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Cross-border healthcare directive: Assessing stakeholders' perspectives in Poland and Portugal

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ABSTRACT

Within the context of the EU, a succession of rulings from the European Court of Justice addressed the gap of specific healthcare legislation. These rulings shook the member states assumption of health provision autonomy and led the European Commission to produce a specific directive concerning cross-border healthcare. In spite of different viewpoints of member states, including Poland and Portugal, the directive was approved and expected to be implemented by October 2013.

The objective of this study was to analyse stakeholders' perspective towards the directive, unveiling the factors that supported a different viewpoint, and to identify challenges and assess the expected impact associated with the directive implementation on Poland and Portugal, using the WHO health systems conceptual framework.

Information was collected through a literature review, identifying potential stakeholders. Primary qualitative analysis was conducted through the dissemination of open-ended questionnaires. Content and critical analysis was performed considering the available literature intertwined with the WHO health systems conceptual framework.

The directive appears to be positive regarding patient rights, increased transparency, and potential to set new information technologies and healthcare networks. However, it also seems to potentially generate access inequalities between home and foreign patients, and increase healthcare costs due to the short-term investments needed.

1. Introduction

Historically, the organisation, resource allocation, and provision of healthcare among European Union (EU) member states (MS) were kept as a national responsibility issue. These responsibilities worked in conjunction with the traditional healthcare responsibilities at the greater EU level, including public health issues, cross-border health threats, promotion of health education, sponsorship of Research and Development (R&D) and provision of expertise guidelines within and to MS [1].

The approval of the cross-border healthcare Directive,[2] was considered the first step in addressing the matter of how to interpret the fundamental principles of EU – freedom of movement towards services, goods, people and capital – within the context of healthcare. This has, however, shaken the assumption that MS healthcare provision was free from EU intervention [2].

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[2] Directive 2011/24/EU of 9 March 2011, on the application of patients' rights in cross-border healthcare.

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As secondary EU legislation, the Directive has binding powers for all MS, requiring its' incorporation into national legislation, regardless of political stance.

From the literature research, it was clear that approval of the Directive was not unanimous. Within European Council, some countries opposed or abstained from voting on the Directive, among these MS were Poland and Portugal [2–4].

The inevitability of this piece of legislation becomes clear after the rulings of the European Court of Justice (ECJ), where since 1998, some cases concerning patient mobility and reimbursement across MS were presented and ruled. However, it is not clear if this Directive marks a step in the direction of a European healthcare system or simply intends to bring some clarity within EU legislation and, consequently, patient awareness of their own rights as EU citizens. This seems to differ according to each stakeholder's perspective [2,5].

The impact of the EU on health outcomes can be linked to the economic development that derived from the creation of a single market. Improvement of health outcomes in MS, was mainly achieved through institutional reforms and economic convergence of periphery MS countries and regions. This was particularly noticeable in Portugal, where health outcomes improved after joining, at the time, the European Economic Community (EEC) in 1986. We can infer that this effect is a positive externality of the economic development derived from the single market creation. In other words, it can be considered an indirect way of EU impacting health outcomes. Otherwise, EU health policies have a direct impact on healthcare; health policy can be broadly defined as all the policies, from public or private stakeholders, that impact a health system and ultimately, health outcomes [6,7].

This study aimed to analyse stakeholders' perspectives towards the Directive, determining the factors that supported their viewpoints, and to identify challenges and assess the expected impact associated with the implementation of the Directive in Poland and Portugal, utilising the WHO health systems conceptual framework. The findings of the qualitative assessment and further analysis promoted a better understanding of Directive's challenges and expectations, in the selected MS [8].

