such as to remove such treatment from the sphere of services within the meaning of Article 60 of the Treaty*"[44]; in the *Müller-Faure* judgement[45], this conclusion was later extended to medical care provided within the framework of a national health service.

According to the Court, it is indoubt that the medical care provided in the framework of a benefits-in-kind system is the element of remuneration that is required to trigger the application of the Treaty provisions on the free movement of services. In its words, "*the essential characteristic of remuneration [is] the fact that it constitutes consideration for the service in question*"[46], and also Article 50 EC [now Article 57 TFEU] "*does not require the service be paid for by those for whom it is performed*"[47].

In *Geraets-Smits and Peerbooms*, it further clarified that "*the payments made by the sickness insurance funds […] albeit set at a flat rate, are indeed the consideration for the hospital services and unquestionably represent remuneration for the hospital which receives them and which is engaged in an activity of an economic character*"[48][49].

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[43] Case C-368/98 *Vanbraekel* [2001] ECR I-5363 para. [41]

[44] Case C-157/99 *Geraets-Smits and Peerbooms* [2001] ECR I-5473, para.[56].

[45] Case C-385/99 *Müller-Faure* [2003] ECR I-4509.

[46] Case C-263/86 *Humbel* [1986] ECR 5365, para. [17].

[47] Case C-352/85 *Bond van Adverteerders* [1988] ECR 2085, para.[16] and Joined Cases C-51/96 & 191/97 *Deliege* [2000] ECR I-2549, para.[56]

[48] Case C-157/99 *Geraets-Smits and Peerbooms* [2001] ECR I-5473, para.[58].

[49] The Advocate General in his Opinion on the *Geraets-Smits and Peerbooms* case reached the opposite conclusion: since the payments are not established on the basis of the cost of the treatment,

These answers of the Court have the merit of establishing standard rules for different frameworks and have as well the consequence of extending the notion of remuneration "to cover payments that bear only indirect relation to the service provided"[50].

Now that we have resolved the loose ends of the *Kohll* judgement, it is time to delve into the second case that is useful to our discussion, the *Decker* judgement. This case, coincidentally, started with disputes that took place in Luxembourg, just like in *Kohll*, and, together with the aforementioned case, managed to have a massive influence in the subsequent case-law as we will see in the final part of the next paragraph.

4. The *Decker* case: a lack of prior authorisation is not a valid ground for refusing to reimburse expenses for medical products purchased abroad

4.1 The facts

The case is about Mr Decker, a Luxembourg national that seeks reimbursement of the cost of a pair of spectacles with corrective lenses that were purchased from a Belgian optician. The said glasses were prescribed by an ophthalmologist established in Luxembourg.

Mr Decker was informed by the *Caisse de Maladie des Employés Privés* ("the Fund") that there would be no reimbursement for the cost of the spectacles since they were purchased abroad without prior authorisation.

The rest of the procedural part of the suit is reminding of the *Kohll* case: Mr Decker contested the decision relying on the Treaty rules on the free movement of goods, but the Fund rejected his claim via a decision of its managerial committee.

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but rather on a series of different elements, these payments cannot be regarded as consideration for the treatments provided.

50 V. Hatzopoulos, *Killing National Health and Insurance Systems but Healing Patients? The European Market for Health Care after the Judgments of the ECJ in Vanbraekel and Peerbooms* [2002] C.M.L.Rev. 683, pp-693-694.

Mr Decker proceeded then to apply to the *Conseil Arbitral des Assurances Sociales*, which rejected it by order.

After that Mr Decker appealed against said order to the *Conseil Arbitral des Assurance Sociales*, which dismissed the appeal on the ground that the matter was deemed as not connected to the free movement of goods, but rather, with social security law (namely Regulation 1408/71).

Finally, Mr Decker appealed to the Court of Cassation, but the judgement was set aside, and the case was remitted to the *Conseil Arbitral des Assurances Sociales*. By judgement, it held that Article 60[51] of the *Code des Assurance Sociales* and Article 58 of the statutes of the *Union des Caisses de Maladie des Salariés* (UCM) applied to the dispute.

The reimbursement for these specific types of products (i.e. spectacle frames and corrective lenses) was governed by Article 78[52] of the UCM statutes and by the collective agreement of 30 June 1975[53], where it was provided on a flat-rate basis with a ceiling of LFR 1.600 for frames.

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51 *"[…] insured persons may obtain treatment abroad only with the consent of their sickness fund, except in the case of initial treatment in the event of accident or illness occurring abroad".*

The sickness fund may not refuse consent if the treatment abroad is recommended by the doctor attending the insured person and a medical adviser, or if the treatment needed is not available in the Grand Duchy"

52 "*The cost of spectacles and other visual aids shall be borne by the sickness fund up to the amounts stated in the tariffs and in accordance with the conditions determined in the agreements or decisions in lieu thereof in accordance with Article 308 bis of the Code des Assurances Sociales.*"

53 "*Without prejudice to Community and international provisions concerning social security of migrant workers and persons treated as such, spectacles are to be supplied to insured persons, in so far as they are permanently or actually resident in Luxem- bourg, by opticians who are registered in the Luxembourg register of trades and established in the Grand Duchy*."

4.2 The question and the answer of the Court

Because the compliance of the national provisions at issue with Community law was uncertain (specifically regarding Articles 30[54] [now Article 34 TFEU] and 36[55] [now Article 36 TFEU] of the Treaty), the *Conseil Arbitral des Assurance Sociales* referred a question to the Court for a preliminary ruling.

It was asked whether Article 60[56] of the Luxembourg *Code des Assurance Sociales* was compatible with Articles 30 and 36 of the EEC Treaty, since it dissuaded the importation, by private individuals, of medicinal products from other Member States.

Mr Decker and the Commission submit that the national rules that prescribe prior authorisation for reimbursement constitute an unjustified barrier to the free movement of goods, while, among others, the Luxembourg government submits that the provisions at issue do not fall within the scope of Articles 30 and 36 of the Treaty since they concern social security.[57]

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[54] "*Quantitative restrictions on importation and all measures with equivalent effect shall, without prejudice to the following provisions, hereby be prohibited between Member States.* "

[55] "*The provisions of Articles 30 to 34 inclusive shall not be an obstacle to prohibitions or restrictions in respect of importation, exportation or transit which are justified on grounds of public morality, public order, public safety, the protection of human or animal life or health, the preservation of plant life, the protection of national treasures of artistic, historical or archaeological value or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute either a means of arbitrary discrimination or a disguised restriction on trade between Member States.*"

[56] Under this Article a social security institution of a Member State A may refuse to reimburse to an insured person, who is a national of Member State A, the cost of spectacles with corrective lenses, prescribed by a doctor established in Member State A but purchased from an optician established in Member State B, on the ground that all medical treatment abroad must be authorised in advance by the above social security institution.

[57] Case C-120/95 *Nicolas Decker v Caisse de maladie des employés privés*, para[30].

Just like in the *Kohll* case[58], the Court underlined how the falling of this particular provisions within the sphere of social security could not exclude the application of the Treaty; only this time is the application of Article 30.[59]

Another point raised by Mr Decker and the Commission, similarly to what was pointed out in the *Kohll* case, is that a system under which reimbursement of the cost of medical products is subject to prior authorisation by the competent institution of that State, where the products are supplied in another Member State, constitutes a restriction on the free movement of goods within the meaning of Article 30 of the Treaty.[60]

The counterargument was that rules such as those at issue do not have the purpose or effect of restricting trade flows, but merely lay down the conditions for the reimbursement of medical expenses. The import, selling and processing of spectacles is not prohibited, and they may be purchased outside of the national territory.[61]

What is observed by the Court is that the rules at issue encourage people insured under the Luxembourg social security scheme to purchase spectacles from, and have them assembled by, opticians established in Luxembourg rather than in other Member States.[62] Moreover, according to said scheme, costs incurred in the State of insurance are not subject to prior authorisation to obtain the reimbursement.

What follows is that these rules must be considered as a barrier to the free movement of goods, since the insured individual is encouraged to purchase the above-mentioned products in Luxembourg rather than in other Member States.[63]

[58] Case C-158/96 *Raymond Kohll v Union des caisses de maladie,* para[21].

[59] Case C-120/95 *Nicolas Decker v Caisse de maladie des employés privés*, para[25].

[60] Ibidem, para[32].

[61] Ibidem, para[33].

[62] Ibidem, para[34].

[63] Ibidem, para[36].

The Luxembourg Government submits that the rules at issue are necessary to control the health expenditure, and are therefore justified.[64]

Mr Decker, instead, claims that, if his purchase were reimbursed, the financial burden on the the budget of the Fund would be the same, as it repays only a flat-rate sum for both frames and corrective lenses sold by an optician. Since said rate is fixed independently of the costs incurred, there is no reason why the Fund should refuse reimbursement if the purchase were made from an optician established in another Member State.[65]

The Court makes clear that reimbursement at a flat rate of the cost of spectacles and corrective lenses purchased in other Member States does not affect on the financing or balance of the social security system[66], just like it did in the *Kohll* case.

Another point submitted by the Belgian, German and Netherlands Governments is that the right of insured persons to have access to quality treatment constitutes a justification for the rules at issue, on the ground of the protection of public health, as provided for by Article 36 of the Treaty[67]. However, the Court points out how the purchase of a pair of glasses from an optician established in another Member State provides guarantees equivalent to those afforded on the sale of a pair of spectacles by an optician established in the national territory thanks to a series of EEC Provisions[68][69]; it should also be noted that said spectacles were purchased on a prescription from an ophthalmologist, which guarantees the protection of public health.[70]

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64 Ibidem, para[37].

65 Ibidem, para[38].

66 Ibidem, para[40].

67 Ibidem, para[41].

68 Ibidem, para[43].

69 Council Directive 92/51/EEC of 18 June 1992 on a second general system for the recognition of professional education and training to supplement Directive 89/48/EEC (OJ 1992 L 209, p. 25); Commission Directive 95/43/EC of 20 July 1995 (OJ 1995 L 184, P. 21), which amended Annexes C and D to Directive 92/51.

70 Case C-120/95 *Nicolas Decker v Caisse de maladie des employés privés*, para[44].

The answer to the case is that Articles 30 and 36 of the Treaty preclude national rules under which a social security institution of a Member State refuses to reimburse to an insured person on a flat-rate basis the cost of a pair of spectacles with corrective lenses purchased from an optician established in another Member State, on the ground that prior authorisation is required for the purchase of any medical product abroad. [71]

4.3 The consequences of the judgement

To understand the implications of this case, we have to first distinguish between products which are covered by the insurance of the competent State and products which are not.

Following the judgement of the Court, individuals that were insured were no longer under an obligation to obtain prior authorisation from the competent insurance organ to receive a full reimbursement for the purchasing of said products abroad (that is as long as they have got a prescription from a doctor that is established in the competent State). In the event that the product purchased abroad is more costly than the one that could be bought "at home", the insurance organ gets to apply its rates, and the difference will be paid by the patient. The only way to obtain a full reimbursement, in this case, was to obtain prior authorisation from the sickness fund, even though a right to approval did not exist.

The safeguard of the financial stability of insurance schemes is very much important. The Court has managed in this case to correctly assess that the only thing that has to be kept under control to this end is the reimbursement of foreign medical products, which is to be limited to the price level of pharmaceutical products in their home territory.

Regarding the medical products that are not covered by the insurance package, there are different implications as a consequence of this judgement.

[71] Ibidem, para[46].

In previous decisions[72], the Court has stated that: "Community law does not detract from the powers of the Member States to organize their social security systems and to adopt, in particular, provisions intended to govern the consumption of pharmaceutical products in order to promote the financial stability of their health care insurance schemes", and that the Member States "may, in order to limit costs, prepare limitative lists excluding certain medical products from the reimbursement scheme in their sickness laws"[73]; the aforementioned limitative lists must be "free from any discrimination to the detriment of imported medicinal preparations. To that end, exclusionary lists must be drawn up in accordance with objective criteria, without any reference to the origin of the products, and they must be verifiable by the importer"[74].

Because in the *Decker* case the products that were part of the dispute were covered by the insurance package of the patient, it is reasonable to believe that the conclusions reached in the *Duphar* case are still to be taken as valid; the consequence of this is a limitation of *Decker*.

If the reasoning of the Court in *Duphar* still holds up in *Decker*, then, it is to be understood that insurance organs are entitled to refuse reimbursement of the cost of products that are included in the limitative lists. Even though a patient may try to obtain a prior authorisation for refund, no such right is in place.

What pharmaceutical companies often do is "split up" the market by selling the same or equivalent product under a different name or packaging in different countries, and this could be a big problem in view of *Decker*. If a patient were to try and buy a prescribed product abroad which was formally not part of his insurance package, but was identical in practice (or at the very least equivalent), he or she would not be able to receive reimbursement.

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[72] Case 238/82 *Duphar* [1984] ECR 523, at 16. See also Case C-249/88 *Commission v Belgium* [1989] ECR I-1275, at 31.

[73] Case 238/82 *Duphar* at 16.

[74] Case 238/82 *Duphar* at 21.

5. A first appraisal of the relevant jurisprudence

What we have seen so far is a series of fascinating events: first and foremost, the Court of Justice has expanded the scope of cross-border mobility for patients through the *Kohll* and *Decker* cases that have been decided in 1998.

Secondly, due to the clarification of the Court on what it meant to seek healthcare inside the territory of the Union, Member States had to keep in mind that their competence over healthcare was getting less absolute than what they thought.

This is particularly true, as the European Union was, and still is, a Union of sovereign nations, where, particularly in the field of healthcare, the last word used to always be left to the Member States.

Thanks to this shift, national governments later convened to bring forth historical changes. On this note, a few things have happened (most importantly the introduction of the European Health Insurance Card), which we will discuss more thoroughly in Chapter 2.

The way in which the Member States decide to address the providing of healthcare for their citizens may vary a lot depending on the political and administrative choices that they make at State level[75]. However, what is common to all the legal systems, when it comes to the social security sphere, is that the rules they contain are to be enforced only inside the borders of the specific country. It is evident, therefore, that a division on the basis of national territory has a decisive influence on what rights are bestowed upon an individual when he seeks treatment.

From the two judgements we can derive that a "neutralisation" of the principle of territoriality of healthcare states has happened[76]: even though the organisation and financing of the healthcare systems are left to the Member States, the European integration has undermined the principle of territoriality profoundly; the *Kohll* and *Decker* cases have demonstrated how in the context of Regulation 1408/71 socially insured citizens may be reimbursed for cross-border healthcare consumption.

The territorial organisation of healthcare (be it national or regional) presents itself with a series of plus sides as well as negatives: smaller regions tend to be easier to administrate and may lend themselves to better providing of services; it is easier to

[75] See more about the competences of Member States and the EU in Chapter III, paragraph 2.1

[76] Hans Vollaard. 2007. *The challenge of patient mobility to healthcare states in the EU*, p.1

provide precise assistance to territories depending on their specific needs (which in turn may be very useful in the case of a public health crisis), and, most importantly, access to healthcare can be easier if smaller realities are not left behind or incorporated with more prominent, sometimes more clumsy, healthcare administrations.

Coming to the negatives we are sometimes reminded, in our daily life, how smaller realities may mean fewer services, less staff and less resources, that in turn have the effect of "forcing" people with more complex needs to seek care somewhere else, and this is where we come to the actual numerical impact of cross-border healthcare which we will analyse in more detail in Chapter 4.

Another negative aspect of the territorial organisation is reflected in the lives of patients living in frontier regions in the moment of need to go to a hospital. They could cross the border and be treated as necessary; however, they may have to travel towards a structure farther away since that is the only one they are entitled to be cured by[77]. This problem is even more evident when the healthcare system they are entitled to suffers from long waiting-lists, while they could if given the right, go where lines are much shorter or non-existent. On this note, such a mechanism was in place for frontier workers. In essence, under Article 19 of Regulation 574/72[78] they had the right to receive medical care both in the State of residence and insurance, but only obtain medical products in the State where they have chosen to "go to the doctors". This mechanism did not apply to the family of the frontier worker unless a case of medical urgency arises and they received prior authorisation of their sickness fund, or the State of residence and the competent institution had concluded an agreement to this effect. What was also ludicrous was that at the

[77] See e.g. A.P. van der Mei, 'Patients' Access to Cross-Border Care and Insurance', in: Alliance nationale des Mutialités Chrétiennes/Association Internationale de la Mutualité, *Competition and Solidarity – Can They Co-exist in Europe's Health Care Systems?*, (AIM, 1997) 68 at 69.

[78] In the case of frontier workers or members of their families, medicinal products, bandages, spectacles and small appliances may be issued, and laboratory analyses and tests carried out, only in the Member State in whose territory they were prescribed or recommended, in accordance with the legislation of that Member State.

moment frontier workers retired, they lost the right to choose on which side of the border they wished to receive medical care.[79]

Different realities have different needs and problems, and while the territorial organisation may address some of them, having the possibility to freely circulate in the territory of the Union and be treated without bearing out-of-pocket costs would solve a lot of problems: for example, there are Member States where a shortage of various types of treatment is present, while in others there is a surplus of the same or comparable types[79]; this alone would bring forth a more balanced use of resources and faster providing of treatment for those in need.

Analysing the data at our disposal, it is undeniable that such management has left its imprint on how citizens act when seeking healthcare. In 1997, a year before the *Kohll* and *Decker* cases, of the public health expenditures, the cross-border consumption of healthcare was estimated at 0,50%[80] within the EU-area, and this is why the role of the Court of Justice comes into play. If on the one hand, the Court expanded the scope of cross-border healthcare with it falling under the freedom of services and goods and the freedom of movement, on the other hand, it allowed limits when they are motivated on the basis of objective, non-discriminatory measures that aim to ensure public health as well as the financial equilibrium of healthcare systems and the maintaining of accessible healthcare facilities.

A problem arises when the Court has accepted the fact that the competent insurance organs may reimburse the cost of medical services or products purchased abroad up to the point where the rates of the competent State that would have applied; the consequence of this is that patients who are in a more favourable financial position may enjoy the most of the outcome of *Decker* and *Kohll*.

When we think of the welfare state, where every citizen enjoys a fundamental right to healthcare, we are imagining a society in which, no matter how much money a

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[79] A.P. van der Mei. 1998. *Cross-Border Access to Medical Care within the European Union – Some Reflections on the Judgements in Decker and Kohll*, p.3

[80] Palm, W., Nickless, J., Lewalle, H. & Coheur, A. (2000), *Implications of recent jurisprudence on the coordination of the health care protection systems* (report at the request of DG Employment and Social Affairs). Brussels: AIM.

person makes, he or she can be cured free of charge thanks to the taxes that are paid by the individual and the community; however, when a patient seeking healthcare or medical products abroad is obliged to pay the difference out of his pocket, less wealthy patients may end up being discouraged (if not flat out prohibited) from going to another Member State to be treated or to buy products, with potentially harsh consequences on his health and on the European integration.
It is unacceptable that a less "better off" person is the one losing from this judgement and its reasoning; the hope is that this trend of a European Union (mostly) for the wealthy will phase out soon if not, the fear is that the European may suffer the consequences.

CHAPTER II

THE EARLY 2000s: FROM THE EUROPEAN HEALTH INSURANCE CARD TO THE WATTS CASE. A LOOK INTO THE DEVELOPMENT OF THE LAW AND THE JURISPRUDENCE OF THE ECJ.

1. The European Health Insurance Card (EHIC): the territorial scope

As Europeans, there are many things that unite us: the passion for sports, the massive historical heritage, and the European Health Insurance Card (EHIC).

What may seem counterintuitive is that this beautiful card is more widespread in the continent of Europe than the EU citizenship itself. One would be led to think of this card as a direct consequence of being a citizen of the Union and nothing more since both its flag and colours are widely present on the front and back of this plastic card.

While it is true that the said card derives from EU law, since it was introduced with Regulations 2003/751/EC[81], 2003/752/EC[82] and 2003/753/EC[83], what is peculiar about it is the scope for the application of its effects.

We have established in the previous Chapter how healthcare services have, by nature, a territorial range that tends to be strictly limited, in its application, to the borders of the competent Member State. Because the EHIC is a 'creature of EU law', it would be fair to assume that its validity was restricted to the territory of the Member States.

This, however, would not be a correct assumption, since the EHIC benefits its holder even when he or she is in certain Extra-EU countries. This fascinating

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81 Regulation 2003/751/EC: Decision No 189 of 18 June 2003 aimed at introducing a European health insurance card to replace the forms necessary for the application of Council Regulations (EEC) No 1408/71 and (EEC) No 574/72 as regards access to health care during a temporary stay in a Member State other than the competent state or the state of residence. OJ L 276, 27.10.2003, pp. 1-3.

82 Regulation 2003/752/EC: Decision No 190 of 18 June 2003 concerning the technical specifications of the European health insurance card. OJ L 276, 27.10.2003, pp. 4-18

83 Regulation 2003/753/EC: Decision No 191 of 18 June 2003 concerning the replacement of forms E111 and E111B by the European health insurance card. OJ L 276, 27.10.2003, pp. 19-21

phenomenon is allowed to manifest due to the fact that the EHIC is not only of EU relevance, but also of EEA[84] relevance (plus Switzerland, which is not an EEA country, but an EFTA[85] country)[86] [87].

1.1 The European Health Insurance Card (EHIC): the legal basis, use and characteristics, with statistics

Now that we have clarified where the EHIC is of relevance, it is appropriate to talk about its legal basis before delving into its use and main qualities.

The Union had the competence to introduce the card on the basis of Article 129 of the Treaty [now Article 168 TFEU] where it was stated that EU institutions should "*contribute towards ensuring a high level of human health protection*".

Regulation 1408/71 and Regulation 574/72 are also referenced multiple times in the 'Whereas' of the Regulations establishing the EHIC.

[84] The EEA is the European Economic Area, an International agreement to which are Contracting Parties: Iceland, Norway, Liechtenstein and the European Union Member States.

[85] The EFTA is the European Free Trade Association, a trade organisation of which are members: Norway, Iceland, Liechtenstein and Switzerland.

[86] Notably, Switzerland has a series of bilateral agreements in place with the European Union, which allow it to participate in the internal market.

[87] At the time of writing it is still uncertain what will come about regarding this topic to the United Kingdom. What is certain is that in 2020 the UK will have to decide whether it still wants the relevant provisions on the EHIC to apply to its citizens or not.

While Regulation 2003/751/EC cites Article 81(a)[88] of the former Regulation and Articles 2(1)[89] and Article 117[90] of the latter[91], Regulation 2003/752/EC references the Administrative Commission Decision No 189/2003[92].

[88] "*The Administrative Commission shall have the following duties:*
(a) to deal with all administrative questions and questions of interpretation arising from this Regulation and subsequent regulations, or from any agreement or arrangement concluded thereunder, without prejudice to -the right of the authorities, institutions and persons concerned to have recourse to the procedures and tribunals provided for by the legislations cof Member States, by this Regulation or by the Treaty; "

[89] "*Models of certificates, certified statements, declarations, applications and other documents necessary for the application of the Regulation and of the Implementing Regulation shall be drawn up by the Administrative Commission. Two Member States or their competent authorities may, by mutual agreement and having received the Opinion of the Administrative Commission, adopt simplified forms for use between them.*"

[90] "*1. One or more Member States or their competent authorities may, after receiving the Opinion of the Administrative Commission, adapt for data-processing the models of certificates , certified statements , declarations, .claims and other documents together with the operations and methods of transmission of the data provided for the implementation of the Regulation and of the Implementing Regulation.*
2. The Administrative Commission shall, when the development of data-processing in the Member States makes it possible, undertake the studies required to standardize and bring into general use the methods of adjustment resulting from the provisions of paragraph 1."

[91] It is worth noting that in its 'Whereas' (2), the Regulation refers to the decision taken in the European Council of 15 an 16 of March 2002, where, at point 34, is stated that "*that a European health insurance card will replace the current paper forms needed for health treatment in another Member State. The Commission will present a proposal to that effect before the spring European Council in 2003. Such a card will simplify procedures, but will not change existing rights and obligations*".

[92] Decision No 189 of 18 June 2003 aimed at introducing a European health insurance card to replace the forms necessary for the application of Council Regulations (EEC) No 1408/71 and (EEC) No 574/72 as regards access to health care during a temporary stay in a Member State other than the competent State or the State of residence.

Regulation 2003/753/EC cites the aforementioned Decision, as well as Administrative Commission Decision No 190/2003[93], Administrative Commission Decision No 187/2002[94] , and Regulations 1408/71 and 574/72.

With these legal bases in mind, we can proceed to define what the EHIC is.
It is a free card that gives the rightful holder access to medically necessary, state-provided healthcare, during a temporary stay abroad, under the same conditions and at the same cost as people insured in that country (this means that treatment free of charge could be provided for the patient in some States). Because each State has a different healthcare system, the card does not guarantee the providing of medical services for free.
The card is not an alternative to travel insurance, since it does not cover any private healthcare or costs, and it is not a mean for reimbursement if the purpose of travel is to obtain medical treatment.
The card is issued for free by the holder's relevant national authority. The said authority decides how long it should be valid for[95]. The card shows the holder's name, date of birth and personal identification number[96]. The information also includes details of the holder's medical insurance organisation. [97]

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[93] Administrative Commission Decision No 190 of 18 June 2003 concerning the technical specifications of the European health insurance card.

[94] Administrative Commission Decision No 187 of 27 June 2002 on model forms necessary for the application of Regulations (EEC) No 1408/71 and (EEC) No 574/72 (E 111 and E 111 B).

[95] Relevant differences are in place when comparing different Member States' legislations on this specific topic. At the time of writing the validity is 6 years in Italy, up to 5 years for the UK and Germany, 2 years in France. As is clear, even within the 4 biggest EU Member States there is no uniformity on the validity of the card, which can in turn lead to some problems. More on this later in this Chapter.

[96] Concerns where raised for the protection of the privacy of the card holders. Specifically in the 1996 report of the European Parliament's Committee on the Environment, Public Health and Consumer Protection, chaired by Giacomo Leopardi (The Leopardi Report). A more detailed analysis of the said document will follow in this chapter.

[97] The information which must be visible on the European card is defined in Article 6 of Administrative Commission Decision No 189.

When an insured person is unable to produce the card, they may be issued a provisional replacement certificate of limited validity.[98]

The card is designed according to a uniform format and specifications to ensure it can be easily recognised by medical staff and insurance companies.[99]

What the card does, is it demonstrates insurance coverage, and since every EU citizen is insured by its national social security scheme, everyone is eligible to get the EHIC[100]. Even a third-country national living temporarily in a Member State is eligible to get it, as long as he is covered by the host country's social security scheme.

To understand the impact of the card, we will provide two graphs with the percentage of people that were insured with a valid EHIC in 2015, as well as its validity period depending on the Member State.

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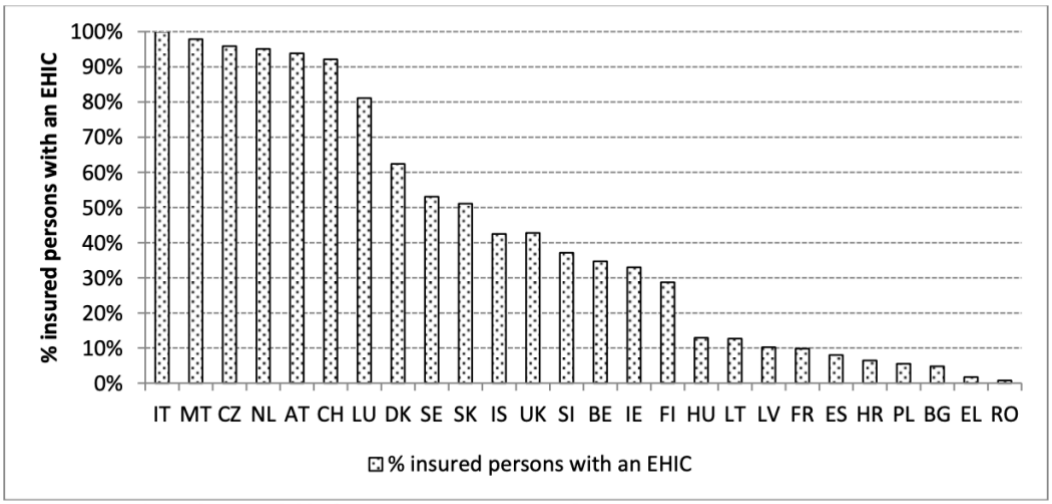
98 "*When exceptional circumstances prevent the person concerned from producing the European card, a provisional replacement certificate in accordance with a uniform model must be made out*." Whereas No 3 of Administrative Commission Decision 190 of 18 June 2003 concerning the technical specifications of the European health insurance card. "*Exceptional circumstances" may be the theft or loss of the European card or departure at notice too short for a European card to be obtained*." Whereas No 6 of Administrative Commission Decision Decision No 189 of 18 June 2003.

99 "*The European card must conform to a single model defined by the Administrative Commission, which should both help facilitate access to health care and help to prevent irregular, abusive or fraudulent use of the card*." Whereas No 4 of Administrative Commission Decision No 189 of 18 June 2003.

100 European Commission 2004 a: 2

% insured persons with a valid EHIC, 2015



* No data available for DE, EE, CY, PT, LI and NO.
Source Administrative data EHIC Questionnaire 2016

The validity period of the EHIC, 2015

MS	Validity period of the EHIC
BE	1 to 2 years (i.e. until 31/12 of the next year)
BG	1 year (economically active persons), 5 years (children), 10 years (pensioners)
CZ	5 years
DK	(max) 5 years, shorter periods for specific cases
DE	several days/weeks to several years (same period of the national card)
EE	max 3 years (adults), max 5 years (children)
IE	4 years
EL	1 year (employed and self-employed), 1 to 3 years (pensioners), app. 6 months (students)
ES	2 years, 12 months (one competent institution)
FR	2 years
HR	3 years (all insured persons), 4 to 5 years (diplomatic personnel)
IT	6 years
CY	max 5 years
LV	3 years
LT	max 2 years (active population), up to 6 years (those insured by State means), max 1 year (students)
LU	3-60 months (proportionate to the length of the insurance record), min 1 year for defined groups registered with an S1
HU	max 3 years (insured persons), max. 4 years for posted civil servants
MT	5 years (subject to the applicant moving to another country throughout the validity period)
NL	1, 3 and 5 years Most competent institutions issue an EHIC for a period of 5 years.
AT	1 or 5 years, 10 years (pensioners)
PL	6 months, 5 years (pensioners), shorter periods in defined cases
PT	3 years
RO	1 year
SI	1 year, 5 years (pensioners and their family members, children)
SK	indefinite (possibility of a limited duration for foreign workers on fixed-term contracts)
FI	2 years
SE	3 years
UK	5 years, 1 year maximum for frontier workers – Gibraltar residents
IS	3 years, 5 years (pensioners)
LI	5 years
NO	3 years
CH	between 3 and 10 years (5 years on average)

Source Update EHIC report 2015 – Table 2 (Pacolet and De Wispelaere, 2015)

From the collected data, a correlation can be drawn between the validity of the card and the number of people that have it. What is not surprising, following this logic,

is that Italy is at the top of the first graph, having a validity of 6 years, while France and Spain are at the bottom with their "short" 2 years.
Somewhat surprisingly, the card does not contain medical data. It is arguably a choice that is hard to justify, specifically in the light of a better European integration as an end that this card definitely should have pursued.

