ACCESS TO CROSS-BORDER HEALTH CARE IN THE EUROPEAN UNION: IMPLICATIONS FOR MALTA

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1. Introduction

Placed fifth in the World Health Organisation's ranking of world health systems, Malta's public healthcare system follows the Beveridge model, where funding is based on taxation and is operated through a national health service.[1] Since 78%[2] of healthcare services in Malta are publicly-funded from the state budget, this model necessitates that healthcare spending is weighed against other spending priorities that the country may have. Government expenditure on healthcare continues to rise annually, with the Government allocating more than 13% of its recurrent expenditure on health and elderly care, with an additional €5,367,000 invested in capital projects in the first three-quarters of 2011.[3]

Significantly territorial in nature[4], the Maltese healthcare system provides an extensive list of health services to all persons who are, or have been, a citizen of Malta and any of their children younger than eighteen years old; European Union (hereinafter '**EU**') citizens or nationals; non-EU citizens with a work permit issued under the Immigration Act and paying contribution under the Social Security Act; citizens of countries entitled in lieu of reciprocal healthcare agreements; citizens or nationals of non-EU countries and their dependents needing healthcare during their stay in Malta when invited in

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[1] This model William Beveridge owes its name to Sir William Beveridge, an economist appointed by Prime Minister Winston Churchill, who penned the 1942 Report of the Inter-Departmental Committee on Social Insurance and Allied Services, known commonly as the Beveridge Report.

[2] Ministry of Health, Elderly and Community Care, *Annual Report 2010* (Healthcare Services Division 2001) 1.

[3] The allocation to Health and Elderly Care was €222.4 million out of the €1667.7 million of government expenditure. See also Ministry of Finance, Economy and Investment, *Economic Survey November 2011* (Economic Policy Department, 2011) 189.

[4] B Von Maydell, *Treatment of Third Country Nationals in the Member states of the European Union and the European Economic Area in Terms of Social Law* (Peeters 1996) 148-149.

Malta in an advisory or consultative capacity to the Government or if rendering a service to a government department or to a parastatal body so-certified by the Minister, responsible for that department or body, as the case may be. Healthcare in Malta is equally free for non-EU citizens or nationals enrolled at the University of Malta, the Malta College of Arts, Science & Technology, and the Institute of Tourism Studies.[5]

Malta's public health system is complemented by the private sector run by voluntary or involuntary private organisations at a primary, secondary, and tertiary level of care, which is funded by direct payments from the patients or insurance companies based on pre-existing insurance plans made by the patient.

2. Malta's Bilateral Agreements

Malta has become almost self-sufficient by providing most tertiary care with the main teaching hospital, Mater Dei Hospital, providing the main acute general services incorporating all specialised, ambulatory, inpatient care, and intensive care services. This notwithstanding, patients are sent overseas for highly specialised care required for treatment of high cost and low patient volumes, typically bone marrow transplants, liver transplants, major spinal surgery, and paediatric cardiac surgery, *inter alia*.[6]

Even though outward patient mobility takes place from both the public and private healthcare systems, there is no data on the extent of movement from the private sector.[7]

2.1. United Kingdom – Malta Bilateral Agreement

In the public sector, patient mobility has been predominantly governed by the bilateral United Kingdom (hereinafter '**UK**')-Malta agreement. Through this agreement, patients in Malta are offered medical treatment to which UK nationals registered with the National Healthcare System (hereinafter '**NHS**') are entitled to. The agreement foresees a total of 180 patients being sent to the UK for treatment through a referral system. When quota numbers are insufficient, as is often the case, Malta pays for the services rendered. In the first ten months of 2011, a total of 264 patients were sent for treatment in the UK; 296 and 306 patients were sent to the UK in 2009 and 2010, respectively.[8]

[5] Healthcare (Fees) Regulation, Chapter 35.28 of the Laws of Malta, art 2(1).

[6] N Azzopardi Muscat and others, 'Sharing capacities – Malta and the United Kingdom' in M Rosenmöller, M McKee and R Baete (eds), *Patient Mobility in the European Union – Learning from experience* (WHO 2006) 122.

[7] Azzopardi and others (n 6) 121.

[8] Data obtained following questions submitted to the Office of the Chief Medical Officer at the Ministry for Health, the Elderly and Community Care.

Inversely, the agreement gives access to healthcare services in Malta to UK nationals while in Malta. As highlighted in *Hazel Pannel v Tabib Prinċipali tal-Gvern*, care to UK nationals, within the ambit of the bilateral treaty, is limited to short stays and not to UK residents residing in Malta.[9]

Access to the *National Highly Specialised Overseas Referral Programme* (hereinafter '***Referral Programme***') must be through prior authorisation from the Treatment Abroad Committee (hereinafter '**Committee**'). The authorisation process follows internal procedural customs with no legislation formalising the practice to be followed. The current *modus operandi* foresees that each referral application is evaluated through an assessment on the access in Malta to the care being sought or the equivalent thereof; if all possible locally-available treatment has been provided; and whether the service being requested is clinically proven.[10] The referral application must be endorsed by the patient's caring consultant, locally employed with the Government, and the Clinical Chairperson of the referring speciality.

