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Daria Goscinska

# Transposition of the Patients' Rights Directive 2011/24/EU

A discourse analysis in  
Germany, Poland and Austria

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Department of Health Care Management



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**Transposition of the Patients' Rights Directive 2011/24/EU**

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## Abstract

The Directive on the application of patients' rights in cross-border healthcare was adopted by the Council of the European Union and the European Parliament on March 9th, 2011. In the context of the adoption deadline on October 25th 2013, as well as considering the national positioning towards the Directive and the interpretational leeway left, it is interesting to see how and to what extent national legislators transpose the Directives' implications. This paper will focus on the process of transposition, specifically domestic public consultations. The analysis is a two-level comparison: on the one hand, it presents an intrastate study of the various stakeholders involved in the discourse of the transposition process, whereby a country-specific picture of diverse proposals, opinions and challenges can be drawn. On the other hand, the paper marks an inter-country comparison, offering a sample of European adaptational patterns. The healthcare systems of the analysed countries Germany, Poland and Austria are characterised by a Statutory Health Insurance (SHI) system, nevertheless they differ from each other concerning systemic specifics of healthcare, its voting behaviours towards the Directive and initial situation regarding transposable provisions.

The study of domestic discourses from an actor-centred perspective concludes on the most critical points of the Directive, which reflect on prior authorisation, reimbursement, information provision and National Contact Points, and on transposition patterns in the member states. Hypotheses on the goodness of fit, the scope of patients' rights and difficult interpretational areas of the Directive were tested and partly verified. The intrastate study and cross-national comparison revealed considerable differences among a small sample of EU-states, with only some analogies regarding stakeholder and governmental behaviour. The contrast is visible in the number and type of stakeholders, timing of public consultations, the emphasis set in the discourse, frequency of discussed articles and accurateness of implementation. This results not only from the difficult and debated area of health policy, but also from country-specific characteristics. Overall, the analysis indicates how important the process of transposition, as part of EU law-making, is for the correctness and success of European policies. An emphasis on the implementation phase is required to closely understand, analyse and improve the functioning of the *Acquis Communautaire*.

## Zusammenfassung

Die Richtlinie über die Ausübung der Patientenrechte in der grenzüberschreitenden Gesundheitsversorgung wurde vom Rat der Europäischen Union sowie dem Europäischen Parlament am 9. März 2011 verabschiedet. Im Kontext der Umsetzungsfrist am 25. Oktober 2013 sowie unter Berücksichtigung nationaler Positionen gegenüber der Richtlinie und dem zur Verfügung stehenden Interpretationsspielraum, gilt es zu erforschen, inwieweit die nationalen Gesetzgeber die Implikationen der Richtlinie umsetzen. Diese Arbeit beschäftigt sich mit dem Transpositionsprozess der Richtlinie 2011/24/EU, insbesondere mit den nationalen Konsultationen während der Umsetzungsphase. Die Analyse besteht aus einem Zwei-Ebenen-Vergleich: einerseits präsentiert sie eine innerstaatliche Studie über diverse, in den Transpositionsprozess involvierte Stakeholder, wodurch eine länderspezifische Skizze bezüglich verschiedener Umsetzungsvorschläge, Meinungen sowie Herausforderungen gezeichnet wird. Andererseits stellt die Studie einen zwischenstaatlichen Vergleich dar, durch welchen Europäische Transpositions- und Implementierungsmuster verdeutlicht werden. Die drei ausgewählten Staaten Deutschland, Polen und Österreich sind jeweils durch das Gesundheitssystem der Gesetzlichen Krankenversicherung gekennzeichnet, nichtsdestotrotz unterscheiden sie sich im Hinblick auf die systemischen Ausprägungen, ihr Abstimmungsverhalten zur Richtlinie im Rat der Europäischen Union sowie ihre Ausgangsposition der Transposition.

Die Analyse der nationalen Diskurse aus einer akteurzentrierten Perspektive mündet in einer Zusammenstellung der kritischsten Aspekte der Richtlinie, welche die Vorabgenehmigung, Kostenerstattung, Informationsbeschaffung und die Nationalen Kontaktstellen beinhaltet. Gleichzeitig fasst die Studie die Transpositionsmuster der Mitgliedstaaten zusammen. Die Hypothesen zu "Goodness of fit", zur Reichweite der Patientenrechte sowie zu interpretativen Problemfeldern der Richtlinie wurden getestet und teilweise verifiziert. Sowohl der inner- wie auch zwischenstaatliche Vergleich zeigt die enormen Differenzen einer relativ geringen Staatenprobe auf, mit lediglich wenigen Analogien in Bezug auf die Stakeholder und das Verhalten der staatlichen Entscheidungsträger. Der Kontrast zeigt sich insbesondere hinsichtlich der Anzahl und des Typs der Akteure, der zeitlichen Koordinierung der öffentlichen Konsultationen, des Diskursschwerpunkts, der Häufigkeit der diskutierten Umsetzungsartikel sowie der Transpositionsgenauigkeit. Die hervorstechenden Differenzen sind nicht nur Ausdruck eines sensiblen und umstrittenen Politikfelds, sondern resultieren aus den staatspezifischen Eigenschaften. Insgesamt zeigt die Analyse auf, wie wichtig der Transpositionsprozess als Teil der EU-Gesetzgebung für die Korrektheit und den Erfolg Europäischer Politik ist. Die Fokussierung auf die Implementierungsphase ist notwendig, um die Funktionsfähigkeit des *Acquis Communautaire* genau verstehen, analysieren und verbessern zu können.



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## List of Abbreviations

<b>Abbreviation</b>	<b>English</b>	<b>German/Polish</b>
ABGB	Austrian Civil Code	Allgemeines Bürgerliches Gesetzbuch
AKÖ	Austrian Chamber of Employment	Bundesarbeitskammer Österreich
AMVV	Drug prescription regulation	Arzneimittelverschreibungsverordnung
APK	Association of mentally-ill	Aktion Psychisch Kranke
Art.	Article [law]	Artikel
ASVG	National Insurance Act	Allgemeines Sozialversicherungsgesetz
BAG Selbsthilfe		Bundesarbeitsgemeinschaft Selbsthilfe von Menschen mit Behinderung und chronischer Erkrankung und ihren Angehörigen e.V.
BÄK	German Medical Association	Bundesärztekammer
BÄO	Federal Act for Medical Practitioners	Bundesärzteordnung
BGB	German Civil Code	Bürgerliches Gesetzbuch
BIQG	Institute of Quality in Healthcare	Bundesinstitut für Qualität im Gesundheitswesen
BPtK	Federal Chamber of Psychotherapists	Bundespsychotherapeutenkammer
BZÄK	German Dentist Association	Bundeszahnärztekammer
Cl.	Clause [law]	
DGB	German Trade Union Federation	Deutscher Gewerkschaftsbund
DIR	Directive 2011/24/EU	
DKG	German Hospital Federation	Deutsche Krankenhausgesellschaft
DKH		Deutsche Krebshilfe
DPWV		Deutscher Paritätischer Wohlfahrtsverband – Gesamtverband e.V.
DSG	Austrian Data Privacy Act	Datenschutzgesetz
DVKA	The German Liaison Office for Sickness Insurance-Abroad	Deutsche Verbindungsstelle Krankenversicherung-Ausland
EC	Council of the European Union	
ECJ	European Court of Justice	
EKD		Diakonisches Werk der Evangelischen Kirche in Deutschland
EU	European Union	
EU-PMG	Patient Mobility Law	EU-Patientenmobilitätsgesetz
G	Law	Gesetz

