INNOVATION AND EU HEALTH POLICY
(A Legal Analysis of the Latest Developments in Cross-Border Healthcare)

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Abstract
The ex-post evaluation of the 2nd Health Programme 2008-2013 of the European Union was published by the European Commission 10 May 2016 with the aim of presenting the results and conclusions of the programme as well as improving the current 3rd Health Programme.

On the subject of summarizing the results of EU health policy, an interesting question is how the EU can promote 'smart' solutions and 'inclusive growth' with regards cross-border healthcare in line with Europe 2020 strategy and the e-health action plan. This is a field, however, where health policy is strongly connected to several specific questions including economic and technological efficiency, social sustainability, the relation of EU law to the law of the Member States and even the international human rights approach. The current paper focuses on the question, how EU legislation can enable innovation and smart solutions while safeguarding fundamental rights of individuals, administrative autonomy of Member States and the sharing of competences within the EU. The analysis is primarily based on the documents of EU institutions complemented with the statements of the relevant international secondary literature. The review is completed by the aspects of jurisdiction and fundamental rights.

Keywords: e-health, European Reference Networks, patients' rights, competences of the EU, data protection

1. Introduction

The ex-post evaluation[1] of the 2nd Health Programme 2008-2013[2] of the European Union (hereinafter: EU) was published by the European Commission (hereinafter: Commission) in May 2016 with the aim of presenting the results and conclusions of the programme as well as improving the current 3rd Health Programme[3]. On the subject of summarizing the results of EU health policy, an interesting question is how the EU can promote 'smart' solutions and

[1] European Commission (2016): *Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Ex-post evaluation of the 2nd Health programme 2008-2013 under Decision No 1350/2007/EC establishing a second programme of Community action in the field of health (2008-2013)*, Brussels. COM(2016) 243 final. Downloaded 23 November 2016 from http://ec.europa.eu/health/programme/docs/ex-post_2nd-hp-2008-13_comm-report_en.pdf

[2] European Parliament; Council of the European Union (2007): *Decision No 1350/2007/EC of the European Parliament and of the Council of 23 October 2007 establishing a second programme of Community action in the field of health (2008-13)*. OJ L 301/3. Downloaded 23 November 2016 from http://eur-lex.europa.eu/legal-content/GA/TXT/?uri=CELEX:32007D1350.

[3] European Parliament; Council of the European Union (2014): *Regulation (EU) No 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020) and repealing Decision No 1350/2007/EC.* OJ L 86/1. Downloaded 24 November 2016 from http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0282.

'inclusive growth' in line with Europe 2020 strategy[4] and the e-health action plan[5] with regards cross-border healthcare. It is apparent from all these documents that cross-border health policy can only be effective, if its scope extends "*beyond 'classical' public health issues, such as the promotion of health and protection from communicable diseases*" to "*new approaches such as e-health and health technology assessment, and to medicinal products*" (Commission, 2016, 3.).

This is a goal, however, where health policy measures can only be successful if they are well-integrated in the economic, technological and legal framework. In the following, the question will be examined, how EU legislation can enable innovation and smart solutions while safeguarding fundamental rights of individuals, administrative autonomy of Member States and the sharing of competences within the EU.

2. The definition of cross-border health care

A basic precondition of such an analysis is to define cross-border healthcare. At normative level the patients' rights directive (hereinafter: Directive) can be a starting point, which defines in its Article 3 cross-border healthcare as "*healthcare provided or prescribed in a Member State other than the Member State of affiliation*". Although this definition seems to be adequate to determine the scope of a given piece of legislation, it is not precise enough to give guidance for scientific studies as regards the aims, directions, and forms of cross-border healthcare.

