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A Three-Country Analysis**

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One Year after the EU Patient Mobility Directive: A Three-Country Analysis

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Abstract

On October 25, 2013, a new era in the patient mobility debate began with the entering into force of the Cross-Border Health Care Directive (2011/24).¹ This legal document allows EU citizens to seek healthcare in other Member States. The Directive is the result of a number of rulings by the Court of Justice of the EU on reimbursement claims for medical treatment abroad based on the free movement principles. After its formal approval by the European Parliament (2011), Member States have been working to incorporate the Directive into national law. The question is whether they have been successful, and if so, whether their legal framework is Europe-proof. This article addresses specific topics regulated in the Directive, including prior authorisation, establishing national contact points, e-health, mutual recognition of prescriptions, and the co-operation on health technology assessment. Moreover, a three-country analysis is presented, covering Croatia, Italy and the Netherlands. Representing different health care systems, each of these Member States seems to have dealt with the Directive in its own way, though respecting the underlying principles. The diversity also reveals the unique problems countries are facing when implementing the Directive. At the same time, there are several commonalities indicating signs of a so-called Europeanisation of health care systems.

Introduction—background and content

The Directive on Patients' Rights in Cross-border Health Care (Directive 2011/24, or the Directive) is the outcome of a fierce political debate since it touches upon the heart of health care policy-making, namely the organisation and financing of health care. Boosting the European integration process, the earlier Services Directive—initiated by the former EU Commissioner Bolkestein but cruelly dubbed the “Frankenstein directive” by critics—removed major barriers to the free movement of (health) services. Although the Services Directive expressly excluded health services and social services, health care is

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¹ Officially, Directive 2011/24 on the application of patients' rights in cross-border healthcare [2011] OJ L88/45.

regarded as falling within the definition of services.² As a consequence, national restrictions such as the prior authorisation requirement for receiving health care abroad would be abolished. Some Member States feared that abandoning this prerogative could initiate uncontrolled liberalisation of national healthcare markets. The European Commission gave in to that fear by presenting a “tailor-made” health care directive. By submitting the cross-border care directive, the Commission hoped to regain control over an area dominated by the judiciary. After a rather long amending process, the initial proposal was adopted in 2011 and came into force on October 25, 2013. The Directive has been discussed extensively by others.³ Without repeating these contributions, this article briefly introduces the Directive’s key principles and addresses a number of specific implementation issues.

First, Member States remain responsible for providing safe, high-quality, efficient and quantitatively adequate healthcare to citizens on their territory (art.4). Simultaneously, they have to respect basic legal principles. In the case of cross-border care this means applying objective, non-discriminatory criteria—which should be known in advance—as well as providing access to a judicial review procedure if granting cross-border health care is refused, while taking into account all relevant circumstances. It follows that, when there is a delay, it is not allowed to use waiting lists merely as a necessary planning argument to refuse authorisation, without taking into account the patient’s medical history, needs and degree of pain. Secondly, though prior authorisation violates the free movement principles, it can be justified for reasons of public interest, but only if the patient needs hospital and high technology care (art.8).⁴ No prior authorisation is required for out-patient healthcare services abroad. This restriction to in-patient healthcare is the direct result of previous Court of Justice rulings since it is assumed that consuming out-patient healthcare abroad will not disrupt the financial balance of national healthcare systems. Thirdly, the obligation to reimburse cross-border healthcare is limited to services the insured person is entitled to. As such, the Directive respects the fundamental ethical choices of Member States. If controversial medical interventions (e.g. abortion, stem cell therapy) are excluded from the benefit package at home, one cannot claim reimbursement when such an intervention is performed abroad (art.7(1)). Furthermore, the reimbursement level of health care costs abroad is limited to the assumed costs in the home Member State/state of affiliation. Fourthly, the recognition of prescriptions from another Member State should not affect the professional or ethical duty that would require pharmacists to dispense the prescription (art.11). Fifthly, a new element includes the establishment of national contact points for cross-border healthcare (art.6), tasked with providing information on healthcare providers, safety and quality standards that would enable informed choices on where to receive healthcare in the EU. Finally, the Directive facilitates co-operation initiatives on e-health (art.14) and health technology assessment

² See *Luisi and Carbone Ministero del Tesoro* (286/82) [1984] E.C.R. 377; [1985] 3 C.M.L.R. 52.

³ See for instance, M. Peeters, “Free Movement of Patients: Directive 2011/24 on the Application of Patients’ Rights in Cross-Border Healthcare” (2012) 19 Eur. J. Health Law 29; M. Sheppard, “Treatments of Low-priority and the Patient Mobility Directive 2011, an End to Legal Uncertainty for the English NHS?” (2013) 20 Eur. J. Health Law 295; S. Taylor, “Cross-border Patients and Informed Choices on Treatment in English and French Law and the Patients’ Rights Directive” (2012) 19 Eur. J. Health Law 467; H. Nys, “The Right to Informed Choice and the Patients’ Rights Directive” (2012) 19 Eur. J. Health Law 327; S. Greer, “Avoiding Another Directive: the Unstable Politics of European Union Cross-border Health Care Law”, *Health Economics, Policy and Law* (October 8, 2013) pp.415–421; J. van de Gronden et al., *Health Care and EU Law* (The Hague: T.M.C. Asser Press, 2011), pp.79–241; T. Sokol, *Croatian Yearbook of European Law and Policy*, Vol.6 (2010).

⁴ Other reasons that justify prior authorisation are: treatments presenting a particular risk for the patient or the population (art.8(2)(b)); and health care provided by a provider that, on a case-by-case basis, could give rise to serious and specific concerns relating to the quality or safety of the care (art.8(2)(b)–(c)).

(art.15). Since the enactment of the Directive, supplementary measures have been taken by the Commission on a variety of issues.⁵

Country experiences by subtopic

Despite the Commission's initiatives, individual Member States are free to decide within a wide scope how to implement the Directive at national level. This discretionary power has resulted in different solutions, depending on the national health care system.

This article explores the Directive's outcomes in three Member States (the Netherlands, Croatia and Italy). The focus is on health care access-related issues such as prior authorisation and reimbursement of transborder care, national contact points providing information to patients in search of health care abroad, the recognition of foreign prescriptions, and the co-operation on health technology assessment (HTA). Outside the scope of this impact analysis are patients' rights issues such as access to medical records, complaint mechanism procedures, systems of liability insurance and the conformity with EU data protection legislation, as discussed on other occasions.⁶ This three-country analysis illustrates the difficulties and successes encountered in the process of incorporating EU law into the Member States' national legal framework.