In order to understand where we are today, it is appropriate to analyse the historical development that brought to life such a tool. After the next subparagraph, it will become apparent how the political context of the years that preceded its creation has had an influence over the way the EHIC works.

1.2 The European Health Insurance Card (EHIC): some historical mentions and the Leopardi report

The concept of a card such as the one we have today goes back to the late 1970s. All the way up to its creation, many suggestions and indications were made by the Council[101], the Europan Parliament[102], the Commission[103], and the European Council[104].
What was apparent was the need to have a system that allowed for further harmonisation in the field of social security, and specifically healthcare. As we have discussed previously in Chapter 1, the Treaty provided already for the freedom of movement of persons (specifically migrant workers). Such an environment cannot aim for a truly efficient movement if the individual finds his or her social security sphere not adequately protected at the Community level.

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101 In 1978, the health ministers of the Member States that were meeting in the Council expressed their interest in a European health card, and stimulated the Commission to formulate proposisions on the topic.

102 In 1981 the European Parliament argued in favour of a common European health card.

103 In 1983 the Commission recommended adopting an emergency health card.

104 In 1986 the European Council supported the recommendation of the commission with a Resolution which specified that "in order further to protect the health of European citizens and to enhance their freedom of movement, [it was] desirable to provide for means whereby in an emergency their pre-existing or present health problems can be identified".

As also mentioned in the previous Chapter, it was possible, thanks to the many forms provided by EC law, to travel in the territory of the Community and receive medical treatment as well as medical products, whether it was planned or it was an emergency. However, problems had yet to be tackled when it came to the coordination of medical records of the patients[105].

An important step in the process that brought us closer to the creation of the card is the 1996 Leopardi Report[106]. What it did was call the Commission to create "*a European health card to be issued to every European citizen*" while stating reasons to support its development.

It referenced the Treaty on the European Union where it provides for the introduction of the European citizenship[107]: this introduction would aim to ease the daily life of its citizens while increasing the protection of their rights and interests. What can be derived from this is a strong link between EU citizenship and the fundamental freedom of movement, whose 'quality of enjoyment' should always be improved. A necessary implication is that the rights of the individual are not 'left at the door' when he or she departs from his own country.

It was considered technically possible already, at the time, to introduce a health card which could be used in all the countries of the European Union and outside its borders. What this reasoning argues against is, in essence, the inhomogeneity of the paperwork that each Member State provided for its citizens when it came to social security (and specifically healthcare). A European health card could, theoretically, solve two problems in one fell swoop: it could reduce bureaucracy, and it could harmonise a fundamental aspect of the life of an EU citizen, its social security sphere.

It is also specified that the 1995 data protection Directive[108] provided the legal framework for the confidentiality of data entered on health cards. As it is

[105] Problems which, we will see, are yet to be completely solved.

[106] Report of 26 March 1996 on the European health card - Legislative initiative pursuant to Article 138b, paragraph 2, of the EC Treaty.

[107] 'Whereas A.' of the European Parliament Resolution on the European health card.

[108] Directive 95/46/EC. No longer in force, repealed in 2018.

understandable, the health data of an individual is very sensible and must be treated with the utmost care.

The card, the Report stated, should never be used as a surveillance tool for public authorities of whatever nature[109].
It can always be concerning when a new mean of identification is introduced at State level, since, as has disgracefully happened in the past, discrimination and surveillance can be the consequence of its creation.
This topic was particularly on point in the historical context where it came about: in 1996 there was a general distrust of the EU due to a series of occurrences that we will analyse more in detail in this Chapter.
What must be kept in mind is that this tool, at the time, could very well have been conceived as an EU ID, which in turn would have raised many eyebrows due to its potential danger. To put it plainly, if a wary citizen is always careful when a new identification method is issued, imagine the impact of a supra-national ID in the mind of the said citizen.

The Report also recommended that the information on the card should not be held in any data file, but should appear only on the card itself. The citizen would, therefore, be able to decide what data should appear, and could have the right to omit certain information; to change the information on the card should be easy, and its issuing should not involve the cardholder any expense[110].
From the point of view of the aforementioned Directive on the protection of personal data, the conditions set out by the Report are certainly to be applauded.
A problem with this model, however, arises when a citizen loses its card: since its data would not have been kept in any database, the card would have had to be issued from scratch, which would prove cumbersome[111].

[109] 'Whereas H.' of the European Parliament Resolution on the European health card.

[110] Idlib.

[111] The consequence of this is, ironically, that the objective of the reduction of beuracracy fails to be achieved.

This Report has created a legacy that brought us closer together as Europeans, as it managed to introduce concepts that carried over in time and helped shape the EHIC to what it is today.

1.3 The scandal of the Santer Commission and the 'renaissance' of the Prodi Commission

In 1999, only three years after the Leopardi Report, a crisis struck the Union, as the Santer Commission collectively resigned.

Serious allegations were raised against the Commission for regarding the mismanagement of funds, as well as its overall conduct. For these reasons the European Parliament voted in favour of a resolution that called for the setting-up of a committee of outside experts that would scrutinise how the Commission handled fraud, mismanagement and nepotism[112]; all of this was based on the provisions of the Treaty of Amsterdam that required the Commission to ensure greater openness, vis-à-vis citizens[113].

After two months of examination and deliberation, on the 15th of March 1999, the "Committee of Independent Experts" presented its first Report. It confronted the charges brought against the Commissioners, and while it mostly answered negatively to them[114], it 'broke the camel's back' stating that "*the studies carried out by the Committee have too often revealed a growing reluctance among the members of the hierarchy [of the Commission] to acknowledge their responsibility. It was becoming increasingly difficult to find anyone who has the slightest sense of responsibility*"[115]. Hours later the Commission collectively resigned.

It is not hard to see why such an event can have massive implications on the policies that the Union will enact: a weak Commission means weak propositions, which in turn will constitute a more fragile Union.

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[112] European Parliament Resolution of 14 January 1999 point 1.

[113] As referenced in idlib, letter A.

[114] The exception is the French Commissioner Edith Cresson.

[115] Committee of Independent Experts**,** First Report on Allegations regarding Fraud, Mismanagement and Nepotism in the European Commission, 15 March 1999, 9.4.25, p.144.

It is during these crucial years that the story of the European Health Insurance Card will find a turning point.

Merely days after the resignation of the Santer Commission, and "after 10 minutes of discussion"[116], the European Council supported the Prodi Commission in March 1999, and the European Parliament approved the choice in early May.

Notwithstanding the massive amount of reforms that were brought forth by the Prodi Commission regarding the accountability of the EU officials, it is fair to say that this is the Commission that gave birth to the European Health Insurance Card we all know today.

The next stepping stone in this chronological travel of ours is, therefore, put in place by the Commission, which was tasked to deliver propositions on the matter before the 2003 Spring European Council meeting[117].

The Commission delivered on the task, concluding that the card was "an ambitious project serving the interests of a real citizens' Europe"[118].

What the Commission did next was urge the Member States to 1. Change their legislation in order to have all insured persons be entitled to the same level of care[119], and 2. To remove the formalities that were needed for the obtainment of care or the presentation of the form.[120]

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116 Peterson J. 2002: 'The College of Commissioners', in J. Peterson and M. Shackleton (eds.) The Institutions of the European Union. Oxford: Oxford University Press, 79.

117 European Council 2002; pts 33,34.

118 As stated in the conclusion of the Communication from the Commission concerning the introduction of a European health insurance card /* COM/2003/0073 final */.

119 The differences in the way Member States categorised insured citizens were considered by the Commission "a complicating factor [that] could increase the cost, in that the cards would have to carry a means of identifying the 'category' of the insured, and the producers for checking entitlement between social security institutions would be more involved", European Commission 2003 a: 11.

120 What happened was that, in some Member States, the insured had to go to the competent social security institution of the place of stay before having the possibility to see a care provider; the introduction of the card would eliminate this requirement. It cannot be understated how much of a benefit the card was (and is) for the citizen, as it removed unnecessary formalities and made everyones' lives better.

In June 2004 the EHIC was first issued and depending on the Member State, it is either widely used or rarely so.

The future of the card is looking neither bright nor dark: it is a handy tool that is used by many every day, and will probably continue to be so for the foreseeable future.

One might hope for an expansion of the uses of this card, from a better-implemented harmonisation of the healthcare systems, all the way to a European identity number (along the lines of the Social Security Number that is in place in the United States of America), however, this does not look like it is going to happen anytime soon.

As long as we keep this card with us, we will all have a piece of Europe in our pocket.

2. Regulation 883/2004[121]: the legal basis and the content

Things are finally starting to take form, albeit slowly. The introduction of the European Health Insurance Card has been revolutionary: not only because of its magnitude and scope but also because of what it represents. It is a symbol of a truly united Europe. Even though today it is more of a token than a tool to many people, it still is a marvellous and concrete manifestation of the Union in the lives of its citizens.

We have mentioned the term ‘harmonisation’ a lot in our discourse, and rightfully so, since when it comes down to building a ‘well-oiled’ European machine, its components have to work together as one in order for it to run.

[121] Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems, *OJ L 166, 30.4.2004, p. 1–123.*

Before analysing the content of the Regulation, it is appropriate for us to examine its legal basis. Article 42[122] TEC [now Article 48 TFEU] and Article 308[123] TEC [now Article 352 TFEU] are the primary law sources upon which the Regulation is based. It is also worth noting that the provision was created taking into account the proposal from the Commission presented after having consulted with the social partners and the Administrative Commission on Social Security for Migrant Workers[124], as well as the opinion of the European Economic and Social Committee[125].

Regulation 883/2004 was created with the aim to coordinate the social security legislation of the Member States. The previous relevant provision in this field, Regulation 1408/71, had been drafted thirty-three years earlier and had been amended and updated many times in order to take into account both the developments at the Community level (in which the judgements of the Court of Justice play a significant role), and the changes in legislation at the national level. These factors made it so that Community coordination on the relevant topic began to be complicated and lengthy. The introduction of Regulation 883/2004 comes into play with the objective in mind to modernise and simplify the coordination rules, which is an essential task for the achievement of true freedom of movement of persons. Individuals moving in the territory of the Community must be guaranteed by the coordination rules the retainment of the rights and advantages acquired as

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122 "*The Council shall, acting in accordance with the procedure referred to in Article 251, adopt such measures in the field of social security as are necessary to provide freedom of movement for workers; to this end, it shall make arrangements to secure for migrant workers and their dependants:*

(a) aggregation, for the purpose of acquiring and retaining the right to benefit and of calculating the amount of benefit, of all periods taken into account under the laws of the several countries;

(b) payment of benefits to persons resident in the territories of Member States. "

123 "*If action by the Community should prove necessary to attain, in the course of the operation of the common market, one of the objectives of the Community, and this Treaty has not provided the necessary powers, the Council shall, acting unanimously on a proposal from the Commission and after consulting the European Parliament, take the appropriate measures."*

124 OJ C 38, 12.2.1999, p. 10.

125 OJ C 75, 15.3.2000, p. 29.

well as those in the course of being received. It is also important to subject them to the social security scheme of only one Member State, as to avoid overlapping of the applicable provisions of national legislation and the complications which could result therefrom.

Regulation 883/2004 introduced some 'general principles'[126], one of which is the principle of good administration, which is crucial for the smooth implementation of rules in a context of cooperation.

This principle was already mentioned in Regulation 1408/71[127]and was reiterated in Article 76 of Regulation 883/2004.

In order to to see the bigger picture, we have to look at the Implementing Regulation[128], which aims at the simplification of procedures and at the reduction of the time that institutions take for the response and processing of cross-border cases in the context of social security.

Regulation 987/2009 is based on Article 42 TEC and 308 TEC, just like Regulation 883/2004, as well as Article 89[129] of the aforementioned provision.

Regulation 987/2009 contains in Article 2 the scope and rules for exchanges between institutions in the context of data sharing and modes of data transfer and

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126 Commentators are often in disagreement on how many and which are these principles. Those generally recognised are the equal treatment, the aggregation of periods, the export of benefits and the applicable legislation, as well as the good cooperation and administration. – Yves Jorens and Filip Van Overmeiren, *General Principles of Coordination in Regulation 883/2004*, 2009

127 In Article 84 it is stated that *"The competent authorities of Member States shall communicate to each other all information regarding : (a) measures taken to implement this Regulation; (b) changes in their legislation which are likely to affect the implementation of this Regulation.*

For the purposes of implementing ' this Regulation , the authorities and institutions of Member States shall lend their good offices and act as though implementing their own legislation. The administrative assistance furnished by the said authorities and institutions shall, as a rule, be free of charge. However, the competent authorities of the Member States may. agree to certain expenses being reimbursed."

128 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 (OJ L 284, 30.10.2009, p. 1–42.

129 "*A further Regulation shall lay down the procedure for implementing this Regulation.*"

in Article 3 the scope and rules for exchanges between the beneficiaries and the institutions. These Articles and what they contain are clearly based on the principle of good administration, as they have the intention to decrease the consequences of administrative complications when it comes to the enforcement of the rights of the beneficiaries. The Regulation also provided for stringent deadlines for the presentation of claims, for the resolution of disputes and for the payment of reimbursements between institutions in the context of settlements between the Member States.

When it comes to the impact of Regulation 883/2004, there is a particular field where it is most noticeable: the electronic exchange of data.
Regulated in Article 78, it states that "*Member States shall progressively use new technologies for the exchange, access and processing of the data required to apply this Regulation and the Implementing Regulation*". There is also a reference to this topic in 'Whereas (3)' of Regulation 987/2009[130]
It is easy to see why such an issue is of massive relevance in today's world: just for the sake of simplification, new technologies can produce incredible results that provide for less bureaucracy and hassle for the citizens and the Administrations. Better coordination between institutions is another logical consequence of this provision, as more advanced technology implies superior tools to tackle problems that inevitably arise. There is also an advantage for the citizen, as his data is more flawlessly available to him: e-health apps on the smartphone are very much relevant on this topic, and they will be discussed more in-depth in Chapter 4.

[130] "*Electronic communication is a suitable means of rapid and reliable data exchange between Member States' institutions. Processing data electronically should help speed up the procedures for everyone involved. The persons concerned should also benefit from all the guarantees provided for in the Community provisions on the protection of natural persons with regard to the processing and free movement of personal data.*"

As we previously mentioned, the work of the ECJ is of high relevance to our discussion regarding the evolution of cross-border patient mobility in the EU, which is why we are going to focus on a 2006 case, the *Watts* case[131].

3. The *Watts* case. The applicability of Article 49 EC and the reimbursement for the accessing of foreign healthcare systems

The *Watts* case is a crucial stepping stone, as it is linked with most, if not all, of the provisions and jurisprudence we discussed previously.

It represents a turning point for the field of cross-border patient mobility, as it answers questions that were not discussed in the prior jurisprudence. In Chapter 1 we have seen how the *Kohll* and *Decker* judgements dealt mostly with the issue at hand without delving too much in the specifics of the national social security schemes; just like the Court mentioned there, Community law does not detract from the sovereignty of the Member States in the said field.

In the *Watts* case, questions about the duties of the healthcare institutions have risen, specifically when it comes to the assessment of the clinical situation of the patient. This is linked to Regulations 1408/71 and 883/2004 that we previously mentioned, as the case is concerned with the issuing of an E-112 form, as well as the administrative responsibility of the healthcare providers of the State of affiliation of the patient when it comes to prior authorisation and a system of waiting lists.

3.1 The facts

Mrs Watts is a UK citizen who suffered from arthritis of the hips. She made enquiries of Bedford Primary Care Trusts ('Bedford PCT') as to the possibility of her undergoing surgery abroad under the E-112 scheme.

It is useful to bear in mind that during this time, in 2002, the E-forms were still an essential tool at the disposal of the citizen in order to obtain healthcare abroad. The E-111 form was still present for emergency treatment (although it would soon be replaced by the European Health Insurance card) as well as the E-112 form, which

[131] Case C-372/04, Judgment of the Court (Grand Chamber) of 16 May 2006. *The Queen, on the application of Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health*, European Court Reports 2006 I-04325.

a citizen could use to ask the relevant insurance institution for the obtainment of medical care in another Member State.

In October of 2002, Mrs Watts met with a UK consultant who informed Bedford PCT that she was "*as deserving as any of his other patients with severe arthritis, that her mobility was severely hampered and that she was in constant pain*"[132]. What seems strange, however, is that he classified her case as 'routine', which in turn would constitute a waiting time of close to one year in order to receive surgery in a local hospital.

In November 2002, Bedford PCT informed Mrs Watts that the authorisation for the receiving of treatment abroad was rejected on the basis of Article 22(2) of Regulation 1408/71, according to which "*The authorisation […] may not be refused where the treatment in question cannot be provided for the person concerned within the territory of the Member State in which he [or she] resides*". It was considered that Mrs Watts would receive the treatment she needed in a local hospital "*within the government's NHS Plan targets […] without undue delay*"[133].

Mrs Watts proceeded to apply for judicial review of the refusal decision in December 2002.

At the beginning of January 2003, Mrs Watts met with a consultant in France who told her that her need for surgery was becoming more urgent due to deterioration in her State of health.[134]

On the 22nd of January 2003, in front of the High Court of Justice of England and Wales, Queen's Bench Division (Administrative Court), The Secretary of State for Health and Bedford PCT suggested, consequentially, the re-examination of the Decision.

On the 31st of January 2003, Mrs Watts was re-examined by the same consultant who had examined her in October 2002. He stated afterwards that Mrs Watts should be categorised as a patient requiring surgery 'soon'. This classification would put her in a category that is between the most urgent cases and the routine cases, which

[132] Idlib, par.25.

[133] Idlib, par.26.

[134] Idlib, par.28.

in turn would mean waiting time of, approximately, three or four months for the surgery.[135]

In February 2003, the request for the issue of the E-112 form was once again rejected, only this time it was on the grounds of the reduction of the waiting time due to the reassessment of the situation of Mrs Watts; according to Bedford PCT, no undue delay was in place.

On the 7th of March 2003, Mrs Watts underwent a hip replacement operation in France, where she paid for the surgery out of her own pocket around GBP 3.900. She then continued her application for permission to apply for judicial review of the refusal, claiming, in addition, the reimbursement of the medical fees incurred in France.

On the 1st of October 2003, the High Court of Justice of England and Wales, Queen's Bench Division (Administrative Court), held that the medical services that Mrs Watts received in France fell within the scope of Article 49 EC [now Article 56 TFEU][136], notwithstanding the fact the reimbursement of the costs of the treatment received is applied for under the NHS.[137]

The Court found that "*any national authority properly directing itself in accordance with the principles laid down by the [Court of Justice][138] would have been bound to conclude in October-November 2002 that the anticipated delay of approximately one year was 'undue', and thus such as to trigger the claimant's right under Article 49 EC [now Article 56 TFEU] to reimbursement of the costs of obtaining more timely treatment in another Member States*"[139]. It also stated that after the reassessment in 2003, no undue delay would have been faced by Mrs Watts. Therefore, a waiting time between three and four months was not a valid

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[135] Idlib, par.29.

[136] The Court came to this conclusion after having reserved judgement on the case until the delivery of a Case of the Court of Justice (Case C-385/99 *Müller-Fauré and van Riet* [2003] ECR I-4509).

[137] Case C-372/04, *Watts* [2006], at 33.

[138] In Particular Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473 and *Müller-Fauré and van Riet.*

[139] Case C-372/04, *Watts* [2006], at 34.

reason for her to receive treatment abroad and to claim reimbursement of the costs from the NHS. Consequentially, the application of Mrs Watts was dismissed.
Both Mrs Watts and the Secretary of State for Health proceeded to appeal against the judgement: the former based her action on the dismissal of her application for reimbursement and on the considerations set out in the judgement according to which the waiting time applicable in national law is a relevant factor in applying Article 49 EC [now Article 56 TFEU] and an element of fundamental importance in the context of Article 22 of Regulation 1408/71. The latter based its appeal on the argument that NHS patients are not entitled to rely on Article 49 EC so that the case involving Mrs Watts should solely be under the scope of Article 22 of Regulation 1408/71.

3.2 Necessary clarifications of the Court before examining the questions.

With clarity and conciseness in mind, we are going to structure this subparagraph following the order in which the Court of Justice answers the questions.

Before dissecting the response of the Court the numerous questions, it is necessary to present some preliminary considerations that it makes.
First and foremost, it is clarified how the applicability of Article 22 of Regulation 1408/71 to the present case does not, preclude it from also falling within the scope of Article 49 EC [now Article 56 TFEU][140].
Moreover, the fact that a national measure may be consistent with a provision of secondary legislation, in this case, Article 22 of Regulation 1408/71, does not have the effect of removing that measure from the scope of the provisions of the Treaty[141]. On this line of reasoning, it is evident the footprint left by the *Kohll* case[142], which the judgement references towards since the issue on this specific matter is very much similar.

[140] Case C-372/04, *Watts* [2006], par.46.

[141] Idlib par.47.

[142] Case C-158/96, *Kohll* [1998], par.25.

It is also specified in paragraph 48 of the judgement, that the applicability of Article 22 of Regulation 1408/71 to the situation in question does not mean that the person concerned may not simultaneously have the right under Article 49 EC [now Article 56 TFEU] to have access to healthcare in another Member State under rules on the assumption of costs different from those laid down by Article 22[143].

With these clarifications in mind, we may now follow through with the actual questions and answers.

3.2.1 The crucial role of the medical assessment for the refusal of the authorisation.

The ECJ starts by answering Question 5[144], clarifying that it already interpreted the second condition set out in Article 22(2) of Regulation 1408/71 in the *Inizan* judgement[145] accordingly to the reading of the term 'undue delay' it reached in *Smits and Peerbooms*[146], and in *Müller-Fauré and van Riet*[147], when it comes to the compatibility with Article 49 EC [now Article 56 TFEU] "*of a national provision making the assumption of the cost of hospital treatment planned in another Member State subject to a requirement that that treatment is necessary*".[148]

As was pointed out in the Opinion of Advocate General Geelhoed, there was no reason which would justify different interpretations depending on whether the context is Article 22 of Regulation 1408/71 or Article 49 EC [now Article 56 TFEU]. This was because in both cases the question was whether the hospital

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143 See Case C-368/98 *Vanbraekel and Others* [2001] ECR I-5363, par.37 to 53.

144 "*On the proper interpretation of Article 22(1)(c) of Regulation No 1408/71 and in particular the words "within the time normally necessary for obtaining the treatment in question":*

a) Are the applicable criteria identical with those applicable in determining questions of "undue delay" for the purposes of Article 49 EC?

b) If not, to what extent is it necessary or permissible to have regard to the matters set out in Question 4?", Case C-372/04, *Watts* [2006], par.42.

145 Case C-56/01 Inizan [2003] ECR I-12403, par.45-46.

146 Case C-157/99 *Smits and Peerbooms*, par.103-104.

147 Case C-385/99 *Müller-Fauré and van Riet*, par.89-90.

148 Case C-372/04, *Watts* [2006], par.59.

treatment required by the patient's medical condition could be provided on the territory of the Member State of residence within an acceptable time, which in turn would ensure its usefulness and efficacy.[149]

The Court held in the *Inizan* case that the aforementioned condition, which is contained in Article 22(2) of Regulation 1408/71, is not satisfied whenever it is apparent that the same treatment or an equally effective one can be obtained without undue delay in his Member State of residence.[150] What follows is that, in order to determine whether treatment which is equally useful for the patient can be obtained without undue delay in the Member State of residence, the competent institution is required to have regard to all the circumstances of each specific case, taking due account not only of the patient's medical condition at the time when authorisation is sought but also of the nature of the disability, the degree of pain, and the medical history.[151]

The consequence of this is that the competent institution cannot base its Decision exclusively on the existence of waiting lists on that territory without taking account of the specific circumstances of the patient's medical condition.[152]

The Court of Justice recognises the possibility to institute waiting lists, should the need arise. However, in order to be entitled to refuse the authorisation referred to in Article 22(1) of Regulation 1408/71 on the ground of waiting time, the competent institution must establish that the waiting time does not exceed a period which is acceptable in the light of an objective medical assessment of the clinical needs of the person concerned, taking into account its medical condition and personal history, as well as the probable course of his illness, the degree of pain and the nature of his disability at the time when the authorisation is sought.[153]

If the waiting time arising from the general planning objectives does not exceed a medically acceptable waiting time within the terms stated above, the competent

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149 Idlib, par.60.

150 Case C-56/01 *Inizan* [2003] ECR I-12403, par.45.

151 Case C-56/01 *Inizan* [2003] ECR I-12403, par.46.

152 Case C-385/99 *Müller-Fauré and van Riet*, par.92.

153 Case C-372/04, *Watts* [2006], par.68.

institution is entitled to find that the condition is not satisfied and may, therefore, refuse to grant the authorisation sought by the patient.[154]

The Court also held that the financial planning of Member States, when it comes to healthcare, is taken into account by the relevant provisions.
In fact, if patients were able to travel and receive healthcare of equivalent kind to the one they could have obtained without undue delay by remaining in the State of residence, the allocation of resources of Member States in the healthcare sector would be compromised.
The Court stated, however, that the fact that the cost of the hospital treatment envisaged in another Member State may be higher than it would have been, had it been provided in a hospital covered by the national system in question, cannot in such a case be a legitimate ground for refusing authorisation.[155]
The fact that granting the permission would oblige a national health service to establish an *ad hoc* financial mechanism, which in turn would enable the said service to satisfy the request for reimbursement from the institution of the host Member State, is also not a legitimate ground for refusing authorisation[156].

In essence, the answer to the fifth question is that, in order to be entitled to refuse to grant the authorisation referred to in Article 22(1)(c)(i) of Regulation 1408/71 on the ground that there is a waiting time for hospital treatment, the competent institution is required to establish that the said time does not exceed the period which is acceptable on the basis of an objective medical assessment of the clinical needs of the person concerned in the light of all of the factors characterising the medical condition at the time when the request for authorisation is made or renewed.[157]

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154 Idlib, par.70

155 Idlib, par.73.

156 See to that effect Case C-385/99 *Müller-Fauré and van Riet*, par.105.

157 Case C-372/04, *Watts* [2006], par.79.

3.2.2 The existence of waiting lists is not, by itself, a valid ground to refuse the authorisation.

The referring court asks, in the first four questions[158], whether and in what circumstances an NHS patient is entitled, under Article 49 EC, to receive hospital treatment in another Member State at the expense of that national service.[159]

First, it is established by the Court of Justice that Article 49 EC is relevant to the case, and that the way in which the NHS operates when it comes to the reimbursement mechanism is irrelevant to the matter at issue. [160]

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158 "*The first question asks whether, given the particular characteristics of the NHS, a person residing in the United Kingdom is entitled under that article to receive hospital treatment in a Member State other than the United Kingdom at the expense of the NHS. As part of that question, the referring court asks in particular whether, in interpreting Article 49 EC in such a context, account should be taken, first, of the fact that there is no fund available to NHS bodies out of which such treatment may be paid for, and, second, of the fact that there is no duty on the NHS to pay for hospital treatment received by an NHS patient in a private hospital in England or Wales. It also asks whether the failure to request authorisation or notify the competent NHS body in advance has a bearing on the interpretation of Article 49 EC.*

By the second question, the referring court asks whether, in order to answer the first question, it is necessary to determine whether hospital treatment provided by the NHS constitutes services within the meaning of Article 49 EC.

By the third question, it asks, on the assumption that that provision is applicable, whether a series of factors which it lists may validly be relied upon by the national competent authorities in refusing to grant the prior authorisation necessary in order for the NHS to assume the costs of hospital treatment to be obtained in another Member State.

The fourth question, which coincides with the third, asks which factors may or must be taken into account in determining whether the hospital treatment required by the patient's state of health may be provided without undue delay in an NHS establishment and whether, consequently, the authorisation sought by that patient for reimbursement of the cost of treatment to be obtained in another Member State may be refused by the competent institution." Case C-372/04, *Watts* [2006], par.81-84.

159 Idlib, par.80.

160 "*According to settled case-law, medical services provided for consideration fall within the scope of the provisions on the freedom to provide services (see, inter alia, Case C-159/90 Society for the Protection of Unborn Children Ireland [1991] ECR I-4685, paragraph 18, and Kohll, paragraph 29), there being no need to distinguish between care provided in a hospital environment and care*

Secondly, it is underlined by the Court that, while Community law does not detract from the power of the Member States to organise their social security systems when exercising the said legislative power, the Member States must comply with Community law, and in particular the provisions on the freedom to provide services[161], which prohibit the Member States from introducing or maintaining unjustified restrictions on the exercise of that freedom in the healthcare sector.[162]
The Decision of the 20th of February 2004 of the referring Court made it so that NHS patients cannot have treatment paid for by the NHS in a hospital of a different Member State without prior authorisation. It is found by the ECJ that the said system may deter or prevent the patients concerned from applying to providers of hospital services established in another Member State, and, therefore, constitutes an obstacle to the freedom to provide services.[163] As previously mentioned in Chapter 1, it is possible for such a restriction to be justified on the grounds of serious risk of undermining the financial balance of the social security system[164];

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provided outside such an environment (Vanbraekel, paragraph 41; Smits and Peerbooms, paragraph 53; Müller-Fauré and van Riet, paragraph 38; and Inizan, paragraph 16).