If the referral procedure is followed, and approval by the Committee is granted, a patient is not required to pay for treatment. Additionally, patients under 18 years qualify for free air tickets and upon a voluntary means test, elder patients may equally qualify. Through agreements between the Maltese Government and the Franciscan Sisters in London and Puttinu Cares Foundation, accommodation services are offered to patients receiving treatment. Transport is provided from and to airports. Additionally, two Franciscan Friars provide any interpretation services necessary to patients referred from Malta or their relatives.

The Maltese High Commission in the UK acts as liaison between Malta and the UK Hospitals. To secure continuity of care, several overseas specialists from the UK visit Malta to carry out a follow-up assessment of patients who would have received treatment in the UK.[11]

2.2. Italy – Malta Bilateral Agreement

On 6 September 2012, Malta and Italy signed three bilateral agreements which will allow Maltese patients requiring specialised care to obtain treatment in 'Highly Specialized Regional Centres and Hospitals in Italy'.12 Building on a previous memorandum of understanding signed between the two countries, the three bilateral agreements include in their scope the diagnosis and treatment of patients in Italy; the

[9] *Hazel Pannel v Tabib Prinċipali tal-Gvern* [2004], Court of Magistrates 1330/1998/1, 3.

[10] Azzopardi and other (n 6) 124.

[11] Ibid., 123.

[12] Ministry of Health, 'Maltese Patients to Benefit from Historic Agreement Signed between Malta and Italy' <http://goo.gl/CGhBU> accessed on September 2012.

exchange of medical information and research; specialised treatment for health professionals in the two countries; the joint participation in medical networks; as well as research and development projects in other projects between Italy and Malta.

While positioned as being an alternative channel to the UK-Malta bilateral agreement route, it can be expected that patients obtaining treatment through Italy-Malta bilateral route will also require the prior authorisation from the Committee.

3. Malta and its European Union Membership

In spite of the fact that the EU lacks formal legal power to develop its own law in the field of healthcare,[13] since its accession to the EU, Malta has been faced with the challenge of introducing changes to the way healthcare benefits are offered to Maltese and European Union or European Economic Area (hereinafter '**EU/EEA**') citizens.[14] This is due to positive integration in the field of healthcare that has been developed through other areas of EU law, namely Internal Market law, Competition Law, Social, and Employment Law, as well as the link to the Charter for Fundamental Rights,[15] making the EU's healthcare policy 'something of a patchwork'.[16]

4. Social Security Regulation in the European Union

Since its inception, the European coordination policy in social security matters was based on the principle of equal treatment of nationals and the nationals of other Member States.[17] Since The Treaty of Rome[18]and until 1998, cross-border treatment

[13] The Treaty for the Foundation of the European Union sets out that the European Community must contribute to a 'high level of health protection'. Under the Article 152 TFEU 'Community action in the field of public health [must] fully respect the responsibility of the Member states for the organisation and delivery of health services and medical care' with Member states retaining the right to define 'the fundamental principles of their social security systems' in lieu of Article 153(4).

[14] Azzopardi and others (n 6) 120.

[15] Despite the central position of the patient in healthcare is stressed in several international regulations and in specific treaties, regulations and directives and the legal status granted to the Charter of Fundamental Rights which through Article 35 provides for the right of healthcare, the *status quo* does not present the right to healthcare as falling within the classical notion of human rights, which are often spoken of within the context of them being inalienable and sometimes even absolute. This is in spite of the fact that following the entry into force of the TFEU in 2009 the fundamental rights' charter has the same legal value as the European Union treaties.

[16] T Hervey and B Vanhercke, 'Healthcare and the EU: the law and policy patchwork' in E Mossialos, G Permanand, R Baeten, T Hervey (eds) *Health Systems Governance in Europe: the role of EU law and policy* (CUP 2010) 85.

[17] D Wyatt and A Dashwood, *The substantive law of the EEC* (first published 1987, Sweet & Maxwell) 549.

[18] Treaty establishing the European Economic Community [1961], OJ 7.

across the EU was regulated by Regulation (EEC) No 1408/71[19] and its implementing Regulation, Regulation (EEC) No 574/72.[20] This Regulation introduced the mechanism which allowed EU/EEA patients to receive medical care from another Member State at the expense of a national sickness insurance institution.