2. Methods

The study's design included three consecutive and interdependent phases: literary review, qualitative open-ended questionnaires and analysis of the findings based on the content analysis. For this study, content analysis involved directed approach, categories were predetermined with WHO health systems conceptual framework [Annex I]. Divided in 6 building blocks: health services, health workforce, health information, medical products, health financing and leadership and governance. This conceptual framework clarifies the essential health system functions and promotes a common understanding for all stakeholders. For the purpose of this study it provides a structured process that facilitates elaboration of the respondents' reasoning concerning the Directive's implementation [9].

Finally, a literature review was used to identify key stakeholder organisations, as well as complement the findings of the qualitative research, fill the gaps of missing perspectives of key stakeholder organisations and also to enrich findings of the qualitative research analysis. The review also included a document review of policy papers from the national and EU level, as well as conference reports and press releases. The search involved four databases: PubMed, Embase, Cochrane Library and Google Scholar.[3] From the reading of the abstracts, studies not directly related with the cross-border healthcare Directive were excluded.

In this particular study, a qualitative study approach was applied in order to gain insight on stakeholders' perception towards a specific health policy. Quantitative methods were considered inadequate, as the Directive was not yet in practice.

Qualitative research is a suitable approach to social processes; it is considered effective in evaluating healthcare services organisation and policy implementation. Qualitative data collection was conducted through semi-structured open-ended questionnaires that were completed by identified key stakeholders. A goal of contacting 5 stakeholders at national (Poland and Portugal) and EU organisation level[4] was set, thereby reaching a total of 15 respondents. It is shown that in qualitative research, a small sample size as opposed to a larger one provides a better understanding of the topic area, given the diversity of the response pool and saturated information. The semi-structured data collection tool more commonly used during face-to-face interviews, is believed to be successfully employed in this cross-sectional internet based survey. The respondents are expected to reiterate their perspective clearly in a multi-country context. [10,11].

Purposive sampling was applied to choose relevant stakeholder organisations that work in the area of cross-border healthcare, and were identified via literature review. These organisations were contacted and indicated individuals that work or have special interest in the focus area of this study. The qualitative research also built on the momentum gained through this process by identifying additional respondents through snowball sampling (e.g. by attending conferences concerning the topic of cross-border healthcare). Despite significant efforts, both Portuguese and Polish delegations on the European Commission (EC) at the time of the voting were contacted but did not respond.

Once respondents were identified, qualitative data was collected via semi-structured open-ended questionnaire, using an e-mail service to reach selected stakeholders[5]

[3] The search was limited to publications written in English, Portuguese and Polish. Which included the following key words: cross-border healthcare Directive; patient mobility Directive; Directive 2011/24/EU; cuidados de saúde transfronteiriços; transgraniczna opieka zdrowotna; European health policy; European health strategy; European Union health and European Union law. For the literature and document search strategy Boolean operators were used (e.g., AND, OR).

[4] This includes EU institutions or others that work within EU health policy.

[5] The first email contact included an invitation to participate on the present study, as well the information letter and the contacts of the

[Annex I]. The survey was conducted from February to April 2013, following the pilot survey results and ethical approval. Data analysis was conducted using the WHO conceptual health system framework, and applying directed content analysis. This is a commonly applied analysis in recent health studies that allows data summarisation, and enables a more comprehensive and transparent data analysis. The WHO conceptual health system framework, allowed the respondents to structure their responses, and facilitated data ordering and interpretation in the results stage [9,10,12].

Data analysis was conducted alongside data collection; this was done to optimise time, and to become familiarised with the data. The ongoing data analysis enabled the collection of new data through literary review and to fill identified gaps [13].

3. Results

Data from the open-ended questionnaires was summarised according to the respective conceptual framework categories and included the respondents organisation profile [Annex II]. This profile identifies each stakeholder and their country of origin. Thematic Categories were further broken down in more detailed categories to facilitate interpretation of the data and analysis across stakeholder responses.

The survey responses highlighted that 4 out of 5 country level stakeholders were aware of their respective country's viewpoint on approval of the Directive, whereas 2 out of 5 stakeholders at the EU level were aware. Additionally, country level respondents showed greatest concern for the Directive's impact on the financial component of the health system, in contrast to the EU level respondents concern for the Directive's impact on healthcare information.