It has also been held that the freedom to provide services includes the freedom for the recipients of services, including persons in need of medical treatment, to go to another Member State in order to receive those services there (see Joined Cases 286/82 and 26/83 Luisi and Carbone [1984] ECR 377, paragraph 16).

The fact that reimbursement of the hospital treatment in question is subsequently sought from a national health service such as that in question in the main proceedings does not mean that the rules on the freedom to provide services guaranteed by the Treaty do not apply (see to that effect Smits and Peerbooms, paragraph 55, and Müller-Fauré and van Riet, paragraph 39). It has already been held that a supply of medical services does not cease to be a supply of services within the meaning of Article 49 EC on the ground that the patient, after paying the foreign supplier for the treatment received, subsequently seeks the reimbursement of that treatment from a national health service (see Müller-Fauré and van Riet, paragraph 103)." – Case C-372/04, *Watts* [2006], par.86-89.

161 See *Smits and Peerbooms*, par.44-46; *Müller-Fauré and van Riet*, par.100; and *Inizan*, par.17.

162 Case C-372/04, *Watts* [2006], par.92.

163 Idlib, par.98. See also *Smits and Peerbooms*, par.69, and *Müller-Fauré and van Riet*, par.44.

164 Idlib, par 103. See *Kohll*, par.41; *Smits and Peerbooms*, par.72; and *Müller-Fauré and van Riet*, par.73.

maintaining a balanced medical and hospital service open to all[165]; guaranteeing the treatment capacity or medical competence on national territory[166], but this is not the case.

In paragraph 113 the Court finds that Community law does not preclude the right of a patient to receive hospital treatment in another Member State, at the expense of the system with which he is registered, from being subject to prior authorisation. However, it continues in the subsequent paragraph, the conditions attached to the grant of such approval must be justified in the light of overriding considerations (like those previously mentioned) that must satisfy a requirement of proportionality[167].

To sum up, the Court held that: Article 49 EC does apply to the case at issue, and it does not preclude reimbursement of the cost of hospital treatment to be provided in another Member State, from being subject to the grant of prior authorisation by the competent institution.
A refusal to grant prior permission cannot be based on the mere existence of waiting lists without carrying out an objective medical assessment of the patient's medical condition[168]. Where the delay arising from such waiting lists exceeds an acceptable time, the competent institution may not refuse the authorisation on the ground of the existence of the said waiting lists.

[165] Idlib, par 104. See *Kohll*, par.50; *Smits and Peerbooms*, par.73; and *Müller-Fauré and van Riet*, par.67.

[166] Idlib, par 105. See *Kohll*, par.51; *Smits and Peerbooms*, par.74; and *Müller-Fauré and van Riet*, par.67.

[167] See *Smits and Peerbooms*, par.82, and *Müller-Fauré and van Riet*, par.83.

[168] Case C-372/04, *Watts* [2006], par.119.

3.2.3 The reimbursement of the costs sustained must be in full.

The Court begins to answer question 6[169] by establishing that the rules for reimbursement to be applied are the ones of the host Member State[170]; it is also specified that the competent institution remains responsible for the subsequent compensation in favour of the institution of that State[171].

It must also be established whether a patient is entitled, according to Article 49 EC, to receive from the competent institution "*a greater proportion of the cost of hospital treatment received in the host Member State than would be the case under the provisions of the legislation of that State*"[172].

It is pointed out in the judgement that the Court already held in previous case law that, the fact that the legislation of the competent Member State does not guarantee a patient (who has been authorised to receive hospital treatment in another Member State) covered by that legislation a level of payment equivalent to that to which he would have been entitled if he had received hospital treatment in the competent Member State is to be considered an unjustified restriction of the freedom to provide services[173]. Where the law of the host Member State does not provide for the reimbursement in full of the cost of hospital treatment in that State, the competent institution must reimburse the patient with the difference between the cost of the equivalent treatment and the amount refunded by the institution of the State (when

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169 "*By this question, the referring court asks essentially whether the reimbursement which a Member State is required by Community law to provide of the cost of hospital treatment in another Member State should be calculated under Article 22 of Regulation No 1408/71 by reference to the legislation of the Member State in which that treatment was provided (the host Member State), or under Article 49 EC by reference to the legislation of the Member State of residence of the patient (the competent Member State). It also wishes to know whether the fact that the hospital treatment is provided free of charge by the national health service in question and the fact that there is therefore no tariff for reimbursement in the legislation of the competent Member State have any bearing on that question. It also asks whether the obligation to fund hospital treatment provided in the host Member State includes the travel and accommodation costs.* " Idlib, par.124.

170 Idlib, par.126.

171 As provided for in Article 36 of Regulation 1408/71. See also *Vanbraekel*, par. 33.

172 Case C-372/04, *Watts* [2006], par.128.

173 See Vanbraekel, par.43-52.

the first amount is higher than the second)[174] Travel and accommodation costs are included as well in the context of reimbursement[175].

These points established by the Court are in line with Article 22(2) of Regulation 1408/71, in that its purpose is to confer on patients covered by the legislation of one Member State, that received authorisation to access treatment in another Member State, on conditions of reimbursement that are as favourable as those enjoyed by patients covered by the legislation of the other State.[176]

3.2.4 The role of Article 152(2) EC implies a possibility for the Member States to adapt their legal systems.

Regarding question 7[177], it is held by the Court that reimbursements do not ignore budgetary considerations, but rather are based on the need to balance the objective of the free movement of patients against overriding national aims relating to the management of the available hospital capacity, control of health expenditure and financial balance of social security systems. [178]

Article 152(2) EC[179], while stating that Community action in the field of public health has to respect the responsibilities of the Member States for the organisation and delivery of health services and medical care, it does not exclude the possibility that the Member States may be required to make adjustments to their national

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[174] Case C-372/04, *Watts* [2006], par.131.

[175] Idlib, par.134.

[176] See *Vanbraekel*, par.32, and *Inizan*, par.21.

[177] "*By this question, the referring court asks whether Article 49 EC and Article 22 of Regulation No 1408/71 must be interpreted as imposing an obligation on Member States to fund hospital treatment in other Member States without reference to budgetary constraints and, if so, whether such an obligation is compatible with Article 152(5) EC.*", Case C-372/04, *Watts* [2006], par.144.

[178] Idlib, par.145.

[179] "*The Community shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action.*

Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination."

systems of social security. This is not to be considered as undermining their sovereign powers in the field[180].

The answer to the seventh question is, therefore, that the obligation of the competent institution to authorise a patient registered with a national health service to obtain, at the institution's expense, hospital treatment in another Member State where the waiting time exceeds an acceptable period, does not go against Article 152(2) EC.

4. The implications of the *Watts* judgement.

As we have seen, this very articulate judgement has given us answers to stimulating questions on the State of cross-border healthcare and patient mobility.

It was recognised by the Court that a patient in the position of Mrs Watts is entitled to seek hospital treatment abroad as long as it cannot be provided under the national system within a medically acceptable waiting time. This interpretation is positive for the individual patient: its position is more carefully protected thanks to the medical assessment of the circumstances of its condition. It is not hard to imagine why such a task would be administratively onerous, but it is undoubtedly the most patient-friendly and appropriate, which in turn resolves the tension between "*the inevitable existence of waiting lists and their role as an instrument for managing and allocating limited resources [and the] interests of patients receiving adequate and timely treatment*"[181].

Having the patient 'transformed' into a consumer has the upside of the presence of choice for where to receive care, but brings with it adverse effects as well. The most 'well off' patients would choose to receive the best possible care, while the less wealthy would be confined to the 'discounts' of the health care systems.[182] This

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[180] See *Müller-Fauré and van Riet*, paragraph 102, and, by analogy, Case C-376/98 *Germany v Parliament and Council* [2000] ECR I-8419, par.78.

[181] Opinion of Mr Advocate General Geelhoed delivered on 15 December 2005, *European Court Reports 2006 I-04325*, par. 86.

[182] Freedom of Health and Medical Care Services within the European Union, *Recent Jurisprudence of the European Court of Jus- tice, with Particular Reference to Case C-372/04 Yvonne Watts*, 16 May 2006, Flaminia Tacconi, p.206.

could have the effect of creating areas of the EU where medical treatment is very active and of high quality, while other zones remain marginalised.[183]

Although the outcome of the judgement was somewhat predictable in the light of the previous case-law[184], we have the possibility to see its shortcomings. For example, the Court avoided altogether the question as to whether national health systems themselves fall within the scope of Article 49 EC. On this point, the legal doctrine has already provided criticism regarding the qualification of medical treatments as economic activities[185]. It is also worth noting that the qualification of medical services as falling within the meaning of the provision relating to the freedom to provide services is unlikely to be reviewed in the future by the Court of Justice.[186]

Another issue is that measures that aim to integrate the European health care systems are mostly negative, in that they are about the removal of barriers to the free movement of health services between member states. It would be more appropriate to have positive integration measures in a field that is so delicate, but they are either absent or minimal. The fact that the development of this legal field

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[183] The only patients that are better off with this, notwithstanding their income, are those who live in areas that are near national borders, where travel to other Member States is more affordable.

[184] See, in particular, *Müller-Fauré* at par.103.

[185] See Gallo, I servizi di interesse economico generale: Stato, mercato e welfare nel diritto dell'Unione europea 351 ff, 623 f; Gallo, 'Social Security and Health Services in EU Law: Towards Convergence or Divergence in Competition, State Aids and Free Movement?' 11 f and references cited therein. Differences which have been pointed out between the free movement and competition lines of case law in the assessment of the existence of an economic activity have been considered, in many cases, inherent to the EU law legal system: see O Odudu, 'Economic Activity as a Limit to Community Law' in The Outer Limits of European Union Law 225–245, esp 235 ff; Hancher and Sauter 127 ff and, once more, Gallo, I servizi di interesse economico generale: Stato, mercato e welfare nel diritto dell'Unione europea 356 ff. See also Gekiere, Baeten and Palm, 465 ff. For a detailed analysis of these problems with reference to the case law on patients' mobility, see Baquero-Cruz.

[186] See Cisotta, R. "*Limits to Rights to Health Care and the Extent of Member States' Discretion to Decide on the Parameters of Their Public Health Policies*." In *Services and the EU Citizen*. Ed. Frank S. Benyon. London: Hart Publishing, 2013. P.159.

is brought forth on a case-by-case approach has the consequence of lacking an 'end-game' plan; it is not clear where cross-border healthcare and patient mobility are headed without positive legislation and political discourse around it.

Moreover, the approach of the Court to the matter at issue had the effect of reaffirming the existence of a 'dual system of cross-border healthcare'[187] under both the Treaty and Regulation 1408/71[188]. While the Court tried to align the two systems via the adoption of the same interpretation of 'undue delay', it nonetheless exacerbated the differenced between them having different approaches to the reimbursement of costs, travel and accommodation expenses.
This interpretation had the consequence of certainly benefiting some individual patients since it gave them options to choose from in order to receive a more favourable reimbursement of costs. The implication of this is that it creates a significant administrative burden: from the simple administering and financing of the system to the 'new' complication that is the evaluating the cost of equivalent treatment in the competent State, as defined in the *Watts* case.

Implications also arise when it comes to the allocation of costs due to the existence of two separate systems under EU law.
First, under Article 22 of Regulation 1408/71, medical treatment is provided, on behalf of the competent State, by the host State "in accordance with the legislation which it administers". What this means is that a patient under the said Article is subject to the rules of the host country when it comes to reimbursement. The consequence of this is that the competent State is responsible for the compensation to the host State for the medical treatment provided under Article 36 of the said Regulation; however, because the rules on reimbursement of costs vary from Member State to Member State, the individual may face different fees depending

[187] Patient Mobility and National Health Systems, Case C-372/04, *The Queen on the application of Yvonne Watts* v *Bedford Primary Care Trust and Secretary of State for Health*, judgment of the European Court of Justice, 16 May, 2006, [2006] ECR I-4325, Mel Cousins, Legal Issues of Economic Integration Volume 34, Number 2, 2007, p. 192.
[188] Case C-372/04, *Watts* [2006], par.48.

on the host State (this is the end result of the lack of harmonisation, or any significant coordination, in the field of social security systems between the Member States, as previously mentioned in the discussion about the lack of positive integration).

Secondly, under the relevant Treaty provisions, a patient may receive reimbursement, where this is to its advantage, under the rules of the competent institution. The 'new' factor to be taken into account thanks to the *Watts* judgement is that the amount that is reimbursed cannot be higher than the amount of 'equivalent treatment' in the competent State.

Having the possibility to go abroad and obtain reimbursement for all the fees does indeed enable and uphold EU cross-border medical care, but this does nonetheless raise issues of possible discrimination between citizens of the same Member State.[189]

Mrs Watts was in a financial position that allowed her to travel to France in order to obtain medical treatment; if she so chose, she could have gone to a private clinic in the UK spending around the same amount of money. This possibility is clearly not open to all individuals, specifically those that do not have that same economic possibility.

In order to achieve better freedom of patients to travel to the other Member States to receive treatment, there is the chance of creating an 'elite of patients'[190] which have the possibility to obtain the care they need abroad. If the aim of the ECJ is to foster a more homogeneous higher level of medical care within the Union, this would not be a coherent choice, as it would actually facilitate the development of discrimination.

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189 M. L. Flear, '*Developing Euro-Biocitizens Through Migration for Healthcare Services*' (2007)Maastricht Journal of European and Comparative Law 3, 239–261 argued that the case law on patients' mobility gave rise to a new European generation of patients and the potential destabilisation of national health systems should have been managed through adequate EU-driven governance and legislation.

190 Freedom of Health and Medical Care Services within the European Union, *Recent Jurisprudence of the European Court of Jus- tice, with Particular Reference to Case C-372/04 Yvonne Watts*, 16 May 2006, Flaminia Tacconi, p.206.

The actions of the ECJ could, in turn, be having the effect of trying to rebalance demand and supply of hospital treatment, while in actuality they risk creating distortions in the different domestic health systems; the problem is exacerbated when one thinks about how, such a non-coordinated and non-harmonised patient mobility, would have potentially disastrous effects on the system of waiting lists. Would foreign patients be bound to respect the mechanism of the host State? Would they have a preferred queue? This could cause discrimination among EU citizens, which is not to be desired.

Let us recap: in this Chapter, we have started with what happened shortly after the *Kohll* and *Decker* judgements. The introduction of the EHIC brought forth a shift in the way politics in the Union are conducted; the card sets an example of how policy should impact the citizens, at least ideally, in its implementation. The card is both a pragmatic solution to a concrete problem and a symbol of something greater, that can unite a continent as very few things can.
The political context in which the EHIC was introduced can teach us how leadership in the Union, as well as officials acting responsibly, are crucial for the achievement of excellent results.
We proceeded by dissecting Regulation 883/2004 on the coordination of social security systems, whose impact is felt throughout the subsequent jurisprudence, both in the *Watts* judgement, which we analysed in this Chapter and in the *Petru* judgement, which we are going to discuss in Chapter 3.
The *Watts* case has cleared up a few things: the system of waiting lists is appropriate for managing the providing of hospital services, but are not enough in and of themselves to deny prior authorisation for treatment to be received abroad in compliance with Regulation 1408/71 and the E-112 mechanism therein disciplined. The judgement also managed to state that administrative burdens on the national health systems are not valid reasons for rejecting to refund patients that obtained healthcare abroad, giving an advantage to the patient.
We will see how the principles that are derived from what we discussed will impact notably the provisions of today.

In Chapter 3, we are going to discuss the legislation that is in force today, dissecting its legal bases as well as its content. A 2014 case will give us even more clarity on the rights of EU citizens when it comes to the receiving of treatment abroad.

CHAPTER III

THE REGIME OF TODAY. FROM DIRECTIVE 2011/24/EU TO THE LATEST JURISPRUDENCE ON PATIENT MOBILITY.

1. A brief outline of the evolution of the legal context relevant to cross-border healthcare up to the new Directive of 2011.

Our journey began in 1958 with the entry into force of the Treaty of Rome, which brought many novelties with it, the ramifications of which we still see to this day. The four fundamental freedoms were introduced in the EEC Treaty in order to build a different Europe based on peace and trade rather than on war and conflict. The freedom of movement of goods (Articles 9 to 37 EEC) made it so that no duties or tariffs would be put in place when it came to trade; the freedom of movement of services and establishments (Articles 52 to 66 EEC) aimed at integrating the market by enhancing the mobility of service providers and of those who wanted to establish themselves in a different Member State; the freedom of movement of capitals (Articles 67 to 73 EEC) had in mind the objective of fostering the flow of currencies between European countries; and the freedom of movement of workers (Articles 48 to 51 EEC), which is crucial to our discussion, strived for the possibility of individuals to seek work opportunities abroad. Having the chance to work in another country brought with it the risk of getting sick and, in turn, of not having the possibility to fully enjoy the aforementioned freedom. This is why our discussion plants its roots into the freedom of movement of workers. Even today, the relevant legislation on the matter is deeply linked with the provisions on the mobility of workers, as we are going to see later in the chapter.

In order to implement what was generally stated in the relevant Articles of the Treaty, Regulation 3/1958 was drafted, and with it came a much-needed explanation on what it meant to be free to move in the European Economic Community.

After many amendments, a need to make order arose at the Community level. Regulation 1408/1971 was the consequence of this need, which in turn made it so that the relevant provisions could be updated. Regulation 1408/1971 also brought forth the introduction of the E-111 and E-112 forms, which became useful for many

people both in situations of emergency or of planned treatment. As already mentioned, these forms came with their criticalities, of which we discussed in Chapter 1.

The next relevant developments happened at the hands of the Court of Justice, which, in the *Kohll* and *Decker* judgements, helped extend the scope of cross-border patient mobility. The role of the Court cannot be underrated, as it also produced many other relevant judgements, of which we dissected *Watts* in Chapter 2.

New legislation was introduced with Regulation 883/2004, which provided rules for the coordination and, at least on paper, better harmonisation of national social security schemes.

We have also analysed the introduction of the European Health Insurance Card with a brief mention of the socio-political context that made it so that the Card could become a reality.

With this background, we have finally arrived at our set destination: Directive 2011/24/EU[191].

2. The exercise of the EU and Members States competence in the healthcare sector: from the relevant primary law provisions to the analysis of the legal basis of Directive 2011/24/EU

Directive 2011/24/EU mentions as its primary legal basis Article 114 TFEU and Article 168 TFEU[192], while also having regard to the Opinion of the European

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[191] 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. 45–65.

[192] "*A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.*

Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health.

The Union shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.

The Union shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action. It shall in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas.

Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation. The European Parliament shall be kept fully informed.

The Union and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.

By way of derogation from Article 2(5) and Article 6(a) and in accordance with Article 4(2)(k) the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns:

(a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from main taining or introducing more stringent protective measures;

(b) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;

(c) measures setting high standards of quality and safety for medicinal products and devices for medical use.

The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States.

The Council, on a proposal from the Commission, may also adopt recommendations for the purposes set out in this Article.

Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. The measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood."

Economic and Social Committee[193] as well as the one of the Committee of the Regions[194]. We are going to explain the meaning of the legal basis of the Directive briefly, taking into account the many 'Whereas' that it contains.

First of all, Article 168(1) of the TFEU foresees a high level of human health protection that has to be ensured in the implementation of the Union policies. This brings forth the consequence that human health protection must be guaranteed at a high level in the adoption of Union acts.[195] The presence of Article 168 TFEU is justified based on the fact that it provides a legal basis for supporting competencies so that the competence of States in public health is preserved.[196] What the Article does, is it confirms the 'complementary' competence of the EU in healthcare-related matters. This is a stark difference with Article 152 TEC since today we find a larger margin of intervention for the Union to 'complete' the policies of Member States in the field, as well as to incentivise the cooperation between them in order to achieve a greater level of harmonisation in bordering regions. When it comes to public health, the Treaty of Lisbon introduced a larger sphere of competence for the Union also from a 'formal' point of view: in the Treaty, we find an *ad* hoc Title dedicated to public health, while no specific provisions on the matter were contained in the 1957 Treaty of Rome; this is understandable since the founding Member States conceived social policies, in general, to be left to the autonomy of the national governments.[197] The competence of the EU in matters relating to

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193 OJ C 175, 28.7.2009, p. 116.

194 OJ C 120, 28.5.2009, p. 65.

195 'Whereas' 1 of Directive 2011/24/EU.

196 This is reinforced by the fact that it is repeated multiple times in the provision how there is a need to preserve competence of the States. To this point see recitals 7, 10, 18, 33 and Articles 1(1) and 1(4).

197 See E. Mossialos, G. Permanand, R. Baeten, T.K. Hervey, *Health Systems Governance in Europe, the Rolee of European Union Law and Policy*, Cambridge, 2010, p.5; F. Costamagna, *I servizi socio-sanitari nel mercato europeo. L'applicazione delle norme dell'Unione europea in materia di concorrenza, aiuti di Stato e libera circolazione di servizi*, Napoli, 2011. p.6; E. Triggiani, *La complessa vicenda dei diritti sociali fondamentali nell'Unione europea,* in *Studi sull'integrazione europea*, 2014, p.9 as referenced in Bestagno F. "*La tutela della salute tra competenze dell'Unione europea e degli Stati membri*", Studi sull'integrazione europea, XII (2017) p.318.

healthcare is to be exercised only when there is a European objective[198] to be achieved as a justification for its intervention. The vast majority of the decisions are, therefore, to be taken only by the Member States for their own particular situation. The consequence of this is that the action of the Union is not supposed to replace the national competence in the field of healthcare; therefore, unless the Treaty is amended, and particularly Article 168(7) TFEU, no positive integration can be brought forth by the Union, be it a reform of national health systems that aims for their harmonisation or the creation of a unified healthcare EU system.[199]
The Article is consistent with Article 9 TFEU[200] which contains the social objectives that the EU must seek when defining its policies and actions, as well as with Article 35 of the Charter of Fundamental Rights (CFR); more specifically, the latter, foresees a sort of 'compromise'[201], since it acknowledges the right of EU citizens to healthcare with respect to national law and practices, while also 'demanding' the respect of a high level of human health protection in the implementation of all Union policies and activities[202]. What must be noted,

198 See declaration 32 of Article 168(4) letter c).

199 See G. Fares, M. Campagna, *La tutela della salute nell'ordinamento comunitario,* in P. Gargiulo, *Politica e diritti sociali nell'Unione europea,* Napoli, 2011, p.325-332, 348, as referenced in Bestagno F. "*La tutela della salute tra competenze dell'Unione europea e degli Stati membri*", Studi sull'integrazione europea, XII (2017) p.320.

200 "*In defining and implementing its policies and activities, the Union shall take into account requirements linked to the promotion of a high level of employment, the guarantee of adequate social protection, the fight against social exclusion, and a high level of education, training and protection of human health.*"

201 Hans Vollaard, "*The challenge of patient mobility to healthcare states in the EU*", p.17.

202 On the application of the Charter, See B. De Witte, "*The scope of application of the EU Charter of Fundamental Rights*", in *The Right to Family Life in the European Union*, Routledge, London, 2017, pp.29-39; M.E. Bartolini, "*Ambito d'applicazione del diritto dell'Unione europea e ordinamenti nazionali: una questione aperta*", Edizioni Scientifiche Italiane, Napoli, 2018; A. Tizzano, "*L'application de la Charte de droits fondamentaux dans les États membres à la lumière de son article 51, paragraphe 1*", in *Il Diritto dell'Unione Europea*, 2014, pp. 429-437; B.Nascimbene, "*Il principio di attribuzione e l'applicabilità della Carta dei diritti fondamentali: l'orientamento della giurisprudenza*", in *Rivista di diritto internazionale*, 2015, pp.49-78.

regarding Article 35 CFR[203], is that, while it does not foresee, *per se*, a right to health that is assured by EU law[204], it does, however, recognise a principle of access to health-related services that are based on national legislation. While the CFR is of the utmost importance in the hierarchy of legal sources in the EU law environment, its relevant Articles (34 and 35) are barely mentioned in the case-law of the Court of Justice and in the Directive 2011/24/EU. While in the *Petru* judgement, Ms Petru did rely on the CFR, she did so only in a vague way[205]. Even the Court, in its ruling, opted for a technical interpretation of Article 22 of Regulation 1408/71 instead of bringing up Article 35 of the CFR, which is certainly an odd choice, considering that referring to a primary law provision would offer a more solid basis for the conclusion reached.[206] While Directive 2011/24/EU did mention the Charter in its 'Wheareas'[207], it did so only with respect to the protection of personal data. From what we can gather it can be concluded that the provision of the CFR remains mostly unused in the relevant case-law and legislation in the field of cross-border healthcare

Secondly, Article 114 TFEU is indicated as legal basis due to the fact that most of the provisions contained in the Directive have the objective of improving the functioning of the internal market and the free movement of goods, persons and

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[203] For comments to the provision, see A. Lucarelli "*Art. 35 Protezione della salute*", in *L'Europa dei diritti. Commento alla carta dei diritti fondamentali dell'Unione europea*, Il Mulino, Bologna, 2001, pp.245-251; T. Hervey, J. Mchale, "*The Right to Health Care*", in *The EU Charter of Fundamental Rights. A Commentary*", Hart Publishing, Oxford, 2014, pp.951-968; G. Di Federico, "*Spiegazione relativa all'articolo 35 – Protezione della salute*", in *La Carta dei diritti fondamentali dell'Unione Europea, "Le fonti del diritto italiano"*, Giuffré, Milano, 2017, pp.664-679.

[204] Stephane De La Rosa, "*The directive on cross-border healthcare or the art of codifying complex case law*", p.21.

[205] Case *Petru* C-268/13, par. 14

[206] Vassilis Hatzopoulos, "*Some thoughts on the fate of poorer Member States' healthcare systems after the ruling in Elena Petru*", p.5

[207] 'Whereas' 8 of Directive 2011/24/EU.

services. Moreover, in Article 114(3) TFEU, it is required that, when achieving harmonisation, a high level of protection of human health has to be guaranteed.[208][209] While there are evident limitations to the positive action that the Union may exercise in the field of healthcare, it would be wrong to assume that the relevant EU institutions are not capable of applying political pressure towards the Member States when taking policy decisions regarding health-related services.[210] This possibility is further reinforced by the fact that the protection of human health is considered a common objective of all Union politics[211], both internal and external. Having such a 'soft power' may be considered by some as being too little. Although it is true that, in some circumnstances, applying soft power measures can prove to be the best way forward, in a field as delicate as healthcare, it would be better, in our view, to have 'hard law' mechanisms in place. To make an example, the Union has a certain level of oversight on the budgets of the Member States so that they can respect the European objectives. The economic constraints that make possible the achievement of the said aims would not be respected as thoughroughly if they were enforced through soft law. Therefore, in our opinion, there is an evident need for a reinforcement of the Union powers in this field, encompassing both a power of intervention as well as 'punitive' powers were the Member State to stray away from the common objectives defined in the Treaties.

What is peculiar of the Directive is the many references that are made to EU values in the field of public health; heavy emphasis is placed on the need to respect them, particularly "*universality, access to good quality of care, equity and solidarity*". The reason for this focus is that it aims to reflect a desire to recognise rights for

[208] 'Whereas' 2 of Directive 2011/24/EU.

[209] It is worth noting how no reference is made to the provisions regarding EU citizenship: access to necessary medical servicesi s foreseen as a duty falling upon the Member States rather than as a subjective right bestwowed upon the citizen.

[210] As correctly pointed out by G. Di Federico; S. Negri "*Unione Europea e Salute. Principi, azioni, diritti e sicurezza*", CEDAM, Milano, 2019, p.22.

[211] This is present in Articles 114(3), 153 point 1 lett. A), 169 point 1 and 191 point 1 TFEU.

patients that are in line with the social orientation that the Union deems as appropriate.

Ever since the entry into force of the Treaty of Lisbon, there has been an attempt from the Union to make its social commitment plausible by way of affirming rights in the Charter of Fundamental Rights, of which we analysed relevant Articles 34 and 35 in Chapter 1, as well as inserting a multi-sector social clause (or transversal clause) into primary law. This last point reflects the scope of Article 9 TFEU where it states that "*In defining and implementing its policies and activities, the Union shall take into account requirements linked to the promotion of a high level of employment, the guarantee of adequate social protection, the fight against social exclusion, and a high level of education, training and protection of human health*". The aspect regarding health protection is repeated in 'Whereas' 4 and 5, where it is stated that the Member States are responsible for providing "*safe, high quality, efficient and quantitatively adequate healthcare to citizens of their territory*".

The implication for this line of reasoning is that when the Directive gets transposed into national legislation, it should not encourage its patients to receive treatment outside their Member State of affiliation[212]. On this point, we can see a somewhat paradoxical situation: the free movement of persons should always be fostered and encouraged according to EU law. The problem is that delicate aspects of public administration, like the providing of healthcare, tend to be held close by the Member States for mainly two reasons. First, state-provided health services, while they are made with the interests of the citizens in mind, are characterised by having a political dimension as well; choosing what treatments are guaranteed, and at what condition, is part of the discourse of each country on the policy at issue. Secondly, another crucial aspect to this point is the economic one: providing such services is rather costly, and it is reasonable for a Member State to be willing to spend as little as possible in the most efficient and effective manner. This is why we ended up with a Directive that aims to clear the path for the receiving of cross-border healthcare, while, at the same time, inviting the implementing Member States to not encourage their citizens to seek healthcare outside their borders.

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[212] To this point see O. Golynker "*Patient mobility and healthcare in the EU*", University of Leicester School of Law Research Paper No.14-33, 2014.

'Whereas 5' presents the Council Conclusions[213] according to which there are shared operating principles adopted by health systems in the Union. The said principles are deemed necessary in order to ensure that patients trust cross-border healthcare. The faith of patients in the principles is fundamental for the fostering of patient mobility as well as a high level of health protection.

It is recognised by the Council that these principles vary significantly depending on the Member State, particularly when it comes to what extent patients are entitled to receive healthcare.

In the Conclusions, the Council recognised the values of universality, access to good quality care, equity and solidarity that we previously mentioned. The implication of these principles is that the Member States are under the responsibility to ensure that they are respected regarding patients and citizens from other Member States; they should all be treated equitably according to their healthcare need rather than on the basis of their Member State of residence.[214]

Having dissected the legal basis of the Directive, it is now appropriate to talk about its content and scope.