The major sources of secondary literature in this field usually do not give a definition, but consider the concept of cross-border healthcare as given and lead back to the concept to the market freedoms guaranteed in the EU, especially to the freedom to provide services. (Craig – de Búrca, 2011, 521; Tuori, 2014, 387). This view can be undermined on the basis of the case-law of the Court of Justice of the European Union (hereinafter: ECJ), too: "*While the national rules (...) do not deprive insured persons of the possibility of approaching a provider of services established in another Member State, they do nevertheless make reimbursement of the costs incurred in that Member State subject to prior authorisation, and deny such reimbursement to insured persons who have not obtained that authorisation. (...) Consequently, such rules deter insured persons from approaching providers of medical services established in another Member State and constitute, for them and their patients, a barrier to freedom to provide services*".[6]

Nevertheless, if possible directions of innovation stand in the centre of analysis, the summary of the main categories of cross-border healthcare can be a more useful alternative. According to a communication of the Commission (Commission, 2006, 5.) the forms of cross-border health-services can be summarized as follows: "*1.) Cross-border provision of services (delivery of service from the territory of one Member State into the territory of another), such as telemedicine services, remote diagnosis and prescription, laboratory services; 2.) Use of*

[4] European Commission (2010): *Communication from the Commission: EUROPE 2020 A strategy for smart, sustainable and inclusive growth*, Brussels. COM(2010) 2020 final Downloaded 24 November 2016 from http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:2020:FIN:EN:PDF.

[5] European Commission (2012): *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century*, Brussels. COM(2012) 736 final. Downloaded 24 November 2016 from http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52012DC0736&from=EN .

[6] Court of Justice of the European Union. Case C-158/96, *Raymond Kohll v Union des Caisses de Maladie*, judgment of 28th April 1998, ECR 1998 I-01931, paras 34-35.

services abroad (i.e.: a patient moving to a healthcare provider in another Member State for treatment); this is what is referred to as 'patient mobility' (…); 3.) Permanent presence of a service provider (i.e.: establishment of a healthcare provider in another Member State), such as local clinics of larger providers; and 4.) Temporary presence of persons (i.e.: mobility of health professionals, for example moving temporarily to the Member State of the patient to provide services)". (Similary, e.g. Smith Jervelund – Neerup Handlos, 2015, 228; Azzopardi-Muscat et al., 2015, 1285; Rosenmöller et al., 2006, 6-7).

Along these basic directions, we can examine the multidisciplinary framework of new solutions in cross-border healthcare.

3. Multidisciplinary framework of new solutions

After defining the concept of cross-border health services, it has to be examined, or at least outlined,[7] why the participation of the EU is necessary at this field and what the basic preconditions of such an involvement are. The current analysis is based on the primary and secondary sources of EU law, other documents and communications of EU institutions, complemented with the statements of the relevant secondary literature. On the basis of these sources is it possible to determine the multidisciplinary framework of innovative solutions in European context.

3.1. The social aspects

Drawing up the basic preconditions of innovative health solutions – under which later the more precise evaluation of certain measures is possible – firstly it seems to be indispensable to concentrate on the social background. Complex development strategies in cross-border healthcare can only be successful, if they react to existing and urgent social needs. From the individual patient's point of view the following factors that have to be taken into account: There are increasing expectations towards healthcare providers as regards professionalism, organisation and time-aspects. As medical information are available from several different electronic sources, acknowledged and supported sources of information have to be able to "stand out" (Pellegrino – Nicoli, 2012, 144.). The new solutions have to react with special awareness to the fact that besides acute illness, chronic diseases stand equally in the centre of attention (Hasselaar, J. et al, 2014, 282), making more frequent, or longer-term contact necessary.

From the policy-makers', legislators' point it is of crucial importance that the struggling for more standardization has to take the changes in the composition of the population into account; the solutions have to be generally accessible and should not lead to de facto discrimination of underprivileged social groups.

If we take the medical experts' point, cross-border coordination of health policies has to be able to provide easily accessible assistance in emergency situations (e.g. technical experts, strategic support, resource mobilization, guidance development, training and capacity-building, supplies and logistical support and expediting research and development) as well as concerning complex medical problems including all territories where medical expertise is rare (e.g. World Health Organization, 2016).

3.2. The economic framework

[7] It is not aim of this chapter to describe in details all social, economic and legal preconditions of cross-border healthcare. It is rather intended to highlight those aspects that can determine the most important development tendencies and innovation possibilities in the current framework.

The next question is to determine the financial aspects: The latest data of the EU show that increased spending on health-care does not automatically lead to the improvement of the level of services. "*Empirical evidence suggests a non-linear relationship between health spending and outcomes, reflecting the impact of other factors, inter alia, historical expenditure patterns on health and other welfare policies, socioeconomic variables, lifestyle behaviour, and environmental factors*" (Medeiros – Schwierz, 2015, 10.).