Snowballing led to the identification of several EU level stakeholders, namely Maastricht University in the Netherlands. Maastricht University has a strong interest in cross-border healthcare issues, especially within the EUREGIO and Benelux Euroregions, where the first ECJ cross-border healthcare cases arose [5].

4. Discussion

4.1. Viewpoints towards the Directive

During the analysis of the results, it was clear that despite some common reasoning that supported a mutual negative viewpoint towards the Directive approval, there were other underlying reasons respective to the healthcare systems [13].

Focusing on the first objective – to determine the factors that supported a different viewpoint from Poland and Portugal it is more convenient to break down the answers considering the stakeholder's level and the country viewpoint. Some of the factors identified as common arguments for opposing the Directive are outlined below.

4.1.1. Poland

Among Polish respondents, identified factors that could support the Polish viewpoint towards the Directive include the potential risk to the health system, through reimbursement of care abroad for Polish citizens, which would cause financial constraints to home providers. Additional resistance to the Directive was noted through responses echoing a concern for the prestige of Polish medical professionals, should a high number of patients begin to seek healthcare abroad. EU organisations' respondents identified the private provider inclusion issue as the main argument for Poland's objection to the Directive. There is a resistance to reimburse private care abroad, as Polish patients cannot currently be reimbursed for private care in Poland. Polish patients may start demanding access to private providers within Poland as question of equal access as compared with other MS patients.

4.1.2. Portugal

Among the Portuguese respondents, identified factors that could support the Portuguese viewpoint towards the Directive include that the National Health Service (SNS) is based on Beveridge model. This model, mainly financed through taxes, already has severe sustainability issues and the Directive might cause more financial burden.

Excluding prior authorisation also threatens the safeguard of SNS. Arguments such as quality of care abroad and potential prioritisation of external patients were also expressed. An EU level respondent noted that Portugal never supported the idea of reimbursement of healthcare abroad, even after the ruling of Watts case (C-372/04) in the ECJ. This ruling determined that the patient should be reimbursed for medical treatment in another MS if the waiting time in their own country was considered excessive, based on a medical assessment and their clinical needs [2,5,14]. Portugal's lack of support for reimbursement of healthcare abroad is highlighted in an infringement case that opposed the EC (C-255/09). In this case Portugal failed to include a national provision for the reimbursement of non-hospital care, and was therefore incompatible with the EU's free movement of services principle (Regulation(EEC) No 1408/71), and already existing ECJ jurisprudence [5,15].

4.1.3. Common viewpoint

Common factors identified by Polish and Portuguese respondents include the uncertainty of negative impact on their respective health systems and the inclusion of private providers without any contract with the Ministry of Health (MoH), which is against the internal logic of both health systems. They noted that this Directive is a violation of article 168 of the Lisbon treaty, concerning MS competences. Other arguments include the potential risk of medical tourism, inherent costs for the health system

researcher and research assistant, for any additional questions. The questionnaire was designed and disseminated via "Google docs", a free online software. Besides the original in English, potential respondents were offered with two additional versions of questionnaires, Portuguese and Polish. These language options enabled potential respondents to use the language with which they were most comfortable for answering the questionnaire. For reducing translation bias, back-to-back translation was used to assess the questionnaires in different languages to maintain similarity with the original design.

and the generation of access inequalities. EU organisations' respondents pointed out that ECJ rulings did not collect much support among MS. Even those MS that supported the Directive might be driven by the desire of preventing more intrusive ECJ legislation. Although, it is not clear if the Directive will reduce future court cases. MS also feared the uncertainties that might be derived from the Directive implementation, as well as the risk of generating potential inequalities [16–18].