Regulation (EEC) No 1408/71 has since been revised by Regulation (EC) No 883/2004 (hereinafter '**2004 Regulation**'),[21] which, implemented through Regulation (EC) No. 987/2009[22], applies to nationals of a Member State, stateless persons,[23] and refugees[24] residing in EU Member States who are or have been subject to social security legislation of an EU Member State. The provisions of the Regulation are extended also to members of the family and survivors.

Using the distinction in Regulation (EC) 883/2004 itself, in discussing the rights patients have, a distinction shall be made between temporary stays and travel for planned care.

4.1. Healthcare Rights During a Temporary Stay

The right of patients during temporary stays[25] is of particular significance to Malta in light of the ever increasing inbound and outbound tourism flows.[26] With more than 1.3

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[19] Council Regulation (EC) No 1408/71 of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the European Community [1971], OJ L 149

[20] Council Regulation (EEC) No 574/72 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 [1972], OJ L 74.

[21] Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems [2004], OJ L 166.

[22] 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 [2009], OJ L 284.

[23] The Regulation makes reference to the meaning assigned to the term in Article 1 of the Convention relating to the Status of Stateless Persons signed in New York on 28 September 1954. Article 1(1) of the said Convention construes the term 'stateless person' as meaning 'a person who is not considered as a national by any State under the operation of its law'.

[24] The Regulation cross-references to the definition in Article 1 of the Convention relating to the Status of Refugees, signed in Geneva on 28 July 1951.

[25] A temporary stay is a period during which an EU citizen is staying in a place other than the one where one usually lives without any interest of move one's centre of activity. For the purpose of social security coordination, a temporary stay is not limited to a defined period of time but attached to the idea of residence.

million inbound tourists in the first ten months of 2011, tourism in Malta is one of the main pillars of the economy with the vast majority of the tourists visiting Malta annually arriving from EU/EEA countries.[27] To date, Malta has offered uncomplicated access to healthcare for temporary visitors where all emergency or urgent cases are immediately treated, with claims being settled *ex post facto*.[28]

During a temporary stay, insured persons[29] and family members are entitled to benefits-in-kind that may become necessary for medical care as though the patients are insured under the legislation of the state providing such care (hereinafter '**Member State of Care**').[30] Taking into account the nature of the benefits in question and the expected length of stay, it is up to the Member State of Care to establish the duration of the care.

In line with Regulation (EC) No. 987/2009, EU/EEA temporary visitors in Malta automatically receive free treatment that becomes necessary during their stay upon presentation of a European Health Insurance Card (hereinafter '**EHIC**'). Costs are then transmitted from the Entitlement Office within the Ministry for Health, Elderly and Community Care (hereinafter '**MHEC**') to the Ministry of Health where the patient is insured (hereinafter '**Member State of Insurance**'). Since cost mechanisms are dependent on the system of the Member State of Care, a person insured in Malta may be charged a fee for care, which may afterwards be reimbursed.[31]

4.2. The Rights of Long-term Residents Outside the Member State of Insurance

When residing in the Member State of Insurance,[32] insured persons and their family members are entitled to all healthcare benefits provided for under the legislation of that Member State. When residing in a different Member State, they become entitled to all

[26] The National Statistics Office defines 'inbound tourists' as non-residents travelling to and saying in a country which is outside their usual environment while 'outbound tourists' are defined as *r*esidents travelling outside the country and outside their usual environment.

[27] National Statistics Office, 'Departing tourists: October 2011', [2011].

[28] Azzopardi and others (n 6) 129.

[29] Article 1(c) of Regulation (EC) 883/2004 defines an insured person as a person that qualifies for benefits under the legislation of the Member State that grants such benefits.

[30] (n 20) art 19 (1).

[31] Established at the Barcelona European Council, the European Health Insurance Card was designed to replace paper forms that were required for occasional health treatment when in another member state. It substituted forms E111, E110, E119 and E128.

[32] (n 20) art 1 (c).

healthcare benefits-in-kind provided for under the legislation of the host Member State as if insured there.[33]

Insured persons pursuing an activity as an employed or a self-employed person in more than one Member State are subject to the legislation of the Member State of residence if it is where a substantial part of the activity[34] takes place, being the office, or the place of business of the employer[35] for the employed or, in the case of the self-employed, where the centre of interest of the activity is situated,[36] determined by the turnover, working time, number of services rendered, and income.[37] If a person engages in activities both as an employed person and a self-employed in different Member States, the applicable legislation is where the activity as an employed person is carried out.[38]

Through Article 12, the 2004 Regulation addresses the specific needs of posted workers,[39] be it employed or self-employed persons, who normally pursue an activity in a Member State, but are pursuing a similar activity on behalf of their employer in another Member State, who continue to be subject to the legislation of the Member State from where they depart. This provided that the anticipated duration of the work does not exceed twenty-four months.