Prior authorisation and reimbursement of cross-border health care

Prior authorisation and reimbursement of cross-border health care are of paramount importance in grasping the actual approach of Member States towards the content of the Directive. Indeed, from both the width of circumstances under which prior authorisation is to be applied for and the reimbursement policy, it is possible to infer whether the incorporation of the Directive into national law is "Europe-proof". For achieving patient mobility, art.7 stipulates the key principles of the reimbursement of cross-border care. In the Netherlands, the *Smits/Peerbooms* and *Muller/Fauré* cases made clear that the prior authorisation mechanism as applied in the former Dutch Health Insurance Act was not in line with European law.⁷ The financial sustainability argument justified a restrictive contracting mechanism for in-patient care as prescribed in Dutch law. However, national law applied an overly restrictive condition for prior authorisation (i.e. "normal according to *national* professional circles"), which was replaced by a more objective criterion to the effect that the requested treatment should be evidence-based according to *international* standards. The new Health Insurance Act 2006 incorporated the Court ruling by granting prioritisation of services following "international standards of science and practice".⁸ Since then, national law in the Netherlands was considered in conformity with EU law.⁹

Recently, a new proposal was submitted to the Dutch Parliament aimed at restricting reimbursement rules to less than 80 per cent, and even zero, in case of non-contracted care.¹⁰ Formally, this would affect non-contracted domestic and foreign providers equally but in practice all local hospitals are contracted,¹¹

⁵ Decision 2011/890, setting rules for the e-health network; Directive 2012/52, laying down measures to facilitate the recognition of medical prescriptions issues in another Member State; Decision 2013/329 setting rules for the HTA network.

⁶ See for instance, the Eur. J. Health Law's special issue on the Directive (2014) no.1.

⁷ *Geraets-Smits v Stichting Ziekenfonds VGZ* (C-157/99) [2001] E.C.R. I-5473; [2002] 2 C.M.L.R. 21; *Muller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA* (C-385/99) [2003] E.C.R. I-4509; [2004] 2 C.M.L.R. 33.

⁸ Besluit Zvw art.2.1(2).

⁹ Minister of Health Appendix Handelingen Kamerstukken II, 2011–12, Appendix 2664.

¹⁰ Parliamentary proceedings (Kamerstukken 2011–2012, 33362, no.2).

¹¹ Although this may change when the selective contracting option will become effective.

therefore discriminating against foreign providers with regard to the level of reimbursement. Commissioner Borg confirmed this viewpoint in response to questions raised in the European Parliament.¹²

The Dutch Government replied that the Commissioner's statement was based on incomplete information.¹³ The proposed measure respects the consumer's choice to opt for either a so-called benefit-in-kind or a reimbursement policy arrangement. Although the benefit-in-kind option offers less choice of provider, therefore limiting cross-border health care, it is generally cheaper than a reimbursement policy. Well-informed consumers have therefore accepted the consequence of limited choice. However, owing to the price difference, one may question the "choice of policy" argument, particularly since only 9 per cent of the population (in 2013) opted for the reimbursement variant.¹⁴ Formally, the insured have a choice of insurer and insurance policy, and possible restrictions are the consequence of their own decision. In addition, the Dutch Government argued that a discriminatory effect is limited to non-contracted *in-patient* health care, allowing full reimbursement of non-contracted out-patient (non-"high tech") and emergency care. At the same time, the discriminatory effect can be justified for reasons of general interest, i.e. guaranteeing the financial sustainability of a competitive health insurance system.¹⁵ As a consequence, the latest proposal is in line with Union law.¹⁶

In Croatia, major regulatory changes were introduced during its accession to the EU (July 1, 2013). Prior to that date, unplanned health care abroad was already covered to eliminate direct threat to life and health for several categories of persons. Incidentally, prior authorisation requirements were applicable for dialysis and very expensive treatment. Crucially, there was a dual system based on both bilateral agreements and general rules when the agreements were not applicable. These agreements were predominantly based on the co-ordination logic, resulting in coverage of treatments obtained from providers who were affiliated with the social security system of the state of treatment according to its rules and tariffs. In other cases, patients could obtain treatment also from non-affiliated providers, whose services were paid for in advance. In those cases, Croatia covered the real cost of treatment, minus the general domestic co-payment requirement. Additionally, patients receiving health care abroad needed to pay a special contribution,

¹² Parliamentary questions April 25, 2013 by Ria Oomen-Ruijter and Ester de Lange. E-004616-13; Answer given by Mr Borg on behalf of the Commission (June 14, 2013).

¹³ Parliamentary Proceedings (Kamerstukken II 2013–2014, 33362 no.10, pp.27–28).

¹⁴ NZa, *Marktscan en beleidsbrief Zorgverzekeringsmarkt* (2009–2013), p.8.

¹⁵ *Muller-Fauré* (C-385/99) [2003] E.C.R. I-4509 at [43]; *Geraets-Smits* (C-157/99) [2001] E.C.R. I-5473 at [65]–[66]; and *Commission v Luxembourg* (C-490/09) January 27, 2011 at [40].

¹⁶ Confirmed by the Dutch Council of State in its latest advisory opinion, see Raad van State, Advice W13.14.0351/III/Vo (October 22, 2014), <http://www.raadvanstate.nl> [Accessed February 19, 2015]; see also A.G. Keus at the Dutch Supreme Court, ECLI:NL:PHR:2014:295 (in Dutch) at [2.19]. Contrary: J. van de Gronden, "Grensoverschrijdend patiëntenverkeer in de Zorgverzekeringswet: is de voorgenomen wijziging van artikel 13 Europeesrechtelijk houdbaar?" (2013) 1 TvGr 4.

while there were no detailed rules on the recognition of prescriptions issued in other countries.¹⁷ A similar regime was applicable to planned health care abroad.¹⁸

As to the Patient Mobility Directive, Croatia adopted rules which clearly provide entitlement to coverage, according to Croatian domestic rules and tariffs, for treatment received from providers who lawfully provide health care abroad (in the state of treatment). The treatment costs are paid in advance and patients are reimbursed after their return to Croatia. The Directive's provisions on prior authorisation have been largely translated into national law, and the Health Insurance Institute of Croatia (HIIC) set out a list of defined treatments requiring prior authorisation.¹⁹

More problematic is the exclusion from reimbursement of travel and accommodation costs for planned health care abroad (art.31 of the Croatian Health Insurance Act). At the same time, however, domestic travel and accommodation costs are covered by social insurance. In our view, it seems difficult—if not impossible—to justify such preferential treatment of domestic providers. Therefore, there is reason to conclude that the Croatian Government did not implement the Patient Mobility Directive correctly, even though art.7(4) allows Member States to decide upon reimbursement of travel and accommodation costs. Once included, discrimination by nationality cannot be justified. Overall, however, Croatia opted for incorporating the Directive in its Health Insurance Act mainly by translating its relevant provisions. How this will affect cross-border health care remains unclear.