The most common argument for justifying the negative viewpoint of both Poland and Portugal was the potential cost increment, and ultimately, the risk to the sustainability of their health systems. Another common concern of both countries was the lack of control of private providers, causing uncertainty about direct external access and the ability of governments to control their healthcare services provision and associated costs [2,19].

In fact, what was before considered an exclusive competence of MS, reinforced by the Lisbon treaty in 2007, was already questioned by the ECJ rulings since 1998, grounding their rulings on the freedom of services and people movement in opposition of the Treaty stated MS competences [5].

4.2. Challenges and expected impact of Directives' implementation, according to WHO conceptual health system framework

Regarding the challenges of transposing the Directive to national legislation and, consequently, to respective health systems. Respondents forwarded their opinion on the expected impact of the Directive on health systems, in accordance with the WHO conceptual health system framework [8].

Challenges and expected impact were grouped under the respective building block of the health system framework. This provided a clearer view of respondents' perspectives, enabling a comprehensive presentation of results, and respective discussion, considering the current knowledge.

4.2.1. Health system component, respective challenges and expected impact

Due to the broad scope of the EU legislation, imperative to all MS, responses that identified national level potential challenges and expected impact were correlated with the Directive itself, and other EU level legislation. This facilitated the analysis of the results, and provided a deeper insight into respondents' viewpoints in line with the building blocks of a health system framework [8].

4.2.2. Financing

Financing mechanisms, including which tariff to apply, especially in countries with a statutory health insurance (SHI) model such as Poland, seems to pose a real challenge to the Directive implementation. In these models, tariffs for similar healthcare services can vary according region (voivodoship) and type of provider, public or private. For compliance with the Directive, Poland's and Portugal's healthcare systems, have to improve their financing procedure, namely the pricing and payment mechanisms, and accounting systems, for both public and private providers. One of the respondents raised the issue of reimbursement of healthcare abroad for poorer MS, but considering the Directive itself, treatment abroad is only reimbursed until the tariff on the home country if treatment is available; travel expenses are meant to be covered entirely by patient. This premise can be linked with access inequalities, developed further in the service delivery paragraph below [20].

Another important challenge that remains uncertain concerns the voluntary network of European Reference Networks (ERNs), ongoing pilot programmes led by DG SANCO and DG Research. These networks remain important in the domain of shared databases for research, shared expertise, production of common guidelines and networking for improving health professionals' skills. One of the respondents at the EU organisation level raised the question of the source of funding for ERNs. Recommendations from the European Union Committee of Experts on Rare Diseases (EUCERD) state that ERNs financing should be a competence of the MS, considering their location, whereas the costs of research and development, and networking specific costs, due to their inherent long-term nature, should be funded via EC [21].

In terms of challenges, it is expected by the stakeholders that the Directive will improve the cost control mechanisms on MS health systems. The need to determine a tariff for a specific healthcare service will pressure accounting mechanisms to determine their real cost, and therefore improve efficiency. The question of sustainability does not seem to have a basis if we take the historical statistics on cross-border care into account. According to the 2007 Eurobarometer survey, 4% of Europeans received medical treatment in another MS between 2006 and 2007 (1 year period), with Polish and Portuguese respondents reporting 3.5% and 4.3%, respectively. The report also showed that 54% of EU citizens were willing to travel to another MS to seek healthcare. This apparent contradiction between the current numbers of cross-border patients and potential patients might be due to lack of information on patient rights as EU citizens. With implementation of National Contact Points (NCPs), this situation may change, particularly in Euroregions, where cross-border patient flow is expected to increase, and where languages and cultural barriers are not so relevant [20,22].

More recent data from the Eurobarometer 2014 survey covers the period after the Directive (2013–2014) was passed, and shows that on average, 5% of Europeans received medical treatment in another MS, with 3% being unplanned and 2% being planned; both Polish and Portuguese respondents reported 7%. This illustrates a small increase of 1% on average, and around a 3% increase at the country level, in receiving medical treatment in another MS after the Directive's approval [23].