When moving to another Member State to seek employment, wholly unemployed persons[40] have the right to benefits for up to three months extendable to up to six months by the Member State of origin. This extension is allowed by the Member State of origin if it does not exceed the total duration for which he is entitled to such benefits. If the person was registered as a work-seeker and remained available to the Maltese

[33] Article 11(1) of Regulation (EC) No 987/2009 lays down elements that must be weighed in for determining residence. As per Article 11(2), if the various criteria do not lead to a conclusive agreement on a person's place of residence, his apparent intention is considered as decisive to establish the place of residence.

[34] (n 20) arts 13(1)(a) and 13(2)(a).

[35] (n 20) art 13(1)(b).

[36] (n 20) art 13(2)(b).

[37] (n 21) art 14(8)(b).

[38] (n 20) art 13(3).

[39] These are defined in Article 20 of Regulation (EC) 883/2004 as employees pursuing an activity in a Member state on behalf of an employer who posts the employee on his behalf to another member state where the employer normally carries out his activities.

[40] The emphasis on the term 'wholly' indicates that partially unemployed EU citizens may only claim medical benefits as non-residents.

employment services for a minimum period of four weeks,[41] then Malta must provide benefits at its expense under the same conditions as Maltese nationals.[42]

In light of an ageing population both in Malta and within the EU, the situation of pensioners is of particular interest from an economic and policy point of view. Pensioners outside their Member State of Insurance may still have access to healthcare in the Member State of residence if they are entitled to care in at least one EU Member State, which would also be the state bearing the costs. In the case that a pensioner is entitled to benefits-in-kind in two or more Member States, the cost is borne by the state to whose legislation the person has been subject to for the longest period of time.[43]

4.3. Rights to Cross-border Planned Care

Subject to prior authorisation from the Member State of Insurance, all insured persons and their family members may go to another Member State to receive medical treatment.[44] Once there for care, the patient is entitled to benefits-in-kind as though insured in the Member State of Care.

The Member State of Insurance cannot refuse authorisation if the treatment is among the benefits provided in its legislation but which cannot be provided within a time limit that can be medically justified. In determining whether the waiting time is justifiable, the patient's state of health and the probable course of illness must be taken into consideration.[45]

Automatic authorisation of planned care arises if the Member State of Insurance does not give a reply to the patient within the time limit set in its national legislation.[46] To date, Malta does not have a fixed time-frame within which decisions must be taken; however, the Committee meets on a monthly basis to discuss pending cases. In urgent cases, the decision is taken via electronic correspondence.[47]

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[41] Article 64(1)(a) of Regulation (EC) 883/2004 foresees the possibility that the competent employment services authorise the departure before the four-week period.

[42] (n 20) art 64(1)(d).

[43] Ibid., art 24.

[44] Ibid., art 20 (1).

[45] Ibid., art 20 (2).

[46] (n 21) art 26 (2).

[47] Ministry for Health, Elderly and Community Care, 'Treatment Abroad Committee' <http://goo.gl/70IDB> accessed December 2011.

As aforementioned, within the Referrals Programme, prior authorisation is not given for experimental treatment. In *Geraets-Smits*,[48] the Courts of Justice of the European Union (hereinafter '**CJEU**') clarified that if pre-authorisation is not based on a pre-established list of treatments for which payment is guaranteed, the standard of measure by which normality of a treatment is to be established must not be confined to the medical circles at a national level but according to 'the state of international medical science and medical standards generally accepted at international level'.[49]

When outside the Member State of Insurance, should the beneficiary require 'urgent vitally necessary treatment',[50] authorisation should be granted by the Member State of residence on behalf of the Member State of Insurance, provided that the patient is entitled to such care in the Member State of Insurance, and such care cannot be provided in the said Member State within a medically justified time limit. The institution in the Member State of residence must inform the Member State of Insurance,[51] which may opt to have a doctor of its choice examine the insured person in the state providing care.[52]

5. Healthcare and the Application of Internal Market Rules

In addition to the 2004 Regulation, following the landmark *Kohll*[53] and *Decker*[54] rulings, Malta's healthcare policy must uphold Internal Market rules, which act as an alternative and parallel route through which patients may access cross-border care.[55] As laid out in Article 26(2) TFEU, the cornerstones of the EU's Internal Market are the free movement of people, goods, services, and capital.

Notwithstanding the special nature of certain services, the CJEU argued that it does not remove them from the ambit of the fundamental principle of freedom of movement.[56]

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[48] Case C-157/99 *Geraets-Smits v. Peerbooms* v *Stichting Ziekenfonds* and *H.T.M. Peerbooms* v *Stichting CZ Groep Zorgverzekeringen* [2001] ECR I-05473.

[49] MHEC (n 46) para 96.

[50] (n 21) art 26 (3).

[51] Ibid.

[52] Ibid., art 26 (4).