2.1 The aim and the scope. The reimbursement mechanism and the impact of the work of the Court of Justice.

In Article 1 of the provision, it is stated how it "*provides rules for facilitating the access to safe and high-quality cross-border healthcare*" while promoting cooperation on healthcare between the Member States, keeping in mind the national competencies for the organisation and delivery of healthcare. It is also mentioned how the Directive aims at clarifying the legal context on the matter as well as its relation with Regulation 883/2004. The Directive applies to the provision of healthcare to patients, regardless of how it is organised, delivered or financed.[215]

It is recognised in 'Whereas 8' that issues relating to cross-border healthcare, such as the reimbursement for treatment provided in a Member State different than the

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[213] Council Conclusions of 1- 2 June 2006 on Common values and principles in European Union Health Systems, OJ C 146, 22.6.2006, p. 1.

[214] 'Whereas' 21 of Directive 2011/24/EU.

[215] Article 1(2) of Directive 2011/22.

one affiliated to the patient, have been addressed by the Court of Justice as we have seen already in previous chapters of this discussion. The aim of the Directive is to "*achieve a more general and effective application of principles developed by the Court of Justice on a case-by-case basis*".

With legal certainty in mind, this provision wants to establish rules that facilitate access to safe and high-quality cross-border healthcare in the Union, while, at the same time, ensuring patient mobility in accordance with the principles established by the Court of Justice.[216] A clear example of this is present in 'Whereas 29' of the Directive, where it is stated that foreign patients should enjoy a reimbursement of the cost of healthcare that is at least at the level of the one that would have been provided in the Member State of residence, keeping in mind that it should not have any significant effect on the financing of the national healthcare system. This is stated once again in Article 4(4) of the Directive, where the Member State of treatment is under a responsibility to guarantee that the healthcare providers on their territory apply the same scale of fees for healthcare for patients of other Member States as for domestic patients in a comparable medical situation. What is derived as well from the relevant jurisprudence is that the rights that are bestowed upon the patient come from internal market law, specifically from the freedom to provide services, and not directly from the social or health competences of the Union.[217]

Article 7 of the Directive is also relevant to this topic, stating what the general principles regarding the reimbursement of costs are. The Member State of affiliation has to ensure the reimbursement of costs sustained by an insured person when it receives cross-border healthcare as long as it (the healthcare) is part of the benefits to which the individual is entitled to in the Member State of residence[218]. Paragraph 4 of the said Article also states how the aforementioned costs shall be reimbursed by the Member State of affiliation up to the level of fees that would have been assumed by it had the service been provided in its territory, without exceeding the actual costs of healthcare received. The possibility for the reimbursement to be higher in case of more significant costs sustained by the patient

[216] 'Whereas' 10 of Directive 2011/24/EU.

[217] This derives from the *Kholl* judgement.

[218] Article 7(1) of Directive 2011/24/EU.

is foreseen in the same paragraph, as well as the option to reimburse other related expenses such as those about accommodation or travel.

2.2 The role of the individual and of the providing State in the reimbursement mechanism.

The beneficiary of this Directive is the individual patient who decides to seek healthcare in a Member State different from the one of residence. The said Member State may choose to limit the reimbursement of the costs sustained for reasons that are related to the quality and safety of the healthcare provided in situations of overriding reasons of general interest relating to public health[219].

When it comes to reimbursement, the providing of healthcare in a Member State other than the Member State of affiliation and the prescription, dispensation and provision of medicinal products are covered by the Directive.

The rights of the insured person regarding the assumption of costs of healthcare are not affected by the Directive when they are sustained for necessities based on medical grounds during a temporary stay in another Member State in accordance with Regulation 883/2004. The Directive does not affect the right of an insured person which is granted treatment in another Member State when the conditions provided for in Regulation 1408/71 and Regulation 883/2004 are met.

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[219] This specific principle we have already seen in previous case law of the Court of Justice. "*The concept of 'overriding reasons of general interest' to which reference is made in certain provisions of this Directive has been developed by the Court of Justice in its case-law in relation to Articles 49 and 56 TFEU and may continue to evolve. The Court of Justice has held on a number of occasions that overriding reasons of general interest are capable of justifying an obstacle to the freedom to provide services 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. The Court of Justice has likewise acknowledged that the objective of maintaining a balanced medical and hospital service open to all may also fall within one of the dero- gations, on grounds of public health, provided for in Article 52 TFEU, in so far as it contributes to the attainment of a high level of health protection. The Court of Justice has also held that such provision of the TFEU permits Member States to restrict the freedom to provide medical and hospital services in so far as the maintenance of treatment capacity or medical competence on national territory is essential for public health.*" 'Whereas' 12 of Directive 2011/24/EU.

The provisions of the Directive regarding prior authorisation and reimbursement mechanisms of healthcare provided in another Member State, aim to enable freedom to provide healthcare for patients and the removal of unjustified obstacles in the Member State of affiliation of the patient. Any difference in national healthcare systems and the responsibilities of Member States for the delivery of healthcare, as well as its organisation, have to be respected when the Directive is implemented into national legislation.[220] Again we see in the words of the law the impact of the work of the Court of Justice: we can see how the principle of respect of the national sovereignty over social security schemes is reiterated still due to its importance in the discourse about cross-border patient mobility.

Moreover, in 'Whereas 38', in the light of the established jurisprudence of the Court of Justice, it is stated how if a statutory social security scheme or a national health system makes the assumption of costs of healthcare provided in another Member State subject to prior authorisation, that would be a restriction to the free movement of services. This is stated more prominently in Article 7(8) of the Directive, where an exception to this principle is allowed in light of Article 8 of the same provision. A system of prior authorisation for reimbursement of costs has to be limited to what is necessary and proportionate in order to achieve the objective, and shall not amount to arbitrary discrimination or an unjustified obstacle to the free movement of patients. The said mechanism may be set-up for three main categories of healthcare: 1. When it is made subject to planning requirements related to ensure sufficient and permanent access to treatment in the Member State or to control costs in order to avoid waste of financial, technical and human resources; 2. When it involves treatment presenting a particular risk for the patient or the population; or 3. When It is provided by a healthcare provider that, depending on the case at issue, it could give rise to serious concerns relating to the quality or safety of care.

The previous authorisation may be refused by the Member State of residence in four cases: 1. The patient would be exposed to a risk concerning its safety that is not acceptable according to a clinical evaluation; 2. The general public would be exposed with reasonable certainty to a substantial safety hazard as a consequence

220 'Whereas' 35 of Directive 2011/24/EU.

of the providing of cross-border healthcare; 3. The healthcare provider in question raises serious concerns to the respect of standards on quality of care and patient safety; and 4. Equivalent healthcare can be provided on the territory of the Member State of Residence within a time limit that is medically justifiable, keeping in mind the State of health and probable course of the illness of each patient concerned.

We can see here the impact of the *Watts* judgement, as discussed in Chapter 2. The Directive was also influenced on this regard since it abided by another principle enunciated in the said judgement, according to which considerations of an administrative or financial order cannot be imposed on patients in the handling of their request for authorisation. There is certainly not a condemnation of the system of waiting lists inside the Directive, but there is nonetheless a responsibility for them to be flexible in order to respect the aforementioned values and the fairness requirement contained in the provision. Only the condition of the patient is to be taken into account, notwithstanding administrative or bureaucratic arguments that could potentially get in the way. It can be concluded that the Directive does not go beyond the *Watts* jurisprudence since it merely codifies it[221].

2.3 Exceptions to the rule in case of overriding reasons of general interest.

The Directive recognises that inflows of patients may have the potential to create a demand that exceeds the capacity of a Member State for a given treatment. Were this to happen, the Member State may act on the grounds of public health with respect to Articles 52[222] and 62[223] TFEU without prejudice to the obligations set out

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[221] For example, while a medical-based waiting list is permitted, 'Whereas 43' states how "*the refusal to grant prior authorization may not be based on the ground that there are waiting lists on national territory intended to enable the supply of hospital care to be planned and managed on the basis of predetermined general clinical priorities, without carrying out an objective medical assessment*".

[222] "*The provisions of this Chapter and measures taken in pursuance thereof shall not prejudice the applicability of provisions laid down by law, regulation or administrative action providing for special treatment for foreign nationals on grounds of public policy, public security or public health. The European Parliament and the Council shall, acting in accordance with the ordinary legis lative procedure, issue directives for the coordination of the abovementioned provisions.*"

[223] "*The provisions of Articles 51 to 54 shall apply to the matters covered by this Chapter*."

in Regulation 883/2004.[224] This is also mentioned in Article 4(3), where the principle of non-discrimination with regard to nationality is enshrined. The Member State may adopt measures about the access to treatment with the objective of fulfilling the responsibility to ensure sufficient and permanent access to healthcare within its territory in case of overriding reasons of general interest. The said measures shall be limited to what is necessary and proportionate, and shall not amount to arbitrary discrimination.

It is however recognised in 'Whereas 39' that the flow of patients is expected to remain limited due to the fact that most of the patients in the Union tend to receive healthcare in their own country and prefer to do so. There are obviously exceptions when it comes to highly specialised care, of which we will discuss more in detail in Chapter 4.

The Commission Report on the Directive[225], which we are going to discuss in this chapter, is going to expand on the possibility of a higher level of patient mobility.

2.4 The protection of personal data and the responsibilities of the Member State of affiliation.

'Whereas' 25 mentions how Article 8 of the Charter of Fundamental Rights[226] of the European Union recognises a fundamental right to the protection of personal data. The said data has to travel as seamlessly as possible from Member State to Member State with the caveat that the fundamental rights of the individual have to be respected at all times.[227] At the time of the introduction of the Directive, the provision on the protection on the protection of individuals with regard to the

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[224] 'Whereas' 21 of Directive 2011/24/EU.

[225] *EC, 2015a, Evaluative Study on the Cross-border Healthcare Directive (2011/24/EU),* Brussels: KPMG, Technopolis group, empirica GMBH.

[226] "*Everyone has the right to the protection of personal data concerning him or her.*
Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.
Compliance with these rules shall be subject to control by an independent authority. "

[227] See more on E. Stefanini, "*Telemedicina, "mHealth" e diritto"*, in *Rassegna di diritto farmaceutico e della salute*, 2016, pp.1023-1032.

processing of personal data and on the free movement of the said data was Directive 95/46/EC[228], which was later repealed and replaced by Regulation 2016/679[229] (also known as GDPR, General Data Protection Regulation).
Personal data protection is also considered as a fundamental right according to Article 8 CFR[230] and Article 8 ECHR[231].

When it comes to the responsibilities of the Member States of affiliation, we rely on Article 5, where a list of obligations is present. It is stated how the cost of cross-border healthcare shall be reimbursed in accordance to what we mentioned previously in this Chapter and generally establishes the presence of mechanisms that provide patients who request it, information on their rights and entitlements in that Member State relating to receiving cross-border healthcare.
A crucial introduction of the Directive is the one regarding National Contact Points. In 'Whereas 48' it is recognised how appropriate information on all essential aspects of cross-border healthcare is fundamental in order to enable patients to exercise their rights on cross-border healthcare in practice. The establishing of

[228] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, OJ L 281, 23.11.1995, p. 31–50.

[229] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ L 119, 4.5.2016, p. 1–88.

[230] According to some authors, the Charter has been the first primary law source to recognise such right. See more in G. Gonzales Fuster, "*The emergence of Personal Data Protection as a fundamental Right of the EU*", Springer, Cham, 2014, pp.198.

[231] European Court of Human rights, judgement of 25th february 1997, *Z. v Finland*, n. 22009/93, it was observed in point 95 how "*without such protection [of clinical data], those in need of medical as- sistance may be deterred from revealing such information of a personal and intimate nature as may be necessary in order to receive appropriate treatment and, even, from seeking such assistance, thereby endangering their own health and, in the case of transmissible diseases, that of the community*". National laws have, therefore, to guarantee the protection of health data according to Article 8 ECHR.

National Contact Points has to take place in each Member State; their role is to serve as a mechanism for the providing of information for cross-border mobility.
The Member States are free to decide the form that these National Contact Points may take; they may be, as usually happens, incorporated or built on activities of existing information centres, as long as it is clearly specified that they are National Contact Points as well. The possible explanation as to why such a margin of choice is left to the Member States could be that a more detailed provision on how National Contact Points should have been set up could have amounted to an infringement of the competences of the Member States. It is useful to remind ourselves how much the Court of Justice and the dispositions we analysed in our discussion tread carefully when it comes to the overlapping with the autonomy of the Member States in the context of social security and healthcare.
It must be ensured that patients receive, from the National Contact Point, information on the standards and guidelines regarding treatment options, their availability, quality and safety in order to make an informed choice[232].
A problem regarding this topic is the lack of informed citizens on their existence. We will expand more on this in Chapter 4.

2.5 The implementation in the Italian legislation.

As we know, a Directive needs to be implemented in the national legal system of each Member State in order for its effects to take place. In 2014 the Italian law received the Directive with Legislative Decree 38/2014[233] in which the adoption of Directive 2012/52/EU[234] was also contained. The law provided for the ratification of these two Directives due to their interlinked nature.

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[232] Article 4(2) letter a) and b) of Directive 2011/24/EU.

[233] Decreto Legislativo 4 marzo 2014, n. 38, Attuazione della direttiva 2011/24/UE concernente l'applicazione dei diritti dei pazienti relativi all'assistenza sanitaria transfrontaliera, nonche' della direttiva 2012/52/UE, comportante misure destinate ad agevolare il riconoscimento delle ricette mediche emesse in un altro stato membro. (14G00050) (GU Serie Generale n.67 del 21-03-2014).

[234] Commission Implementing Directive 2012/52/EU of 20 December 2012 laying down measures to facilitate the recognition of medical prescriptions issued in another Member State, OJ L 356, 22.12.2012, p. 68–70.

The Legislative Decree states that what can be reimbursed are the healthcare services which are guaranteed by the Italian National Health System; however, Regions are able to refund more of them if they fall within the regional health standards, as long as they are regional financial resources. The role of the Regions in this context should not be underestimated, after all, Italian citizens are all covered by a National Health System that is administered by regional facilities, which in turn offer different services and products depending on their budget.
The Government Act establishes how cross-border costs are refunded according to the regional standards after considering the co-payments of patients for that service; this is the consequence of the introduction at the regional level in Italy of an obligation for citizens-users to co-pay a proportion of the costs of social and healthcare services. The said reimbursement shall not be higher than the actual expenses sustained by the patient. The tariffs have to be communicated by the Regions to the National Contact Point.

When it comes to the reimbursement of costs sustained as a consequence for cross-border healthcare services, according to the Legislative Decree, they can be limited for overriding reasons of public interest (such as the need to ensure sufficient and permanent access to high-quality services in Italy) as well as for the necessity to control health costs so as to avoid waste of financial and human resources.
These provisions are enforced with a Decree[235] of the Ministry of Health in operation with the Treasury and the Regions' Coordination Committee so that the limits on access to cross-border healthcare can be defined clearly. In it, we find confirmation of the prerogative of the Central Government to set financial limits and determine the amount and quality of healthcare services that are to be provided at the national level. At the same time, it states that the limitations can be confined to the Regions or local health authorities, with the consequences that there are different models inside the same national health system. The said limitations are to be communicated to the Health Ministry and the National Contact Point.

[235] Decreto 16 aprile 2018 , n. 50, Regolamento in materia di assistenza sanitaria transfrontaliera soggetta ad autorizzazione preventiva. (18G00075) (G.U. Serie Generale , n. 117 del 22 maggio 2018).

To sum up, it can be said that the way the Italian legal system received Directive 2011/24/EU is very much articulate; the said complexity is justified on the ground of the federal structure in which regional legislators formulate health policies, and then local health authorities provide healthcare services.

It should be said that the limitations that are put in place in order to restrict cross-border healthcare should be necessary, proportionate, non-arbitrary and non-discriminatory (as already mentioned in our discussion). However, it happens in practice that the limitations tend to be both arbitrary and discriminatory as they vary between regions, and create as a consequence a series of unclear barriers for Italian citizens to obtain healthcare abroad. It may be derived, therefore, that the way the Italian legislator implemented Directive 2011/24/EU did not do so in compliance with Article 7(9) of the provision on "*regulatory and administrative formalities*". It is yet to be seen whether a preliminary ruling on this matter will be raised in front of the Court of Justice.

2.6 The Evaluative Study of the Commission on the Cross-border Healthcare Directive (2011/24/EU)

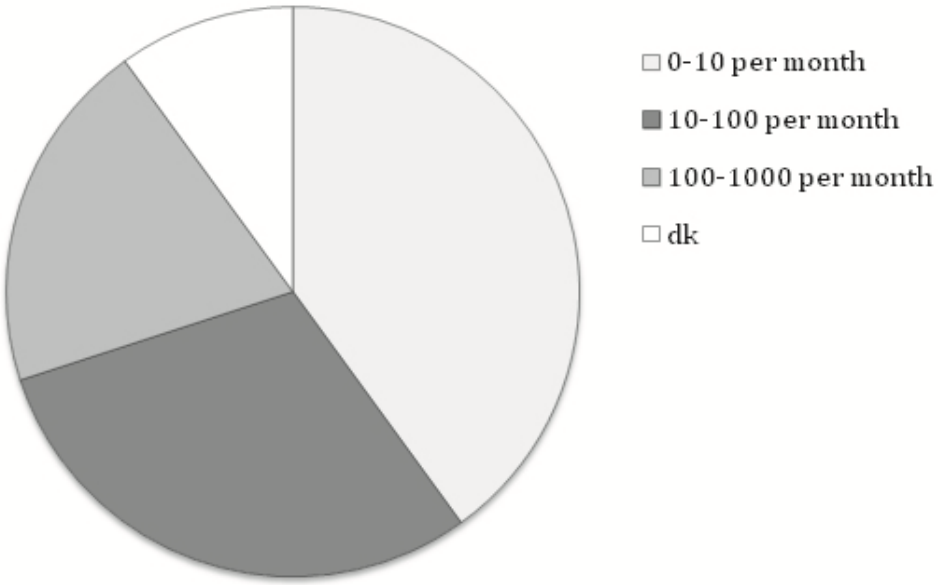
In compliance with Article 20 of the Directive, the Commission was under the obligation to prepare a report on the operation of the said provision by October 2015 in order to submit it to the European Parliament and the Council.

The report reached the conclusion that no specific problem was identified with the reimbursement procedures, as each cross-border healthcare claim requires an individual assessment on a case-by-case basis by health insurers.

It should be kept in mind that if the number of patients seeking cross-border care increases, unforeseen consequences could manifest themselves, although to this day there still is not a level of mobility that raises concerns on the matter. It should be noted, nonetheless, that National Contact Points find themselves with quite a few

requests to deal with every year, which could imply that the demand could be there.[236] The following figure helps us visualise the magnitude of the phenomenon.

Frequency of patients' requests for information from NCP

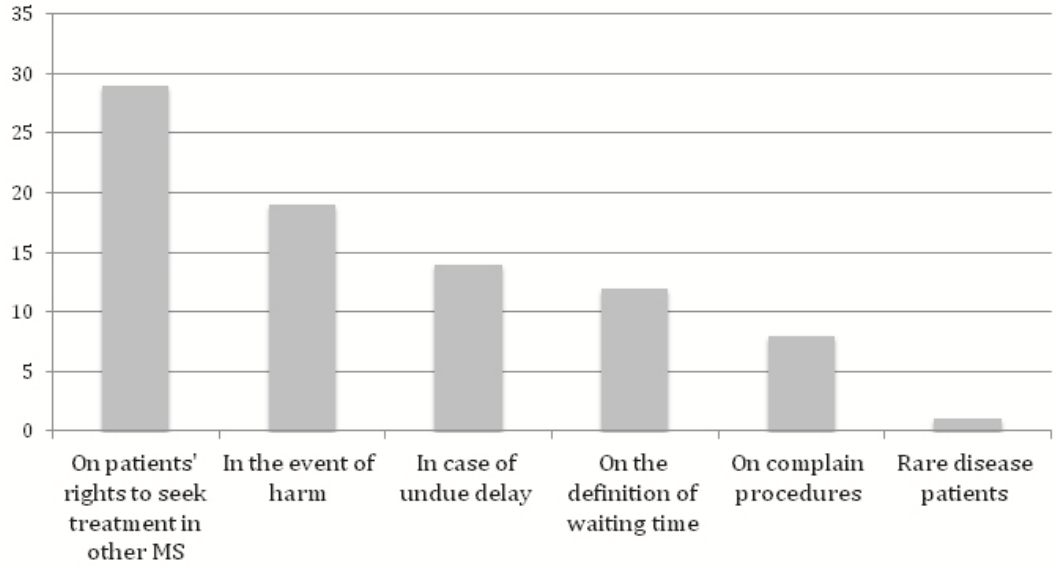


Source: Based on the data in EC, 2015a, Evaluative Study on the Cross-border Healthcare Directive (2011/24/EU), Brussels: KPMG, Technopolis group, empirica GMBH.

As we had seen when we talked about NCPs, the possibility for potential patients to obtain information is crucial. The following figure allows us to see what type of data is displayed in the relevant websites of NCPs.

NCP websites which contain information on patients' rights

[236] To put things into perspective, the National Contact Points are usually manned by one to three person tops. These individuals find themselves with more than a hundred requests per month from potential cross-border patients.



Source: *Based on the data in EC, 2015a, Evaluative Study on the Cross-border Healthcare Directive (2011/24/EU),* Brussels: KPMG, Technopolis group, empirica GMBH.

Indeed, there is an adequate level of information that, on average, is found on the websites; it must be noticed, however, that more detailed content is lacking. Having the possibility to know what rights a patient is entitled to when seeking healthcare abroad is the basis, there is a need for more accessible and detailed information overall, and NCPs have a duty in this regard. As the report puts it "*further progress is still possible and indeed desirable*"[237] since the stakeholders interviewed in the study held that citizens are not informed enough regarding the new opportunities available under the Directive or even of the existence of National Contact Points.

Regarding quality and safety, the NCPs' websites contain information on the matter that is often not comprehensive, as they are not considered by the stakeholders interviewed as a critical driver in patients' choices.

The patient groups questioned held that administrative burdens concerning prior authorisation procedures are the main reasons that prevent patients from enjoying the mechanisms put in place by the Directive. This is somewhat understandable: a

[237] *Evaluative Study on the Cross-border Healthcare Directive (2011/24/EU),* Brussels: KPMG, Technopolis group, empirica GMBH, p.12

patient that seeks cross-border healthcare has to first and foremost go through administrative processes that, if they prove to be too cumbersome, will become a deterrent rather than an incentive.
The quality and safety part is considered secondary also because patients, according to the report, tend to trust acquaintances' and friends' opinions on healthcare providers more so than official statements.

The report concluded that the Directive was at an early stage of implementation; consequentially, some of the fields of application of the Directive are not mature enough to be evaluated, also due to the small number of related cross-border healthcare referrals.
The implementation of the Directive could benefit from more targeted and regular publicity since the evidence shows that the demand for cross-border healthcare would be higher if the patients were made aware of the possibilities offered.
The usefulness of the information provided on the websites of the NCPs should be enhanced through cross-referencing and by involving patient organisations in defining standards' requirements.

2.7 The codifying effort of the Directive: the problems descending from an upfront payment system.

It is clear that this Directive had a lot of weight to lift: a fifty-three-year-old baggage of provisions and case-law was to be taken up and assembled into something that would help the cross-border mobility of patients. We can safely say that the Directive managed to reach that objective by not only codifying the incredible amount of case-law but also by holding high the values that the European Treaties and the Charter of Fundamental Rights have enshrined.
The Directive made it so that the rules for the reimbursement of care are manifest, which was not an easy task, considering they were previously established on a case-by-case basis.
It recognised a right to information for the patients, helping them with the introduction of procedural safeguards after the presenting of a request for prior authorisation for care outside the Member State of residence.

It also managed to remain in the tight boundaries that are set for the competence of the Union, respecting the autonomy of the Member States thanks to a recognition of categories of care that require prior authorisation, while also creating mechanisms that foster cooperation.

With the introduction of the Directive, patients obtain the possibility to have their care abroad reimbursed for most types of outpatient care without the need of prior authorisation from their funding institution; the consequence of this is that patients who consider the domestic care of lower quality could be encouraged to travel in order to receive treatment.

While not being codified in the Directive, the principles derived from the *Watts* judgement reimain valid[238]: according to the Court, a refusal to grant authorisation for treatment in a different Member State than the one of residence is illegitimate in the event that it is based on the existence of a sistem of waiting lists.[239]

With all of this success, there are still issues that are left without an answer.

While the presence of competence of the Union in matters relating to healthcare is certainly a positive development for the correct enforcement of the social values of the EU; and while it is true that patients have the possibility to obtain sufficient information on their rights and on the whole process of cross-border mobility, nonetheless, the Directive does not take into account the social situation of the patient. Access to cross-border care is, therefore, guaranteed only to individuals that have the cognitive and social resources that would allow them to move between the Member States. This is also amplified by the fact that patients that are looking for treatment abroad that is not covered by the domestic benefit package that they are subject to will not obtain funding due to the fact that reimbursement is limited to what they would have received in the Member State of affiliation.

What is needed is to form a genuine policy of care in the EU, in order to go beyond the little margin of movement that the Union has when it comes to social and healthcare issues. Let us consider the following: the wealthiest of individuals has

[238] G. Di Federico; S. Negri "*Unione Europea e Salute. Principi, azioni, diritti e sicurezza*", CEDAM, Milano, 2019, p.204.

[239] Case C-372/04, *Watts* [2006], par.123.

higher chances of conducting a lifestyle that will benefit its health the most, they may exercise more often thanks to personal trainers and their diet may be more varied due to the economic possibility of purchasing higher quality food. In the grand scheme of things, this kind of individual does not tend to need too much support when it comes to healthcare services; besides, they may very well choose private healthcare altogether.

A less wealthy individual may tend to over-stress due to harsher working conditions, may have a less varied diet (which is fueled by junk food due to it being very cheap), and may exercise less due to lack of time. This individual may very well benefit from a national and even European healthcare system that allows for easy mobility in the territory of the Union. The effect of such a system would contribute to a more socially equal environment, as well as facilitating cultural exchange between the lower and middle class of citizens, which would bring to a more integrated EU.

The promotion of equality in relation to medical treaments is both an international duty falling on the Member States as well as a strategic field for the EU[240]; what the Union aims for is the sustainability of the European economy in conjunction with the protection of fundamental rights due to the fact that the public expenditure and the buying power of the individuals is strictly linked with their state of health.[241] This is also connected to the fact that the economic conditions of the individuals are crucial for having the possibility to travel to another Member State to receive treatment, which in turn may prejudice the possibility of enjoying the fundamental freedoms. Unfortunately, on equality in this field, the provisions are few and incoherent[242]; a much needed Union legislative intervention is also not possible

[240] G. Di Federico; S. Negri "*Unione Europea e Salute. Principi, azioni, diritti e sicurezza*", CEDAM, Milano, 2019, p.81.

[241] Commission Staff Working Document, Investing in Health, SWD (2013) 43 final, 20 February 2013.

[242] G. Di Federico; S. Negri "*Unione Europea e Salute. Principi, azioni, diritti e sicurezza*", CEDAM, Milano, 2019, p.82.

since it would violate the principle of subsidiarity[243]. Granting an equal access to quality medical procedures and services would favour the cross-border patient mobility. The stress, on this point, should be put on the efficient use of public and private resources in relation to the organisation of the national healthcare systems, which would be both a consequence and an incentive for a higher degree of mobility of patients across the Member States.

The Directive, while improving access to care and patient choice in some circumstances, may potentially burden patients with costs that they have to pay upfront, with the risk of not receiving reimbursement.[244]

It is now appropriate for us to move once again towards the work of the Court of Justice, accurately analysing the *Petru* case[245], which brought some important news on the State of cross-border healthcare in the Union.

3. The *Petru* Judgement, basic medical tools are to be taken into account when assessing the status of the patient under Regulation 1408/71.

3.1 The facts

Ms Petru is a Romanian national that in 2007 suffered a myocardial infarction, following which she underwent a surgical operation.

In 2009 her condition got worse, and she got admitted to the *Institutul de Boli Cardiovasculare* (Institute for Cardiovascular Disease) in Timișoara (Romania). There, she was examined, and the decision to proceed with open heart surgery was taken, so as to replace the mitral valve and insert two stents.

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243 ComunicazionedellaCommissioneeuropeaalParlamentoeuropeo,al Consiglio, al Comitato economico e sociale e al Comitato delle regioni, "Non discriminazione e pari opportunità: Un impegno rinnovato", COM (2008) 420 def., 2 luglio 2008, p. 5.

244 Cross-border patient mobility in the European Union: in search of benefits from the new legal framework, Journal of Health Services Research & Policy 2014, Vol. 19(4) p. 196.

245 Case C-268/13, *Elena Petru v Casa Județeană de Asigurări de Sănătate Sibiu and Casa Națională de Asigurări de Sănătate*, ECLI:EU:C:2014:2271.

Ms Petru decided, consequentially, to travel to a clinic in Germany for the carrying out of the procedure. The reason behind her choice was that she believed the infrastructure in the hospital establishment to be inadequate for such a surgical procedure. The surgery and the post-operative expenses in Germany amounted to a total of EUR 17.714,70.

In compliance with EU law, Ms Petru asked in 2009 for the cost of the operation to be covered on the basis of form E-112. She presented the request to the *Casa Județeană de Asigurări de Sănătate Sibiu* (Health Insurance Agency, Sibiu District), which rejected it on the grounds that the healthcare service sought by the patient was to be provided in a medical establishment in Romania within a reasonable length of time in the light of the current state of health of Ms Petru and the course of the disease.

In 2011 Ms Petru lodged a civil action against the *Casa Județeană de Asigurări de Sănătate Sibiu* and the *Casa Națională de Asigurări de Sănătate* (National Health Insurance Agency) claiming for the refund of the costs sustained in Germany for her operation by way of damages. The argument was that the hospital conditions at the *Institutul de Boli Cardiovasculare* in Timișoara were particularly inadequate: medication and basic medical commodities were lacking, and the number of beds was insufficient.

In 2012 her action was dismissed by judgement.

Ms Petru proceeded to appeal against the said judgement before the *Tribunalul Sibiu* (Regional Court, Sibiu), on the basis of Article 208(3) of Law No 95/2006, Article 22(1)(c) and the second subparagraph of Article 22(2) of Regulation No 1408/71, and the Charter of Fundamental Rights of the Union.