One of the Portuguese respondents mentioned that the adoption of the Directive will, "add costs to a bankrupted system." In fact, within a health system already at a severe risk of unsustainability, the provision of NCPs and the corresponding investments – providing information and translations to all potential cross-border patients – seem to add short-term costs to the health system. These costs,

however, can be balanced with the gains on information and service delivery. It is the NCP's responsibility to provide clear and transparent information about which healthcare services are available, and the respective reimbursement procedure. This will also prevent uncertainty among patients, and avoid potential legal risks [19,24].

It is important to discuss the adoption of this Directive in its historical context, in 2009, the EU was facing an economic crisis, causing a fall in every EU country Gross Domestic Product (GDP), except in Poland. Portugal was, and remains, among the most affected EU periphery countries, and follows strict austerity policies imposed by external loaners: the International Monetary Fund, the EC and the European Central Bank. Studies show that restrictions on public expenditure on health directly affect the provision of public financed care, such as the SNS and (unless that needs to be specifically tied to overall austerity measures, and not just reduced public expenditure on public financed healthcare) do not leave much room for new investments on the health system [25].

4.2.3. Information

Information gain is considered to be the biggest achievement of this Directive. According to one of the EU organisation level participants, this Directive will be "revolutionary" concerning information gain, providing national citizens and cross-border patients with transparent and comparable information about health systems. While relatively simple for some MS, information sharing can be a challenge to countries that do not traditionally have a culture of transparency regarding healthcare services and costs. Member states will have to balance transparency and flexibility; if they do not want to reimburse a specific healthcare service abroad, they will have to limit their own healthcare offerings at home. The Directive clearly states that the responsibility for relaying this information within MS falls to the MS, and is to be delivered through NCPs. Although, within countries with a SHI system, such as the Narodowy Fundusz Zdrowia (NFZ), or Polish National Health Fund, the SHI should also be considered a main vehicle of information. The Directive also requires that beyond services and costs, information about safety, quality standards, and the complaint procedure, should also be provided [26,27].

This need and flow of information will pose several challenges. Common among these challenges are linguistic – issue of translations – that might impact, among other things, the patient informed consent. There is still a great variation among MS when addressing language barriers, and seeking patient informed consent. Issues surrounding the inherent costs of providing information and translating it in a comprehensible way to one of the 23 EU official languages of potential cross-border patients are also present. The role of health providers on this particular topic is unclear.

As mentioned in Section 4.2.2, the Directive clearly states in Articles 5 and 6, that it is the MS responsibility to provide clear and adequate information to all potential patients and providers. Are they willing to take responsibility for any language issue when delivering treatments? [17,18,28].

A potential solution for the aforementioned issues is provided within the Directive; eHealth has the potential for allowing interoperability of national IT systems across the EU. This allow patients to access their data, and therefore seek healthcare, abroad with no information constraints. This is intended to be achieved on a basis of voluntary participation of MS [29].

4.2.4. Service delivery

Concerning healthcare service delivery, respondents noticed that at a national level, specialised public and private healthcare providers appear to be more prepared to take advantage of the potential external clients that the Directive might bring, more specifically in the already existing Euroregions. This comprises all ongoing projects concerning the provision of healthcare services in neighbouring border regions, namely the Euroregions between Germany and Poland. Some patient flow between borders is expected to increase, if language barriers are attenuated by the NCPs [22,30].

A potential challenge for Poland is related to the services basket provided. For example, abortion is currently considered illegal in Poland, with the exception of rape, or life threatening conditions for mother or foetus. Although even rightful abortion faces access constraints, such as the case (Application 57375/08), it was found by the European Court of the Human Rights that Poland did not grant unobstructed access to abortion procedure to a Polish citizen, and was in clear dissonance with the Human Rights Convention. With the Directive implementation, healthcare services access restrictions seem to lose their predictable effect and patients can seek rightful access to abortion cross-border, without unacceptable waiting time constraints. The question is if over time, this might converge into a harmonized EU common healthcare basket? [31,32].