[53] Case C-158/96 *Kohll v Union des Caisses de Maladie* [1998] ECR I-1931.

[54] Case C-120/95 *Decker v Caisse de Maladie des Employés Privés* [1998] ECR I-1831.

[55] Wolf Sauter, 'The Proposed Patient Mobility Directive and the Reform of Cross-Border Healthcare in the EU' [2008] TILEC DP 34.

[56] Case 279/80 *Webb* [1981] ECR 3305, para 10.

Since the *Decker* and *Kohll* judgments, the CJEU has applied the principle of free movement of goods, enshrined in Article 28 TFEU, in the field of healthcare to pharmaceuticals and medical devices;[57] the principle of freedom of establishment to third sector providers of healthcare;[58] the principle of free movement of persons to healthcare professionals;[59] and more prominently, Treaty rules on free movement of services to care given in hospital and non-hospital settings.

As held in *Luisi and Carbone*,[60] Article 56 TFEU does not merely give the right for one to provide a service, but it also provides for the right for one to receive a service. The CJEU has interpreted Articles 56 and 57 TFEU as requiring a Member State not to impose additional rules on health service providers established outside Malta, or measures that even though are not discriminatory *per se* would impose additional conditions that make it easier for domestic providers to comply with.[61]

With direct relevance to Malta, in the *Watts* case,[62] the CJEU for the first time considered the application of Internal Market rules for Member States that provide benefits-in-kind. The CJEU held that even if the hospital treatment provided in the Member State of Insurance is free of charge, it must reimburse the patient with the cost of medical services equivalent to the treatment entitled in the Member State of Insurance and the 'inextricably linked costs relating to his stay in the hospital'.[63]

Despite the Internal Market's underpinning notions of openness of markets in the EU, Hervey and Mc Hale identify three types of responses to the potential threat that the application of unfettered market rules to the field of healthcare may pose.[64]

At the forefront is the Treaty itself which foresees exceptions to the general free movement rules with restrictions on the free movement of persons, services, and capital

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[57] For example, Case 15/74, *Centrafarm v Sterling Drug* [1974] ECR 1147; Case C-322/01, *DocMorris* [2003] ECR I-14887

[58] Case C-70/95 *Sodemare SA, Anni Azzurri Holding SpA, Anni Azzurri Rezzato Srl, supported by Fédération des Maisons de Repos Privées de Belgique (Femarbel) ASBL v Regione Lombardia* [1997] ECR I-3395.

[59] Case 96/85 *Commission v France* [1986] ECR 1475.

[60] C-26/83 *Luisi and Carbone v Ministero del Tesoro*, [1984] ECR 377.

[61] See also Case 120/78 *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein* [1979] ECR 64.

[62] Case C-372/04, *Watts v Bedford Primary Care Trust*, 2006 ECR I-0432.

[63] Ibid., para 5.

[64] T Hervey and J McHale, *Health Law and the European Union* (Cambridge University Press 2004) 46-7.

being justifiable on the grounds of 'public policy, public security or public health'.[65] In its interpretations, the CJEU has interpreted restrictively the scope of application of the justifications in Article 36 and 45(3) TFEU.

Supplementing Treaty justifications, the CJEU has accepted two main justifications put forward by Member States, namely the Member State's risk of an imbalance in its security system and the Member State's need to ensure a rationalised, stable, balanced, and accessible supply of hospital services in its territory.[66] These exceptions were upheld in the 2011 Directive on Cross-Border Healthcare.

6. The Implications of the 2011 Cross-border Directive Within the Maltese Context

After repeated failures and lengthy consultations, the Directive on the Application of Patients' Rights in Cross-Border Healthcare was adopted[67] with a view of addressing specific issues of concern to patients as recipients of service. This signalled a divergence from a more general framework directive for cross-border healthcare as originally foreseen.

Using Article 114 TFEU as its legal basis, Directive 2011/24/EU (hereinafter '**2011 Directive'**) aims at facilitating the free movement of goods, persons, and services,[68] and at consolidating CJEU jurisprudence to achieve general and effective application of rights when patients' seek care outside the Member State of affiliation.[69]

Aimed at providing clarifications, the 2011 Directive defines healthcare as health services provided by health professionals to the patients to assess, maintain or restore their state of health.[70] The lack of reference to the way the health services are financed means that the Directive applies to both public and private care.

The 2011 Directive reiterates that all types of medical care are within the scope of the Treaty[71] and part of a wider framework of services of general interest[72], with the

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[65] TFEU art 45 (3).

[66] Directorate-General Internal Policies of the Union, 'The ECJ Case Law on Cross-Border Aspects of Health Services: Briefing Note' [2007] 5.

[67] 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 [2011], OJ L 88/45.

[68] Ibid., recital 2.