The respondents in the main proceeding contend that the appeal should be dismissed, stating that Ms Petru did not meet the necessary conditions to allow for the issuing of Form E-112 since she had not demonstrated that it would have been impossible for her to receive the necessary healthcare services in Romania within a reasonable length of time.[246] They rely on Regulations 1408/71 and 574/72, Law

[246] Case *Petru* C-268/13, par. 15.

No 95/2006[247] and Decree No 592/2008[248], as amended by Decree No 575/2009, and Article 8 of Decree No 729/2009[249].

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[247] Article 208(3) of Law No 95/2006 on reform of the healthcare sector (Legea nr. 95/2006 privind reforma în domeniul sănătății, Monitorul Oficial al României, Part I, No 372, of 28 April 2006) provides:

"*Health insurance shall be compulsory and shall operate as a harmonised system. The objectives set out in paragraph 2 shall be achieved in accordance with the following principles:*

(a) the freedom of insured parties to choose between insurance bodies;

(b) solidarity and subsidiarity in the creation and use of the funds;

(c) the freedom of insured parties to choose between providers of healthcare services, medicines and medical devices in accordance with this law and the framework contract;

(d) decentralised, autonomous management and administration;

(e) the compulsory payment of health insurance contributions for the purposes of creating a single national health insurance fund;

(f) the participation of insured parties, the State and employers in managing the single national health insurance fund;

(g) the provision of basic healthcare services to all insured parties in a fair and non-discriminatory manner;

(h) transparency in all activities relating to the health insurance system;

(i) free competition between healthcare providers entering into contracts with health insurance bodies."

[248] Under Article 40(1)(b) of the Annex to Decree No 592/2008 of the President of the National Health Insurance Agency (Ordinul președintelui Casei Naționale de Asigurări de Sănătate nr. 592/2008) of 26 August 2008 approving the detailed rules for use, within the framework of the Romanian health insurance scheme, of the forms provided pursuant to Regulation No 1408/71 and Regulation No 574/72 (*Monitorul Oficial al României*, Part I, No 648, of 11 September 2008), as amended by Decree No 575/2009 (*Monitorul Oficial al României*, Part I, No 312, of 12 May 2009, and the corrigendum published in the *Monitorul Oficial al României*, Part I, No 461/3 July 2009):

"*The E112 form is intended for employed or self-employed persons and members of their family authorised by the competent body to travel to another Member State in order to receive medical treatment.*"

Article 40(3) of the Decree provides:

"*The provision of Form E 112 in the situation contemplated in Paragraph 1(b) may not be refused by the competent body where the treatment in question is among the benefits provided for by the legislation of the Member State on whose territory the person concerned resides and where he cannot be given such treatment within the time normally necessary for obtaining the treatment in*

3.2 The question and the answer.

The referring court states how, in essence, the parties disagree on the interpretation of the provisions of national and EU law applicable to the dispute.

It is therefore asked by the court whether the requirement contained in the second subparagraph of Article 22(2) of Regulation 1408/71 is to be considered as categorical or as reasonable. [250]

The question revolves around the fact that a required surgery could, technically, be carried out in due time in the country of residence, but a lack of medicines and necessary medical supplies and infrastructure could amount to a situation where the required medical treatment cannot be provided for the purposes of the aforementioned provision.

The Court of Justice starts by observing that the second subparagraph of Article 22(2) of the aforementioned Regulation lays down two conditions which, if both satisfied, make the authorisation by the competent institution mandatory. The case at hand is concerned with the second condition contained in the provision, where it is required that the treatment that the patient plans to receive in a Member State different from the one of residence cannot be given within the time usually necessary for obtaining the treatment in question in the Member State of affiliation

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question in the Member State of residence, regard being had to his current state of health and the probable course of his disease."

[249] Article 8(1) of the Annex to Decree No 729/2009 of the National Health Insurance Agency, approving the detailed rules for reimbursement and recovery of the costs of healthcare provided on the basis on international measures in the field of healthcare to which Romania is a party (Ordinul nr. 729/2009 al Casei Naționale a Asigurărilor de Sănătate pentru aprobarea Normelor metodologice privind rambursarea şi recuperarea cheltuielilor reprezentând asistența medicală acordată în baza documentelor internaționale cu prevederi în domeniul sănătății la care România este parte), of 17 July 2009 (Monitorul Oficial al României, Part I, No 545, of 5 August 2009), provides:

"*If a person insured under the Romanian health insurance scheme travels to another Member State of the European Union to receive medical treatment there without the prior authorisation of the Health Insurance Agency with which he is registered as an insured person, he must bear the costs of the medical services provided.*"

[250] Case *Petru* C-268/13, par. 17.

having taken into account the state of health and the probable course of the disease.[251] [252]

The Court has already held, in the previous case-law, that the authorisation required cannot be refused if the same or equally effective treatment cannot be given in good time in the Member State of residence of the patient[253].

With that in mind, it is pointed out that, in order to establish whether a treatment that is equally effective for the patient is available in due time in the Member State of residence, the competent institution has to take into account all the circumstances of the specific case[254].[255]

Of the aforementioned circumstances that have to be kept in mind may be the lack of medication and necessary medical supplies and infrastructure. As the Advocate General mentioned in his Opinion in point 25, the second subparagraph of Article 22(2) of Regulation 1408/71 does not make a distinction between the reasons for which a particular treatment cannot be provided in good time. The lack of medication and of medical supplies and infrastructure can, therefore, make it impossible for the same or equally effective treatment to be provided in good time in the Member State of residence.

The Romanian and United Kingdom Governments, as well as the European Commission, have argued that the question whether it would indeed be impossible must be determined by reference to all the hospital establishments, in the Member State of affiliation, that are capable of providing the treatment in question, as well as the period within which the procedure could be obtained in good time.[256] In the case at hand, it was established by the report of the general practitioner in Romania that Ms Petru needed the surgery to be carried out within three months.

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[251] See *Elchinov*, C-173/09, EU:C:2010:581, par.53 and 54.

[252] Case *Petru* C-268/13, par. 30.

[253] See *Inizan*, C-56/01, EU:C:2003:578, par.45 and 60; *Watts*, C-372/04, EU:C:2006:325, par.61, and *Elchinov*, EU:C:2010:581, par. 65.

[254] See *Inizan*, C-56/01, EU:C:2003:578, par.46; *Watts*, C- 372/04, EU:C:2006:325, par.62, and *Elchinov*, EU:C:2010:581, par.66.

[255] Case *Petru* C-268/13, par. 32.

[256] Idlib, par.34.

It is also observed by the Romanian Government that Ms Petru had the right to approach any other medical establishment in Romania with the equipment necessary to carry out the treatment that she needed. It follows that the referring court should have determined whether the said treatment could have been carried out within three months in another hospital establishment in Romania. [257]

Having considered the aforementioned arguments, the Court of Justice ruled that the authorisation necessary under Article 22(1)(c)(i) of Regulation 1408/71 cannot be refused for lack of medication and essential medical supplies and infrastructure that the hospital treatment concerned cannot be provided in good time in the insured person's Member State of residence. In order to establish whether that is impossible, it has to be decided by reference to all the hospital establishments in the Member State that are capable of providing the treatment in question and by reference to the period within which the procedure could be obtained in good time.[258]

4. The aftermath of the *Petru* judgement. An outlook on the future of cross-border patient mobility.

The *Petru* judgement brings forth consequences for the field of cross-border healthcare as a whole.

Among the many peculiar things that come out of this case, it must be noticed how the Court decided both in favour of the patient and of the government. This was because it was recognised how the lack of medication and basic necessities might result in undue delay, giving the patient the possibility of receiving treatment in an adequate environment. The interests of the governments were, however, still protected due to the fact that the Court stated how the Member States could comply with their obligation to provide treatment with reference to all the hospital establishments located in their territory.

[257] Idlib, par.35.

[258] Idlib, par.36.

It can be derived from this that the quality of the healthcare provided can be, and is, a relevant factor to be considered when it comes to the right of the patient to be treated. The problem with this is that the concept of quality is hard to be strictly defined, as it is very elusive[259]. The meaning of the principle could be derived with the use of the idea of international state-of-the-art, which is, however, hard to adapt due to the fact that it curbs the competence of the Member States to define the national health basket. Complications also arise when the Court of Justice stated that, sometimes, it does not exist[260]. What is clear is that healthcare has to be evidence-based[261].

Some scholars[262] hold that the solution of the Court may prove "extremely toxic for the healthcare system concerned"[263], and it is considered surprising on a series of points.

The first one relates to the conditions that need to be fulfilled in order to be granted authorisation to receive healthcare abroad[264]. Up to the *Petru* judgement, the Court

[259] Legido-Quigley H, Glinos IA, Walshe K, van Beek B, Cucic C, McKee M. Quality and safety. In: Wismar M, Palm W, Figueras J, Ernst K, van Ginneken E, editors. Cross-border health care in the European Union, 121. Copenhagen: European Observatory on Health Systems and Policies; 2011. p. 123.

[260] Mossialos E, McKee M. Is a European healthcare policy emerging? British Medical Journal 2001;323(7307):248.

[261] Council Conclusions on Common values and principles in European Union Health Systems, O.J. 2006 C 146, p. 1 (3).

[262] See Vassilis Hatzopoulos, *Some thoughts on the fate of poorer Member States' healthcare systems after the ruling in Elena Petru*, European Law Review 2016, 41(3), 424-430.

[263] Idlib, p.2.

[264] As we have seen, the two conditions are: 1. The treatment in question should be among those covered by the home State authorities, and 2. The same or equally effective treatment should not be available within reasonable time in the national, and state-funded, healthcare system. If on the other hand the same treatment is available within the national territory but in a privately funded facility, there is no reason why the national facility should be preferred over that of another Member State; see Smits-Peerbooms (C-157/99) [2001] E.C.R. I-5473 .

had interpreted both the criterias of what constitutes 'reasonable time'[265] and of whether treatment available in Member Statee A is 'equally effective'[266] to one available in Member State B. What happened in *Petru* was that, for the first time, the question on the 'equally effective' is asked not regarding the actual treatment offered, but rather, in terms of the material conditions for the treaetment (number of available beds, sterile material etc.). This evaluation of the Court seems inappropriate for judicial review because it ignores the fact that the output of a healthcare system is directly proportional to the inputs allocated towards. The implication of this is that the Court indirectly judges the aforementioned inputs which are part of the political choices of a country which, reasonably so, should not be subjected to judicial review. The standards that citizens expect out of publicly-funded services changes depending on the context, and no judge should be allowed to evaluate whether their expectations are acceptable or not. While in the past the Court did examine the efficiency of public services of the Member States[267], it was done with the objective in mind of achieving efficiency (the relationship between inputs/outputs) rather than the effectiveness (the level of the service provided) of the service at issue.

Another point is raised when it is to be assessed the quality of healthcare services provided by public hospitals, more specifically, it is unclear on what basis should the national court be the judge of that.

It is also concerning that there is no assurance on the fact the the home Member State of the patient at issue (Romania) will actually make the necessary money transfers to the host Member State's competent authorities (Germany). As the Advocate General Crus Villalòn states, it is unlikely to believe that a system which cannot afford sterile bandages and basic tranquillisers at home will repay its debts created by an individual patient in a foreign Member State. This is particularly true

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[265] Müller-Fauré v Onderlige Waarborgmaatschappij oz Zorgverzekeringen UA (C-385/99) [2003] E.C.R. I-4509; [2004] 2 C.M.L.R. 33 ; and Watts (C-372/04) [2006] E.C.R. I-4325 .

[266] See Smits-Peerbooms (C-157/99) [2001] E.C.R. I-5473 .

[267] See Höfner v Macrotron GmbH (C-41/90) [1991] E.C.R. I-1979; [1993] 4 C.M.L.R. 306 at [25], [29] and [31]; Criminal Proceedings against Corbeau (C-320/91) [1993] E.C.R. I-2533; [1995] 4 C.M.L.R. 621 at [19];

in a historic ocontext where ‘rich’ Member States are actively trying to curb social tourism[268]. .

Another problem that arises from the judgement is that the patient is positioned in a hard spot since they have to prove that treatment is not available in other hospital establishments in the country. Luckily for them, this is limited by the concept of undue delay. When enough time goes by, patients are allowed to go abroad if the treatment has not been provided; yet again, however, a problem presents itself, since determining the acceptable waiting time in any specific case can be problematic. Luckily for the patient, financial constraints are no longer able to be invoked in this environment[269]; however, limits to the patient mobility by the Member States may be put in place if they reshape the health basket of their citizens or if they restrict the reimbursement to a specific group of patients[270][271]. This could work, since if treatment is not available “at home”, it cannot be subject to refund if obtained

[268] In particular the UK Government has introduced stricter eligibility measures and has cut down on welfare

benefits, in order to reduce its appeal to putative free movers from poorer Member States; see *G. Hewitt, "Clash over EU migrants and benefits" (27 November 2013), BBC News/Analysis*, http://www.bbc.co.uk/news/world- europe-25117119; this in turn has provoked a similar debate in Germany: see *V. Pop, "German conservatives stir up ‘welfare tourism’ row" (4 December 2013), EU Observer*, http://euobserver.com/social/122339 [Both referenced as of 20 April 2016]. The Court ha salso validated such restrictive practices in Dano v Jobcenter Leipzig (C-333/13) EU:C:2014:2358; [2015] 1 C.M.L.R. 48. And Jobcenter Berlin Neukolln v Alimanovic (C-67/14) EU:C:2015:597; [2016] 1 C.M.L.R. 29 .

[269] This could, consequencially, bring forth an increase of patients that travel in order to receive better healthcare.

[270] On the multi-level mechanisms of interaction between law and governance in the field of healthcare, see G de Búrca and J Scott, ‘Narrowing the gap? Law and New Approaches to Governance in the European Union’(2007) Columbia Journal of European Law 513–17; T Hervey and L Trubek, ‘Freedom to Provide Health Care Services Within the EU: An Opportunity for a Transformative Directive’ (2007) Columbia Journal of European Law 623–47; M Dawson, Three Waves of New Governance in the European Union (2011) European Law Review 2, 208–25, esp 214.

[271] Levaggi L, Levaggi R. Welfare properties of restrictions to healthcare based on cost effectiveness. Health Economics 2011;20(1):101–10,

abroad. This could only be counterargued by the right to life contained in Article 2[272] of the Charter of Fundamental Rights of the European Union in life-threatening cases. This possibility is very much real and is scary for the well being of the citizens as well for the possibility of having a more integrated and united EU.

As we have already discussed, the judgement broadens the freedom of EU citizens when seeking care outside their State of affiliation. There is a consequence of this that tends to be forgotten. What the judgement implies, in essence, is that the healthcare systems of the Member States are put against one another in a "free market", where competition is very much present. The poorer EU countries that struggle already to pay for keeping up and running their healthcare system may see their condition to be worsened in the event that an increasing number of citizens decide to be treated abroad. This is somewhat mitigated by the case-law of the Court of Justice and the EU legislation, where patients are allowed to be reimbursed only up to the point where they would have been covered financially by the social security system of affiliation. In our view these measures would become obsolete if more and more patients manage to actually enjoy their mobility in the EU; were the number of individuals that cross borders in order to obtain healthcare to rise, the Member States would find themselves to have to deal with an ever increasing amount of bureaucracy and administrative burdens. Our hope is that, in the nearest future, the Union is going to come up with a mechanism that is conceived with a type of cross-border patient mobility that is not limited to a small minority of citizens, but rather, one that can withstand large quantities of users.

Of course, some may argue that this would cause a "race to the top", as the Member States might try to incentivise patients to come and use their facilities, creating a positive loop where each country specialises in a specific healthcare sector; however, in a world where public expenditure on healthcare is very low, precisely due to austerity measures, it is hard to predict whether this would be the case. It would be more logical, and somewhat pessimistic at the same time, to suppose that a "race to the bottom" would be created, where, in order to maintain a financially sustainable healthcare system, Member States would opt for the cheapest products

[272] "*Everyone has the right to life.*

No one shall be condemned to the death penalty, or executed "

and doctors, in order to attract less wealthy patients that need to be treated. The sad consequence of this would be that the more better off individuals would be able to travel to the Member States that spend more money on quality treatment rather than to the ones that try to "get by" day by day, while more indigent patients would receive arguably worse therapy because they have lower financial opportunities (notwithstanding the fact that a significant amount of money is usually spent in advance in order to obtain healthcare abroad).
The hope is that the "race to the top" will be a driving mechanism for cross-border healthcare, but only time will tell.

This is where we are today: cross-border patient mobility has changed a lot since the founding of the ECSC and has managed to undermine the principle of territoriality that pervaded the administering of healthcare.
The Petru judgement is, for now, the end of our journey when it comes to the case-law of the Court of Justice on the topic, and the Directive 2011/24/EU is the latest development in EU legislation on the matter at issue.
To better understand where we are headed for the future of EU cross-border patient mobility, in the next chapter, we are going to analyse the actual data on the statistical impact of the topic of our discussion thanks to a 2015 Eurobarometer. Due to the importance of technology for the field of healthcare, we are also going to dissect the eHealth Action Plan 2012-2020 of the European Commission and its Interim Evaluation of 2014.

CHAPTER IV

THE FUTURE OF CROSS-BORDER PATIENT MOBILITY: FROM THE EUROBATOMETER TO EHEALTH, WITH AN INSIGHT ON THE COVID-19 PANDEMIC.

1 The different types of Eurobarometers and their relevance for cross-border healthcare. The usefulness of technology in eHealth and for dealing with the COVID-19 pandemic.

We are now going to discuss on the future of cross-border healthcare, with regard to the effectiveness of the relevant legislation[273], as well as to the role of technology and how it can be of help.

Our work is going to focus on three topics: the first one is about a Special Eurobarometer carried out in 2015. Eurobarometers are surveys that have been conducted regularly by the European Commission since 1973. What they do is they tackle a wide range of topics regarding the European Union and their perception within the citizens of the Member States. The ones introduced in the early 70s are called 'Standard Eurobarometers', which are conducted twice a year, and deal with topics that are consistet throughout the years in order to allow for an easier comparating effort between different editions. However, the one that we are going to focus on is a Special Eurobarometer. Special Eurobarometers were introduced first in 1990, and are focused on topics that are 'complementary' to the ones contained in the Standard edition. They deal with some recurring topics such as agriculture, enegy, environment, family, immigration and technology. With its analysis we are going to investigate on the level of knowledge that Europeans have regarding their rights concerning cross-border healthcare. As we have seen in previous chapters, the field is struggling in terms of publicity and awareness from the public: this is the reason why it is useful to have relevant data, so that possible shortcomings may be tackled appropriately. During the analysis of the study we are also going to compare the relevant data with a 2007 Flash Eurobarometer that was

[273] For a more detailed analysis that discussess the impact of Directive 2011/24/EU, see paragraph 2.7 of Chapter III.

conducted on the same topic. A Flash Eurobarometer is another type of survey: it was introduced in the 1990s and is carried out via telephone in a relatively brief timeframe on a specific topic. The reason why it is useful is that it allows for a quick gathering of data that can be immediately of benefit to the EU institution which asked for it (this is also another relevant difference, since the Commission is not the only institution that can ask for a Flash Eurobarometer).

The second one is about the eHealth Action Plan (eHAP) of 2012, a document drafted by the European Commission, in which a project for its correct deployment is set out. Two years later, in compliance with what is stated in the eHAP, an Interim Evaluation was carried out, and we are going to disccuss it in order to better understand the positions of the stakeholders in the field. The usefulness of technology in the area of healthcare is massive, this is why it is appropriate, for the Commission, to have a plan on how to better integrate them together; all of this must, of course, be done with the protection of the users in mind, both from a user-friendliness standpoint, as well as from a privacy standpoint.

Lastly, we are going to analyse the EU response to the COVID-19 pandemic, primarily focusing on the healthcare-related aspects, as well as briefly mentioning the tools at its disposal and the possible criticalities that could arise from the adoption of contact-tracing applications.

1.1 The Special Eurobarometer 425[274]: an assessment of the perception of the cross-border patient mobility system by the EU citizens.

It has been four years since the drafting of the 2011/24/EU Directive on cross-border patient mobility: two years after its actual entry into force[275], a survey relating to the rights of patients in the context of cross-border healthcare in the European Union was coordinated by the European Commission.

Eurobarometers help us gather indicative data on the perception of EU citizens regarding a specific topic, and are ordinarily carried out by the Commission in every sector in which it has powers of legislative initiative. They are also helpful due to

[274] Special Eurobarometer 425, Patients' rights in cross-border healthcare in the European Union, Conducted by TNS Opinion & Social at the request of the European Commission.

[275] The directive came into force in all EU Member States on the 25th of October 2013.

the fact that, thanks to the findings, EU law can gather valuable inputs in order to become more efficient and closer to its citizens.

As we have seen in the previous chapters, the providing of cross-border health services, as well as their coverage by national health systems, are highly complex processes that may cause legal uncertainties for the patient. Directive 2011/24/EU has cleared up things a bit, but the fact that some judgements of the Court of Justice, like the one in the *Petru* case, manage to be very innovative in their essence, they allow us to see how the legal environment surrounding this topic could and should be improved upon.

It must be mentioned that in May 2007 a similar survey[276] was conducted on "Cross-border health services in the EU" to find out how many people had received healthcare outside their country of affiliation, how much EU citizens were aware of their rights for the receiving of healthcare abroad, and if, and under what circumstances, they were willing to receive medical treatment abroad.

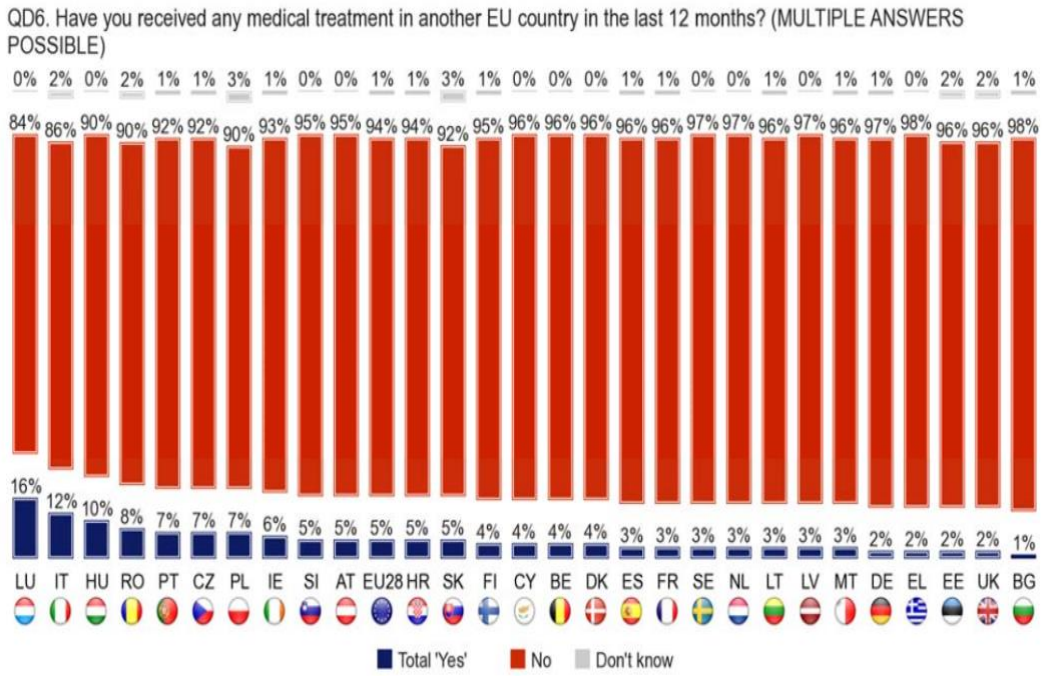
The Special Eurobarometer 425 of 2015 is intended as a follow-up to the Flash Eurobarometer of 2007, in order to evaluate the state of cross-border healthcare after the enforcement of the Directive (the carrying out of the Eurobarometer is not foreseen by the aforementioned provision). The study is designed to investigate four main areas, which we are going to dive into in the next paragraphs. It must be noted that in order to understand more clearly the impact of the provision there will be an indicative comparison between the results of the two studies, and we will present graphs of the 2015 Eurobarometer in order to better visualise the results of the study.

1.2 How many Europeans received medical treatment in another EU country within the last year.

On this question, it is clear that not much has changed in terms of the relative amount of exposure to foreign healthcare systems. In 2007 only 4% of the

[276] Flash EB Series #210, Cross-border health services in the EU, Conducted by The Gallup Organization.

respondents had received treatment in another EU country in the prior 12 months, while in 2015 the number shifted towards 5%



Source: Special Eurobarometer 425, Patients' rights in cross-border healthcare in the European Union, Conducted by TNS Opinion & Social at the request of the European Commission. P.4

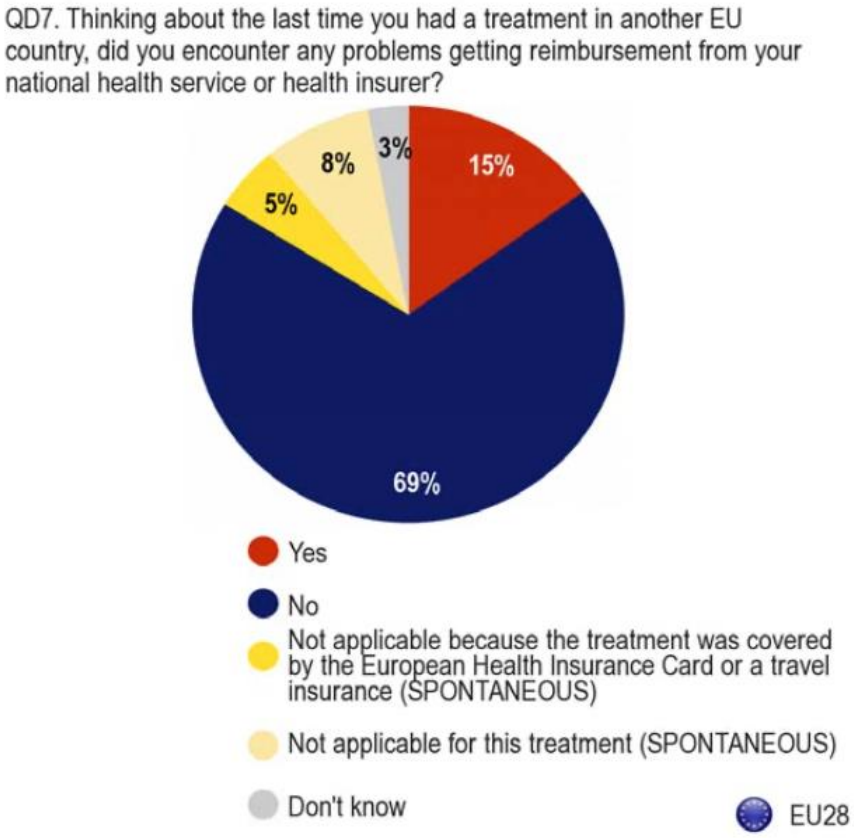
While the median percentage is 5%, there are notably two countries which go beyond 10%, Luxembourg (16%) and Italy (12%). The percentage is undoubtedly low when compared to the expectations that the Directive tried to set with its implementation; however, it is still more than double the average of the EU28.

The position of Luxembourg is also quite peculiar: since it is such a small country that confines with multiple Member States, mobility of patients is more comfortable to achieve. It should, therefore, not come as a surprise that the citizens of Luxembourg are the ones that enjoy the most (out of the EU28) their rights on patient mobility. A higher level of movement from smaller countries, in general,

may also be explained by the possibly lower offer of highly specialised care, which tends to be more profitable in larger states.[277]

The Italian presence should not be surprising as well when its relations with neighbouring Member States Austria and Slovenia are taken into account, mainly thanks to the northern-most bordering regions such as Veneto.[278]

The respondents who answered positively to the first question were asked whether they encountered any problem when trying to obtain reimbursement from their respective competent institution.



Source: Special Eurobarometer 425, Patients' rights in cross-border healthcare in the European Union, Conducted by TNS Opinion & Social at the request of the European Commission. P.5

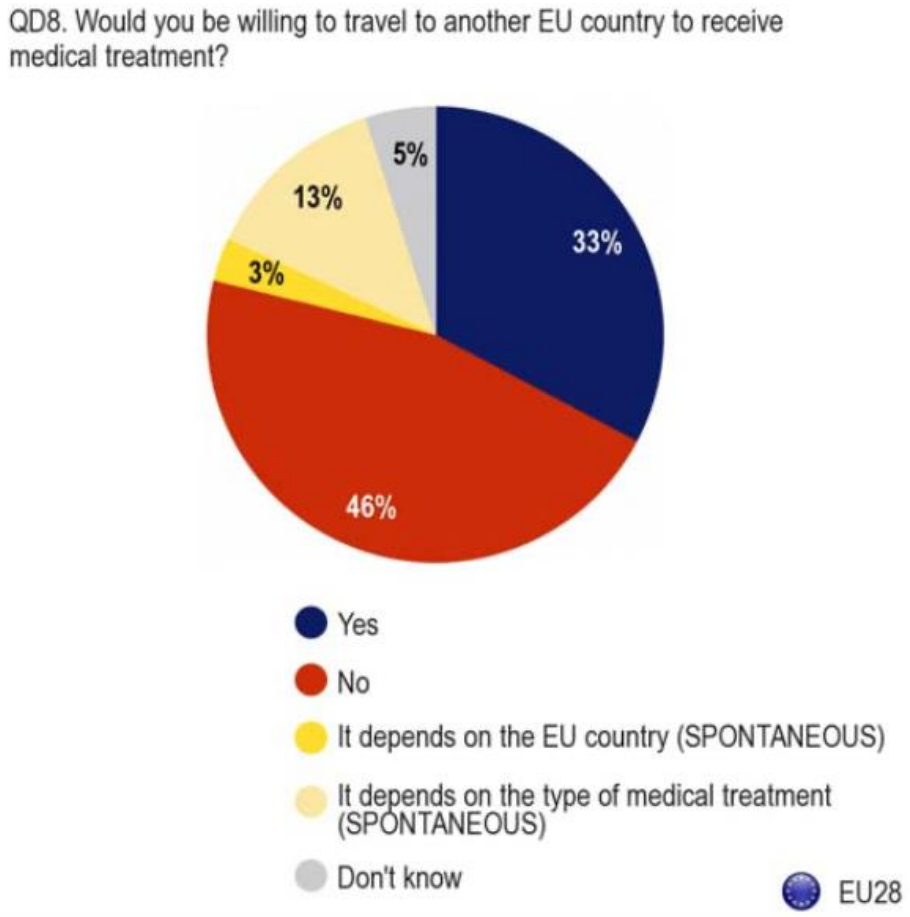
277 Panteli D, Wagner C, Verheyen F, Busse R. Know before you go': information- seeking behaviour of German patients receiving health services abroad in light of the provisions of Directive 2011/24/EU. J Health Serv Res Policy 2015;20: 154–161.