Common challenges stressed by the respondents include the fact that quality monitoring, safety issues, and medical error prevention mechanisms or procedures are not similar across EU. Quality in healthcare is strongly linked with setting indicators based on international guidelines, and implementing monitoring mechanisms for assessment and assurance. In cross-border care, one of the major concerns is the follow-up of patients after obtaining treatment abroad. This will require increased and close cooperation between MS to satisfy EU healthcare quality requirements, and match patient expectations. It will also depend on how effective the patient data can flow among MS. It seems clear, however, that the Directive might lead to increased uniformity in quality standards across the EU [27,28].

In terms of access to services, EU patients appear to have won a new set of rights. Due to the non-discriminatory rules of the new Directive, external EU patients are entitled to the same services and costs within a MS, as compared to their national citizens. As discussed in the Discussion paragraph above (*Common viewpoint*), the Directive approval seemed to prevent more intrusive rulings from the ECJ. This can be sustained by the fact that the Directive itself did not deviate from the already existing rulings. Nevertheless, the gains on information clarity and transparency for both patients and providers are evident [2,20,33].

Equality in access to healthcare services is one of the overarching values that the 2006 EU Health Council identified, although the Directive seems to create inequality in access. For example, a cross-border patient can access private providers within a MS, but if that MS's MoH does not have a contract with the same private providers, national patients cannot access them and expect to be reimbursed by the statutory health system [31].

Other potential access inequalities are related with the cross-border patient profile. It is perceived that to seek healthcare in another MS, affordability related with travel expenses and payment in advance, as well as access to information abroad, are major exclusion factors [34].

The cross-border healthcare Directive seems to be beneficial to neighbouring national region's providers and health systems, allowing a more efficient use of resources; however, demand and need has to consider the push and pull factors, especially with the Directive's possibility of seeking private providers directly abroad [35,36].

4.2.5. Leadership and governance

Respondents seemed to agree that the implementation of the Directive will require new leadership skills among healthcare managers and decision makers. Along with the expected information "revolution", improved accountability mechanisms will be needed to monitor service delivery, cross-border patient numbers and costs.

All the challenges posed by the financing and information components are translated into a great logistical challenge for managers, as they are required to be up-to-date on EU patients newly informed rights in order to avoid potential legal actions from patients [28].

As identified by some of the respondents, specialised public and private providers, seem to be more prepared to attract cross-border patients, generating potential medical tourism activities. However in areas where private providers do not have contract with national MoH, some friction is expected in regards to unequal access between national and cross-border patients [28].

The lack of specificity of the Directive about its implementation and the need of harmonized procedures and mechanisms might lead to a greater demand for EU regulation and therefore a change of responsibilities from the MS to the EU organisations level.

4.2.6. Health workforce

One participant mentioned the risk of potential healthcare workers migrating across the EU. From the literature review, there is no apparent risk of increased migration associated with the implementation of the Directive. Free movement of health professionals, based on the recognition of qualifications, is already an acquired reality when a country becomes a MS and falls under EU legislation [37].

The movement of healthcare professionals is associated with social and economic factors, and can become attenuated when countries' economies converge. On the other hand, the migration of healthcare professionals across the EU can reduce the inherent cultural challenges of cross-border healthcare, and increase the spirit of European identity [37].

As mentioned in *Leadership and Governance*, healthcare professionals will also have to adapt to challenges of implementation of the Directive, turning lifelong learning skills and ERNs into a preponderant factor in providing the most appropriate training and guidelines.