GKV-Spitzenverband	National Association of Statutory Health Insurance Funds	Spitzenverband der Gesetzlichen Krankenversicherung
GMG	Healthcare Modernization Law	Gesundheitsmodernisierungsgesetz
GoÄ	Medical Fee Schedule	Gebührenordnung für Ärzte
GÖG	Health Austria LLC	Gesundheit Österreich GmbH
ICD	International Statistical Classification of Diseases and Related Health Problems	
IGeL	Individual Medical Benefits	Individuelle Gesundheitsleistungen
k.c.	Polish Civil Code	Ustawa z dnia 23 kwietnia 1964 r. – kodeks cywilny
KAKuG	Medical Institution Act	Bundesgesetz über Krankenanstalten und Kuranstalten
KBV	Federal Association for Statutory Health Insurance Physicians	Kassenärztliche Bundesvereinigung
KRAGES	Burgenland Hospital Company LLC	Burgenländische Krankenanstalten-Gesellschaft m.b.H.
KZBV	German Federal Association of Sick Fund Dentists	Kassenzahnärztliche Bundesvereinigung
KZBV	Federal Association for Statutory Health Insurance Dentists	Kassenzahnärztliche Bundesvereinigung
MBO-Ärzte		Musterberufsordnung-Ärzte
MDS		Medizinischer Dienst des Spitzenverbandes Bund der Krankenkassen e.V.
NCP	National Contact Point	Nationale Kontaktstelle (A/DE) Krajowy Punkt Kontaktowy (PL)
NIL	The Chamber of Physicians and Dentists	Naczelna Izba Lekarska
NFZ	Polish National Health Fund	Narodowy Fundusz Zdrowia
ÖÄK	Austrian Medical Association	Österreichische Ärztekammer
ÖGB	Austrian Trade Union Federation	Österreichischer Gewerkschaftsbund
ÖZÄK	Austrian Dentists Chamber	Österreichische Zahnärztekammer)
Para.	Paragraph [law]	Absatz
PKV-Verband	Association of Private Health Insurances	Verband der Privaten Krankenversicherung
PRG	Patients' Rights Law	Patientenrechtegesetz
PsthG	Psychotherapy Law	Psychotherapiegesetz [Austria]
r.r.l.	Regulation of the Minister of Health regarding medical prescriptions	Rozporządzenie Ministra Zdrowia z dnia 8 marca 2012 r. w sprawie recept lekarskich

## List of Abbreviations

REF	The National Federation of Associations of Rheumatics	Ogólnopolska Federacja Stowarzyszeń Reumatyków
RezPG	Prescription Requirement Law	Rezeptpflichtgesetz
Sec. [§]	Section [law]	Paragraph
SGB	Code of Social Law	Sozialgesetzbuch
SHI	Social Health Insurance	
SoVD		Sozialverband Deutschland e.V. Bundesverband
StGB	German Criminal Code	Strafgesetzbuch
STOMOZ	Association of Healthcare Managers	Stowarzyszenie Menedżerów Opieki Zdrowotnej
Stowarzyszenie ZZSK	The Association of Suffering from Ankylosing Spondylitis and its Supporters	Stowarzyszenie chorych na ZZSK i osób ich wspierających
SV	Central Federation of Health Insurance Funds	Hauptverband der Sozialversicherungsträger
SV-EG	Social Insurance Supplement Law	Sozialversicherungs-Ergänzungsgesetz
u.d.l.	The Act on medical activity	Ustawa z dnia 15 kwietnia 2011 r. o działalności leczniczej
u.o.d.o.	The Act on personal data protection	Ustawa z dnia 29 sierpnia 1997 r. o ochronie danych osobowych
u.p.p.	The Act on patients' rights and the Patients Ombudsman	Ustawa z dnia 6 listopada 2008 r. o prawach pacjenta i Rzeczniku Praw Pacjenta
u.r.l.	Act on Drug Refund	Ustawa z dnia 12 maja 2011 r. o refundacji leków, środków spożywczych specjalnego przeznaczenia żywieniowego oraz wyrobów medycznych
vdek	Association of Substitute Insurance Funds	Verband der Ersatzkassen e. V.
vzbv		Verbraucherzentrale Bundesverband e.V.
WKÖ	Austrian Economic Chamber	Wirtschaftskammer Österreich

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## 1 Introduction

The Council of the European Union and the European Parliament adopted the Directive on the application of patients' rights in cross-border healthcare on 9<sup>th</sup> March 2011.<sup>1</sup> The European Commission's proposal for this Directive<sup>2</sup> included provisions far beyond the last decades' rulings of the European Court of Justice (ECJ). Still, the outcome, i.e. the final Directive, is predominantly just a codification of ECJ-rulings, which give patients basic rights while making use of healthcare in other European member states (cf. Soytürk 2012: 185 f.). Scholars and academics commenting on the new Patients' Rights Directive hold the reluctant national governments responsible for reducing its scope (cf. Legido-Quigley et al. 2011: 366 f.; Palm, Beaten 2011). The Council of the European Union (EC), representing the member states, argued with the subsidiarity principle and national sovereignty to undermine the Commission's proposal. Not only is health policy a sensitive area of national responsibility, it is also a very diverse field among European states due to the variety of healthcare systems. Therefore, the final document resembles the general interest of minimal coordination among the member states (cf. Legido-Quigley et al. 2011). Nonetheless, as Delnoij and Sauter (2011: 271) put it, the importance of this legal act derives from its status "as the first harmonization Directive concerning health care".

Bearing in mind the genesis of the Directive and considering the implementation deadline on 25<sup>th</sup> October 2013, it is relevant to examine the national transposition of the Directives' provisions. Since directives of the European Union (EU) define solely the goals to be achieved but leave member states interpretational leeway as to the implementation, the transposition phase is an important step in European and national legislation. It is also worth keeping in mind that transposition is only one part of the implementation process, followed by application and enforcement of the legal measures. Nonetheless, surprisingly little attention has been paid to domestic transposition processes. This is particularly astonishing if one takes into account that European law and measures are only guaranteed if the implementation is correct and timely (Treib 2003: 1).

In the context of domestic adoption of Directive 2011/24/EU, the national positioning towards it and the interpretational leeway left, it is interesting to see how and to what extent national legislators will transpose the Directives' implications. A comparison of national implementation laws and the affiliated stakeholder's discourse of three member states of the European Union shall present insights into transposition scope, depth and its controversies. Such analysis is relevant for several reasons. First, by exploring the speed and interactions during the transposition process within a country on the one hand and comparing the implementation efforts among several EU member states on the other hand, this paper's results may contribute to the overall discussion about the very topical Patients' Rights

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<sup>1</sup> Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare [2011] OJ L 88/45. Henceforth referred to as Directive, Patients' Rights Directive or Directive 2011/24/EU.

<sup>2</sup> Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare, Commission of the European Communities, File 2008/0142(COD), published on 2.07.2008.