278 On this note see Rosenmöller Magdalene, *Patient Mobility in the European Union. Learning from experience*, p.9-22 and 79-96.

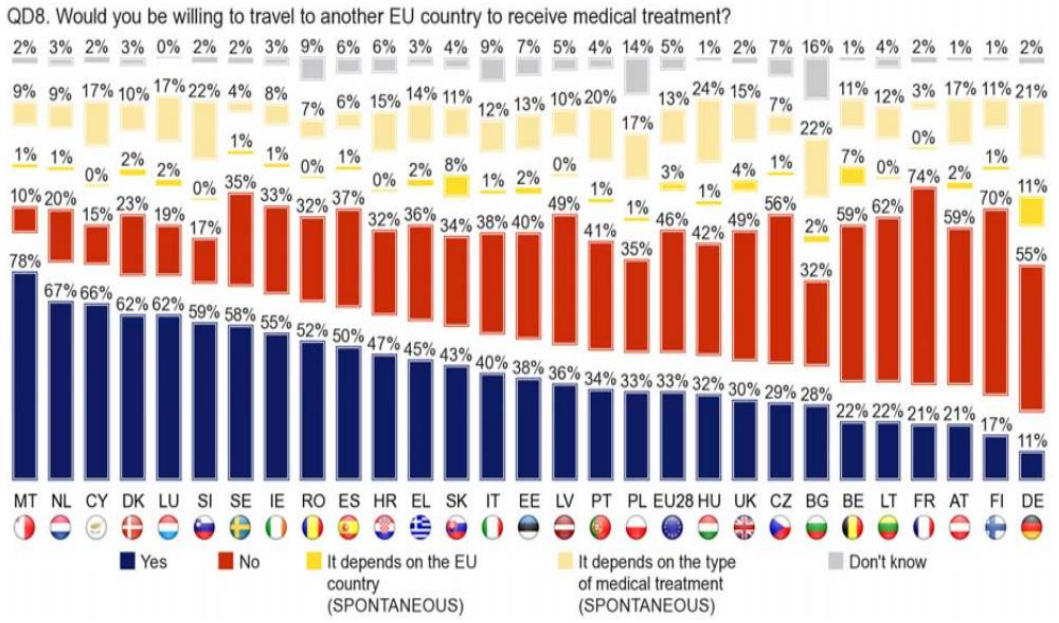
As we can see from the graph, only 15% of them stated that they did have problems, while the vast majority of them, 69%, did not have any kind of trouble.
After the previous negative data on the number of citizens that received treatment abroad, this is undoubtedly a positive sign. What can be derived from it is that the mechanism on the reimbursement set-up by the Directive 2011/24/EU is working; the problem, in line with what was mentioned in Chapter 3 on the Commission Report on the implementation of the Directive, is that the provision lacks publicity, which in turn explains perfectly why there is a 5% relevance among the EU28.

1.3 How willing Europeans are to receive medical treatment abroad and what are the strongest barriers.

Having already established that only around 5% of Europeans tend to take advantage of the possibility of accessing healthcare in other EU countries, it is reasonable to ask ourselves if there is a willingness to actually receive treatment abroad and, if not, what are the barriers that prevent it.
In the 2007 study, 53% of the respondents stated that they would be willing to obtain medical treatment in another EU country. This number has slightly declined over the years since in the 2015 Eurobarometer only 49% of the respondents answered positively to the question,



Source: Special Eurobarometer 425, Patients' rights in cross-border healthcare in the European Union, Conducted by TNS Opinion & Social at the request of the European Commission. P.6



Source: Special Eurobarometer 425, Patients' rights in cross-border healthcare in the European Union, Conducted by TNS Opinion & Social at the request of the European Commission. P.6.

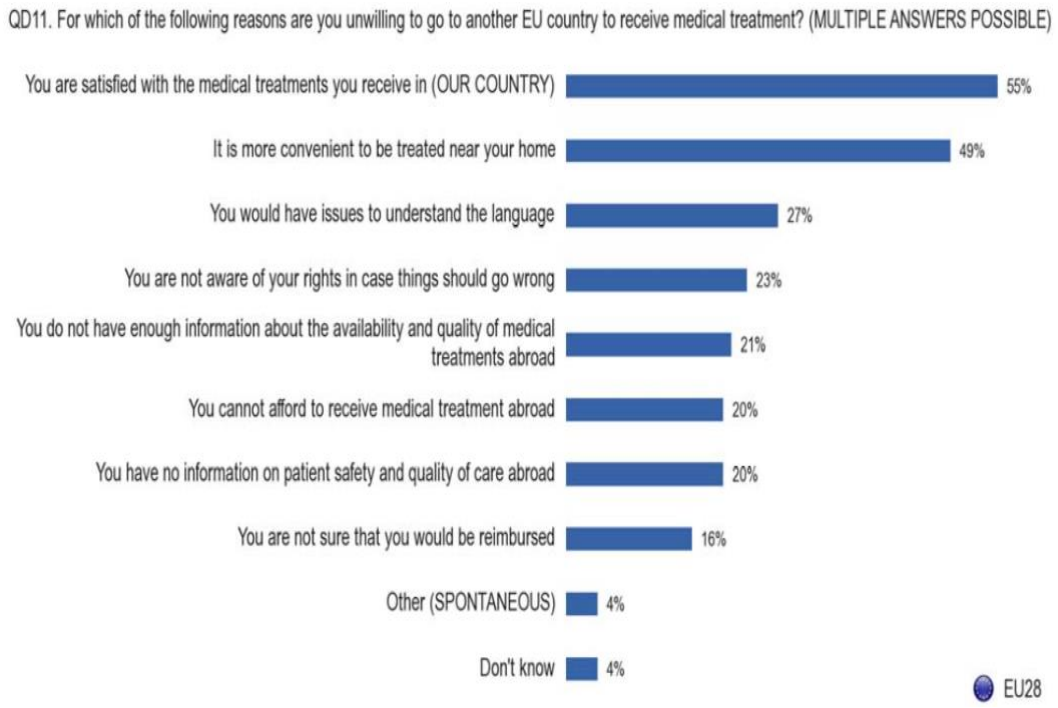
What is not surprising is that the citizens of smaller countries are the ones that are most open to the possibility of receiving healthcare abroad: Malta is in the lead with 78%, followed by the Netherlands with 67% and Cyprus with 66%. In accordance with what we just said, we find Germany and Finland respectively in last place with 11% and second-to-last place with 17%.

There is a sort of pattern here: the smaller the country, the more its citizens are open to the possibility of travelling with healthcare in mind. A smaller Member State may be subject to a scarcity of pieces of equipment or staff, and could, therefore, bring its citizens to cross the borders when in need of treatment.

The contrary is true for the largest nations: France and Germany, for example, have the citizens who are the least likely to exercise their rights on cross-border healthcare due to the fact that a larger nation gives its citizens more extensive possibilities for the obtaining of treatment. This is also to be viewed in light of the *Petru* judgement, where the Court of Justice stated how, when reviewing the possibility of accepting an E-112 form request, the competent institution has to take into account the opportunity of providing the medical service without 'undue delay' in any hospital establishment of the Member State. Another leading factor is probably the satisfaction of the citizens with the national healthcare system: the more a citizen is content with what they are provided with, the more likely they are to remain close to home when being treated.

What we just mentioned is corroborated by the fact that, when the interviewees responded negatively to why they were unwilling to receive treatment in another EU country, 55% of them replied by stating that they were satisfied with the healthcare system of their home State. Almost half of the respondents, 49% of them to be exact, also confirmed what we postulated earlier, that it is more convenient to be treated near their home. The language barrier is also a problem for 27% of the

respondents.



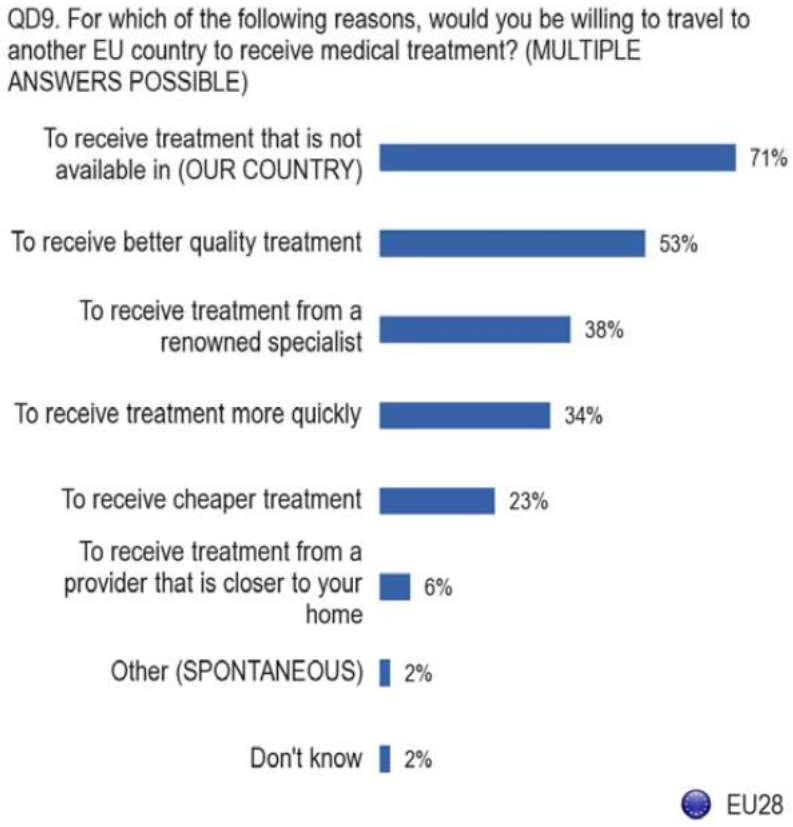
Source: Special Eurobarometer 425, Patients' rights in cross-border healthcare in the European Union, Conducted by TNS Opinion & Social at the request of the European Commission. P.9

All of these answers do not give the EU, or national, legislator any margin for improvement on the relevant provisions; 23% of those interviewed stated that they were not aware of their rights if something were to go wrong, but luckily for them, the National Contact Points were put in place by the Directive 2011/24/EU just for that purpose.

In the previous Chapters, we mentioned multiple times how economic barriers to the receiving of cross-border healthcare could have had a substantial impact on the reason as to why patients could not have received treatment abroad. The results of this Eurobarometer give us a perspective on the fact that, while this is not too much of a crucial factor, it should not be underestimated nonetheless; in fact, 20% of the respondents stated that they could not afford to receive medical treatment abroad. As already stated, creating a system of subsequent reimbursement for the receiving of medical treatment can bring forth disparities that may get larger over time, making the divide between higher and lower-income families even harsher.

A similar question was asked in the 2007 study, and it turned out that the convenience of being treated near the home of the patient was mentioned more than the satisfaction in the healthcare system of the country of affiliation.

Having assessed what the barriers that European citizens encounter when seeking treatment abroad are, it is appropriate to understand in what cases they are instead willing to travel to another EU country for the said reason.

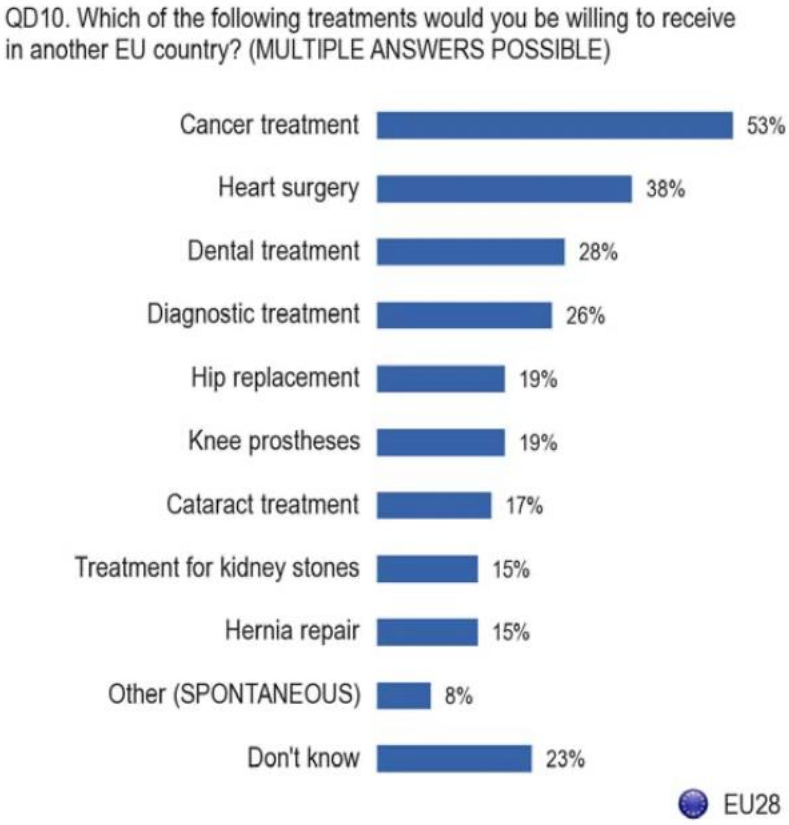


Source: Special Eurobarometer 425, Patients' rights in cross-border healthcare in the European Union, Conducted by TNS Opinion & Social at the request of the European Commission. P.7.

The vast majority of the respondents (71%) stated that they would access a foreign healthcare system to receive treatment that is not available in their country, and a slight majority (53%) would do it in order to obtain treatment of a higher quality. Somewhat surprisingly, only 34% of the interviewees held that they would be willing to obtain healthcare in another EU Member State to receive treatment more quickly. It is useful to keep in mind that the concept of 'undue delay' was heavily influenced, in its historical development, by the system of waiting lists (see *Watts*

case in Chapter 2). The surprising aspect of this data is that waiting times are not a dominant factor in motivating people to seek healthcare abroad, which is somewhat counterintuitive. Interestingly enough, a similar question was asked in the 2007 study, and the results, in terms of the hierarchy of answers, was the same.

The data also suggests that when it comes to seeking healthcare in another EU country, those who are willing to do so decide in favour of it in order to obtain treatments that are particularly complex.

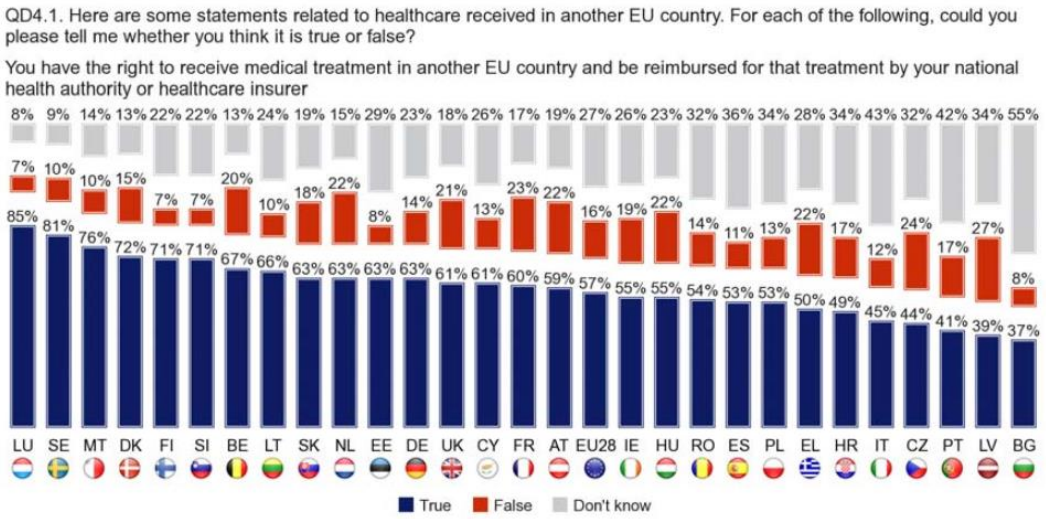


Source: Special Eurobarometer 425, Patients' rights in cross-border healthcare in the European Union, Conducted by TNS Opinion & Social at the request of the European Commission. P.8.

As we can see, 53% of the respondents opted for cross-border healthcare in case of cancer treatment, and 38% for heart surgery. This data goes hand-in-hand with what we previously said about the reasons why EU citizens are willing to travel abroad: if there is a field in which a patient wants the utmost quality possible it is undoubtedly when a complicated treatment is to be carried out.

1.4 How much do Europeans know about their rights, particularly regarding their entitlement to reimbursement by competent healthcare institutions.

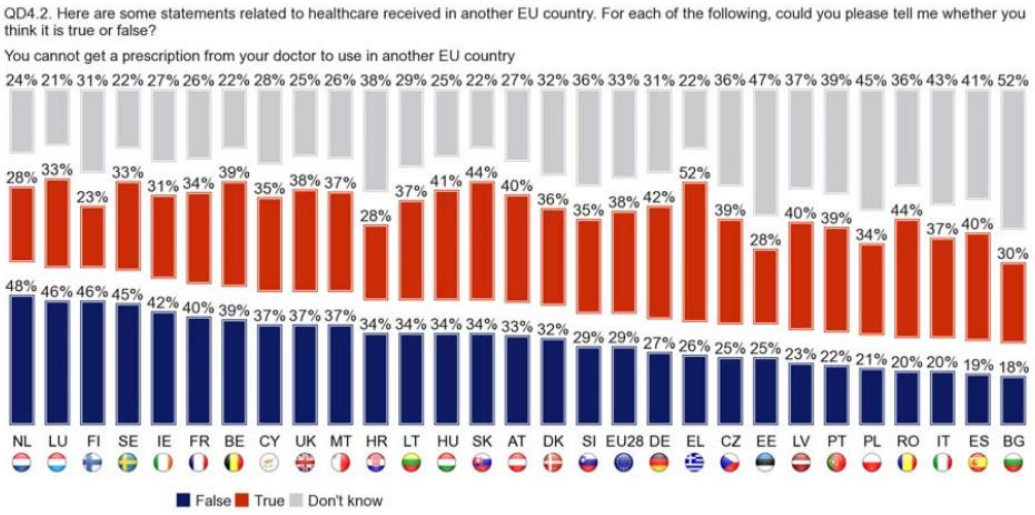
In order to assess the knowledge of the respondents on their rights when it comes to cross-border healthcare, they were given three statements that they had to decide if they were true or false.



Source: Special Eurobarometer 425, Patients' rights in cross-border healthcare in the European Union, Conducted by TNS Opinion & Social at the request of the European Commission. P.10.

The first one was about the possibility of reimbursement from the competent national institution in the case of foreign-provided healthcare; the correct answer is true. The data suggests that the majority of EU citizens (57%) are aware of the fact that there is such a mechanism in place: Luxembourg is rightfully at the top of the list with 85% of its respondents, followed by Sweden (81%) and Malta (76%).

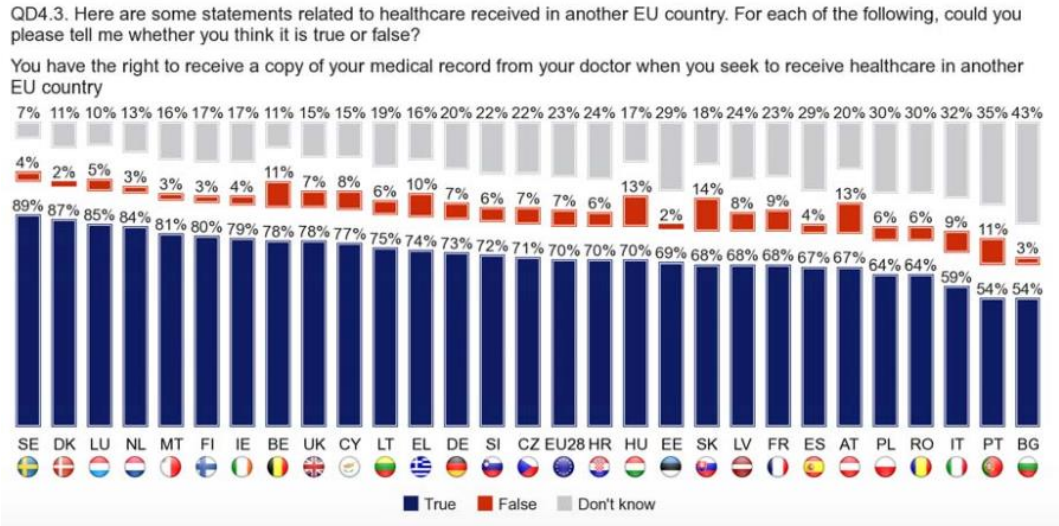
The second question posed to the interviewees was whether it is true that they could not get a prescription from a doctor to use in another EU Member State; the correct answer is false.



Source: Special Eurobarometer 425, Patients' rights in cross-border healthcare in the European Union, Conducted by TNS Opinion & Social at the request of the European Commission. P.11.

On this particular question, most of the respondents are either wrong or unaware. The only exception is Greece, with 52% of correct answers.

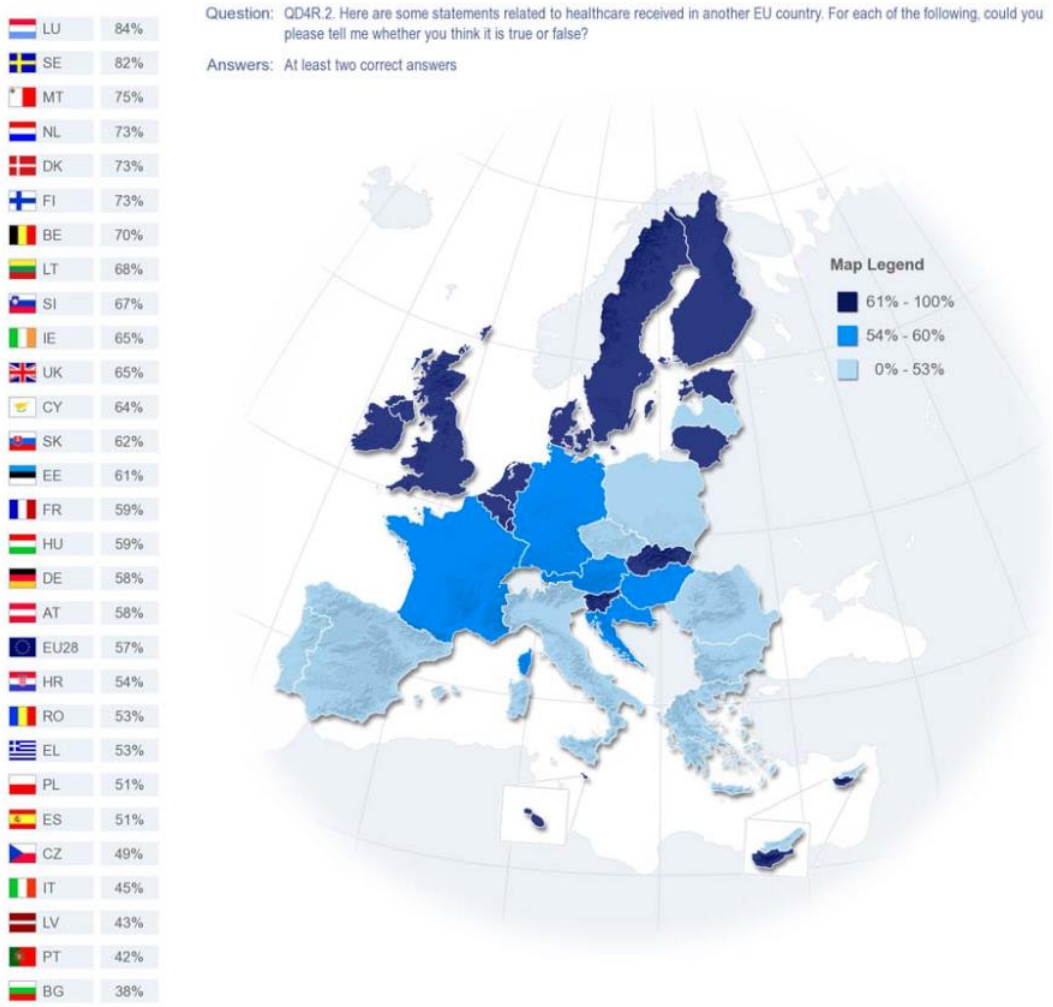
Thirdly, the responders were asked whether they have the right to receive a copy of their medical records; the correct answer is true.



Source: Special Eurobarometer 425, Patients' rights in cross-border healthcare in the European Union, Conducted by TNS Opinion & Social at the request of the European Commission. P.11.

The majority of the respondents have demonstrated here that they are aware of the fact that they are entitled to receive a copy of their medical record when seeking healthcare in another Member State.

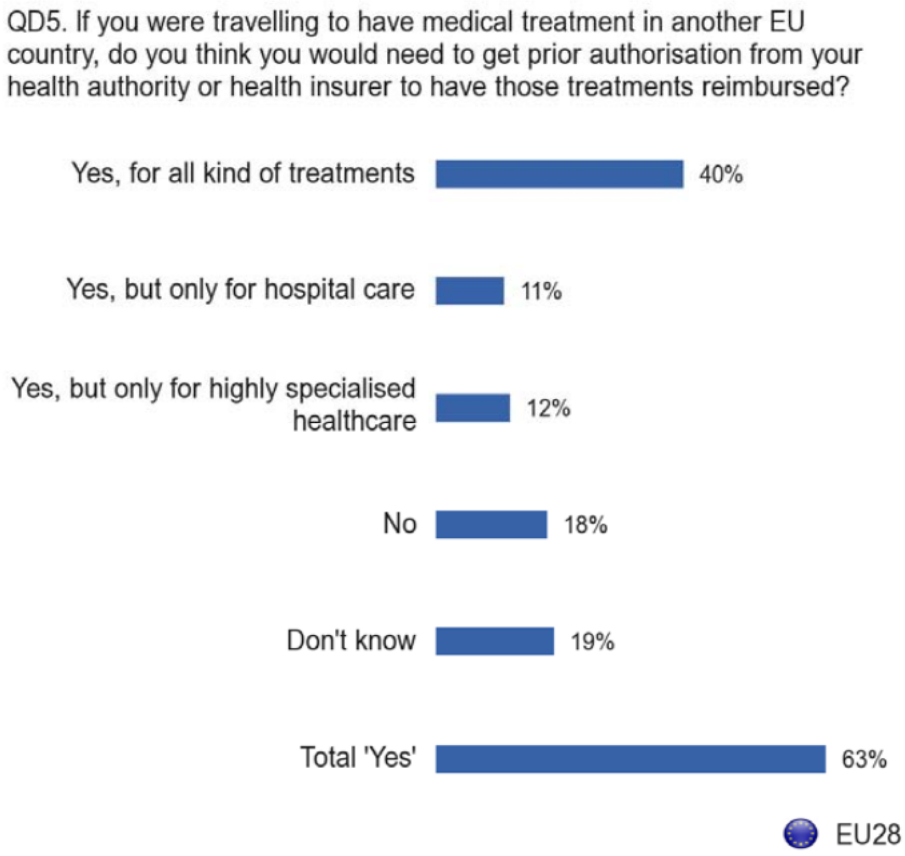
Overall we can safely say that the EU citizens have partial knowledge of their rights when it comes to cross-border healthcare. The map below helps us see both the number of Member States that answered at least two questions correctly, as well as a clear geographical divide between Northern and Southern Member States, and Western and the Eastern Member States.



Source: Special Eurobarometer 425, Patients' rights in cross-border healthcare in the European Union, Conducted by TNS Opinion & Social at the request of the European Commission. P.12.

Such a divide should be prevented from exacerbating in the long run, as it does not benefit anyone. Both the EU legislator and the Member States should address this issue with a more 'advertised' approach towards cross-border patient mobility and the rights that citizens are entitled to.

Discouragingly enough, the trend seems to go the opposite way: the interviewees were asked whether prior authorisation is needed in case of willingness to receive treatment abroad, and they showed evident unfamiliarity with the topic.



Source: Special Eurobarometer 425, Patients' rights in cross-border healthcare in the European Union, Conducted by TNS Opinion & Social at the request of the European Commission. P.13.

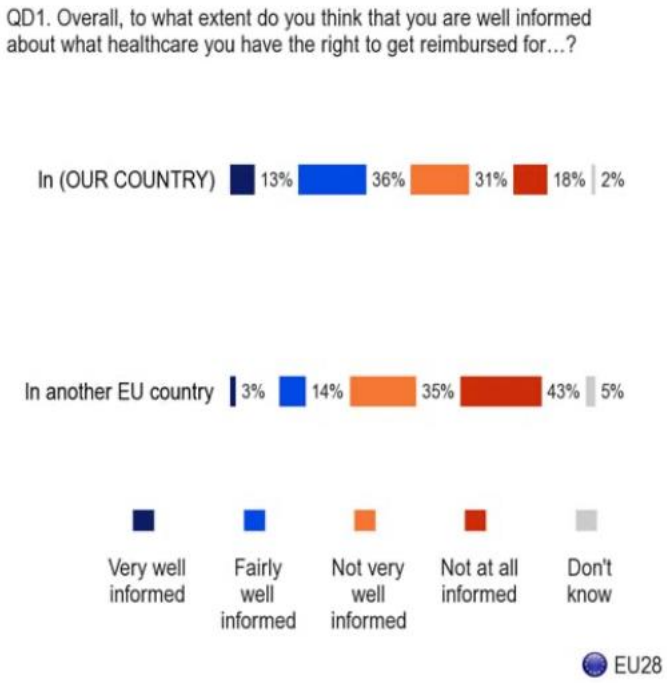
Of the respondents, 40% answered stating that they need a prior agreement for all kinds of treatment, while 18% said no, and 19% admitted that they did not know.