This phenomenon might be lead back – among other factors – to the not-optimal use of resources.

"*Berwick and Hackbart [Berwick – Hackbarth, 2012] claim that reducing waste is the largest and smartest opportunity for developing an affordable health system. They distinguish six categories of waste: 1) health care delivery failures; 2) failures of coordination (e.g. fragmented care); 3) overutilisation; 4) administrative complexity; 5) pricing failures; and 6) fraud and abuse.*" (Lafeber – Jeurissen, 2013, 37) No further explanation is needed to undermine the fact that innovative solutions (no matter if they are of technological, legal or economic kind) play a significant role in "reducing waste", creating an optimum between the costs of cross-border healthcare and the patients' needs.

3.3. Legal background

The last question – concerning the multidisciplinary framework of new solutions – is the legal background. In this regard, firstly, it has to be examined, what kind of powers does the EU have in this field, how the EU can – by means of new legal instruments – influence the healthcare developments if the Member States.

As Article 6 of the Treaty on the Functioning of the European Union (hereinafter: TFEU) prescribes, that in the field of protection and improvement of human health, the Union shall have competence to carry out actions to support, coordinate or supplement the actions of the Member States. These powers mainly cover public health in strict sense, so the improvement of public health, prevention of physical and mental illness and diseases, obviating the sources of danger to physical and mental health, the fight against the major health scourges (research, prevention, health information and education, monitoring) and combating serious cross-border threats to health. (Article 168 TFEU)

This provision alone would mean a relatively limited competence for the EU. However, according to Article 9 of the TFEU, the protection of human health is a so-called horizontal principle, which shall be taken into account in defining and implementing the policies and activities of the EU.

Furthermore, it has to be recalled that cross-border healthcare has been defined by the ECJ as integral part of the freedom to provide services. So, the powers of the common institutions can primarily be deducted from the internal market principle.[8] This is the legal basis for EU-measures e.g. at the fields of production, authorization and marketing of medicinal products

[8] This principle is declared in Article 26 Paragraph (1) TFEU ("*The Union shall adopt measures with the aim of establishing or ensuring the functioning of the internal market, in accordance with the relevant provisions of the Treaties.*") and Article 114 Para (1) TFEU ("*The European Parliament and the Council shall, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.*")

for human use, as they have several connections to the protection of consumers or to competition policy.[9]

Nevertheless, these provisions determine only the basic competences of EU organs; they do not mean that all aspects of cross-border healthcare would be (could be) entirely harmonised. E.g. in case of measures, which might affect the social security schemes of the Member States, the situation is much more delicate. Article 153 Paragraph (4) TFEU emphasizes "*(t)he provisions adopted pursuant to this Article shall not affect the right of Member States to define the fundamental principles of their social security systems and must not significantly affect the financial equilibrium thereof(...)*"

Not only the competences of the EU and Member States might cause delimitations; the human rights aspects have to be respected as well. As far as innovative (technological, smart) solutions are concerned, the protection of personal (highly sensitive) data is of crucial importance. These rights have to be ensured in line with the Charter of Fundamental Rights of the European Union (hereinafter: ChFR), which has gained the same legal status as the Treaties after the Lisbon Treaty entered into force. This means that the fundamental rights guaranteed in the legal order of the European Union (including the provisions of the Charter) are applicable in all situations governed by European Union law.[10] So, in these specific fields, the protection of fundamental rights, like the protection of personal data (Article 8 ChFR), respect for private life (Article 7 ChFR), human dignity (Article 1 ChFR) have to be safeguarded as well.

On the basis of this framework, it can be intended to summarize the possible directions of smart solutions in cross-border healthcare in the EU.

4. The possible directions of innovation

The next step in analyzing the possibilities of innovation is to take a closer look at certain institutions, instruments and to define their role in EU health policy as well as to determine how they can contribute to a more efficient cross-border health care.