Last, the Italian Government has incorporated the Directive by means of Government Act 38, entitled “Ratification of Directive 2011/24/EU concerning the application of patients’ rights relating to cross-border healthcare, as well as Directive 2012/52/EU containing provisions aimed at facilitating the recognition of medical prescriptions issued in another Member State”.²⁰ Enactment was possible after due scrutiny in

¹⁷ See Ordinance on entitlements, conditions, and way of exercising health care abroad (Official Gazette 50/09 to 103/13, 129/12 before 1 July 1, 2013) (Pravilnik o pravima, uvjetima i načinu korištenja zdravstvene zaštite u inozemstvu NN 50/09 do 103/13, 129/12 prije 01 srpnja 2013) (Health Care Abroad Ordinance 2009) and, for instance, Agreement on Social Insurance between Republic of Croatia and Republic of Austria (Official Gazette—International Agreements 15/97 and 13/98) (Ugovor o socijalnom osiguranju između Republike Hrvatske i Republike Austrije NN-MU, 15/97 i 13/98) (Croatia-Austria Agreement 1997) and Agreement on Social Insurance between Republic of Croatia and Republic of Italy (Official Gazette—International Agreements 21/97 and 15/03) (Ugovor o socijalnom osiguranju između Republike Hrvatske i Republike Italije NN-MU, 21/97 i 15/03) (Croatia-Italy Agreement 2003); see also Ordinance on criteria for classification of drugs and on regulation and dispensation of prescription drugs (Official Gazette 82/10) (Pravilnik o mjerilima za razvrstavanje lijekova te o propisivanju i izdavanju lijekova na recept NN 82/10) (Prescription Drugs Ordinance 2010). Bilateral agreements concerning social security coverage of health care were concluded (or taken over from the former Yugoslavia) with the following EU Member States: Austria, Belgium, Bulgaria, Czech Republic, Denmark, France, Germany, Hungary, Italy, Luxembourg, the Netherlands, Poland, Romania, Slovakia, Slovenia, Sweden and the UK: see M. Rismondo, *Zbirka ugovora o socijalnom osiguranju* (Zagreb: Narodne novine, 2007).

¹⁸ See Health Care Abroad Ordinance 2009, Croatia-Austria Agreement 1997 and Prescription Drugs Ordinance 2010, and, for instance, Agreement on Social Insurance between Republic of Croatia and Republic of Slovenia (Official Gazette—International Agreements 16/97 and 3/98) (Sporazum o socijalnom osiguranju između Republike Hrvatske i Republike Slovenije NN-MU, 16/97 i 3/98) (Croatia-Slovenia Agreement 1998). There was a distinction between cases where bilateral agreements (using co-ordination logic) applied, and other situations in which these were not applicable. In addition to that, prior authorisation for obtaining planned health care abroad was warranted. The only exception consisted of very few cases prescribed by bilateral agreements, in which the authorisation could be given afterwards if not requested in advance for justifiable reasons.

¹⁹ See Compulsory Health Insurance Act (Official Gazette 80/13 to 137/13) (Zakon o obveznom zdravstvenom osiguranju NN 80/13 do 137/13) (Health Insurance Act 2013) arts 26–32 and Ordinance on entitlements, conditions, and way of exercising cross-border health care (Official Gazette 160/13) (Pravilnik o pravima, uvjetima i načinu korištenja prekogranične zdravstvene zaštite NN 160/13) (Health Care Abroad Ordinance 2013). For defined treatment options that require prior authorisation, see the Decision of the list of health care procedures undertaken as part of planned cross-border health care (Official Gazette 133/13) (Odluka o popisu postupaka liječenja koji se provode u okviru planirane prekogranične zdravstvene zaštite NN 133/13).

²⁰ Official Journal of the Italian Republic of March 21, 2014, No.67.

parliamentary committees and in the Regions' Coordination Committee.²¹ The 2014 Government Act provided for a "double ratification" of both Directive 2011/24 and Directive 2012/52, concerning medical prescriptions issued in another Member State, which represents an essential part of Directive 2011/24 (see art.12).²² The Act includes the following explanatory notes that clearly set out the very principles on which Directive 2011/24 is based:

- “1. The key goal of the Directive is to enforce patients' rights to access services that they regard as most adequate to their health needs and as close to their home as possible or located near the border.
2. Cross-border access is to be deemed as a fundamental driver for economic growth. Accordingly, a free market implies competition among different national health systems. This represents an opportunity of development and a challenge for the Italian National Health System given the expected increase in the number of patients coming from other countries. At the same time, economic and organisational impact on resources devoted to health care services is to be thoroughly deepened.
3. Mutual medical prescriptions is one of the most original aspects of Directive 2011/24/EU although its implementation is difficult. It is clear that citizens must be provided with specific tools, including online facilities, which allow for a complete treatment cycle. Patients also need to know if medicines or medical devices are to be provided also in the affiliation Member State.
4. This directive is a chance to promote national health excellence centres. Accordingly, the Italian national health system needs to be ready to attract European patients, which means: economic returns, high ranking position at the EU level and an improvement of the national 'corporate image' so as to facilitate foreign investments.”

As to the contents, it is noteworthy that the Italian Act ratifying Directive 2011/24 has introduced two main types of limitations to patient mobility, namely: (1) restrictions on reimbursement of costs incurred for cross-border healthcare; and (2) restrictions on prior authorisation for specific services.

After referring to Regulation 883/2004 if applicable, the 2014 Ratification Act states that only health care services which fall within those guaranteed by the Italian National Health System can be reimbursed. Regions are free to reimburse other services which fall within regional health standards with their own financial resources. As proposed by the Regions' Coordination Committee, the Government Act states that cross-border costs are reimbursed according to current regional standards after considering patients' co-payments for that service.²³ At any rate, the reimbursement—according to the well-known principle

²¹ After a constitutional reform enacted in 2001, the Central Government is responsible for certain subject-matter only, such as foreign relations, defence and justice. All other subject-matter falls either within a shared competence between the Central Government and the regions, or within an autonomous power of the regions themselves. As to public health, while the central Government is responsible for setting out the national health standard levels of services and provisions, regions are called upon to organise and define their own regional health systems. The institutional co-operation mechanism between the Central Government and the regions provided for by the constitutional reform of 2001 is called the Regions' Coordination Committee. This Committee's task is to favour fair co-operation between the Central Government and the regional systems, thus representing the place for political negotiations between central public authorities and the regions. Given its role, the Committee: (1) is where the Central Government is entitled to audit the regional governments on the most important draft Bills which are to interfere with their competences; (2) is called upon in a specific annual meeting to discuss all aspects of the EU policies which also concern regions.

²² The article provides for the recognition of the right to distribute in Italy medicines produced in other Member States, unless there are serious reasons to ensure patients' protection, or doubt about the authentic origin, content or understanding of each single prescription.