The current provisions on prior authorisation depend not just on the country, but also on the treatment concerned as we have seen in previous Chapters. The environment as a whole, in this topic, is highly complex and could benefit from a clearer and more uniform approach by the Union.

At the time of the study, six Member States did not require their citizens to get prior authorisation before seeking treatment in another EU country, the Netherlands, Sweden, Lithuania, the Czech Republic, Estonia and Finland; ironically enough, in these countries a high percentage of the respondents felt that they needed a prior agreement. Of the "total yes", we find 93% for the Netherlands, 83% for Sweden, 72% for Lithuania, 68% for the Czech Republic and 62% for both Estonia and Finland. This discrepancy is, once again, caused by the lack of publicity and knowledge we keep mentioning.

1.5 What is the level of knowledge that the Europeans have on cross-border health services, and what type of information do they feel they have access to.

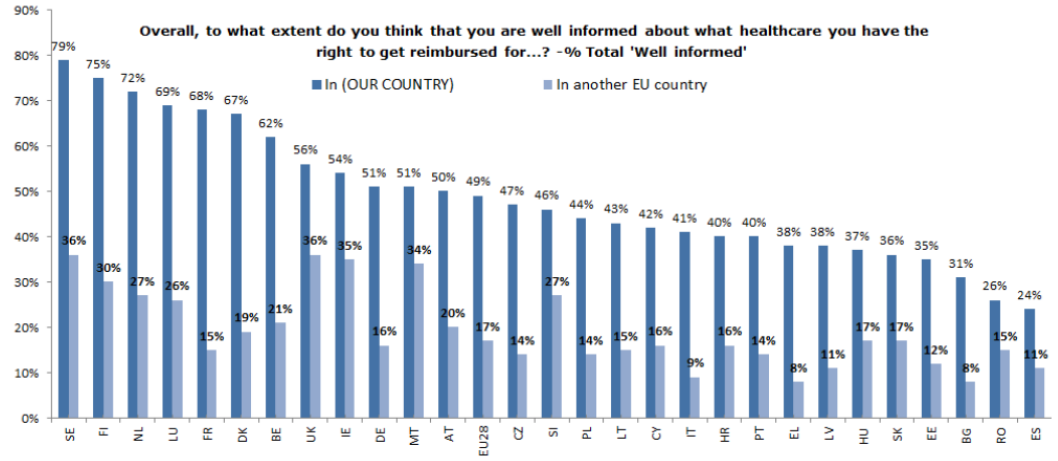
The interviewees were asked how much knowledge they felt they had about their right to be reimbursed for healthcare in their own country.



Source: Special Eurobarometer 425, Patients' rights in cross-border healthcare in the European Union, Conducted by TNS Opinion & Social at the request of the European Commission. P.15.

As we can see from this graph, only half of them said that they felt informed; however, when asked about their rights when being treated in another EU country, less than two out of ten felt that they were informed.

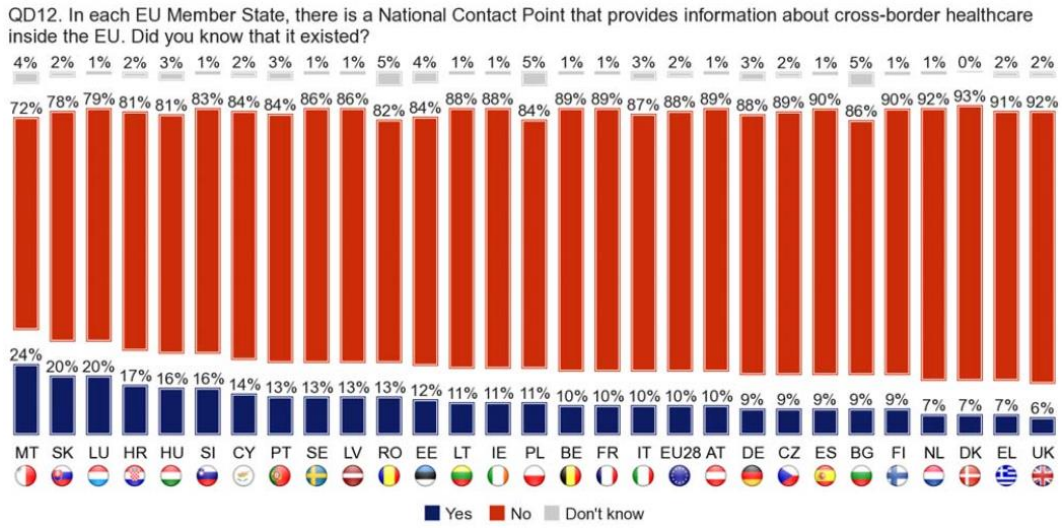
In the chart below, we can see the aforementioned discrepancy of perceived knowledge and how much it changes, sometimes dramatically, from Member State to Member State.



Source: Special Eurobarometer 425, Patients' rights in cross-border healthcare in the European Union, Conducted by TNS Opinion & Social at the request of the European Commission. P.15.

This gap is probably due to the higher familiarity with the national healthcare system of the Member State of residence, as well as the infamous lack of publicity that the European provisions on cross-border healthcare have chronically suffered from.

We have previously seen how the Directive 2011/24/EU establishes the National Contact Points as crucial providers of information in the context of cross-border patient mobility and the rights deriving therefrom.
The respondents were asked if they knew of their existence.



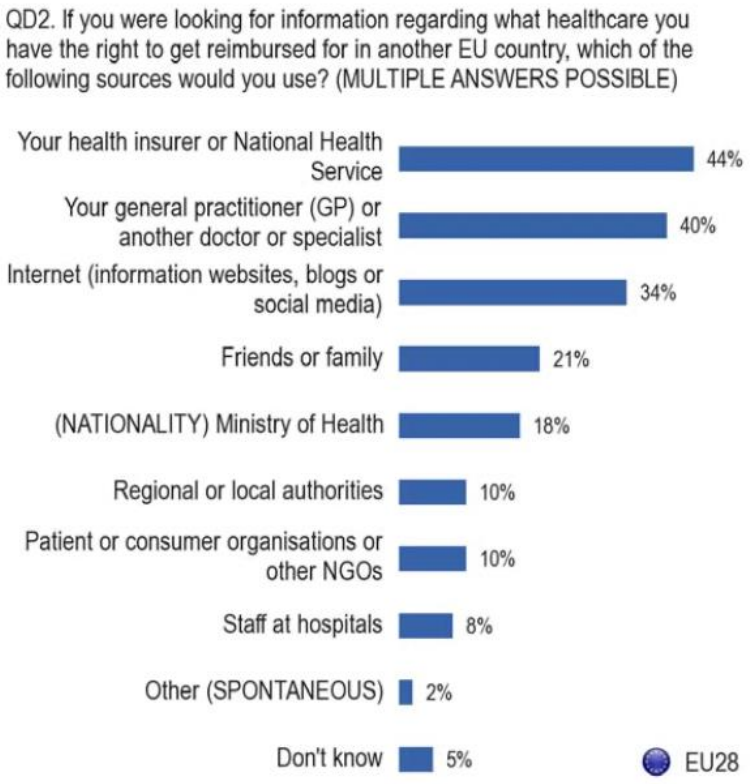
Source: Special Eurobarometer 425, Patients' rights in cross-border healthcare in the European Union, Conducted by TNS Opinion & Social at the request of the European Commission. P.18.

Not surprisingly, the data shows that only one European out of ten was aware of them and of the fact that they provided such information. Even countries that usually "scored" well in this study, like Malta and Luxembourg, responded poorly with 24% and 20% respectively.

Of those who answered positively to the question, only 16% of them said that they ever contacted them in their home country.

What we can derive from this is that National Contact Points are mostly unknown throughout the EU, and so, citizens revolve towards other subjects in order to obtain information in this field.

The respondents were asked about this, and this is what came up.



Source: Special Eurobarometer 425, Patients' rights in cross-border healthcare in the European Union, Conducted by TNS Opinion & Social at the request of the European Commission. P.16.

The interviewees were able to choose several options from a list of possible sources, and a large proportion of them decided to seek information from their health insurer

or National Health Service (44%), while many also chose their general practitioner or another doctor or specialist (40%). Not surprisingly, the internet was present on the list with 34% of the responses.

It is clear how the link between the patient and the national health institutions and the doctors is substantial and would probably be a more appropriate way to carry out information on our topic in coordination with National Contact Points.

1.6 Conclusion of the study: a different system is possible, but hard to achieve.

The recurring theme throughout the carrying out of the Eurobarometer is always the same: not enough citizens are aware of their rights.

The system set-up by the mix of EU provisions and national legislation (together with the jurisprudence of the Court of Justice) is far too complicated to be clearly understood and enjoyed by the average person.

There is a fundamental ignorance of how and at what conditions a patient may be entitled to be treated abroad.

The National Contact Points are a useful tool for the providing of information[279] as long as people know of their existence, which is what in the end is limiting their use from the citizens.

We can derive from the data of the study that a more appropriate system for the providing of information could be put in place if general practitioners and specialised doctors were the ones that divulged the information in concert with the competent health institution for the Member State. The National Contact Point could then become a centre for the precise spreading of information towards the aforementioned individuals, in order to reach as many of them as possible.

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[279] "It is beyond doubt that these national contact points form an indispensable link in the chain of delivering cross-border care": F. Pennings, "The Draft Patient Mobility Directive and the Coordination Regulations of Social Security" in Health Care and EU Law (2011), p.158, underlines that the national points of contact "may help patients to realise their rights". According to others, national contact points "have a vital role in transmitting information to the patient on care delivery in the Member States of treatment". See S. de la Rosa, "The Directive on Cross-border Healthcare or the Art of Codifying Complex Case Law" (2012) 49 C.M.L. Rev. 36.

This would work in principle but is hard to achieve in practice due to the lack of political discourse around true patient mobility in the Union. As we have assessed already in our discussion, the Member States are very much wary when it comes to delegating sovereignty over their national health systems to the EU: much like criminal provisions, the way healthcare is delivered in a specific country is a delicate matter, and the closer the citizens feel that his needs can be met, the better he will perceive the providing of the service.

We have analysed how the current system of cross-border patient mobility is perceived by the European citizens. What we are going to do now is talk about future possibilities in this field, particularly regarding technology and eHealth.

2. eHealth

In this section of our discussion, we are going to analyse two documents of the European Commission[280], as well as present some possible improvements for this field.

It should be noted that the first eHealth Action Plan[281] was adopted in 2004, and, since then, the Commission continued developing targeted policy initiatives that fostered a widespread adoption of eHealth throughout the EU.[282]

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[280] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *eHealth Action Plan 2012-2020 – Innovative healthcare for the 21st century*, COM (2012) 736 final, and
Interim evaluation of the eHealth Action Plan 2012-2020, A study prepared for the European Commission DG Communications Networks, Content & Technology.

[281] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area***,** COM (2004) 356 final**.**

[282] Examples include: eHealth action plan COM(2004) 356 final; the Lead Market Initiative for Europe and the associated eHealth Roadmap [COM(2007) 860 final Annex I – Commission Staff Working Document: SEC(2007) 1729], the Commission Recommendation on cross-border interoperability of electronic health record systems (2008/594/EC), the Communication on benefits of telemedicine for patients healthcare systems and society (COM(2008)689 final)

Moreover, with the adoption of Directive 2011/24/EU on the Application of Patients' Rights in Cross Border Healthcare, the eHealth Network was established in its Article 14[283]; this marked a further step towards formal cooperation on eHealth, which aimed at maximising social and economic benefits through the interoperability and the implementation of eHealth systems.

2.1 eHealth Action Plan 2012-2020, Innovative healthcare for the 21st century

This document has the objective of addressing and removing the barriers that prove cumbersome for the obtainment of a better integration in eHealth across Europe. It also outlined the vision for eHealth in line with the aims of the Europe 2020 Strategy[284] and the Digital Agenda for Europe.

The field of eHealth is one of high growth potential and possibilities for innovation, and it could bring the healthcare providers towards a productive exchange of health data if adequately unlocked. The global telemedicine market proliferated in the

[283] The Union shall support and facilitate cooperation and the exchange of information among Member States working within a voluntary network connecting national authorities responsible for eHealth designated by the Member States.

The objectives of the eHealth network shall be to:

(a) work towards delivering sustainable economic and social benefits of European eHealth systems and services and inter operable applications, with a view to achieving a high level of trust and security, enhancing continuity of care and ensuring access to safe and high-quality healthcare;

(b) draw up guidelines on:

(i) a non-exhaustive list of data that are to be included in patients' summaries and that can be shared between health professionals to enable continuity of care and patient safety across borders; and

(ii) effective methods for enabling the use of medical information for public health and research;

(c) support Member States in developing common identifi cation and authentication measures to facilitate transfer ability of data in cross-border healthcare.

The objectives referred to in points (b) and (c) shall be pursued in due observance of the principles of data protection as set out, in particular, in Directives 95/46/EC and 2002/58/EC.

The Commission shall, in accordance with the regulatory procedure referred to in Article 16(2), adopt the necessary measures for the establishment, management and transparent functioning of this network.

[284] Communication from the Commission Europe 2020 a strategy for smart, sustainable and inclusive growth - com(2010) 2020 final.

years prior to the action plan: from $9.8 billion in 2010 to $11.6 billion in 2011, and was expected to continue to expand to $27.3 billion in 2016, representing a compound yearly growth rate of 18.6%[285].

The benefits of eHealth, when it is applied correctly, can bring the Union towards a more 'citizen-centric' healthcare, which, in turn, would result in it being more targeted and efficient, while, at the same time, empowering the patients[286]. The aforementioned advantages have manifested themselves in the field of telemedicine when managing chronic conditions, mental health and health promotion[287]. Technology-assisted therapies have also produced similar results since they can effectively complement routine clinical care and improve the cost-efficiency of the treatments[288]. Moreover, the facilitation of eHealth is one of the concrete actions that can effectively promote the free movement of EU citizens within the EU[289].

We are now going to focus on the objectives of the Action Plan.

2.1.1 Achieving more extensive interoperability in eHealth services. The role of the eHealth Network.

In the paper, the Commission recognised the need for an eHealth interoperability[290] framework.

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[285] According to a BCC Research study of March 2012, as referenced in the Action Plan at p.4.

[286] "Patient empowerment is a process to help people gain control, which includes people taking the initiative, solving problems, and taking decisions, and can be applied to different settings in health and social care, and self management" [ENOPE 2012].

[287] See Staff Working Document Accompanying eHealth Action Plan – innovative healthcare for the 21st century, as referenced in the Action Plan itself at p.5.

[288] Economic Impact of Interoperable Electronic Health Records and ePrescription in Europe (01-2008/02- 2009):
http://ec.europa.eu/information_society/activities/health/docs/publications/201002ehrimpact_study-final.pdf

[289] EU Citizenship Report 2010 – Dismantling the obstacles to EU citizens' rights COM(2010) 603 final (see action 7).

[290] "Interoperability is where two or more eHealth applications [...] can exchange, understand and act on citizen/patient and other health-related information and knowledge among linguistically and culturally disparate clinicians, patients and other actors or organisations within and across health system jurisdictions, in a collaborative manner".

We have already seen how Directive 2011/24/EU sets up the eHealth Network in Article 14, which is the principal strategic and governance body at EU level that works with the objective of achieving a higher level of interoperability of cross-border eHealth services. The Network also has the duty to produce guidelines on eHealth and on an interoperability framework in the aforementioned field.
Having standards in a European and international context is crucial in order to ensure the interoperability of ICT[291] solutions in general[292]. In eHealth, however, the said standards tend to not be specific enough[293]; this is where the role of the network is crucial since it is bound to give advice containing more detailed specifications. The network also has the duty to draw up guidelines on a non-exhaustive list of data which are going to be included in patients' summaries and can also be shared among healthcare professionals in order to obtain continuity of care and patient safety across borders.

In order to deploy eHealth correctly in Europe, it is fundamental to bring down legal barriers: this objective is addressed by the Directive 2011/24/EU, whose implementation aims at clarifying the rights of patients when it comes to obtaining cross-border healthcare.
On this note, we can also find the Commission Staff Working Paper on the applicability of the existing EU legal framework to telemedicine services[294], which clarifies the EU legislation applicable to issues regarding reimbursement, liability and data protection encountered when providing telemedicine across borders.

2.1.2 Empowering citizens and patients: enhancing rules on data protection.

In order to build trust in eHealth, there must be safeguards that give citizens the possibility to use health and well-being applications with peace of mind, ensuring

[291] Information and communications technology

[292] EU Study on the specific policy needs for ICT standardisation, http://ec.europa.eu/enterprise/sectors/ict/files/full_report_en.pdf

[293] European countries on their journey towards national eHealth infrastructures, EU Study, http://www.ehealth-strategies.eu/

[294] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0689:FIN:EN:PDF

"*the integration of user-generated data with official medical data so that care can be more integrated, personalised and useful for patients*"[295].

In order to modernise and strengthen the harmonisation process for the data protection rules of the time[296], the Commission adopted a proposal[297] for a regulation that would set out a general EU framework for data protection.

The said proposal held that eHealth and well-being ICT initiatives should integrate the privacy principle by default, and should make use of the Privacy Enhancing Technologies (PET's). Issues relating to data protection need to be addressed, moreover, in respect of the use of cloud computing[298] infrastructure and services regarding the processing of data on health and well-being.

Another area that should not be left aside is the one of 'mHealth' (mobile health). Just like the telemedicine market, the mobile health and well-being market have been snowballing; alongside it, the number of software applications for mobile devices (or 'apps') has continuously grown. These apps can offer information and diagnostic tools, as well as new modalities of care, with the consequence that they blur the distinction between the traditional clinical care provided by physicians and the self-administration of well-being. If used correctly, the apps could also be the mean for the interoperability that the EU so badly wants to obtain: softwares like Apple Health or Diasend, for example, provide the possibility to collect and share health data quickly and easily between patients and health professionals.

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[295] eHealth Task Force Report of May 2012 as referenced in the Action Plan p.9

[296] See EDPS Opinion on the data protection reform package, para. 298 and 299, 7 March 2012: http://www.edps.europa.eu/EDPSWEB/webdav/site/mySite/shared/Documents/Consultation/Opinions/2012/12-03-07_EDPS_Reform_package_EN.pdf

[297] Commission proposal for a regulation on the protection of individuals with regard to the processing of personal data and on the free movement of such data: http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf

[298] Cloud computing is a model for enabling ubiquitous, convenient, on-demand network access to a shared pool of configurable computing resources (e.g., networks, servers, storage, applications, and services) that can be rapidly provisioned and released with minimal management effort or service provider interaction. (The NIST Definition http://csrc.nist.gov/publications/PubsSPs.html#800-145)

However, these apps, if left to the forces of the market, could potentially harm users who are not knowledgeable in the field of healthcare. This is why, due to the complexity of the field, there is a need for further clarification on the legal framework that could be applicable to each specific area. Current structures could not be applied simply due to the rapid developments in the sector.

Digital health literacy is also essential for a successful deployment of eHealth; this is, however, where a significant barrier lies. There is a lack of awareness of eHealth opportunities and challenges for users, whether they are citizens, patients or professionals in the field of healthcare and social care.[299]

The objective is to ensure that the market for these apps meets the demand of the citizens for quality and transparency; this could, in our view, be achieved by facilitating high-quality and comprehensible information on the use and performance of these applications and ensuring interoperability between health and well-being areas.

2.1.3 Conclusions of the Commission. Good intentions and inconclusiveness.

The Commission recognises that the EU health systems are under severe budgetary constraints, due to the effects of the economic crisis, while at the same time having to deal with the challenges that are presented by an ageing population and their continually rising expectations, and those relating to the mobility of healthcare professionals and patients.

The possibility that eHealth represents for Europe is the fostering of a spirit of innovation that, in turn, ensures a higher level of health and care for EU citizens, as well as a more transparent and empowering relationship with healthcare as a whole.

There is, from the Commission, a duty to monitor the implementation of the Action Plan, and a report will be made on the progress and results achieved.

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[299] See evidence overview in Staff Working Document Accompanying the eHealth Action Plan and responses to the eHealth Action Plan consultation.
http://ec.europa.eu/information_society/activities/health/docs/policy/ehap2012public-consult-report.pdf

To recap, we can safely say that the Commission had the heart in the right place: eHealth represents an opportunity both for healthcare institutions as well as for patients. Both of them would benefit from the standardisation of protocols, the interoperability of data and the safety of a well-oiled legal and technological environment.

The world of apps on health and well-being can be used as a mean to the end of interoperability, as well as better mindfulness for users on the state of their health; although the low digital literacy represents an obstacle, at least for now, it is fair to say that more time was needed in order to reach a conclusion on how to tackle this challenge effectively.

2.2 Interim evaluation of the eHealth Action Plan 2012-2020

Two years after the drafting of the eHealth Action Plan, the Commission delegated this study in order to provide a first measurement of the progress made regarding the achievement of its objectives.

2.2.1 On the awareness of the eHealth Action Plan 2012-2020

Raising awareness on the eHealth Action Plan is considered one of the most fundamental impacts that it should have had, since, as we have seen time and time again, the lack of knowledge is a recurring theme in our discussion.

Such an increase is therefore not only needed, but also expected on two fronts: the first one is the one of the Commission (and its DGs) which are involved with its deployment, and the second one relates to the new stakeholders that are part of the mHealth and eHealth projects and initiatives.

From the subsequent report, however, it is clear how awareness has remained limited across the board.

The respondents were asked how they would describe their knowledge of the 2012-2020 Action Plan, and this is what came out of it.

Source: Interim evaluation of the eHealth Action Plan 2012-2020, conducted by Deloitte for the European Commission, p.31.

As shown by the graph above, 42% of the eHAP stakeholders consider their knowledge to be either poor (18%) or very poor (24%), while 28% deem it to be fair, and only 26% consider it to be good (16%) or excellent (10%).
This data is indicative on the degree of knowledge of the broader community of eHealth stakeholders; they themselves, when asked, confirmed that awareness and knowledge of the eHAP is not very widespread throughout the said community.
Moreover, several actions of the eHAP are not comprehended by stakeholders in the greater context of eHealth at levels, both national and global[300].

What can be derived is that there is a need to increase awareness of the overall Action Plan so as to bring together a number of eHealth activities and initiatives. The lack of a dissemination strategy for the eHAP as a whole makes it so that its awareness remains low and vague; it should not come as a surprise, then, that the most well-known actions are about the providing of funding opportunities as well

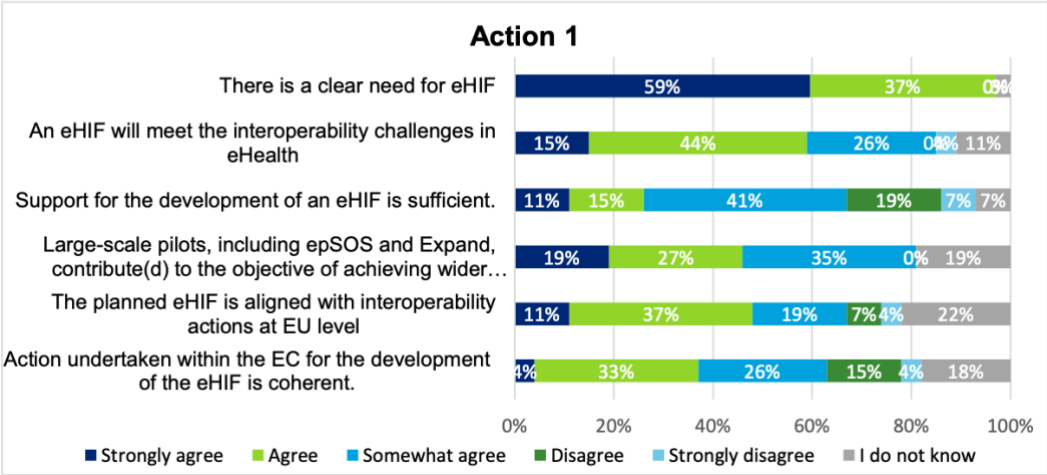
[300] This is demonstrated by the limited awareness of stakeholders on the coherence of eHealth actions at EU level, particularly under objective 4, p.62

as those that were actually promoted and spread via different media. Promoting the totality of the eHAP would convey the existence of a long-term vision of eHealth in the Union, which is what the field is in dire need of. As we mentioned earlier in the discussion, there is an absolute necessity for the whole field to be publicised as well as politically discussed and planned: the absence of a long-term vision for cross-border patient mobility and for eHealth remains one of its most significant flaws.

The study reports that, as suggested by the interviewed stakeholders, an easily accessible and straightforward communication package made available for use and prepared by the Commission would be massively useful for the purposes we mentioned beforehand.

2.2.2 On achieving more extensive interoperability in eHealth services

In order to obtain a higher level of interoperability in eHealth services, the study proposes to build an 'eHealth European Interoperability Framework' (eEIF), which would construct roadmaps for the development of the field, while also being based on the results of studies and research projects.



Source: Interim evaluation of the eHealth Action Plan 2012-2020, conducted by Deloitte for the European Commission, p.33.

According to the data gathered in the study, there is a unanimous agreement on the fact that the eEIF is needed; it is perceived as a way for increasing coordination

between different actors in the eHealth sector in the EU and for developing a cross-border eHealth system.

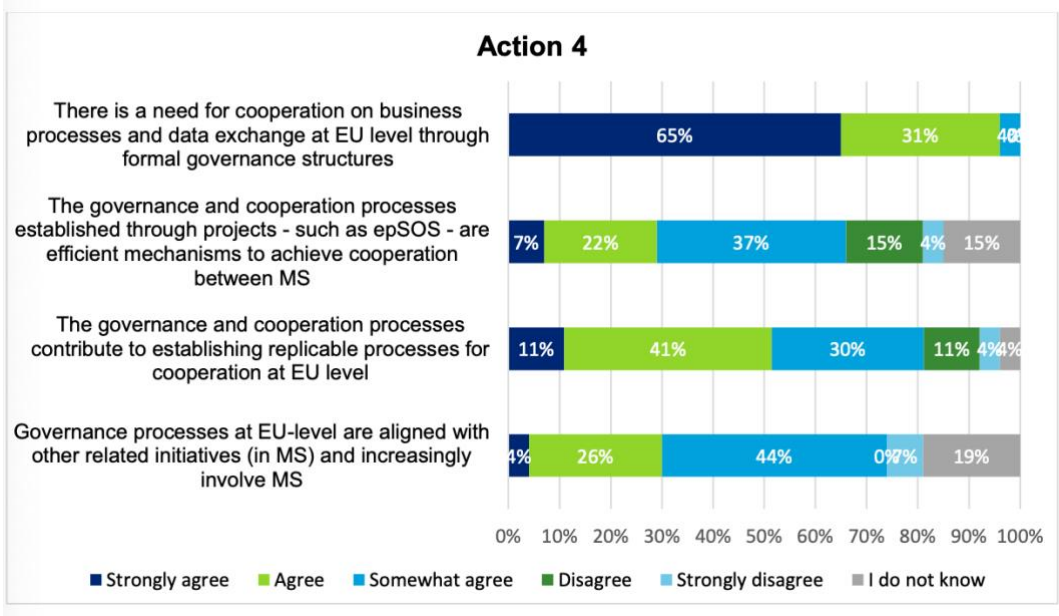
There are, however, doubts among stakeholders regarding the effectiveness of the eEIF when it comes to the challenges in the eHealth sector. The respondents perceive EU-wide interoperability as an ideal, long-term scenario, but the need for short-term help is very much present, and it remains unclear whether the eEIF would be fit for this role.

A short-term action of support is the one carried out by the Commission on the topic of organisational interoperability; its purpose is to achieve a higher level of integration of processes for cross-border eHealth. It is of concern for the way that organisations, like public administrations in the Member States, decide to cooperate in order to achieve their mutually agreed goals on eHealth.

Similar cooperation and integration processes have already been defined through the large-scale pilots such as the epSOS project[301], whose objective was ensuring the deployment of eHealth services across Europe.

[301] Smart Open Services for European Patients, epSOS, is a Europe-wide project organized by 27 beneficiaries representing 23 EU member states, including ministries of health, national competence centres and numerous companies.

The overarching goal of epSOS, is to develop a practical eHealth framework and an Information & Communication Technology (ICT) infrastructure that will enable secure access to patient health information, particularly with respect to basic patient summaries and ePrescriptions between different European healthcare systems.



Source: Interim evaluation of the eHealth Action Plan 2012-2020, conducted by Deloitte for the European Commission, p.39.

According to the perception of the stakeholders, there is a strong need for cooperation on business processes and data exchange at EU level through the use of formal governance structures (65% of them strongly agree, and 31% agree).

Doubts are expressed, however, when it comes to the timeliness and the communication efforts that surround these processes. There is also a feeling of not being sufficiently involved coming from stakeholders from the private sector and civil society.

The data also indicates a lack of clarity regarding the efficiency of large projects such as epSOS when it comes to the achievement of cooperation between the EU Member States.

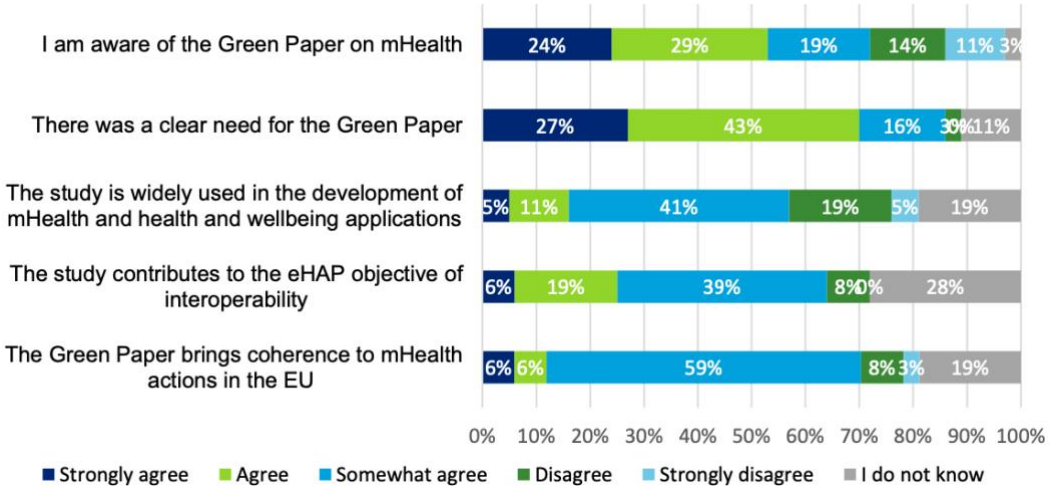
Another point that the gathered data points us to regards the interoperability of ICT-enabled solutions and data exchange: they are seen as the precondition for a higher level of coordination and integration across the whole chain of healthcare delivery and health data exchange, and they would, in turn, unlock the EU eEhealth single market.