Directive. Second, relatively little can be found in literature on transposition of this Directive, even less on the domestic discourse. This paper could partly fill this gap and also assess whether discourse analysis is a helpful tool to understand the Directive's effects on the European healthcare dimension. Third, this paper is to be seen as an intermediate result of the transposition process of Directive 2011/24/EU, which can contribute to further analysis of the Directive's implementation process. This study can help understand the transposition process by explaining possible delays or the impact of consultations on the final national legislation.<sup>3</sup>

### 1.1 Research Aim

This paper aims at inspecting the transposition process of the Patients' Rights Directive. The comparative analysis between the member states Germany, Poland and Austria is a two-level examination. On the one hand, it presents an inside-country study of various stakeholders involved in consultations of the transposition process. By considering the national transposition discourse on single provisions of the Directive, a country-specific picture of diverse proposals, viewpoints and challenges can be drawn. On the other hand, the paper presents an inter-country comparison, offering a sample of adaptational patterns among European member states. According to academic research findings the effects on domestic policies by Europeanization depend primarily on intrastate conditions and resources (cf. Börzel, Risse 2003). Therefore the three case studies exemplify Europe's diversification in regard to transposition and thus illustrate the effectiveness of EU healthcare directives. An actor-centred perspective has been chosen towards the transposition process, since national actors and their interaction are crucial for the implementation process (Treib 2003: 3 f.). Due to the limited scope of this paper only domestic interest groups were analysed in the official consultations, whereas in further research also governmental and administrative actors, political parties and veto players shall be included (Treib 2003: 4).

Geographically, this analysis is limited to three European countries – Germany, Austria and Poland. As a matter of standardization, all countries chosen have a Statutory Health Insurance (SHI) healthcare system, though in detail vast variations exist in satisfaction, standards and practices among these member states. By choosing this sample it can be shown that although systemically and geographically close, even here the differences are huge. The variation increases further among these countries, if one takes into account the divergent voting behaviour towards the Directive and the various initial situations regarding transposable provisions. All three sample countries differ in their behaviour towards the Directive, as Germany had a favourable initial situation, voted for the Directive and thus transposed it properly, Poland voted against it and was in consequence accused of under-implementation. Finally, Austria voted also against the Directive but had then reversely the accusation of over-implementation. Thus, the contrast between the three countries can serve as an indication of how diverse European healthcare systems remain and thus explain why it is such a debated and controversial issue – on both a national and European level.

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<sup>3</sup> This paper was written shortly before the implementation deadline on the 25<sup>th</sup> October 2013, hence most countries did not have a final legislative implementation act for the Directive. This analysis is thus based on the national proposals for transposition.



Next to the study of the transposition process in those countries, the analysis of domestic discourse can demonstrate firstly critical issues and observations of national debates, and secondly test three hypotheses. Those were deduced from transposition literature and academic comments on the Directive. The aim of this paper is thus threefold:

- (1) Process-tracing of the discursive phase of transposition in the selected countries
- (2) Responding to the question of what were key aspects of domestic debates on the Patients' Rights Directive?
- (3) Scrutinizing three hypotheses from academic literature:
  - a) *Goodness of fit – The misfit approach suggests that compliance with EU law depends on the misfit between domestic and European policies and on the involvement and influence of various stakeholders. Adaptational pressure therefore is higher, if the compatibility of policies is lower (Börzel, Risse 2003).*

The importance of the transposition process for deploying the impact of the Patients' Rights Directive derives from the general premise that Europeanization affects member states' politics, policies and polities and causes domestic change under certain circumstances (cf. Börzel, Risse 2003: 57 f., 60). Two conditions are therefore necessary:

"Europeanization must be 'inconvenient', i.e., there must be some degree of 'misfit' or incompatibility between European-level processes, policies and institutions, on the one hand, and domestic-level processes, policies and institutions, on the other. This degree of fit or misfit constitutes adaptational pressures, which is a necessary but not sufficient condition for expecting change. The second condition is that there are some facilitating factors – be it actors, be it institutions – responding to the adaptational pressures."

(Börzel, Risse 2003: 58)

Adaptational pressure is generated through the non-exit option of the member states, given that EU law constitutes part of national legislation (Börzel, Risse 2003: 61). A policy misfit, in contrast to institutional misfit, forces a given country to incorporate potentially "inconvenient" regulatory standards, policy instruments or problem-solving approaches which produce adaptational costs (cf. Börzel, Risse 2003: 61 f.). Policy change is the result of an interaction between the national government responsible for transposition and relevant actors, which affect the direction of implementation (Börzel, Risse 2003). It is hereby assumed that the degree of (mis-)fit determines not only adaptational pressure for national reforms, but constitutes likewise the scope and depth of affiliated debates.

- b) *The Patients' Rights Directive provides not only cross-border rights, but general patients' rights (Peeters 2012).*

The result of the Directive is a much broader legal framework for healthcare. Its impact reaches far beyond its cross-border character and will influence the European healthcare systems entirely. Since the Directive includes rights for patients not only linked to cross-border healthcare it may benefit all patients, also those using just domestic healthcare (Peeters 2012: 33, 51).

- c) *Most problematic areas of the Directive, which may cause implementation differences and difficulties, are administrative, conceptual and practical in nature (Legido-Quigley et al. 2011).*

Areas which could generate confusion in and beyond the implementation phase are the process of prior authorisation, the mechanisms for calculating costs of cross-border healthcare and the reimbursement basket in each member state. Those can appear problematic from an administrative point of view. A second precarious area can be the clear definition of vaguely defined concepts (e.g. definition of medically justifiable time limits). Moreover, their practical domestic translation could result in different interpretations within and among EU countries. Another problematic area is the possible emergence of inequalities among member states (e.g. regarding differences in reimbursement rules, with some states providing only the minimum requested and others deciding to reimburse related costs) (Legido-Quigley et al. 2011: 366).

### 1.2 Approach and Methodology

In order to achieve the above aims, the following structure is given: At first, the approach and methodology of the case study will be presented. This comparative analysis is based on transposition and compliance research findings, and the applied analytical tool is the discourse analysis, as a modification of the qualitative method of content analysis. Following the methodological outline, the case study begins by depicting the initial position of each member state at the time the Directive was adopted. This comparison shall indicate the number of "new" provisions to be transposed and thus provide an indicator for further discourse scope and content. The next step will present the transposition draft of each country, showing the governmental implementation proposal and thereby the national legislator's position. Afterwards, the discourse analysis of affected stakeholders on the proposal in each country will be carried out, outlining key aspects of the domestic debate and critical issues concerned with the Directive. In the conclusion, the discourse will be evaluated on an intra- and inter-state basis, presenting the study's outcome and pointing to future research tasks.

The methodological choice of discourse analysis as "an empirical analysis of discourse" (Keller 2011: 9) results from the actor-centred perspective emphasizing the relevance of stakeholder interaction. Moreover, a discourse is not only an optimal tool to analyse the appropriateness of national implementation proposals, it is also the essence of the policy making process, as "it [language] is constituent of reality, shaping – and at time literally determining – what we understand to be reality" (Fischer, Gottweis 2012: 8). Further, the statements of stakeholders, as organisations affected by and well versed with the subject, contribute to the understanding of what critical aspects the Directive includes. By analysing the discourse content, partly national viewpoints, preferences and mind-sets can be identified.