4.1. The European Health Insurance Card

Firstly, the current system of the European Health Insurance Card (hereinafter: EHIC card) will be introduced, with special regard to the possibilities of the introduction of an electronic EHIC card as a way of facilitating cross-border treatment in urgent cases. This document entitles namely to medically necessary healthcare during a temporary stay in the EU under the same terms as nationals of the country of stay. [The relevant provisions on the EHIC card contain limitations as regards the scope of treatment, reimbursement of costs, available healthcare providers, which are, however, less relevant in this context.] However, time to time cases occur, when the difficulties of identification, determination of entitlement and the administrative workload of reimbursement preclude the efficient use of the EHIC card. In May 2013 the Commission has expressed concerns about refusals by Spanish public hospitals

[9] E.g. this provision (more precisely ex Article 95 TEC was the legal basis for the adoption of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. OJ L 311. Downloaded 23 November 2016 from*:* http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32001L0083&qid=1479899870389&from=HU

[10] Court of Justice of the European Union. Case C-617/10, *Åklagaren v Hans Åkerberg Fransson*, judgement of 26 February 2013, ECLI:EU:C:2013:105, para 19.

to recognise the EHIC-card.[11] The complaints lodged at the Commission described that the providers have failed to ensure the emergency healthcare to temporary visitors from other Member States on the same terms and conditions as are available to Spanish nationals under the public healthcare scheme. Some weeks later similar concerns have been expressed in relation to other Southern-European countries including Portugal.[12]

A smart card solution is undoubtedly the most evident solution for these difficulties. The on-line verification of entitlement could provide up-to-date and reliable information for the health-service provider. At the same time the social security provider of the country of origin could follow the costs of the treatment as well, making the control and reimbursement more efficient. The development of such a card has been supported by the EU; EU-financed projects NetC@rds, epSOS provide the necessary technological framework. "*The NetC@rds project has established a cross-border online pan-European service to authenticate a patient's health insurance card and/or a patient's entitlement to health insurance benefits abroad for unplanned care.*" (Pangalos – Nader – Pagkalos, 2013, 159.)

However, even if all preconditions of interoperability, verification, secure data transmission are given, these are not necessarily sufficient from the legal point of view. The common use of such a system is connected to several concerns: Not only the right of the individual for protection of his personal – and as his health status and personal integrity is concerned – also highly sensitive data is concerned, but also the legitimate interest of the nation states to protect the data of their citizens from unjustified access. The first concern is strongly related to the human rights aspect set out in the methodological chapter. Even if the access is provided only to the basic facts of social security entitlement, the different systems can keep track of the operations performed (Lattanzi , 2008, 33.), this way it can lead to a creation of new databases independently from the original ones. The question of connecting databases might have different standards according to the interpretation of human rights: e.g. in a significant decision the Hungarian Constitutional Court – quite a while ago – stated, that the connection of several databases through a uniform identification number could lead to the creation of a "personality profile", which would adversely affect the right to self-determination and human dignity. [Hungarian Constitutional Court. Decision: 15/1991. (IV. 13.) AB.] Similar considerations have been discussed by the German Bundesverfassungsgericht (Theißen, 2009, 208-209). Such concerns have been raised in a recent opinion of the European Data Protection Supervisor as well: "*In the early 21st century, individuals are increasingly required to disclose much more personal information over the Internet in order to participate in social, administrative and commercial affairs, with ever more limited scope for opting out. With all activity potentially always online, the notion of free and informed consent is placed under enormous strain. (...) This requires a new assessment of whether the potential benefits of the new technologies really depend on the collection and analysis of the personally-identifiable information of billions of individuals*". (European Data Protection Supervisor, 2015, 12-13.) These examples show that technological development, especially smart solutions have a very strong connection to the human rights protection standards, and the interpretation of human rights in the 21st century. That is why more in-depth legal analysis (paying attention to the complex system of human rights protection in the EU and in the single Member States) might be necessary in order to apply e-

[11] European Commission (2013): *European Health Insurance Card: Commission expresses concerns about refusals by Spanish public hospitals to recognise EHIC, Press release*, Brussels. Downloaded 23 November 2016 from http://europa.eu/rapid/press-release_IP-13-474_en.htm.

[12] Portugal implicated for EHIC failings, InsuranceInsight. Downloaded 23 November 2016 from http://www.postonline.co.uk/post/news/2312896/portugal-implicated-for-ehic-failings

health solutions efficiently in the field of cross-border healthcare, in comparison to the mere harmonization of data protection regulations.