4.2.7. Medical products and technologies

Article 11 of the Directive, Chapter IV, points to the common prescription procedure in the EU as the optimal solution to the prescription acceptance among MS. This also seems to pose challenges to the interoperability of prescription systems, and even more challenges in a MS that is not IT based. This common prescription procedure was described by Implementing Directive 2012/52/EU,[6] and was expected to be adopted by 25 October 2013 [38]. In Portugal, it was adopted through specific internal regulation from the Portuguese MoH [39]. In Poland this transposition was performed through regulation from the Polish MoH, and published on 6 November 2013 [40].

For safety purposes, prescription information should be included with patient clinical data, to avoid cross-medication effects, and enable medical professionals of other MS to better diagnose, based on clinical history [28].

Through the establishment of ERNs, an increase in research and development is expected, which can ultimately generate new medical products and technologies, in line with some respondents' responses. This can be linked with the broader EU strategy to allocate 3% of the EU's GDP to R&D [21,41].

One participant mentioned the potential creation of an EU Health Technology Assessment (HTA) network, to avoid duplication of work on already existing European HTA agencies. This has existed since 2006 through an ongoing project, the European network for HTA (EUnetHTA). It is currently on its last phase, Joint Action 2 (2012–2015), setting the framework for a future permanent voluntary EU HTA network, established and supported by EU, as stated within the Directive itself [16,42,43].

5. Conclusions

The main conclusions of the study, considering respondents perspectives by health system component can be summarised in:

- *Financing*: potential for improvement of accounting mechanisms, expected increased costs if patient numbers are higher than anticipated.
- *Information*: expected increment of patient awareness concerning services available, healthcare quality, costs, health system performance; expected development of common or interchangeable IT database.
- *Service delivery*: potential challenge of access inequalities, between national and external patients, potential harmonisation of healthcare services across the EU.

[6] Commission Implementing Directive 2012/52/EU of 20 December 2012, laying down measures to facilitate the recognition of medical prescriptions issued in another MS.

- *Leadership and governance*: will require improved managerial skills with proactive view for healthcare managers.
- *Health workforce*: will require life-long learning processes, no increased migration is expected.
- *Medical products and technologies*: new developments in IT have the potential to implement digital prescription, reinforcement of ongoing HTA network project, creation of ERNs will boost EU R&D.

In general, analysis of the findings shows that there are some uncertainties about the beneficial impact of the Directive, particularly within the health system components of financing and service delivery in Poland and Portugal. Although some of these issues are explored in the *health system component*, *respective challenges and expected impact* paragraph, a deeper research is recommended.

National stakeholders' main concerns were related to the expected impact on the financing health system component, giving far more detailed answers than the joint statement issued during the Directive approval, and pointing to quality issues and concerns about the EUs' incursion MS healthcare services provision. Historically, as noted by an EU stakeholder, Poland and Portugal never approved the involvement of the EU on a matter that they always viewed as strictly under MS competence [2–4].

From the findings of the qualitative assessment, it was clear that the perception of the Directive's impact is quite different considering the level of stakeholder, and indicates that there is a communication deficit between EU organisations and MS. For successful implementation of EU health policies in the future, this communication gap should be reduced.

In Portugal, the Directive was transposed to national legislation through Law No 52/2014 on 1 September 2014 for continental Portugal; the islands will have a specific regional legislation transposition. This legislation established the Health System Central Administration (ACSS) as the main contact point for patients via a webpage, and established that the healthcare professional associations should establish their own point of contact to address healthcare professionals' mobility through the EU. Specific internal regulation from the Portuguese MoH (Order No 11042-F/2014) connected with Implementing Directive 2012/52/EU, set the model for medical prescriptions to be used in another MS [44].

In Poland, the Directive was transposed to national legislation through Law no 1491 on 10 October 2014, amending the previously published act on healthcare benefits financed from public funds. It outlines the reimbursement limits for the period 2014–2023 from the NFZ. Medical prescriptions regulation was established by the Polish MoH (Regulation 1293), transposing the Implementing Directive 2012/52/EU [45].

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.healthpol.2016.02.009.

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