Since discourse analysis has diverse variation, this paper will follow the general implications of the "argumentative turn" (Fischer, Gottweis 2012).<sup>4</sup> As Keller and Viehöfer (2010: 157)

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<sup>4</sup> An argumentative turn is understood as a turn to argumentation and discourse in policy agenda setting, development and implementation. The role is to interpret particular aspects of debates (narratives, social construction, participation etc.) (Fischer, Gottweis 2012: 8 f.).

describe, it is an approach in political science, which conceptualizes the interaction of political actors and stakeholders towards political ideas and interests. It focuses on stabilising stakeholder (or epistemic) coalitions by common problem identification in order to enforce legitimate viewpoints or learning processes in a political discourse. This method of discourse analysis shall not focus on the linguistic and textual specifications but on arguments made during political consultations. As one realizes that public policy is the product of argumentation and deliberation, the argumentative turn becomes apparent (Fischer, Gottweis 2012: 7). The conceptual essence of a discourse analysis, crucial for this paper's study, is that:

"Policy making is fundamentally an ongoing discursive struggle over the definition and conceptual framing of problems, the public understanding of the issues, the shared meanings that motivate policy responses, and criteria for evaluation." (Fischer, Gottweis 2012: 7)

The above idea is applied to the issue of patients' rights in cross-border healthcare, inasmuch as the transposition process in the member states is an interaction between political decision-makers and stakeholders. What follows is the assumption that each government's transposition draft is a discursive starting point, whereas the statements during consultations are a critical examination of the proposal. The construction of discourses and their participants is explained by 'discourse coalitions' and 'story lines'. During a debate political and interest groups, social movements, institutions and individuals argue with different story lines, i.e. combining various arguments (from scientific, economic, social perspective etc.) into a coherent whole (Hajer 1993: 45–47). A discourse is then understood as an ensemble of different argumentative coalitions, implicitly using rivalling story lines to influence the policy-making (Hajer 1993: 47 f.).

In approaching the national discourse analysis, this paper will analyse the various statements as a given reality, without questioning the validity of information. This approach follows the arguments of Bechmann (2007: 120), who points out that not only it is impossible to scrutinize every utterance, it is also unnecessary while using the discourse approach. This follows from the assumption, that the policy process is created by various appropriate or incorrect statements, which influence the discourse in the way they are stated.<sup>5</sup>

### 1.3 Dataset

Several remarks are to be made on the dataset, which consists of governmental documents as well as official records from political hearings and public consultations, all collected within the timeframe of each domestic transposition process.<sup>6</sup> As for Austria, the discourse basis

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<sup>5</sup> Bechmann (2007: 27): „Foucault sucht nach dem Sinn des wirklich Gesprochenen und Gemeinten, was an der Oberfläche der Aussage im Diskurs zu erkennen ist.“

<sup>6</sup> The Austrian consultations can be found at the Parliaments website:

[http://www.parlament.gv.at/PAKT/VHG/XXIV/ME/ME\\_00540/index.shtml](http://www.parlament.gv.at/PAKT/VHG/XXIV/ME/ME_00540/index.shtml). The Polish are available at:

<http://legislacja.gov.pl/lista/1/projekt/133850>. The German Consultations are on the website:

[http://www.bundestag.de/bundestag/ausschuesse17/a14/anhoerungen/Archiv/z\\_Patientenrechte/Stellungnahmen/index.html](http://www.bundestag.de/bundestag/ausschuesse17/a14/anhoerungen/Archiv/z_Patientenrechte/Stellungnahmen/index.html). By the time this paper was published, the documents were moved to the archive:

<http://webarchiv.bundestag.de/cgi/show.php?fileToLoad=2938&id=1223>.

consists of official statements of stakeholders submitted during governmental public consultations from July 5<sup>th</sup> until August 19<sup>th</sup>, 2013. Altogether 28 responses were given, but since several statements did not include relevant information regarding the studied provisions of the Directive, a total of 15 statements was used in this paper.<sup>7</sup> Regarding Poland, public consultations took place from February 8<sup>th</sup> until March 15<sup>th</sup>, 2013. Altogether the Polish Health Ministry received 7 replies, all being included in this discourse analysis. As for Germany, the dataset is unbalanced due to the process of transposition. For background information and an overview of the unspecific transposition, contact was established with the Ministry of Health, Department of General Affairs of the EU (see Appendices). To guarantee comparability, public consultations in the Bundestag (October 22<sup>th</sup> 2012) were scrutinized, even though their content was relevant only regarding two articles of the Directive. From overall 48 statements, 21 were analyzed, and one additionally from the Bundesrat.<sup>8</sup> As there are no unified and complete datasets available, there is little equilibrium regarding the quantity of statements and number of particular stakeholders (healthcare actors, civil society and regional governments). Notwithstanding the occurring comparative bias in public discourse, this dataset ensures analytical analogy. Concurrently, this variety already indicates how diverse the countries are and how varied the transposition process and feedback from the non-governmental sector is.

## 2 Initial Situation in the Member States

The initial position of member states is a significant indicator for policy misfit. Table 1 below summarises the results comparing the pre- and post-Directive situation in each country. It shall indicate how many provisions in this legal act are already laid down in domestic law and how many are still to be transposed. The codification in the table is BD for "transposed before Directive" and DIR for "transposed due to Directive". The analysed articles of the Directive are selected on the basis of their relevance, since only those provisions are to be concrete and bindingly transposed into national law. In further columns domestic regulations implementing the respective provisions are presented. To facilitate the legibility of the table, national legislation implementing the Directive's provisions is presented as an abbreviation:

- Art. 4 Responsibilities of the Member State of treatment
- Art. 5 Responsibilities of the Member State of affiliation
- Art. 6 National contact points for cross-border healthcare
- Art. 7 General principles for reimbursement of costs
- Art. 8 Healthcare that may be subject to prior authorisation
- Art. 11 Recognition of prescriptions issued in another Member State

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<sup>7</sup> The remaining 4 statements came from various ministries, which are excluded from this analysis.

<sup>8</sup> Excluded were 11 responses from individual experts due to their non-representative character. The remaining 16 did not contain relevant comments on provisions from Directive 2011/24/EU.

**Table 1: Initial Situation: Pre- and Post-Directive Status.**

**A Comparison between Germany, Austria and Poland regarding the hitherto national legislation and the to-be-transposed provisions from the Directive.**

Transposition [Before Directive (BD)/ by Directive (DIR)] and national law (or proposal)						
Directive 2011/24/EU <sup>9</sup>	Germany	National Law	Austria	National law	Poland	National Law
<b>Art. 4 (2)</b>	(b) DIR (c) BD (+DIR) (d) BD (+DIR) (e) BD (f) DIR	(b) PRG (c) PRG (d) PRG (e) StGB (§ 203) (f) PRG	(b) DIR (c) BD (d) BD (+DIR) (e) BD (f) BD (+DIR)	(b) KAKuG, ÄrzteG, PsthG (c) ABGB (d) Pharmacy Law, PsthG (e) ÄrzteG (§ 54), DSGVO (f) KAKuG (§ 10)	(b) DIR (c) BD (d) BD (e) BD (f) BD	(b) Transposition Proposal (c) k.c. + u.p.p. (Chapter 13a) (d) u.d.l. (e) u.o.d.o. (f) u.o.d.o. (Art. 23-30)
<b>Art. 4</b>	(3) BD (4) BD	(3) implicit law (4) implicit law (in GoÄ)	(3) BD (4) BD (+DIR)	(3) inherent in laws (4) KaKuG (§ 29)	(3) BD (4) DIR	(3) implicit law (4) Transposition Proposal
<b>Art. 5</b>	(b) DIR	PRG	(b) DIR	(b) GÖG-Law	(b) DIR	(b) Transposition Proposal
<b>Art. 6</b>	DIR	PRG	DIR	GÖG-Law	DIR	Transposition Proposal
<b>Art. 7</b>	BD	GMG (§ 13 Para. 4 SGB V)	BD (+DIR)	ASVG (§ 131) + SV-EG (§ 7b)	DIR	Transposition Proposal
<b>Art. 8</b>	BD	GMG (§ 13 Para. 5 SGB V)	BD (+DIR)	ASVG (§ 150) + SV-EG (§ 7b)	DIR	Transposition Proposal
<b>Art. 11 (1)</b>	DIR	AMVV (§ 2 Para. 1a & 1b)	DIR	RezPG	DIR	r.r.l.