[69] Ibid., recital 8.

[70] Ibid., art 3(a).

[71] Ibid., recital 6.

ultimate responsibility to establish the appropriate type of healthcare being that of each Member State[73]. The 2011 Directive, however, is not to be applied for routine long-term care, allocation and access to organs for organ transplants, and for public vaccination programmes against infectious diseases which are exclusively aimed at protecting the health of population in the territory of a Member State, and which are subject to specific planning and implementation measures.[74]

6.1. Malta as the Sending Member State

One can argue that, under the 2011 Directive, Malta's central responsibility as the Member State of affiliation, is the reimbursement of costs of cross-border healthcare. This responsibility arises only insofar as the benefits are provided for under Maltese legislation.[75] It is at Malta's discretion whether to reimburse the full cost or not when such cost exceeds the costs the patient would have been entitled to had the care been received in Malta[76] and whether to reimburse additional costs such as travel costs or other costs linked to the care.

The 2011 Directive makes a distinction between intramural and extramural treatment, with the requirement of prior authorisation being limited to care that involves either overnight hospital accommodation for at least one night, or which requires the use of highly specialised and cost-intensive medical infrastructure or medical equipment. Authorisation from Maltese authorities would be required even if the treatment would necessitate overnight stays in Malta, but not so in the Member State of treatment since Malta remains responsible for the planning of hospital services on its territory.[77]

Malta may refuse a patient authorisation if the entitled care may be provided by the Maltese healthcare system within a time limit which is medically justifiable[78] in light of the patient's medical condition, medical history, probable course of the patient's illness, and the degree of the patient's pain or the nature of disability at the time when the

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[72] Ibid., recital 3.

[73] Ibid., recital 7.

[74] Ibid., art 1(3).

[75] Ibid., recital 33.

[76] Ibid., art 7(4).

[77] Council of the European Union, 'Note from the General Secretariat of the Council to the Working Party on Competitiveness and Growth: Explanatory note on the provisions of the proposed Directive on services in the Internal Market relating to the assumption of healthcare costs incurred in another Member state with a particular emphasis on the relationship with Regulation No 1408/71' [2004] 6.

[78] (n 66) art 8(6)(d).

request for authorisation is made.[79] Once prior authorisation is granted, reimbursement must be given on the same terms with which authorisation had been granted.[80]

In the event that the treatment being sought is not in the list of benefits offered by the Maltese public healthcare system, Malta must not refuse prior authorisation or reimbursement on the grounds that it is not available within its territory, but must assess if such care corresponds to benefits provided for in its legislation.

Resorting to its public health policies, Malta may refuse authorisation if faced with reasonable certainty that the patient will be exposed to a risk that is not proportional to the potential benefit of the treatment or if the care to be provided raises 'serious and specific concerns'[81] on the standards of care established by the Maltese authorities. In protecting public health, prior authorisation may be refused if, with legal certainty, the public may be, as a result of the cross-border care received, exposed to 'substantial safety hazard'.[82]

In implementing its system of prior authorisation, Malta must set and make public pre-determined criteria and administrative procedures are objective, non-discriminatory, necessary, and proportionate to the objective being sought.[83] To date, the information about such criteria are limited to short pieces of texts on the official website of the MHEC. Furthermore, Malta must set out a time frame within which requests for cross-border care must be dealt with, taking into account the specific medical condition and the urgency and individual circumstances.[84]

In addition to the restriction that individual refusals must be limited only to what is necessary and proportionate to the objective being sought without being arbitrarily discriminatory or acting as an unjustified obstacle to the free movement of patients,[85] Malta must ensure that there are *interim* measures in place pending termination of proceedings.[86] The Maltese legal framework already allows that each review may be challenged in judicial proceedings, contrasting to a much longer procedure whereby infringement procedures are filed against individual Member States.

[79] Ibid., art 8 (5).

[80] Ibid., art 7(10).

[81] Ibid., art 8(6)(c).

[82] Ibid., art 8(6)(b).

[83] Ibid., art 9(1).

[84] Ibid., art 9(3).

[85] Ibid., art 8(1).

[86] Ibid., art 9(4).

Malta may refuse prior authorisation if the outflow of patients jeopardises its planning requirements. Such refusal is permitted if done to ensure sufficient and permanent access to a balanced range of high-quality treatment, or the desire of Maltese authorities to contain costs and avoid waste of financial, technical, and human resources.[87] In lieu of Article 8, Malta would have to provide evidence that the outflow of patients is seriously undermining the social security or hospital planning treatment. With the Directive failing to indicate how the threat to the healthcare system is to be evaluated, one is to expect that this will be determined through litigation and possibly, infringement procedures.