²³ Over the past few years, the Italian legal system, especially at the regional and county level, has introduced the obligation on the part of citizens-users to co-pay a proportion of the costs of social and health care services.

established by the Court of Justice—cannot be higher than the actual cost incurred by the patient. Regions have to communicate their tariffs to the national contact point. Moreover, regions are entitled to reimburse further costs, such as travel and accommodation, to be incurred by disabled people.²⁴

The 2014 Act confirms that patients using cross-border health care services are entitled to the same rights to which they would be entitled should they access those services in Italy. Nonetheless, the Act provides that the reimbursement of costs incurred for cross-border health care services can be limited:

- for imperative reasons of overriding public interest, i.e. to ensure the possibility of a sufficient and permanent access to a balanced set of high quality services in Italy;
- owing to the desire to control health costs and thus to avoid, as much as possible, any waste of financial, technical human resources.

In order to effectuate these provisions, the Act provides for a specific Decree to be passed by the Ministry of Health in co-operation with the Treasury and the Regions' Coordination Committee, defining the limitations on access to cross-border healthcare. The Decree confirms the Central Government's prerogative to set financial limits and define the volume and quality of health care services to be provided at the national level.²⁵ Simultaneously, the Decree allows that such limitations can be confined to the regions, or local health authorities. Therefore, different models are created within the same national health system. Regional governments and local health authorities are bound to promptly inform the Health Ministry about the limitations adopted and also to communicate this to the national contact point.

As to prior authorisation, the Government Act provides for a specific Decree, including a positive list of services requiring prior authorisation. However, citizens are required to apply to local health authorities for cross-border healthcare. Pending this Decree, prior authorisation is provided for any treatment: (1) involving at least one night in hospital, and (2) that requires a highly specialised and cost-intensive medical infrastructure or medical equipment. Simultaneously, regional governments may add further services subject to prior authorisation

Overall, the Italian Government Act allows a range of (delegated) conditions to the prior authorisation principle, therefore restricting cross-border care. This complexity of restrictions is inherent in the federal structure, in which regional governments formulate health policy and local health authorities provide health care services. However, according to the implementing Decree, such limitations must be necessary, proportionate, non-arbitrary and non-discriminatory, as well as promptly published on the websites of the Ministry of Health and of the regions. Moreover, they must be regarded as essential parts of the comprehensive information given by the national contact point. In practice, however, these restrictions appear quite arbitrary and discriminatory since they vary by region, creating a range of unclear barriers to Italian citizens receiving health care abroad. At this point, the arbitrary and discriminatory outcomes show that Italy has not implemented art.7(9) on "regulatory and administrative formalities" of the Directive correctly.

Responsibilities of Member States (national contact points and providing information)

Based on the premise of equal access to healthcare services of good quality, the Directive stipulates that the Member State of treatment ensure quality and safety standards and guidelines (art.4(1)(b)), and provide relevant information on a variety of issues related to health providers (e.g. professional standards, supervision mechanisms of health professions, treatment options, dispute settlement options, and so on).

²⁴ The aforementioned provisions concerning the regions' role and power are to be placed within the legal framework according to which the health care system is to be balanced between the Central Government and the regions.

²⁵ Despite the existence of the "federal" framework that defines the Italian health system, it is up to the Central Government to decide the amount of funds to be channelled to healthcare provisions and services at both the national and regional level.

This information is necessary for individual patients to make informed choices on cross-border healthcare, and will be provided by newly established national contact points (art.6). These national contact points will therefore play a crucial role in the dissemination of relevant information to both patients and professionals. Because of the wide scope of subjects, one may question whether Member States can realise these responsibilities. In Croatia, the HIIC is designated as the national contact point.²⁶ Apart from a basic description of the Croatian health care system, and reimbursement rules, the HIIC's English website contains limited information about domestic quality standards and supervision mechanisms, patients' rights and dispute settlement options. A special telephone number in Croatia is available for inquiries about domestic health care providers.²⁷

Good web-based information services on cross-border health care are generally considered pivotal to incoming and outgoing patients.²⁸ Although the Directive does not impose multilingual information,²⁹ it is obvious that the absence of foreign language information will not contribute to the patient's informed choice. Although the Dutch national contact point provides bilingual information (Dutch and English), the emphasis is on incoming foreigners searching for healthcare services available in the Netherlands. Information on services available in other Member States is relatively poor. The website simply refers to national contact points abroad.³⁰ Confronted with the absence of multilingual information, one must conclude that the Dutch approach of simply referring to other information sources is not in line with the notion of patient mobility.

In essence, the Italian approach to web-based information services on cross-border health care does not really differ from that in Croatia or the Netherlands. As in the Netherlands, web-based information is primarily focused on incoming patients, while a more balanced approach addressing the needs of both categories of patients is required. Criticism of inadequate implementation of information systems on cross-border care has been confirmed by reports from other countries.³¹

E-health

The use of ICT in health care is considered a promising tool to improve patient safety and quality and efficiency of health care, thereby strengthening a health system's sustainability.³² The use of electronic health (e-health) applications is rapidly growing in most Member States and on a global level. Initially starting with electronically storing and exchanging health information, the latest innovations focus on mobile phone applications, or mobile-health (m-health) applications for managing chronic conditions, mental health and health promotion.³³ Despite substantial progress, the European Commission has observed

²⁶ See Health Insurance Act 2013 art.32.

²⁷ See Health Insurance Institute of Croatia, "You are an EU citizen", <http://www.hzzo.hr/en/travel-insurance/english-you-are-an-eu-citizen>; and Health Insurance Institute of Croatia, "FAQ" (2014), <http://www.hzzo.hr/en/travel-insurance/english-faq> [Both accessed February 19, 2015].

²⁸ "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.

²⁹ Article 4(5) of the Directive does not influence the Member States' use of languages when delivering information.

³⁰ See "Netherlands NCP Cross-Border Health Care", <http://www.cbhc.nl/> [Accessed February 19, 2015]. Instead, patients can submit their requests for information to the National Healthcare Institute by email.

³¹ See the Eur. J. Health Law's special issue on the Directive (2014) No.1.

³² EP Resolution on eHealth Action Plan 2012–2020 (2013/20616INI) (January 14, 2014).