From the analyses of this framework follows that efforts for innovation have to be harmonized with several legal, sociological and political considerations. That is why it is not enough to develop a legal framework based on the principle of access limited to the necessary aim and in accordance with the highly different national data protection regimes but adequate mechanisms for the enforcement of rights in case of infringements have to be provided as well.

4.2. National Contact Points

As far as the authorities and health providers are concerned, the example of the Directive on cross-border patients' rights demonstrates the necessity of new solutions in the field of reimbursement of costs of medical care and calls the attention to innovation in the functioning of National Contact Points.

According to Recital (3) of the Directive "*[t]he health systems in the Union are a central component of the Union's high levels of social protection, and contribute to social cohesion and social justice as well as to sustainable development. They are also part of the wider framework of services of general interest*." This approach is in accordance with the fact that Articles 114 and 168 TFEU offer the common basis for the legislation powers of the European Union. Furthermore, it creates the connection to the Europe 2020 strategy, as latter states that "*[f]or our own and future generations to continue to enjoy a high-quality of healthy life, underpinned by Europe's unique social models, we need to take action now. What is needed is a strategy to turn the EU into a smart, sustainable and inclusive economy delivering high levels of employment, productivity and social cohesion"* (Commission, 2010, 10.). Certain authors stress that the Directive represents that "*[t]he focus of the EU rules is not anymore the medical treatment as an economic service, but rather the rights of the patient*" (Bosio, 2015, 16.).

This Directive is considered as important for patients, as it "*offers additional possibilities for patients to obtain healthcare abroad*"; "*provides a minimum set of patients' rights*"; "*requires Member States to provide clear information to patients on their rights and options*"; and "*provides a legal basis for European collaboration in the fields of health technology assessment, eHealth, rare diseases, and safety and quality standards*" (European Patients' Forum).

Realising these aims, the Directive stresses the importance of providing information for patients and in its Article 6 it creates the system of national contact points (hereinafter: NCPs) for cross-border healthcare. The example of NCPs is worth mentioning, because it demonstrates well that the necessity for new solutions supposed by legislators, policy-makers or even EU organisations, does not necessarily meet the social needs.

In line with the Directive, each Member State designated one or more NCPs for cross-border healthcare, which shall provide patients with information concerning healthcare providers, information on a specific provider's right to provide services or any restrictions on its practice, information on patients' rights, complaints procedures and mechanisms for seeking remedies etc.

According to the respective legal orders and institutional systems of the Member States, the designated NCPs are either the competent ministries (e.g. Cyprus, Spain, Italy); health

insurance funds (e.g. Bulgaria, Germany, Poland) or agencies of special jurisdiction including patients' rights or reimbursement issues (e.g. Greece, Hungary, France).[13]

However, when the European Commission prepared a report on the application of the Directive in practice, it came out that "*[o]f nine NCPs surveyed, three had fewer than 10 requests for information per month, four had between 10 and 100 requests, and only two had more than 100 requests per month. (…)A recent Eurobarometer survey indicated that fewer than two out of ten citizens feel that they are informed about their cross-border healthcare rights. (…)only one in ten knew about the existence of NCPs*" (Commission, 2015, 8-9.).

At evaluating these results, the aims of NCPs are decisive. If NCPs serve the goal to provide highly specialized information for individual cases, then the number of requests is rather irrelevant. It is the complexity of legal problems, which makes the intervention of professionalised organisations and their networks necessary.

If, however, the aim is to call the attention to patients' rights, to contribute to the empowerment of patients' in such difficult situations (when they are abroad, need medical care and are not aware of their rights in a foreign legal system), then the classic administrative way of thinking (the canalisation of requests into the public administration) is not always useful; information provided in form of mobile apps, websites etc. are more easily accessible; on demand solutions might have better results.

A possible solution could be a better collaboration of NCPs with patients' organisations and the better realisation of the quality criteria set out by the Commission for health websites.[14] A test by London Economics also offers useful insights: "*1.) access to information on costs and waiting time should be available through the portal; 2.) clear information about healthcare providers in other Member States including liability insurance, quality and safety standards; 3. reviews of other patients experiences in the cross-border country; 4. information that is not too complex for users*" (Duke, 2013, 15).