Ultimately, within the Maltese context, there will be practical difficulties to demonstrate the need for refusal of prior authorisation. Sauter questions how a Member State can be in a position to argue that transferring treatment abroad would jeopardise the financial balance of the system if the cost of an individual treatment is not known. He further questions how a Member State can demonstrate a potential imbalance of a social security system without an assessment if other basic measures of sound administration and business practice have not been taken.[88]

The 2011 Directive does not solely address cross-border care, but also includes the prescription, dispensation, and provision of medical products and medical devices where these are provided in the context of a health service.[89] In the light of the aforementioned, the 2011 Directive also gives the right for a patient to receive any medicinal product authorised in the Member State of treatment, even if not authorised for marketing in the Member State of affiliation. However, this would not impose reimbursement, insofar as the medicinal product is not among the benefits within the system of the Member State of affiliation.[90]

6.2. Malta as the Member State of Treatment

In acting as the Member State of treatment, Malta is primarily responsible of the quality and safety standards set in national and EU legislation. The Directive lays down a categorical statement that when providing treatment, Malta may not exercise any form of preference if favour of domestic patients for financial or planning considerations. Preference may only be given on medical grounds.

[87] Ibid., art 8(2)(a).

[88] Wolf Sauter, 'The Proposed Patients' Rights Directive and the Reform of (Cross-Border) Healthcare in the European Union' [2009] LEIE 36(2) 127.

[89] (n 66) recital 16.

[90] Ibid., recital 36.

In addition, Malta must provide relevant information on treatment options and its availability, quality, and cost of care. Malta's obligation is limited to the information provided to patients residing in Malta.

The Directive obliges Malta to ensure that patients have access to a written or electronic medical record and a copy thereof within the limitations of provisions on protection of personal data.[91]
A major issued that arose out of the *Watts* case is how to address treatment that does not achieve the outcome expected or which can be foreseen. The 2011 Directive imposes upon the Member State the obligation of treatment to set transparent mechanisms for patient's complaints that would allow them to seek remedy according to its legislation for harm arising from healthcare received.[92]

Additionally, Malta must set a system of professional liability insurance or its equivalent to guarantee remedy appropriate to the nature and extent of the risk of the treatment provided in the said Member State.[93] In Malta, as in the UK and Ireland, discretionary indemnity is allowed.[94]

6.3. Cooperation Measures

The 2011 Directive foresees the creation of European Reference Networks, which through assistance from the European Commission will comprise healthcare providers and centres of expertise in the Member States. Within the local context, the Healthcare Services Division liaises with stakeholders to develop and maintain networking and partnerships with *inter alia* non-governmental organisations, Church, private and public sector. The Directorate for Policy Development, EU Affairs, and International Affairs for Health (hereinafter '**DPDEU**'), within the Strategy and Sustainability Division in the MHEC, addresses policy implementation. In addition, the Committee oversees regular visits of a number of UK consultants from different specialties made to provide care and network with local Health Professionals. Maltese organisations representing local professionals, such as the Medical Association of Malta, have international affiliations in the umbrella organisations of their respective field.

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[91] Ibid., art 4(2)(f); The fundamental right to privacy obliges the member state of treatment to process personal data in accordance to national measures implementing the European Parliament and Council Directive 95/46/EC 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 and the Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector.

[92] (n 66) art 4 (2)(c).

[93] Ibid., art 4(2)(d).

[94] Authority of the House of Lords, 'Healthcare across EU borders: a safe framework' (Volume I: Report, February 2009) 38.

In light of a structured and widespread networking opportunities between experts, such reference networks may be beneficial to Malta in that they may serve as a forum that increases cost-effective use of resources through pooling of knowledge, best practice, and technologies. Following the same logic of the UK-Malta bilateral agreement, this network may aid Malta with providing treatment options to patients with particular medical conditions by providing technology or expertise. This may be done through facilitation of virtual and physical mobility of expertise and patients.[95]

The 2011 Directive foresees cooperation for mutual recognition of prescriptions, e-health, and health technology assessment. While it remains to be seen which direction EU action will take, in practice, mutual recognition is difficult to achieve in light of differences in drug names, variations in abbreviations used, as well as the different languages and alphabets in use across the EU.

7. Conclusion: Towards a Healthcare Act?

Following the adoption of the 2011 Directive, EU citizens now have three systems available, namely Directive 883/2004 on coordination of social security systems and the application of Internal Market rules, with patients having the option of choosing the more beneficial rights guaranteed. If the requests for prior authorisation fulfil the requirements of Regulation 883/2004, authorisation shall be granted under the said regulation unless the patient otherwise requests.[96]

In spite of the various routes to cross-border care, to date, Malta has never given prior authorisation for treatment in other EU Member States with the only practical access to care outside the local healthcare system being through the UK-Malta bilateral agreement.[97] In this respect, the *Daniel James Cassar* judgment is deemed to be a landmark decision, in that the Court of Appeal confirmed a judgment delivered in November 2008, which ruled that the refusal of prior authorisation was in violation of EU Laws. This judgment has generated considerable interest, since it also addressed the issue waiting lists, a contentious issue highly debated in the political arena, where the Court of First Instance echoed the *Watts* judgment in which the CJEU held that a refusal of prior authorisation based only on the existence of waiting lists drawn up to enable the supply of hospital care to be planned and managed on the basis of predetermined general clinical priorities, is in breach of EU Law.