Source: Author

<sup>9</sup> When citing law, especially the EU Directive, the following pattern will be used (exemplary): Article 4 Paragraph 2 Letter b – this will be abbreviated as Art. 4 (2) (b). In some cases Paragraph may be abbreviated using Para. Notice, that the German Paragraph (3) is understood as Section (Sec.) in English.

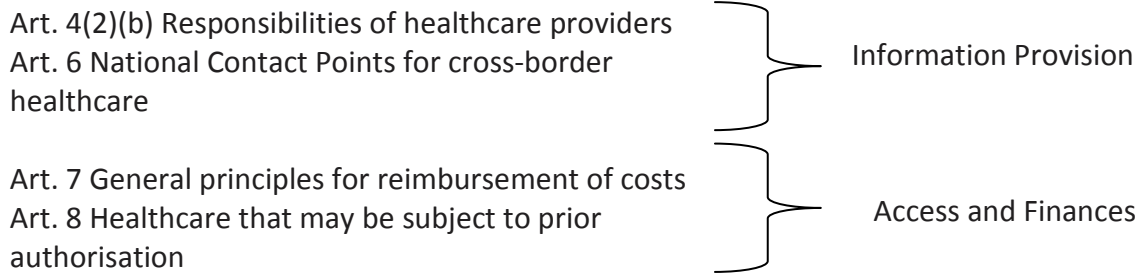
The outcome of Table 1 demands some comments and allows first intermediary results. Beginning with explaining some findings, those articles described as "BD(+DIR)" are mechanisms which were already in place before the Directive was put into force, with some of its aspects being nonetheless relevant for transposition. Although an essential part of the Directive's requirements already existed, the classification criterion was whether new legal acts or amendments were proposed by the national legislator, which is indicated by the wording in parentheses. Those articles are also part of the political discourse, although to a lesser extent than the completely "new" provisions. Second, provisions described as "implicit law" or "inherent in law" refer to rules and rights which are not necessary to transpose because their inherent meaning in national legislation is compatible with the Directive. Especially Art. 4(3) including the non-discrimination clause was understood by the countries as an aspect which, although not explicitly codified in law, is part of it since nothing divergent applies. This law-making is to be understood as a division between positive (i.e. explicit) and negative (i.e. implicit) codification, with both reflecting a similar core meaning of a norm.

A further finding is that all three countries have different initial situations regarding implementation efforts of the Patients' Rights Directive. Comparing alongside the articles, all three states had some provisions implemented beforehand. Several obligations deriving from the Directive concern basic healthcare rights which already existed for national patients and were now just expanded to EU-wide recipients of healthcare. This regards particularly provisions enclosed in Art. 4(2), including rights to transparent appeal mechanisms and complaint procedures, to privacy, to continued care and to a medical record. Thus, the national transposition obligation stemming from the Directive's provision 4(2) was narrowed to mere adjustment or explicit codification in law. To sum up the results from Table 1, it becomes apparent that the Directive is in many parts an explicit codification of provisions already applicable in domestic law. On the other hand, the Directive gives national legislators an opportunity to deal with concrete rights and rules, which were until today only regulated by practiced or judged law. The initial situation in the country sample is an indicator for the goodness of fit hypothesis, illustrating not only the degree of novelty included in the Directive, but revealing information on the scope and intensity of public discourse (for further analysis of the misfit hypothesis see point 4.4).

Several other articles included in Table 1 are irrelevant for further analysis because of their constructions. It should be pointed out that the details for Art. 11 (recognition of prescriptions) were formulated by the European Commission together with the member states. Details on the minimum requirements regarding information and labelling for medical prescriptions were regulated by the Commission's Implementing Directive 2012/52/EU.<sup>10</sup> Hence any discourse on this aspect has presumably taken place at EU-level. Further on, Art. 5(b), Art. 4(2)(a) and Art. 10 Directive 2011/24/EU all include regulations referring to the National Contact Point (NCP), which is fulfilling the information responsibilities of the state of treatment and affiliation. Therefore, all those provisions will be consolidated in the main Art. 6. With respect to the above reasoning, for the analysis of the socio-political discourse only the following articles of Directive 2011/24/EU will be scrutinized:

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<sup>10</sup> Commission Implementing Directive 2012/52/EU of 20 December 2012 laying down measures to facilitate the recognition of medical prescriptions issued in another Member State (Text with EEA relevance) [2012] OJ L 356/68.



The choice is motivated mostly by the discourse content, which to a high degree concentrates only on those provisions. This already leads to the conclusion that those articles are the centrepiece of the Patients' Rights Directive, especially expressing its cross-border healthcare character. The extent to which they are debated in particular countries may vary, partly due to the goodness of fit hypothesis, but the overall discourse focuses on them. Those findings are also supported by the EC's reflections on transposition process, where the EC identified four most challenging aspects of the Directive, congruent with those outlined above (cf. Council EU 2013: 2).

### 3 Transposition Proposals

This section presents the governmental proposals for transposing the Patients' Rights Directive. It refers only to those proposals which are still to be implemented. The already transposed provisions (see Table 1) are not included. It is important to note that all three countries are at different stages in the transposition process of Directive 2011/24/EU.<sup>11</sup>

#### 3.1 Germany

In Germany, the main legal document implementing articles from the Directive is the Patients' Rights Law (Patientenrechtgesetz – PRG), which came into force in February 2013 (cf. BGBl I S. 277). The PRG was not an act prepared solely for the implementation of Directive 2011/24/EU, it was more a reform step in the German healthcare system where some provisions of the Directive were included. This is in accordance with the remark in the legislative draft for PRG, stating that it is compatible with European Law and it even implements aspects of the Patients' Rights Directive (Gesetzesentwurf 2012: 13). Art. 4 (2)(b) Directive 2011/24/EU on the duty to provide patients with relevant information is inherent in the PRG, introducing § 630c and § 630e to the German Civil Code (BGB).<sup>12</sup> The first section obliges medical practitioners to inform a

<sup>11</sup> Germany's implementation law is in force since February 2013. After Poland's consultations in spring 2013, the proposal is still being legislated, with ministries and governmental bodies making arrangements on the final act. In Austria the consultations ended just recently in August, and the legislative process is still ongoing (Status: September 2013).

<sup>12</sup> The difference between § 630c and § 630e is a conceptual novelty, where the first refers to general information on healthcare treatment and options, whereas the latter to a certain medical intervention procedure and its implications (Gesetzesentwurf 2012: 21). Nevertheless, most stakeholders point out that the



patient in advance on relevant treatment data, particularly diagnosis, implications for health condition, treatment and follow-up measures as well as therapy options (cf. DBT 2012a: 9 f.). The list of provided information is non-exhaustive. Dependent on the personal health situation of a patient, further instructions shall be given and other important processes explained (Gesetzesentwurf 2012: 21). Para. 3 of this section states that as preparation of treatment the medical staff shall inform the patient in written form on the estimated costs (cf. DBT 2012a: 10). This obligation is valid, provided that the medical practitioner knows or has enough evidence that the proposed treatment may not be (fully) reimbursed or covered by a health insurance fund. The information duty also includes individual medical benefits (individuelle Gesundheitsleistungen – IGeL), which are solely additional and private, i.e. chargeable services offered by providers (Gesetzesentwurf 2012: 11; 22). The underlying premise of the German legislator is that healthcare providers have more knowledge about the benefit basket of statutory insurance funds in everyday practice and should therefore share this information with the less-experienced patients to protect them against financial burden. This assumption is nonetheless qualified regarding privately insured patients, as their tariffs are defined by individual agreements and are likely to be unknown to medical practitioners (Gesetzesentwurf 2012: 22). In a further paragraph several exceptions from the information responsibility are listed, including situations of exceptional urgency or dispensability and in which the patient explicitly waived its right to information (cf. DBT 2012a: 10).