³³ Commission, "Green Paper on mobile Health ('mHealth')" COM(2014) 219 final.

major barriers “to reap all the benefits from a fully mature and interoperable eHealth system in Europe”.³⁴ Some of these barriers, among which are legal ones, contribute to market failure (e.g. lack of data exchange due to lacking interoperability of cross-border e-health services, lack of clarity of legal norms on data protection, liability and reimbursement issues). By establishing a European network of national e-health authorities (art.14(3) Directive), the Commission is facilitating co-operation and exchange of information.³⁵ The (legal) interoperability of e-health applications and data exchange is improved by developing guidelines on standardisation of patient summary records³⁶ to be exchanged across borders, common measures for interoperable electronic identification and authentication in e-health, and by enhancing the security of exchanging health information.³⁷

At Member State level, too, measures have been taken to facilitate e-health applications. In the Netherlands, legal measures have been introduced with the aim to establish a nationwide electronic health information exchange system using electronic patient health records. In this system, an official eID number, which is linked to the patient record, serves for patient identification and authentication purposes in electronic transmissions.³⁸ Furthermore, the system introduces e-prescription, mandatory for all medical professionals. Owing to strong opposition, however, the e-health strategy was scaled down to establish a regional patient information exchange system, i.e. a dataset of essential health information, accessible for GPs, pharmacists and hospital-based medical specialists only.³⁹ Essential to this exchange system is the patient’s explicit consent for exchanging patient information among regional health providers (opting in). Given the limited number of voluntary opting ins (5 million patients in 2014), the exchange of information remains modest, therefore tempering the underlying objective of stimulating patients’ self-management.⁴⁰

To promote further use of innovative technologies in health care, Dutch health insurance law already covers experimental services, such as local e-health GP consultations, e-mental health care, and telemonitoring the chronically ill.⁴¹ Apart from funding on an experimental basis, administrative barriers in long-term funding seriously hinder a sustainable development of e-health innovations. Further regulatory steps to simplify and extend reimbursement rules for e-health applications are being considered.⁴² At the same time, priority will be given to standardisation of the exchange of information at a national level covering a data set of health information and technical standards for electronic exchange between health providers.⁴³ Simultaneously, new legislation will update the safety and quality standards on so-called “patient portals” and medical apps, aimed at strengthening patient’s self-management.⁴⁴

Although Italy has transposed relevant EU law, such as the Data Protection Directive, into national data protection legislation, and recognised the rights of patients (e.g. access to information, informed consent, and so on), specific legislation on e-health is absent. Related issues have largely been regulated by soft

³⁴ Commission, “eHealth Action Plan 2012–2020—Innovative healthcare for the 21st century” COM(2012) 736 final, p.3.

³⁵ Commission Implementing Decision providing the rules for the establishment, the management and the functioning of the network of national responsible authorities on eHealth [2011] OJ L344/48.

³⁶ Guidelines on minimum/non-exhaustive patient summary dataset for electronic exchange in accordance with the Cross-Border Directive 2011/24, Release 1 (November 19, 2013).

³⁷ “eHealth Action Plan 2012–2020”, p.7.

³⁸ Wet gebruik burgerservicenummer in de zorg Stb 2008, 164.

³⁹ Tweede Kamer 2011–2012 Kamerstukken 27529, Nos 90 and 106 “Informatie en Communicatietechnologie (ICT) in de Zorg”; Tweede Kamer 2012–2013 Wijzigingswet Clientenrechten bij elektronische verwerking van gegevens, 33509 Nos 1–4.

⁴⁰ Status on October 27, 2014, “Facts and figures”, <http://www.vzvv.nl> [Accessed February 19, 2015].

⁴¹ Based on art.57(1)(b) and (c) of the Health Care Market Regulation Act (Wmg).

⁴² Tweede Kamer 2011–2012 Kamerstukken 27529, no.108, p.5.

⁴³ Tweede Kamer 2011–2012 Kamerstukken 27529, no.108, pp.4–5.

⁴⁴ Tweede Kamer 2012–13 Wijzigingswet Clientenrechten bij elektronische verwerking van gegevens, 33509 Nos 1–4.

law and agreements between the regions and national government. Owing to its federal structure, healthcare policy, including e-health issues, remains a regional competence. This might explain the absence of national e-health legislation. Only a few regions have developed regional e-health programmes. For instance, the Lombardia region has introduced an electronic card which functions as a patient's personal health record, facilitates e-prescription, and serves to manage health expenses and identification and authorisation. So far, only regional health providers have access to the patient's health information.⁴⁵ This situation improved slightly in 2013, when patients, too, were given electronic access to their personal health records, although at a regional level only.⁴⁶ At the same time, at a national level, the electronic exchange of patient's medical data with health care providers abroad is quite high (34 per cent).⁴⁷

In 2010, the Croatian Ministry of Health promulgated several bylaws (Ordinances) regulating the use of e-health functionalities, such as e-prescription and electronic patient health records, introducing a minimum set of patient's health data, management information (i.e. insurance data) and electronic identification.⁴⁸ Also, rules were set out on data protection within the centralised electronic health care system (CEZIH).⁴⁹ Furthermore, telemedicine (i.e. the provision of health care at distance by use of information technology) has been regulated, setting the conditions telemedicine providers have to fulfil, and by establishing the Croatian Institute of Telemedicine.⁵⁰ Finally, information on waiting lists in individual hospitals (number of patients waiting) and average waiting times can be accessed by patients via the internet.⁵¹ As a result, the Croatian legislature set out the main legal conditions for facilitating e-health applications. Still, in practice, the use of e-health remains limited, notably with respect to telemedicine and the availability of electronic health record services (e.g. patients' access to electronic medical records).⁵²

What has become clear so far is that all three countries have incorporated a patient identifier and authentication measures in line with art. 14 of the Patients' Rights Directive. Such a unique patient identifier is a necessary condition for each patient to be linked with his electronic medical file in the country of origin, and for exchanging patient information at national and international level. Giving patients online access to their medical records, including the option of uploading the record, could be valuable when a health professional (in country B) has no access to a patient's medical file (in country A).⁵³ Such online patient access (both availability and use) and the exchange of medical information are low, however, in all three countries.⁵⁴ If available, electronic health records are only accessible locally, or at regional level.

⁴⁵ Tweede Kamer 2012–13 Wijzigingswet Clientenrechten bij elektronische verwerking van gegevens, 33509 Nos 1–4, pp.28–29.

⁴⁶ *EpSOS Open eHealth initiative for a European large scale pilot of Patient Summary and electronic Prescription*, Deliverable 1.2.2 Appendix C_Baseline Report epSOS phase II (2013), p.21.

⁴⁷ Versus 22 per cent in the Netherlands and 9 per cent in Croatia in 2013. See *EpSOS Open eHealth initiative for a European large scale pilot of Patient Summary and electronic Prescription* (2013), p.10.

⁴⁸ Ordinance on the management of personal health record in electronic form (Official Gazette 82/10) (Pravilnik o načinu vođenja osobnog zdravstvenog kartona u elektroničkom obliku NN 82/10).

⁴⁹ Ordinance on the use and protection of medical data within the Central Information Health Care System of the Republic of Croatia (Official Gazette 14/10) (Pravilnik o uporabi i zaštiti podataka iz medicinske dokumentacije pacijenata u Centralnom informacijskom sustavu zdravstva Republike Hrvatske NN 14/10).