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[95] (n 66) art 12(2)(h).

[96] (n 66) recital 31.

[97] While limited to diagnosis, Maltese patients requiring lung transplants have, in the past, been assessed at the Mediterranean Institute for Transplantation and High Specialization Therapies in Italy.

The 2011 Directive, which must be transposed in national legislation by 25 October 2013, binds Malta to formalise procedures which are to date based on practice within the Ministry for Health. A legislative text in the form of a Healthcare Act may possibly restrict the *ad hoc* responsiveness in exceptional cases but would allow political decentralisation and legal certainty to stakeholders, notably healthcare providers and the patients themselves.

Irrespective of the way Malta chooses to implement the 2011 Directive, the said Directive must be applied without prejudice to related frameworks, such as regulations for mutual recognition of professional qualifications, protection of personal data, e-health provisions, and for racial equality measures enshrined in the principle of non-discriminatory handling of cross-border care cases. [98]

It can be foreseen that implementation of the 2011 Directive will present a significant cost to the Maltese healthcare system due to the costs incurred from treatment that insured persons in Malta receive in another Member State. While in theory the costs for Malta should be nil, in practice, if patients seek care abroad that is quicker and more convenient, Malta must issue reimbursements costs for financial care obtained abroad that regularly exceed budgetary allocations for health expenditure, running the risk of serious cumulative financial imbalance.

Furthermore, in ensuring better utilisation of accessible services, additional cross-border arrangements to that with the UK may present new healthcare opportunities for Maltese patients and address perceived and *de facto* length waiting times for medical treatment.

Aside from the direct costs related to the cross-border care, in absence of an existing framework, Malta will be exposed to implementation costs, such as the setting up of administrative committees or the taking of measures to adhere to the provisions of the Directive.

In light of the information requirements set in the 2011 Directive, additional costs will factor in the equation, with Maltese authorities now becoming legally responsible for informing citizens about access to cross-border care.

At this stage it is premature to predict the full impact of the 2011 Cross-border Directive on the Maltese health system. The Commission is entrusted with the preparation of a report on the implementation of the Directive which must be published and submitted to the European Parliament and to the Council at the end of 2015 and subsequently, every three years thereafter.[99]

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[98] Ibid., art 21(1).

[99] (n 66) art 20.

The significance of this report is quite high in that, as a number of Member States have outlined, it will not be possible to identify the Directive's impact until it has been transposed. Reporting in 2015 is timely since any measures taken may be reversed with minimal impact on the Member States and their citizens.

What is certain is that a comprehensive Healthcare Act would give the legal certainty to providers and clients of the Maltese Healthcare system, avoiding the need of *ad hoc* closing of loopholes within the existing system. The *Daniel James Cassar* judgment and the suspension of the Permanent Residency Scheme[100] are two recent red flags for local health authorities.

While it is not foreseen that many patients insured in Malta seeking care abroad will shift their preference to countries other than the UK, notably due to language and the referral links between local and consultants in the UK, the current EU legislative framework necessitates a shift in mentality of the *modus operandi* of the existing referral system that is biased towards cross-border care within the limitations of the UK-Malta Bilateral Agreement. Following the spirit of the 2011 Directive, this change must revolve around individual patients' rights.

[100] Designed in 1988, the Malta Permanent Residence Scheme was designed to attract high net worth individuals to reside permanently in Malta without the necessity of obtaining and renewing an entry visa. Once living in Malta, holders of the Permanent Residence Permit became entitled to free public health services. The scheme was suspended in December 2010 due to abuses linked to the low minimal rental obligation. Unconfirmed reports in local press indicated that the suspension was triggered by the case of a British cancer patient who received €500,000 worth of free treatment in Malta after buying a €100,000 property. In 2011, Malta announced a new scheme addressing High Net Worth Rules, which require, inter alia, that the holder of the certificate is in possession of sickness insurance in respect of all risks normally covered for Maltese nationals for himself and the members of his family. See also: Matthew Xuereb, 'Expat gets €500,000 in free treatment thanks to property scheme', (Monday, April 11, 2011)) < http://goo.gl/7OM6O> accessed December 2011; and Ministry of Finance, the Economy and Investment, 'Guidance Notes on the amendments to the Resident Scheme Regulations', <http://goo.gl/h2ewf> accessed December 2011.