As already mentioned previously, the eHealth Network plays a crucial role here, since it has the duty to draw up guidelines on a non-exhaustive list of data for

patients' summaries for health professionals, as well as common measures for interoperable electronic identification and authentication. To this point, what the data makes clear is that there is a broad agreement (80%) among stakeholders when it comes to the necessity to have EU-wide standards in eHealth at a technical level.

2.2.3 On mHealth and data protection

In 2014 the European Commission adopted a Green Paper on mobile health[302] ("mHealth") following the recommendations of the eHealth Task Force, which also pointed out its interest in the discussing of the concept of ownership and control of data and of its flow across health and care systems.[303]



Source: Interim evaluation of the eHealth Action Plan 2012-2020, conducted by Deloitte for the European Commission, p.43.

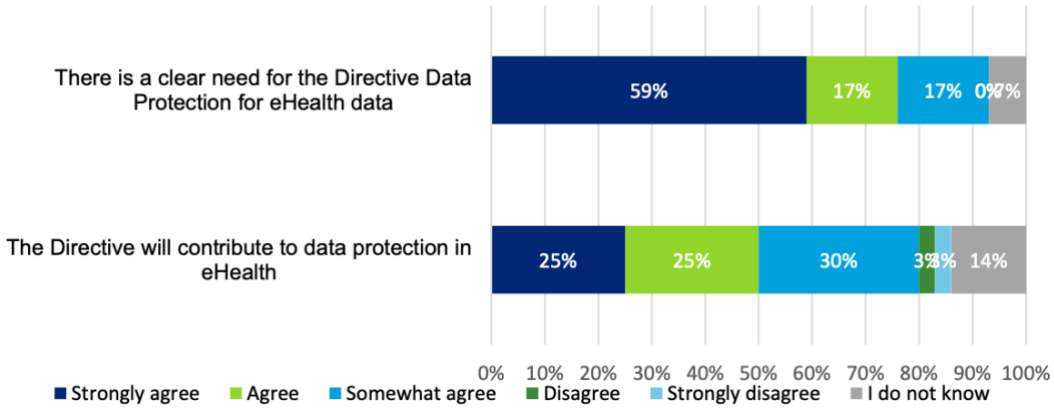
According to a vast majority of the stakeholders (70%), there was a need for the Green Paper on mHealth; however, when it comes to its awareness, results are mixed, even though it represents one of the most well-known actions of the eHAP.

302 https://ec.europa.eu/digital-single-market/en/news/green-paper-mobile-health-mhealth

303 The report of the eHealth Task force underlined the need to provide more clarity on the conditions for accessing and re-using health data for research and public health purposes. On the flow of data, it also held that it would be appropriate for it to be protected. eHealth and wellbeing ICT initiatives, it arguers, should integrate the privacy principle by default.

Although more than half of the stakeholders interviewed agree or strongly agreed on the fact that the Green Paper enjoys a satisfactory level of awareness, 25% of the respondents claim that a large number of stakeholders involved in the development of mHealth applications are unaware of it.
The feedback regarding the effectiveness of the Green Paper is generally positive, in that it contributes well to the eHAP objective of interoperability.

On the issue of data protection, at the time of the study, there was a clear consensus on the fact that an EU provision on Data Protection was necessary.



Source: Interim evaluation of the eHealth Action Plan 2012-2020, conducted by Deloitte for the European Commission, p.44.

According to half of the interviewees, such a Regulation would contribute to data protection in eHealth; it is also underlined how the involvement of patients would be crucial for its correct deployment.
The proposed provision came into existence in 2016 with the drafting of Regulation 2016/679[304], also known as 'GDPR'; in Article 9[305], it provides rules for the processing of special categories of data, among which we find health data.

[304] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

[305] Processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data

for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation shall be prohibited.

Paragraph 1 shall not apply if one of the following applies:

(a) the data subject has given explicit consent to the processing of those personal data for one or more specified purposes, except where Union or Member State law provide that the prohibition referred to in paragraph 1 may not be lifted by the data subject;

(b) processing is necessary for the purposes of carrying out the obligations and exercising specific rights of the controller or of the data subject in the field of employment and social security and social protection law in so far as it is authorised by Union or Member State law or a collective agreement pursuant to Member State law providing for appropriate safeguards for the fundamental rights and the interests of the data subject;

(c) processing is necessary to protect the vital interests of the data subject or of another natural person where the data subject is physically or legally incapable of giving consent;

(d) processing is carried out in the course of its legitimate activities with appropriate safeguards by a foundation, association or any other not-for-profit body with a political, philosophical, religious or trade union aim and on condition that the processing relates solely to the members or to former members of the body or to persons who have regular contact with it in connection with its purposes and that the personal data are not disclosed outside that body without the consent of the data subjects;

(e) processing relates to personal data which are manifestly made public by the data subject;

(f) processing is necessary for the establishment, exercise or defence of legal claims or whenever courts are acting in their judicial capacity;

(g) processing is necessary for reasons of substantial public interest, on the basis of Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject;

(h) processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services on the basis of Union or Member State law or pursuant to contract with a health professional and subject to the conditions and safeguards referred to in paragraph 3;

(i) processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy;

(j) processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be propor tionate to the aim pursued, respect the essence of the right

We have mentioned earlier how another significant barrier for the correct deployment of eHealth is the lack of awareness of opportunities and challenges for users. This is further exacerbated by the low levels of digital health literacy of citizens[306] against which the Commission supports activities that aim at increasing it.

According to the data gathered in the study, over 90% of the respondents agree on the fact that there is a need to increase funding for the eHealth digital literacy of citizens. A significant barrier for the achieving of this objective is identified in the lack of user-friendly tools and applications related to eHealth.

Over 80% of the stakeholders also agree on the fact that there is a need to develop guidelines for telemedicine services for health professionals.

2.2.4 Conclusions on the Interim evaluation of the eHealth Action Plan 2012-2020

From the data that we have gathered in our analysis of the study, we can say that there are two topics of interest for the eHAP.

First of all, there is a need for more publicity: the problem of the lack of awareness, when it comes to this kind of policy, is crippling. Topics like cross-border healthcare and eHealth can produce their best effects only when there is a large number of individuals that are at least aware of them. Specifically, when it comes

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to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

Personal data referred to in paragraph 1 may be processed for the purposes referred to in point (h) of paragraph 2 when those data are processed by or under the responsibility of a professional subject to the obligation of professional secrecy under Union or Member State law or rules established by national competent bodies or by another person also subject to an obligation of secrecy under Union or Member State law or rules established by national competent bodies.

Member States may maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health.

306 See Flash Eurobarometer report No. 404 "European citizens' digital health literacy" https://ec.europa.eu/public_opinion/flash/fl_404_en.pdf

The barometer assessed the type and sources of health-related information citizens search for using online and mobile technologies as well as their satisfaction with the information found and their future expectations for online health-related information.

to eHealth and mHealth, users are what keeps the lights on, this is why more publicity is needed. In our view, the Union could push the eHealth agenda forward by campaigning for a higher level of awareness, trying to reach users via social media. It is however understandable why that is hard to achieve since the political discourse is far from interested to this topic, and when it does, it looks at it in a narrow-minded way that is confined to the territory of a nation.

The second topic of interest to us is the fact that, according to the data, stakeholders are always in favour of a higher level of action from the Commission and the Union in this field: green-papers, as well as standards and guidelines, are almost always welcome. This should not come as a surprise: the Union, as we have seen, has problems in its communication, and users can reasonably feel abandoned by the entity that should foster the field the hardest. The EU has an incredible amount of human and financial resources that could allow it to push further eHealth and its correct deployment. If the Union gives guidelines on how to act, stakeholders will be much more confident in their actions when entering the market with their products or services. Because the field of eHealth is still in muddy waters, reasonable actors are induced to tread carefully, while unreasonable actors could profit from the lack of guidance from the Union.

We can assess, therefore, that eHealth and mHealth are still in their initial phase of growth in the EU area, but they need to be followed carefully by both stakeholders and the Union in order for them to create a thriving market and be a useful tool for their users.

It is appropriate for us to briefly mention the COVID-19 pandemic that is impacting so many lives around the globe.

It should be noted that, at the time of writing, the situation is still in development, therefore, all the information presented will have to be taken with a pinch of salt.

3. The COVID-19 pandemic: the tools at the disposal of the EU

The spreading of Coronavirus Disease 2019 (COVID-19) in many European countries lets us ask if the EU foresees the possibility of adopting policies or legislation in a case like the one at hand.

As we have discussed previously in our discussion, Member States hold most if not all of the cards when it comes to public health, and the situation of a pandemic is not different, as the Member States have the right to define their own healthcare policies under Article 168 TFEU.

The Union has however adopted a series of mechanisms that should be useful in case of an epidemic or a pandemic; already in 1998, with Decision 2119/98/EC[307], it set up a network for the epidemiological surveillance and control of communicable diseases in the Community. Later on, Decision No 1082/2013/EU[308] repealed and replaced the aforementioned provision; this new Decision revived the network for the epidemiological surveillance of communicable diseases and related special health issues. It also contained rules on the data and information that competent national authorities have to communicate, and it also provided for continued coordination of the network by the European Centre for Disease Prevention and Control (ECDC)[309].

This Decision also sets up, in its Article 8[310], the Early Warning and Response System (EWRS), which is a digital alert system for notifying, at EU level, on

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307 Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community

308 Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC.

309 The ECDC is an indipendent agency on public health that supports the European Commission and provides an advisory role for national governments regarding the prevention and control of transmittable diseases and related healthcare issues.

310 A rapid alert system for notifying at Union level alerts in relation to serious cross-border threats to health, an 'Early Warning and Response System' (EWRS), is hereby established. The EWRS shall enable the Commission and the competent authorities responsible at national level to be in permanent communication for the purposes of alerting, assessing public health risks and determining the measures that may be required to protect public health.

The Commission shall, by means of implementing acts, adopt procedures concerning the information exchange in order to ensure the proper functioning of the EWRS and the uniform implementation of Articles 8 and 9 and to avoid overlap of activities or conflicting actions with existing structures and mechanisms for monitoring, early warning and combating serious cross-border threats to health.

serious cross-border threats to health. This system allows the European Commission and EU countries to be in a state of permanent communication for the purposes of alerting, assessing public health risks and determining the measures that may be required to protect public health.

The procedures that have to be observed when it comes to the notification of alerts are contained in Commission Implementing Decision (EU) 2017/253[311].

The rapid response mechanism regarding dangers with a cross-border nature is coordinated, at EU level, by the Health Security Committee (HSC), whose role was formalised and strengthened by Decision 1083/2013/EU; composed by representers of each Member State (usually the Ministry of Health), it fosters the exchange of information between its components regarding risks and urgent situations of public health, including the events of emergency declared by the World Health Organisation (WHO). The HSC also decides on the communications that are to be transmitted to the health institutions and the public, so that coherent and appropriate news are spread depending on the circumstances.

In case of a higher level of danger with a cross-border nature, a Member State may ask the Civil Protection Mechanism[312] (CPM) for assistance, whose role is to "[...] strengthen cooperation [...] in the field of civil protection, with a view to improving prevention, preparedness and response to disasters. When the scale of an emergency overwhelms the response capabilities of a country, it can request assistance via the Mechanism. Through the Mechanism, the European Commission plays a key role

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18(2).

311 Commission Implementing Decision (EU) 2017/253 of 13 February 2017 laying down procedures for the notification of alerts as part of the early warning and response system established in relation to serious cross-border threats to health and for the information exchange, consultation and coordination of responses to such threats pursuant to Decision No 1082/2013/EU of the European Parliament and of the Council

312 The CPM was originally set up by Council Decision 2001/792/EC and later recast by Council Decision 2007/779/EC. Today it is disciplined by Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism.

in coordinating the response to disasters in Europe and beyond and contributes to at least 75% of the transport and/or operational costs of deployments"[313].

While the Member States have tried to manage the pandemic all by themselves, in the end, a unified approach to the problem was needed. The CPM was, and is being, used to tackle the pandemic, but was not enough to put an end to the crisis due to the magnitude of the problem at the hands of the national governments.

What can make the difference in this situation is the technology and what the countries make of it.

3.1 The apps against the pandemic: how they should work and the necessity of a harmonised approach.

In order to tackle COVID-19, national governments are currently having trials on the possibility of using contact-tracing technology through the installation of a specific app on the smartphone of individuals. In Italy, the aforementioned app is called 'Immuni', which is going to use a protocol that was elaborated by both Apple and Google. This protocol aims at maximising the protection of the privacy of users while allowing for as precise of a tracing as possible. The technology works as follows: the smartphone will generate an anonymous ID code inside of it, and it will be exchanged via Bluetooth anytime it comes in range of another smartphone that has it for a set period of time (five to fifteen minutes). This mechanism sets up a dialogue between devices that can alert other smartphones that have come into contact with the one of an infected subject in case its owner is found positive of the virus. The reason as to why this is absolutely the best solution, at least from an *a priori* point of view, is that the national governments will not be able to use the information generated from the devices as means to enforce a surveillance state; they will be able, nonetheless, to protect public health.[314]

[313] https://ec.europa.eu/echo/what/civil-protection/mechanism_en

[314] It is worth noting that, to this day, it is still unclear how the information will be handled at the governmental level: the individuals are protected by the way that this technology functions, but the information that can be derived from it is still to be handled with care.

The EU did not stand still, however, when the Member States started to toy with the idea of adopting a contact tracing app. The Commission[315], the European Parliament[316], the Council of Europe[317] and the European Data Protection Board (EDPB)[318] have indicated guidelines that the aforementioned app has to abide by. They are mostly similar to each other, so we are going to collectively mention some of them just to have an overview.

When it comes to the treatment of data, the national healthcare authority should be the one entitled to it. However, if another subject takes part in the process, their roles must be defined clearly, while, at the same time, the users must be informed about it with the same degree of clarity.

In order to comply with the GDPR, the use of personal data must be specified and shall not serve additional purposes that are not correlated with the handling of the health crisis (e.g. commercial use or surveillance use from police forces). Their use must be adequate, necessary and proportionate.

A GPS-tracking-system shall not be allowed since only Bluetooth technology guarantees an acceptable standard of privacy for the user.

The use of a decentralised data-collecting server is encouraged but not mandated; it is also advisable to retain the sensible data in the devices of the users rather than in a single and centralised server.

The source code of the technology shall be published in a transparent way in order to verify the correct functioning of the app and also to avoid bugs of any kind.

There must be a law that serves as a legal basis for the treatment of data, in alternative to the consent of the user, which foresees the protection of the user as well as the public interest of the State.

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315 https://ec.europa.eu/commission/presscorner/detail/en/ip_20_670

316 European Parliament resolution of 17 April 2020 on EU coordinated action to combat the COVID-19 pandemic and its consequences (2020/2616(RSP))

317 Joint Statement on Digital Contact Tracing by Alessandra Pierucci, Chair of the Committee of Convention 108 and Jean-Philippe Walter, Data Protection Commissioner of the Council of Europe of 28 April 2020.

318 Guidelines 04/2020 on the use of location data and contact tracing tools in the context of the COVID-19 outbreak Adopted on 21 April 2020. https://edpb.europa.eu/our-work-tools/our-documents/usmernenia/guidelines-042020-use-location-data-and-contact-tracing_it

Having the application in the device shall be a free decision which shall not be subject to restrictions or incentives linked to the possibility of receiving healthcare-related treatments or with the freedom of movement since such conditions would be discriminatory. The suggested provision shall foresee some guarantees like a specification of the ends and limitations of the app, as well as other essential elements, also indicating when the application shall be uninstalled and who has the authority to make the call.
In order for the app to make an actual difference, it is advised that at least 60% of the individuals install it in their devices, which would be an impressive achievement for a voluntary process.

When the individual is alerted by the app as having come into contact with someone who tested positive, the user should be immediately tested in order to verify if the infection has actually happened and, if so, they shall be treated as appropriate. This mechanism is great in theory but tends to clash with the reality regarding the testing, which is done very conservatively[319].
Another problem that arises from the fact that the pandemic is tackled mostly at the national level, rather than at EU level, is that each Member State is adopting a different application, which is not necessarily based on the same technology.[320] While harmonisation measures are currently being developed at the international level[321], we are still far from a real solution to the problem. Having different applications based on different technology would produce the unfortunate effect of not actually being a useful tool in one of the physical environments that is the most affected and vulnerable in the current situation, that is when individuals travel and cross national borders. At the present date, there is a real risk that an EU citizen might have to download a different contact-tracing app for each Member State they set foot in.

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[319] https://www.ilpost.it/2020/04/04/coronavirus-tamponi-test-problemi-numero/

[320] https://www.agendadigitale.eu/sanita/coronavirus-il-ballo-delle-app-nazionali-ecco-le-scelte-in-europa-australia-india/

[321] See Luckas, Ulrich et al., *Interoperability of decentralised proximity tracing systems across regions*

An issue of the size of a pandemic can only be tackled with harmonised measures and with an approach that has the big picture in mind. The European Union has at its disposal some tools that make it possible for it to not only be of assistance to the Member States but also to foster a unified approach to health crisis such as the one that we are living in right now. While operating with somewhat limited tools, there is a responsibility that rests on the shoulders of the Union to keep fighting, in order to reach solutions that coordinate the needs and the wills of the different Member States with the necessities that arise from actually having a 'bigger picture' approach.

The protection of the privacy of the individual must be of paramount importance, but so should be the protection of public health. The world of apps may save lives if its potentialities are correctly exploited: while paying the price of privacy may seem appropriate in case of a crisis the size of the pandemic we are living in today, we must not forget that a balance between the protection of public health and personal rights must be found.[322] There is the possibility of coordinating these two objectives in order to achieve satisfying results, but different actors (i.e. the Member States, the Union and the international community as a whole) must come together and act as one. Now more than ever, united we may stand, but, if divided, we will fall.

[322] Examples of 'temporary measures' that took rights away from the citizens in situations of emergency have taught u show sometimes the said rights were never given back to the individuals after the situation was over. To this note see the 'Patriot Act' in the USA and the concerning events that are happening in Hungary during these days.

CONCLUSIONS

We have begun our journey analysing the historical development of cross-border healthcare mobility. Starting with the Treaty of Rome of 1957, we have seen how the possibility of workers to receive healthcare outside their Member State of residence was a logical consequence of the groundbreaking creation of the four fundamentals freedoms of movement. Article 51 EEC posed as the legal basis for the subsequent implementation of a law that would expand on the protection of the aforementioned individuals.

The role of the Community legislator was, therefore, present since the very beginning in the field of our discussion: in 1958, with Regulation 3/1958, the idea of a more united Europe was starting to take shape. All socially insured workers were, thanks to this provision, able to be treated when working in the territory of the Community.

With the passing of time came historical and political changes. The "*practical experience of its implementation*", as well as developments in the national legislation of the Member States made it clear that there was a need for the legal context to be remade for the sake of clarity. This is where a fundamental piece of legislation came about: in 1971 Regulation 1408/71 (and its implementing counterpart, Regulation 574/72) was drafted, and with it came some news as well. The Regulation introduced the possibility, for citizens of other Member States, to receive the same emergency treatment that residents of the host State had the right to. This was made possible thanks to the E-111 form, which foresaw the possibility of coverage of costs for immediately necessary care during a temporary stay abroad for professional or private purposes. The mechanism described beforehand was made viable due to the fact that, after the providing of treatment, the competent institution of the State of residence of the patient would be charged for the costs sustained by the host State.

Another relevant news that came about thanks to Regulation 1408/71 was the E-112 form, which regulated the possibility of authorised treatments to be obtained in a country different from the one of residence of the individual. Citizens of a Member State had the chance, thanks to this mechanism, to get medical benefits in

the other Member States when they received the prior authorisation of the competent institution of the country of affiliation. The Regulation also foresaw two conditions that, if both present, had to amount to a granting of the authorisation from the Member State of residence. These conditions were about the carrying of treatment asked by the patient, since it had to be part of the healthcare package of the individual, and, for the authorisation to be guaranteed, the said treatment could not have been given without undue delay.

Following that, we introduced in our discourse the massive contribution of the Court of Justice to the field of cross-border patient mobility; thanks to the *Kohll* and *Decker* judgements of 1998, the range of possibilities for patients dramatically increased. The Court also clarified what it actually meant to seek healthcare inside the territory of the Community: the consequence of the two cases was a 'neutralisation' of the principle of territoriality relating to healthcare. While the organisation and financing of the healthcare systems are left to the Member States, the judgements have demonstrated how, with regard to Regulation 1408/71, socially insured citizens have the possibility to be reimbursed for the consumption of cross-border healthcare. A problem that arose with the judgement, and that persists to this day, is the fact that competent insurance organs may reimburse the cost of medical services or products abroad only up to the point where the rates of the competent State would have applied. What this implies is that patients who are wealthier may enjoy the most the possibility of crossing the border in order to receive medical products or services, which is, in our view, unacceptable.

Having dissected the legal environment from the 1950s to the late 1990s, we proceeded to delve into the early 2000s, with the revolutionary introduction of the European Health Insurance Card (EHIC). Its presence in the life of many citizens has become a staple during the years subsequent to its introduction.

From the historical point of view, the EHIC came to life at a very delicate point in the existence of the Union. The Santer Commission had resigned after a corruption scandal, and the trust of the Europeans in the Union was at an all-time low. The newly appointed President of the Commission, Romano Prodi, managed to push

substantial reforms that led to having the EU regain the trust of its citizens, thanks to mechanisms of accountability introduced by the new Commission.

While the EHIC was certainly not conceptualised by the Prodi Commission, it is fair to say that it is thanks to its political strives that the Card we know today managed to actually come to life.

The Card gave the rightful holder access to medically necessary, state-provided healthcare, during a temporary stay abroad, under the same conditions and at the same cost as people insured in the host State. While the EHIC does not guarantee the providing of medical services for free, it certainly proves its usefulness in cases of necessity.

The Card is, however, not spread equally throughout the territory of the Union; while in certain countries it goes well beyond 90% of adoption (Italy, Malta, the Czech Republic, the Netherlands, Austria), in some, it is far from even 10% (Belgium, Greece and Romania). The validity period of the Card is also up to national legislation on the matter, with a margin of variety that widely differs from State to State (from as low as 6 months up to 10 years). All of this can cause a degree of enjoyment of rights deriving from the EHIC that is too inhomogeneous, which in turn may cause social unrest between citizens. It goes without saying that a uniform adoption of the Card, both in its duration of validity and its territorial presence, is advisable.

Another essential piece of legislation we analysed was Regulation 883/2004: it was created with the objective in mind to coordinate the social security legislation of the Member States. This role was previously filled by the aforementioned Regulation 1408/71, however, with the passing of time came the necessity to modernise and simplify the coordination rules in order for the individuals that cross the borders to retain the rights and advantages acquired as well as those in the course of being received. The aim of the Regulation is twofold since another essential thing is to subject the individual to the social security scheme of a single Member State so as to avoid overlapping of the applicable provisions.

Even though the 19th century ended, the 'service' of the Court of Justice to the field of cross-border healthcare did not. The 2006 *Watts* case marked another milestone in its jurisprudence and introduced a series of news.

In the judgement, the Court clarified how, in order for the competent institution to be entitled to refuse to grant the authorisation referred to in Article 22 of Regulation 1408/71 on the grounds of the presence of waiting time for hospital treatment, the aforementioned institution has to establish whether the said time does not exceed a period that is acceptable. The acceptability of the waiting time has to be based on an objective medical assessment of the clinical needs of the person concerned in the light of all the factors that characterise the medical condition at the time when the request for the authorisation is made or renewed.

Another point that was cleared by the words of the Court of Justice was that authorisation might not be refused on the sole ground of the existence of a waiting list system without carrying out an objective medical assessment of the patient's medical condition; when the delay arising from the aforementioned lists exceeds an acceptable amount of time, the competent institution is obliged to grant the authorisation and shall disregard the existence of the waiting list if that is the only ground that would justify the refusal. While a system of waiting lists is appropriate for managing the providing of hospital services, they are not enough in and of themselves to deny prior authorisation for treatment to be received abroad.

The decision of the Court also held that the fact that accepting to refund patients that receive healthcare-related services abroad would pose for the Member State of residence a significant administrative burden is not a valid reason for the aforementioned State to deny a refund to its citizen.

Regarding the competences of the Union and the Member States in the field of healthcare, we have seen how there is a prominent presence of the latter ones when it comes to the power to legislate on the matter. Article 168 TFEU presents itself as the defining primary law provision that disciplines the limited possibilities of the EU. While foreseeing a high level of protection for human health when adopting Union acts, the Article stands for an EU competence that is 'complementary' to the one of the Member States. The Union finds itself with the possibility to exercise its powers in the field of healthcare only in presence of a European objective that needs to be achieved, or when a higher level of coordination between Member States can be incentivised.

Another primary law source that we discussed about is Article 35 of the Charter of Fundamental Rights (CFR), which foresees the right of EU citizens to access healthcare with respect to national law and practices. This Article, while presenting itself as one of the most fundamental pieces of EU legislation relating directly to the field of healthcare, is mostly left 'unused' by both the provisions that could be based on it, such as Directive 2011/24/EU, as well as the Court of Justice. Interestingly enough, the latter, when having the possibility to make use of it (such as in the *Petru* judgement) prefers to take a more complex route, relying on a technical interpretation of a secondary provision (Article 22 of Regulation 1408/71). Given the importance of the CFR in the hierarchy of legal sources in the EU legal system, one would hope for a more widespread use of it, but, for the time being, there is no sign of either the law or the case-law being interested on taking that route.

The next provision we analysed is the one that is in force today, Directive 2011/24/EU, around which the whole field of cross-border healthcare rotates. Its aim is to provide rules that facilitate the accessibility health-related services abroad, while also promoting cooperation in the field of healthcare between the Member States. The Directive does, however, remain aware of its limits, recognising the national competencies for the organisation and delivery of healthcare.

On the implementation of the Directive, the Commission prepared an Evaluative Study in 2015, according to which no specific problem was found with the reimbursement procedures since each cross-border healthcare claim needs an individual assessment on a case-by-case basis by health insurers. The report also concluded that the Directive was in its early stage of implementation, and, therefore, some of the fields of application of the Directive are not mature enough to make a correct assessment possible. The Directive, it continues, could, nonetheless, benefit from more targeted and regular publicity. The evidence shows that the demand for cross-border healthcare could be higher if the citizens were made aware of the possibilities that are offered.

The Court of Justice managed once again to provide us with a very relevant case. The *Petru* judgement recognised how the lack of medication and basic necessities might result in undue delay, which is a concept present in Regulation 1408/71. It

was also clarified how the Member States could comply with their obligation to provide treatment having checked all the hospital establishments located in their country. This last point raises a problem for the patient, as they are placed in a spot where they have to prove that the treatment is not available in any other hospital that is established in the relevant Member State. What the judgement implies is that the quality of the healthcare provided can be a relevant factor that must be considered when it comes to the right of the patient to be treated.

Three official documents were also discussed on the future perspectives of the topic subject of our discussion.

The first one was a Special Eurobarometer that had the aim to assess the perception of the cross-border patient mobility system. The study concluded that not enough citizens are aware of their rights. The system that is currently in place, which is a mix of EU law and national legislation, with the input of the Court of Justice prominently in place, is far too complex to be entirely enjoyed by the average person. What was found was a fundamental ignorance of how and at what conditions a patient may be entitled to be treated abroad. There is, from our point of view, a need for a more appropriate system that would provide information to the citizens thanks to the cooperation of general practitioners with the National Contact Points.

The second one was the eHealth Action Plan of 2012, which had the objective of addressing and trying to remove the barriers that prove cumbersome for the obtainment of a higher level of integration in eHealth across Europe. In the document, the Commission recognised that the EU health systems are under two strains, the former being their severe budgetary constraints as a consequence of the economic crisis, and the latter regarding the continually rising expectations of its ageing population. The paper also foresees a duty of the Commission to monitor the implementation of the eHAP and to produce a report on the progress made and the results achieved.

This is precisely the third official document that we discussed, the 2014 Interim evaluation of the eHealth Action Plan. The conclusion of the study is once again familiar for us: first of all, a need for further publicity of the eHAP is found as a

necessity of the first order. The lack of awareness, when it comes to a policy like the one at issue, can be crippling, as eHealth can produce its best effects when there is a large number of individuals that are at the very least aware of it. The Union could push the eHealth agenda forward by advertising it heavily in social media, but whether there is a political will to do it, it is up to debate. Secondly, stakeholders tend to be in favour of a higher level of intervention from the Commission in the field. The use of green-papers, as well as the production of standards and guidelines, is mostly welcomed by the respondents to the study. What is assessed, in the end, is that both eHealth and mHealth are in the initial phase of their growth in the EU area, and, therefore, they need to be followed carefully so as to allow them to create a thriving market both for stakeholders and for users.

Lastly, we mentioned the COVID-19 pandemic and what tools are at the disposal of the EU. Among them, we find the Early Warning and Response System, the European Centre for Disease Prevention and Control and the Civil Protection Mechanism. These tools have been used as appropriate by the Member States and the Union, but due to the complexity of the pandemic we find ourselves in, they have not been enough to stop its spread in Europe. While these tools have not worked as well as hoped, technology may come to our rescue, specifically contact-tracing mobile applications. Based on a protocol developed by Apple and Google together, it aims at optimising the needs to protect the privacy of the mobile user as well as give the user as much information as possible regarding their surroundings and their possible contact with an infected individual. While the apps are currently in development, they have a few flaws: the fact that not all of them are going to be based on the same protocol, the fact that each Member State is going to adopt its own, the fact that at least 60% of the citizens need to install the app in order for it to actually produce appreciable results, and the fact that it is unclear whether the national governments are going to cooperate in order to reduce the hassle for the citizens that just want to protect themselves, all of this, casts a shadow on the actual helpfulness of technology during a pandemic. As with many things in life, precisely due to the evolving nature of the current events, only time will tell how much of an impact these apps are going to have.

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