⁵⁰ Ordinance on conditions, organisation and way of conducting telemedicine (Official Gazette 138/11 and 110/12) (Pravilnik o uvjetima, organizaciji i načinu obavljanja telemedicine NN 138/11 i 110/12) and Health Care Act (Official Gazette 150/08 to 22/14) (Zakon o zdravstvenoj zaštiti NN 150/08 do 22/14) arts 106, 107.

⁵¹ On waiting lists, see Health Insurance Institute of Croatia, "Liste čekanja" (2014), http://www.hzzo-net.hr/e_listei.htm [Accessed February 19, 2015].

⁵² Commission, "Benchmarking Deployment of eHealth among General Practitioners (2013)—Country Profile Croatia" (2013).

⁵³ For instance, in the case of seasonal migration.

⁵⁴ But not limited to these three countries, confirmed by the Commission, "eHealth Action Plan 2012–2020" COM(2012) 736 final, p.5.

The border-crossing accessibility of these records (or patient summaries) remains therefore largely absent. Sharing transborder patient information carries the risk that the patient summary will not be updated since the home country professional may reject the information provided by a professional in another country.⁵⁵

Mutual recognition of prescriptions

The annual total number of cross-border medical prescriptions in the EU is estimated between 1.1 million and 8 million (total number of prescriptions: between 6.5 and 10 billion).⁵⁶ Despite this relatively low number, there are concerns about both quality and free movement. For instance, diversity in national dispensing rules may endanger patients' health and hamper free movement, notably that of chronic patients. To solve this problem the Commission drafted an implementing Directive that facilitates the mutual recognition of prescriptions dispensed in another Member State (art.11).⁵⁷ The Directive introduces a minimum data set covering relevant information that would enable a health professional to verify the authenticity of foreign prescriptions. So far, this implementing Directive has been incorporated into national law, recognising Member States' prescriptions.⁵⁸ Until now, it is unknown whether and to what extent this measure has improved patients' access to medicines abroad. Further Commission measures, such as guidelines supporting the interoperability of e-prescriptions, can be expected soon.

The practical implication is that pharmacists are allowed to dispense medicinal products prescribed in another Member State. Restrictions on the recognition of individual prescriptions can be justified "to safeguard human health or based on legitimate and justified doubts about the authenticity or content of the prescription". Moreover, such "EU-prescriptions" should respect domestic legislation, i.e. the prescribed medicine is marketed on the national territory.

As early as 2007 it was concluded that the recognition of foreign prescriptions was not automatic.⁵⁹ Barriers to the cross-border recognition of prescriptions were linked to the impossibility, for pharmacists, of identifying the correct product from country-specific brand names. Prescribing by brand remains a common practice in most countries. Furthermore, generic substitution of non-available prescribed medicines (brand names) is prohibited in Belgium and the UK,⁶⁰ but encouraged in the Netherlands. Still, the most important reasons are prescriber authentication and the minimum data needed in prescriptions complying with domestic dispensing rules.⁶¹

Electronic prescribing is suggested to solve the problem of incomplete prescriptions, which in its turn hampers the recognition of cross-border prescriptions. E-prescriptions are prescriptions that are exchanged by providers through email or e-health information systems, *and* the recording of dispensation in the patient's record. E-prescriptions will decrease the number of adverse effects due to errors in hand-written

⁵⁵ Epsos, *Smart Open Services for European Patients*, D1.4.2 (2012), p.18, http://www.epsos.eu/uploads/tx_epsosfileshare/D1.4.2_Country_status_outline_and_template_specification_v1.00.pdf [Accessed February 19, 2015].

⁵⁶ Commission Staff Working Paper, "Impact Assessment, Commission Implementing Directive 2012/52", p.14.

⁵⁷ Directive 2012/52. The format includes data such as: (1) patient information (name, date of birth); (2) authentication of the prescription (date); (3) identification of prescribing health professional; and (4) information of the prescribed product using a non-proprietary name, etc.

⁵⁸ Croatia: Ordinance on criteria for classification of drugs and on regulation and dispensation of prescription drugs (Official Gazette 86/13 to 102/14) (Pravilnik o mjerilima za razvrstavanje lijekova te o propisivanju i izdavanju lijekova na recept NN 86/13 do 102/14) (Prescription Drugs Ordinance 2013) arts.15–16; NL: Amending the Medicines Act Regulation art.6.14; as for Italy, it is noteworthy that the recognition of medical prescriptions is included in s.12 of the Act that has ratified Directive 24/2011.

⁵⁹ M. Mäkinen, "Electronic Prescriptions are Slowly Spreading in the EU" (2011) 17 *Telemedicine and eHealth* 217.

⁶⁰ L. San Miguel et al., "Recognition of Pharmaceutical Prescriptions across the European Union: A Comparison of Five Member States' Policies and Practices" (2014) 116 *Health Policy* 206.

⁶¹ Commission Staff Working Paper, "Impact Assessment, Commission Implementing Directive 2012/52", Results of public consultation, p.12.

prescriptions, thereby improving the quality of patient care. Except for some countries, such as the Nordic countries, a nation-wide e-prescription system is not widely used in the EU. In the Netherlands, e-prescribing is considered an indispensable element in the GP computerised information system, which is being used by the majority of general practitioners (95 per cent).⁶² From January 1, 2014, electronic prescribing became the norm.⁶³ Computer-based prescribing appears to be successful, therefore, particularly because it is integrated into the billing system and lowers GPs' administrative workload. Although common practice at national level, transborder e-prescription remains a black box. As for Croatia, e-prescription was ordered by law, is fully operational and functioning without particular problems.⁶⁴

Apart from some initiatives experimenting with functional e-prescription services at regional level, electronic exchange of prescriptions in Italy remains below the European average (9 per cent in 2013).⁶⁵

Co-operation on health technology assessment

Health technology assessment (HTA) is generally described as a systematic evaluation of the effects of health technology. It is a multidisciplinary process, evaluating the medical, social, economic and ethical/legal impact of using a health technology.⁶⁶ Its main purpose is to inform technology-related policy-making in health care, and thus improve political and legal accountability of HTA decision-making on coverage and pricing of health care services. This definition emphasises that evaluating health technologies is not restricted to economic science (i.e. cost-effectiveness studies) only, but requires a multidisciplinary approach, including legal and organisational aspects (as understood from "social issues"). HTA takes therefore an integral approach of relevant disciplines, providing input to decision-making in policy and practice. So far, most HTAs in the Netherlands, as well as in other countries, focus on economic evaluation, ignoring the input from other disciplines, thereby putting the comprehensiveness and usefulness of the analysis at risk.⁶⁷ Moreover, the available HTA studies focus on newly developed medicines, excluding other medical technologies such as medical devices, diagnostic procedures and complex treatment interventions.⁶⁸

The lack of systematic assessment in the Netherlands was one of the reasons to plead for the formalisation of cost-effectiveness analyses, which are a kind of HTA study, of coverage and reimbursement

⁶² Nictiz eHealth Monitor 2013, Annex, p.39.