Complementarily, § 630e BGB necessitates medical staff to fully explain to the patient examination and treatment procedures, risks and chances as well as other associated circumstances. This explanation and information shall be conducted in an understandable and timely manner (cf. DBT 2012a: 11 f.). As a rule this should be conducted in oral form, i.e. during a personal conversation, with optional references to textual brochures or information material. The timely manner is not specifically defined and depends on the discretion of healthcare providers, which should nonetheless give the patient enough time for considerations. Regarding comprehensibility, the patient has got also the right to be informed in non-German language, but would have to bear the costs for an interpreter (cf. Gesetzesentwurf 2012: 25). § 630e was generated by judged law and results from the general right of people to self-determination. On the received information basis patients shall reach a decision regarding their healthcare (Gesetzesentwurf 2012: 24).

Although Art. 4(2)(c) Directive 2011/24/EU on complaint procedures was already granted in Germany through legal recourse and extrajudicial arbitration boards (cf. DBT 2013: 4 f.), the PRG clarified the contract details governing medical treatment and the burden of proof for treatment errors (BGBl I S. 277: § 630h). Regarding the need for a professional liability insurance for medical staff (Art. 4(2)(d) DIR 2011/24/EU), the German legislator changed the Federal Act for Medical Practitioners (BÄO). It allows suspending a practitioner's license if the liability insurance

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conceptual differentiation is neither understandable nor convincing, thus for transparency purposes should be clarified or modified. Doubts are raised that any conceptual differentiation between both information sections will be possible in practice, therefore – conversely to the legislators expectations – more confusion and less legal certainty are forecasted (BÄK; KBV 2012a: 11 f., SoDV 2012: 5, DPWV 2012: 6, Sozialverband VdK 2012: 3, BZÄK; KZBV 2012: 14, vzbv 2012: 11). On the other hand, the GKV-Spitzenverband (2012: 12 f.) welcomes the explicit division between § 630c and § 630e, since such clarity gives patients more ability towards an 'informed consent'.



is insufficient (cf. BGBl I S. 277: § 4c). Rules about professional liability insurance already existed, primarily regulated by judged law and state-law, as this healthcare area is the competence of the German Länder (DBT 2012a: 2, 43 f.). Since PRG cannot bring full harmonization regarding liability insurance on federal level, standardization is guaranteed by the guidelines provided in § 21 of the Musterberufsordnung-Ärzte (MBO-Ärzte) (Igl 2011: 7). For the transposition of Art. 4 (2)(f) Directive 2011/24/EU, the PRG introduced § 630g into the German Civil Code (BGB), whereby the patient has the right to look into her/his medical records and obtain a copy of such documentation, covering the duplication costs (cf. BGBl I S. 277).

Responsibilities to provide information as a member state of affiliation as well as treatment are fulfilled by the construction of a National Contact Point (Art. 6 Directive 2011/24/EU). Under the PRG, § 219d was introduced in the Code of Social Law (SGB V), establishing and defining the duties of the NCP. The latter will function as of 25<sup>th</sup> October 2013 as a modification of the German Liaison Office for Sickness Insurance-Abroad (Deutsche Verbindungsstelle Krankenversicherung-Ausland – DVKA), expanding its competence towards cross-border healthcare in the sense of Directive 2011/24/EU. As appears from the newly formulated article, the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) shall cooperate closely with affected organisations, especially the Federal Association for Statutory Health Insurance Physicians (KBV), the German Federal Association of Sick Fund Dentists (KZBV), the private health insurers and the German Hospital Federation (DKG) (BGBl I S. 277: § 219d). Besides providing the NCP with necessary information, the organisations share the financial costs of the NCP. This is justified by the fact that the NCP is not assigned to a specific sector, but to the healthcare field as such (DBT 2012b: 5). Details on the cooperative behaviour among the health organisations are regulated in a separate agreement (BGBl I S. 277: § 219d). Nonetheless, the German legislator specifies the cost shares among all affected organisations, which shall be in place unless the above mentioned agreement decides otherwise (DBT 2012b: 5).

Regarding implementation efforts and costs which the law amendment will bring for Germany, the legislator calculates no additional implementation efforts for German medical establishments, since it is assumed that most of the legal provisions are judged law and therefore already being followed in practice. Thus, the mere codification into PRG should not cause any further costs (Gesetzesentwurf 2012: 14). Moreover, in an ideal case scenario, healthcare providers and patients will act effort-saving – assuming that the information provision will minimize the amount of complaints (Gesetzesentwurf 2012: 13 f.).

### 3.2 Poland

The transposition proposal from the government was published in February 2013 (cf. MZ 2013) and is the basis of this analysis. Concerning Art. 4(2)(b) and related Art. 4(4) the Polish government plans to amend the Act on medical activity (u.d.l.) inasmuch as healthcare providers will be obliged to publish necessary information on professional authorisation, treatment options and prices in their office and on websites (if available). An obligation to issue an invoice specifying the received medical treatment for incoming patients, according to the ICD-Classification of Diseases, will also be included.<sup>13</sup> Lastly, an explicit prohibition of different treatment towards foreign patients, especially as to the prices, is foreseen (cf. MZ 2013: 11 f.).

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<sup>13</sup> International Statistical Classification of Diseases and Related Health Problems (ICD).

Since reimbursement of costs is not present as the Directive requires, the Polish government proposes that a person exercising her/his right to cross-border healthcare will be reimbursed by the regional National Health Fund (NFZ) according to the medical invoice. However, the legislator makes use of Art. 7(7) Directive 2011/24/EU and places in a non-discriminatory manner conditions on patients treated abroad, i.e. they must possess either a referral (assessment made by a health professional) or a prescription (for medical products) (MZ 2013: 4). Because the right to reimbursement will apply solely to services within the benefit basket of Poland, a distinction is made among drugs and medical products. The reimbursement principle up to the amount laid down in the Act of Drug Refund (u.r.l.) shall apply to drugs bought outside Poland or in Poland using an EU-foreign prescription, except for medications which are offered only as part of the state's medication programme<sup>14</sup> (MZ 2013: 4–6). Additionally, the draft defines a "transparent mechanism for calculation of costs of cross-border healthcare" (Art. 7(6) Directive 2011/24/EU), since the provision of health services in different voivodeships<sup>15</sup> may vary in refund rates depending on the healthcare provider. It is therefore proposed, that the average cost of such medical services, calculated from the providers contracted by a regional NFZ, shall serve as a calculation basis (MZ 2013: 5f). Moreover, details on the application and consideration of requests for prior authorisation and reimbursement are to be defined by a Health Ministers' decree (MZ 2013: 6). The possibility to appeal against a negative decision shall be guaranteed by the option to request for reconsideration at the regional NFZ office. If the latter is unsatisfying for the patient, s/he has the right to issue a complaint to regional administrative courts (MZ 2013: 6).

Further, the Polish legislator wish to call upon the possibility of requiring prior authorisation (Art. 8 Directive 2011/24/EU), particularly in view of the necessity to control costs (MZ 2013: 6). Therefore a Minister's decree shall be issued, specifying the list of treatments requiring authorisation. An authorisation refusal is to be issued if the needed healthcare can be provided on Polish territory within a timeframe not exceeding the maximum waiting time (MZ 2013: 7). Regarding the submission and consideration of applications, it is proposed to apply similar procedural rules as used in Regulation (EC) 883/2004,<sup>16</sup> since some applications submitted through the Directive may result in receiving permission as foreseen in the Regulation. The latter would not only reimburse the medical costs but cover all spending during healthcare service in another EU member state (MZ 2013: 8).