This example shows that in order to achieve certain social goals successfully, legal regulations and smart solutions have to be in accordance with the social aim.

4.3. European Reference Networks

Finally, the implementation of European Reference Networks (hereinafter: ERNs) shall be introduced as a framework of collecting and disseminating medical expertise. Article 12 of the Directive contains the rules applicable for the establishment and development of ERNs. Considering Recital (54)[15] of the Directive, the ERNs could play a significant role in the fields of highly specialized care (e.g. rare diseases, chronic conditions) making an exchange of expertise, medical training and research, information dissemination and evaluation possible in fields where medical expertise is rare (e.g. Nitzlnader et al., 2016, 39-45). Certain authors argue that ERNs can be an "*effective way of delivering affordable, high-quality and cross-border healthcare*" (Pennings – Vonk, 2015, 510.), especially if its scope could be broadened

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[13] List of National Contact Points. Downloaded 24 November 2016 from: http://ec.europa.eu/health/cross_border_care/docs/cbhc_ncp_en.pdf

[14] European Commission (2002): *Commission recommends Quality Criteria for Health Websites,* Brussels. [Press Release (IP/02/1819)]. Downloaded 24 November 2016 from http://europa.eu/rapid/press-release_IP-02-1819_en.htm .

[15] *„European reference networks can improve the access to diagnosis and the provision of high-quality healthcare to all patients who have conditions requiring a particular concentration of resources or expertise, and could also be focal points for medical training and research, information dissemination and evaluation, especially for rare diseases.*"

in comparison to the current model of exchange of medical expertise. What kind of solutions are used by ERNs? E.g. Virtual Consultation System, supporting researchers in management of complex clinical cases through online consultations (Czauderna, 2015); complex Digital Service Infrastructures (Martins, 2015); or the elaboration and dissemination of indicators and guidelines (Ritchie, 2015).

The ERNs – as a form of cooperation between healthcare providers and centres of expertise in the Member States – shall be supported by the Commission. This way of collaboration is based on a call for interest to establish ERNs published by the Commission.[16] "*Any group of at least 10 healthcare providers established in at least 8 Member States may collectively respond by the deadline indicated in the call for interest with an application containing a proposal to establish a Network in a given field of expertise.*" [Article 2 Paragraph (2) Implementing Decision] The first call for application was published earlier this year by the Commission.[17]

This system shows that ERNs can be considered rather as a framework for cooperation between Member States, where the own initiative of the Member States, especially healthcare providers is of crucial importance; the EU provides structures and funding for this collaboration. Through these means, it is possible to give more space for the expert decisions (enabling to choose the professionally most efficient solution), but at the same time, the Directive and the decisions of the Commission integrate ERNs into the EU level system of smart health solutions, including the necessary guarantees for their functioning.

4. Conclusions

The documents of the EU – mentioned in the introduction – show that smart solutions are – and accordingly – will be integral parts of cross-border health-care. This is also in line with the needs and claims of the actors in the field of cross-border healthcare: "*new ways of thinking and collaborating in the field of chronic diseases are needed that comprise educational support, shared decision-making and skills development – for both the health care provider and the patient. In this context, e-health can help to facilitate changes in health systems and to promote patient empowerment by providing education and offering opportunities for individualized, tailored healthcare.*" (Budych et al., 2014)

Nevertheless, as the examples described above demonstrate, the definition of the actual need and the tools applied have to be consistent with each other (see the questions mentioned regarding NCPs), at designing the rules of data protection the human rights standards have to be considered in a broader sense as well, and the solutions have to be in line with the general policies and competences of the EU.

So, it can be concluded that the EU health policy offers an appropriate framework for innovative solutions, and smart solutions can lead to significant development of the health systems, if there is an optimal balance among the legal, economic and social factors.

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[16] The criteria for recognition as ERN are set out in:
European Commission (2014). *Delegated Decision of 10 March 2014 setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfill*. (2014/286/EU). OJ L 147/71. Downloaded 23 November 2016 from http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2014.147.01.0071.01.ENG&toc=OJ:L:2014:147:TOC

[17] European Commission (2016): *Call for applications 2016*. Downloaded 25 November 2016 from http://ec.europa.eu/health/ern/implementation/call/index_en.htm.

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