⁶³ On request of the Health Inspectorate, the Dutch Medical Association developed a Guideline on e-prescription.

⁶⁴ Ordinance on way of prescribing and dispensing of prescription drugs (Official Gazette 17/09 to 81/14) (Pravilnik o načinu propisivanja i izdavanja lijekova na recept NN 17/09 do 81/14) and Health Insurance Institute of Croatia, "Pravo na korištenje lijekova" (May 7, 2014), <http://www.hzzo.hr/zdravstveni-sustav-rh/pravo-na-koristenje-lijekova> [Accessed February 19, 2014].

⁶⁵ Commission, *Benchmark Deployment of eHealth among General Practitioners: Final Report (2013)*, Italy, p.9.

⁶⁶ World Health Organization, "Health technology assessment of medical devices", WHO Medical device technical series (Geneva: 2011), p.11.

⁶⁷ A brief literature search on "HTA and Law" yielded a limited number of citations (2005–2013), e.g. R. Franke and D. Hart, "HTA in den Entscheidungsprozessen des IQWiG und G-BA" (2006) 3 *Bundesgesundheitsblatt, Gesundheitsforsch-Gesundheitschutz* 241; G. Soskuty, "Technologiebewertung aus Sicht der Medizintechnologie: richtig und wichtig!" (2006) 9 *MedizinRecht* 524; B. Potter et al., "Ethical, Legal, and Social Issues in Health Technology Assessment for Prenatal/preconceptional and Newborn Screening: a Workshop Report" (2009) 1 *Public Health Genomics* 4; T. Herve, "Cooperation between Health Care Authorities in the Proposed Directive on Patients' Rights in Cross-Border Healthcare" in *Health Care and EU Law* (2011), pp.181–184; K. Syrett, "Health Technology Appraisal and the Courts: Accountability for Reasonableness and the Judicial Model of Procedural Justice" (2011) 6 *Health Economics, Policy and Law* 469; C. Sorenson and K. Chalkidou, "Reflections on the Evolution of Health Technology Assessment in Europe" (2012) 7 *Health Economics, Policy and Law* 25. Still, there are numerous subjects that justify a legal assessment (organ transplantation, new medical technologies, such as genetic technologies, nanomedicine, etc).

⁶⁸ A search on "cost-effectiveness" in the *International Journal of Technology Assessment in Health Care* yielded more than 1,200 citations, mostly focusing on new medicines.

decision-making by law.⁶⁹ Such a statutory HTA requirement emphasises the multidisciplinary approach. The “Dutch approach” was inspired by the German Social Code, incorporating the cost-effectiveness criterion in its social health insurance law.⁷⁰

The Croatian health assessment body (the Agency for Quality and Accreditation in Health Care and Social Welfare) has an advisory role in health policy-making. Additionally, the Health Insurance Act dictates that the listed medicines covered by social health insurance should be medically and economically cost-effective. This list is defined by the Health Insurance Institute (HIIC).⁷¹ Therefore, health technology assessment has a legal basis in Croatian health insurance law.

In Italy, the practice of HTA has not been codified by law, though HTA bodies have a supportive role in health policy decision-making.⁷² Academics advocate a more institutional approach on HTA policy-making within the Italian decentralised healthcare system in which the Ministry of Health co-ordinates the specific activities of HTA bodies.⁷³ At the same time, the Ministry remains the responsible body for setting priorities (“essential level of health care”) based on HTA outcomes, and provided by the regions.

Article 15 of the Directive supports and facilitates co-operation and the exchange of information of HTA studies between Member States. A first step towards further collaboration was the formal launch of an EU-wide network on HTA (EUnetHTA).⁷⁴ EU-wide collaboration and the exchange of information (applied criteria, methodology, research outcomes and so on) will prevent duplication in HTA research of new technologies, and might help less experienced countries in making more transparent and well-balanced health policy decisions (by spreading “best practices”). In practice, however, defining common criteria for joint modelling and assessments appears problematic. The diversity of methods and local context determined conditions criteria complicate the transferability of outcomes.⁷⁵ An important tool for standardising and sharing HTA information is the EUnetHTA’s HTA Core Model, a methodological framework identifying nine research domains: health problems and current use of technology; description

⁶⁹ See, e.g. the Dutch Healthcare Institute (Zorginstituut), Advies “Kosteneffectiviteit in de zorg: Op weg naar een genuanceerd en geaccepteerd gebruik van Kosteneffectiviteitsgegevens in de zorg”, Annex Kamerstuk 29689 no.476, <https://zoek.officielebekendmakingen.nl/> [Accessed February 19, 2015]; see also A. den Exter, “Cost-Effectiveness Analysis and the Law” (2014) 1 Int J. Law and Medicine 285–297.

⁷⁰ Sozialgesetzbuch (SGB) Fünftes Buch (V) §12 Wirtschaftlichkeitsgebot (1) “Die Leistungen müssen ausreichend, zweckmäßig und wirtschaftlich sein; sie dürfen das Maß des Notwendigen nicht überschreiten. Leistungen, die nicht notwendig oder unwirtschaftlich sind, können Versicherte nicht beanspruchen, dürfen die Leistungserbringer nicht bewirken und die Krankenkassen nicht bewilligen.” See *Sozialgesetzbuch.de* [Accessed February 19, 2015].

⁷¹ See Quality of Health Care and Social Welfare Act (Official Gazette 124/11) (Zakon o kvaliteti zdravstvene zaštite i socijalne skrbi NN 124/11) (Health Insurance Act 2013 Act) art.20; and Agency for Quality and Accreditation in Health Care and Social Welfare, “The Croatian Guidelines for Health Technology Assessment Process and Reporting” (2011). In Italy a decentralised regional network of HTA institutions is conducting HTAs, missing a multi-layer organisational framework of HTA information. O. Ciani et al., “Diffusion and Use of Health Technology Assessment in Policy-making: What Lessons for Decentralised Healthcare Systems?” (2012) 108 *Health Policy* 194.

⁷² Ciani et al., “Diffusion and Use of Health Technology Assessment in Policy-making” (2012) 108 *Health Policy* 194.

⁷³ See also A. Cicchetti et al., “La definizione delle priorità nel processo di Hta tra esigenze centrali e regionali” (2012) 13 *Politiche sanitarie* 245.

⁷⁴ See Commission Implementing Decision providing the rules for the establishment, management and transparent functioning of the network of national authorities or bodies responsible for health technology assessment [2013] OJ L175/71, <http://www.EUnetHTA.net> [Accessed February 19, 2015].