The Polish NCP (Art. 6 Directive 2011/24/EU) is proposed to be created within the structure of the NFZ headquarters since it possesses the specialized competence necessary for this function. The NCP shall assume its responsibilities towards incoming foreign patients and outgoing Polish citizens via personal consultations, means of electronic communication and an internet homepage, all in Polish as well as in English (MZ 2013: 9 f.). As for outgoing patients, next to the NCP, regional branches of the NFZ shall inform on request and via websites about the specific amounts of reimbursement for listed medical services and other requirements (MZ 2013: 10).

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<sup>14</sup> Pol. Programy lekowe refundowane ze srodków publicznych.

<sup>15</sup> Pol. Województwo, territorial administration province in Poland.

<sup>16</sup> Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems [2004] OJ L 166/1.

For transposition purposes, the Polish legislators undertook an evaluation of possible effects of the Directive, and assessed that about 18 % of Polish patients, particularly from border regions,<sup>17</sup> will make use of treatment abroad, mostly in the ambulatory sector (MZ 2013: 12 f.). A calculation based on data from 2011 assumes 200 million zloty in additional costs for the NFZ for reimbursement purposes, plus further operational costs resulting from NCP formation and extra staff, but no additional expenditures for the public (and regional) budget (MZ 2013: 13 f.). It is further estimated that the inflow of foreign patients improves the financial and qualitative situation among Polish healthcare providers. Simultaneously, Polish citizens are expected to partly make use of the new treatment opportunities abroad, which may slightly reduce the waiting time for national health services and also create a feeling of improved quality of life (cf. MZ 2013: 14 f.).

### 3.3 Austria

In July 2013 the Austrian Ministry of Health published a transposition proposal implementing Directive 2011/24/EU – the Patient Mobility Law (EU-PMG, EU-Patientenmobilitätsgesetz).<sup>18</sup> For the provision of relevant information according to Art. 4(2)(b) Directive 2011/24/EU, the Austrian legislators propose to oblige hospitals and affected healthcare providers to inform about treatment process, costs and their liability insurance. It is further foreseen to prepare an explicit and detailed invoice, which will fulfil the reimbursement requirements in other EU-countries. This applies to medical institutions (see new §40(3) in KAKuG) and medical practitioners (changing ÄrzteG 1998, Musiktherapiegesetz, Psychotherapiegesetz) (cf. BMG 2013b: 9–11, BMG 2013c: 10, 17, 20, 22). Additionally, the Pharmacy Law and Psychotherapy Law (PsthG) will be amended as to the obligation to possess a professional liability insurance (Art. 4(2)(d) Directive 2011/24/EU). Other medical groups were already obliged to it (cf. BMG 2013b: 10 f.). Further, the right to access the medical record and if necessary make a copy (Art. 4(2)(f)) will be explicitly laid down in the KAKuG, even though this right was already applicable due to national court rulings (BMG 2013b: 9). To transpose Art. 4(4) of the Directive the non-discrimination provisions from Regulation EC/883/2004 shall be extended to incoming patients under the Directive (BMG 2013b: 9).

For the implementation of Art. 6 Directive 2011/24/EU the Austrian Ministry mandates the Health Austria LLC (Gesundheit Österreich GmbH – GÖG) with the creation and maintenance of the NCP, by including this provision into the GÖG-Law. More specifically, as the GÖG is a national body combining several institutes on healthcare research, planning and promotion, the Institute of Quality in Healthcare (Bundesinstitut für Qualität im Gesundheitswesen – BIQG) will be responsible for it (BMG 2013b: 2). The Austrian legislators propose therefore to use the already existing public-health online homepage (öffentliches Gesundheitsportal<sup>19</sup>) as a platform for NCP. The information provided shall fulfil the responsibilities of the member state of treatment and affiliation, as foreseen in the Directive (cf. BMG 2013: 2 f.). Nonetheless, the NCP

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<sup>17</sup> It is assumed in a maximal scenario, that from the voivodeships bordering on Germany, 35 % citizens will use this Directive, those bordering on the Czech Republic about 20 % and 10 % from other regions (MZ 2013: 12)

<sup>18</sup> For the legal text proposed by the Austrian Ministry see:

[http://www.parlament.gv.at/PAKT/VHG/XXIV/ME/ME\\_00540/fname\\_314264.pdf](http://www.parlament.gv.at/PAKT/VHG/XXIV/ME/ME_00540/fname_314264.pdf).

<sup>19</sup> see: [www.gesundheit.gv.at](http://www.gesundheit.gv.at).

should provide only general information on Austrian healthcare system and treatments, not an individual case assistance (BMG 2013b: 2). The act amendment includes further the obligation for healthcare bodies to cooperate with and thus provide necessary data for the BIQG (a list of cooperating organisations is laid down in § 15b(4) GÖG). NCP requests shall be answered via electronic or telephonic means, either in German or, if needed, in English (BMG 2013b: 3). It is further proposed to exclude the NCP from liability as for the correctness and completeness of information (BMG 2013b: 3).

The Austrian system of cost reimbursement and prior authorisation is already to a high degree compatible with the requirements set by European law (respectively Art. 7 and Art. 8 Directive 2011/24/EU). Thus, although § 150 and § 131 of the National Insurance Act (ASVG) provide Austrian patients with refund and grant possibilities, § 7b shall be introduced in the Social Insurance Supplement Law (SV-EG) to bring clarity and differentiation (BMG 2013b: 4).<sup>20</sup> Since the existing refund possibilities are still applicable and in some cases even more favourable for patients, the new paragraph will only regulate the reimbursement of treatments subject to prior authorisation according to the Directive (Art. 8 (2)) (BMG 2013b: 4). The respective competent health insurance body shall therefore decide upon authorisation requests, and if needed specify by regulation those treatments presenting a particular risk (Art. 8 (2)(b)). Exemptions are medical emergencies, where a patient already abroad requires unexpected (hospital) treatment without having a prior authorisation (BMG 2013b: 5 f.). Further, an obligation to obtain a permit for treatment abroad will be introduced if the necessary treatment cannot be guaranteed within a justifiable time in the country (so called "systemic failure"), although the Austrian Ministry does not expect many such cases in view of the high quality level of Austrian healthcare (BMG 2013b: 6). Any deviations from the rule of prior authorisation, i.e. a release from it, may be regulated by the Central Federation of Health Insurance Funds (Hauptverband der Sozialversicherungsträger – SV) (BMG 2013b: 6 f.).

Regarding cost reimbursement for the above mentioned treatments, the Ministry proposes to differentiate between two situations, as already in place in the current refund system. The demarcation lines run along hospital and ambulatory treatment on the one hand, and ambulatory voluntary or involuntary care. In the first case, hospital treatment with prior authorization is refunded as to the amount calculated by real costs, i.e. taking the regional healthcare fund's tariffs as a basis. Hospital care without a needed authorization will be subsidized as if the patient would use non-contracted partners within the country (BMG 2013b: 7). In the second case, ambulatory treatment is reimbursed regarding one of two possible tariffs. If the treatment abroad is involuntary, i.e. due to extensive waiting time a prior authorisation is obligatorily issued, the reimbursement amount is equivalent as if the treatment would be given in Austria by a contracted partner (100 %) (BMG 2013b: 8). In other situations, if the treatment abroad was a voluntary and conscious choice, the reimbursement amount is equivalent to a treatment given by a domestic non-contracted partner (80 %). The 20 % deduction results from administration costs which arise during a conscious choice against the domestic and for the EU-foreign treatment (BMG 2013b: 8).