⁷⁵ For instance, Kristensen et al. identify differences relating to the demographic make-up and the epidemiology of the disease in the target populations. Also, transferability is affected to some degree by differences in other factors concerning unit costs, the relative efficiencies of health systems, health-care practices, social values and preferences. F. Kristensen et al., “What is Health Technology Assessment?” in M. Velasco Garrido et al. (eds), *Health Technology Assessment and Health Policy in Europe: Current Status, Challenges and Potential* (Copenhagen: World Health Organization, 2008), p.44.

and technical characteristics of technology; safety; clinical effectiveness; costs and economic evaluation; ethical analysis; organisational aspects; social aspects; and legal aspects.⁷⁶ The legal domain identifies several indicators, including human rights, planning and regulating health services, health insurance and pharmaceuticals, and liability issues, as well as sources of law (national, international and European law), which are of importance to such an assessment. Evidence generated from the legal assessment, combined with economic, medical and policy arguments, will be applied to support decisions on the value of medical technologies. In the end, the information provided by such an assessment may justify the need for making hard choices in health care, i.e. denial of treatment as a result of scarce resources—but at least such a painful decision is then based on the principles of transparency, legal reasoning, good governance and public accountability.⁷⁷

The proliferation of soft law instruments, such as the HTA core model, its methodology and multidisciplinary format, may even contribute towards a certain degree of convergence in health policy decision-making processes and outcomes, although the Directive explicitly excludes any harmonising effect of the information exchange.⁷⁸

Conclusions

One year after the Patient Rights Directive came into force, a first analysis has made clear that the Member States have taken considerable steps to realise the Directive's aims: facilitating free movement of patients in the EU, and achieving a high level of protection of human health. Although the focus of the analysis was on a selected number of key elements, these still reflect the core of what the Directive stands for. As such, these outcomes explain whether the Directive has been successfully implemented, or not.

The first key element is prior authorisation and reimbursement of cross-border care. Country analysis has made clear that each of the three countries in question have taken regulatory steps incorporating these mechanisms, whether or not forced by previous Court of Justice rulings, from a mainly “copy and paste” approach (Croatia) to a highly complicated multilevel decision-making process (Italy). In between is the Dutch approach, just confirming these conditions as “standing procedure”. The diversity of measures taken raises the question whether they are all in conformity with the Directive. It was argued that lowering the Dutch reimbursement option for non-contracted care still respected the Directive's aim. More questionable is the potential discriminatory effect of excluding travel and accommodation costs for planned health care abroad in Croatia, whereas the Italian multilevel approach seems overly complicated, discouraging patients from seeking cross-border health care. In both cases (failure to fulfil their obligations under either art.7(4) or 7(7) of the Directive), the Commission may then start a procedure under art.258 TFEU, calling on Member States to comply with EU law by removing arbitrary and discriminatory restrictions on cross-border care. In addition, individuals may even consider a more innovative approach by challenging the incorrect implementation under the EU Charter of Fundamental Rights (art.35, the right to health care) joined with the non-discrimination provision, based on nationality (art.21(2)), before the national court.

The second condition, establishing a national contact point, has been realised by all three Member States by launching a web portal providing basic information on cross-border care. To be successful, the information should be easily accessible and adequate. Whether this requirement has been fulfilled can be questioned. First of all the lack of multilingual information—although not required by the Directive—and

⁷⁶ EUnetHTA, “The HTA Core Model Application for Medical and Surgical Interventions (2.0)”, <http://www.eunetha.net> [Accessed February 19, 2015].

⁷⁷ See also D. Exter, “Cost-Effectiveness Analysis and the Law” (2014) 1 Int J. Law and Medicine 292.

⁷⁸ Directive 2011/24 art.15(7) and Recital 35.

focus on national health care services may prevent patients from making well-informed choices, and discourage less-literate patients from seeking health care abroad.

Despite the European ambition towards a more patient-focused health care system made more efficient by the e-health revolution, we find considerable legal obstacles in the way of the application and exchange of electronic health applications (including e-prescriptions) in a cross-border context. So far, it seems that Member States' national e-health agendas are ignoring the cross-border dimension. The Directive's e-health provision makes it clear, however, that a more ambitious European or even global approach is necessary. The technical and legal complexity of such an approach should nevertheless not be underestimated, so that a more gradual approach seems the most likely to be successful. One essential element of such an approach is extending e-health pilot projects, such as eSOS. Technical and other shortcomings will urge Member States to solve interoperability issues at a bilateral level and, moreover, to standardise quality and safety standards at European level. In this way, an impetus is created for "soft law" harmonisation.

Lastly, setting up the EU HTA network has been an important step towards co-operation and exchange of information of HTA studies between Member States. The developed HTA core model goes a long way towards uniformity of criteria and indicators, and as such helps to rationalise health policy decision-making. Moreover, the use of common indicators, legal principles and norms, in line with the methodology of the core model, contributes to what has been referred to as the incremental "Europeanisation" of decision-making in the health sector through "soft law".⁷⁹

The use of non-legally binding instruments, such as the use of shared guidelines, models and the exchange of best practices, facilitated and encouraged by "hard law" Directives, has also been applied in other health care areas such as e-health, i.e. establishing a network of national responsible authorities on e-health, formulating guidelines on the standardisation of patient summary records and interoperable e-prescription systems in the EU, combined with "hard law" Directives introducing minimum data sets and common eID measures. The use of such soft law mechanisms shows a convergence of approaches in health care policy-making in the Member States, though this is not necessarily restricted to the three selected studies. Europe-wide, Member States are participating in these voluntary networks, exchanging best practices and starting to carry out joined HTA studies, and mostly for non-legal reasons: cost-effectiveness, efficiency, clinical effectiveness and patient safety. Although the use and effectiveness of "soft law" mechanisms may vary by country, the overall tendency with respect to the areas as discussed is clear: an implicit convergence of European health care standards without legal obligations. Overall, the implementation of Directive 2011/24 should allow the overcoming of a purely economic approach to health services so as to reach out for a new relationship between citizens and welfare state. This relationship is to depict enforceable rights also within the legal framework of patient's mobility: cross-border health care is expected then to strike a balance between the fulfilling of citizens' needs and the obligation of Member States to ensure financial sustainability of the budgets of their national health systems. Such a goal cannot be accomplished when Member States build up barriers against the freedom of movement, thus preventing European citizens from migrating out of their health systems. Hence, it is not a question of market freedom versus European social market. It is rather a question of implementing procedures aimed at supporting cross-border health care services, which could actually bring in important changes in the organisation and management of national health systems.

⁷⁹E. Brooks, "Europeanisation through Soft Law: the Future of EU Health Policy?" (2012) 6 *Political Perspectives* 86.