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<sup>20</sup> The Austrian legislator mentions also the problematic division between the rights and entitlements deriving from Regulation 883/2004/EC and Directive 2011/24/EU, which is one reason Austria was not in favour of the latter (BMG 2013b: 4).

The Austrian Ministry of Health made an evaluation of possible costs associated with the transposition of the Directive. It assumes no relevant increase in financial burden for Länder, companies and citizens, but additional expenditures for the Ministry's budget. The latter, nationally responsible for health, will provide necessary means to create and maintain the NCP, which is expected to cost 90.000 Euro each year starting from 2014 (plus 20.000 Euro in 2013 for the creation of NCP) (BMG 2013a: 4 f.).

## 4 National Discourse Analysis

### 4.1 Germany

#### 4.1.1 Information Provision

In the case of Germany, the domestic discourse and overall transposition process of Directive 2011/24/EU deviates from the regular implementation procedure regarding EU law. This originates from the fact that Germany (as derives from Table 1) already implemented provisions regarding reimbursement and prior authorisation, thus only the information provision (Art. 4(2)(b) and Art. 6 Directive 2011/24/EU) is relevant. Moreover, it derives from the statement received from the Ministry of Health, that a broad public debate did not take place in Germany due to the only partial demand for transposition (cf. Appendix A). The Ministry did not see any controversies evolving from the transposition. As declared, the minimal transposable aspects were included in the PRG, particularly the information on diagnosis and treatment, treatment options as well as costs as presented in § 630c (partly § 630e). For other elements of Art. 4(2)(b), i.e. information on availability, quality, registration status, insurance coverage and issuance of invoices, German Länder are responsible, therefore neither a legislative nor public debate on federal level took place (cf. Appendix A). An additional deviation from the transposition discourse in other member states, which had one legal implementing act, regards the delayed inclusion of NCP (§ 219d) into the PRG. This amendment was officially published in November 2012 by the modification application Austausch-Änderungsantrag zu ÄA Nr. 7, which occurred after the original draft was presented and only shortly before it was put to public consultations (cf. DBT 2012b). Therefore not all stakeholders had the chance to review this proposal and take a position. Keeping this contextual exception in mind, the debate presented hereafter will focus on few statements of stakeholders towards the NCP, as well as on several (see Dataset 1.3) commenting on Art. 4(2)(b). Lastly, it is to note that not presented were statements which did not provide remarks towards the analysed provisions or if the proposed changes were solely semantic in nature or only demanded clarity on specific concepts, causing no essential change towards the governmental proposal despite the wording.

The Federal Council of Germany (Bundesrat), which shall be regarded in this discourse as the position of the German Länder, proposed several changes to the governmental PRG draft. Diverse remarks made by the Bundesrat are of semantic nature, referring to the comprehensiveness of medical information for patients or a wider scope of their rights (cf. Bundesrat 2012). However, next to those corrections in wording, the Bundesrat and several patients' organisations propose to oblige medical practitioners – when appropriate – to hand out in the forefront written patient summaries including all treatment information, called "Patientenbrief". This would not only guarantee a more complete treatment understanding for



the patient, serving as a written memorandum to evaluate own healthcare options. It would further act as a proof for the doctor that necessary information had been provided to patients (Bundesrat 2012: 4–8; BAG Selbsthilfe 2012: 8f; SoDV 2012: 5; DGB 2012: 7f; EKD 2012: 6; Sozialverband VdK 2012: 4; vzbv 2012: 12). Further, several entities propose to oblige medical practitioners to offer mentally ill patients a treatment plan and agreement defining which medical interventions and procedures are to be conducted in case of any inability (Bundesrat 2012: 8; BPtK 2012: 4–6; EKD 2012: 8; APK 2012: 3 f.).

Moreover, the Bundesrat, the Association of mentally-ill (APK) and GKV-Spitzenverband require the list of exceptions from the information duty, as incorporated in § 630c Para. 4 and § 630e Para. 3, to be restricted to the medical minimum and to be exhaustive, meaning that under no further circumstances can the patient be denied treatment explanation (cf. Bundesrat 2012: 10,13; APK 2012: 4f; GKV-Spitzenverband 2012: 15). In contrast, the German Trade Union Federation (DGB) pledges for cancellation of any exceptions from the information duty, since patients have in any case the right to information and self-determination (DGB 2012: 17). Nonetheless, if the patient does not want to make use of her/his information right, s/he should confirm it in written form, as to avoid later manipulations or misunderstandings for both the patient and the medical practitioner (PKV-Verband 2012a: 5; vzbv 2012: 12).

A critical issue in the information provision refers to the costs of treatment. The Federal Association of AOK (AOK-Bundesverband) demands their explanation to be coupled with information on the necessity and effectiveness of the respective treatment. Additionally, a right to withdrawal shall be given to the patient if cost information is uncertain or false (AOK-Bundesverband 2012: 10). Similarly, the Social Association VdK (Sozialverband VdK 2012: 7) demands changing costs to be timely explained to the patient. Still, they should not deviate from the original price information up to a specific percentage (e.g. 10 %). The Association of Private Health Insurances (PKV-Verband) remarks, that since privately insured do not have to be informed on additional treatment costs due to their special agreements with private insurance funds, they nonetheless often pay for their treatment. Therefore medical practitioners shall inform patients in any case about additional costs if they exceed 300 Euro (PKV-Verband 2012a: 4 f.).

On the other hand, the German Medical Association (BÄK) and the Federal Association for Statutory Health Insurance Physicians (KBV) refuse in their joint statement<sup>21</sup> the cost information duty for doctors, since it is not the medical practitioners but the health insurance funds who have detailed knowledge on benefit baskets. Besides, in medical codes of conduct (MBO-Ärzte) similar responsibilities are imposed on practitioners, which would cause a legal duplication (BÄK; KBV 2012a: 16 f.). Likewise, the respective dentists' chambers BZÄK and KZBV propose the abolition of a general cost information duty and add the provision "if requested". They remark, that the mere conjecture of costs possibly uncovered by health insurance funds cannot in legal and practical terms oblige dentists to information provision (BZÄK; KZBV 2012: 17–23). Similar, the German Hospital Federation states, that revealing all possible costs of hospital treatment is impossible and should not be required by law (DKG 2012: 7).

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<sup>21</sup> Regarding the joint statement BÄK/KBV, their positioning towards the draft (Referentenentwurf) and not the legislative proposal (Gesetzesentwurf) was taken. This was due to their declaration in the latter, that their comments remain mostly the same as mentioned in the draft.

Regarding the additional IGeL services, several social and patients' organisations request more detailed and strict information provision, with concrete explanation on the possible health gains and alternatives included in the statutory healthcare basket. Also, medical practitioners should be obliged to inform the patient which of the presented treatments are IGeL services, since due to their lack of evidentiary healthcare improvement they are seen as not medically urgent or necessary (cf. SoVD 2012: 4f; BAG Selbsthilfe 2012: 7; DGB 2012: 17; DPWV 2012: 6; MDS 2012: 3; vdek 2012a: 12; vzbv 2012: 8 f.,13). Moreover, GKV-Spitzenverband and other civil groups go even further, demanding a 24-hour retention period for IGeL-services. This time must not be used by the patient, but guarantees him/her occasion to evaluate (chargeable) options (cf. GKV-Spitzenverband 2012: 14; Deutscher Caritasverband 2012: 9f; DKH 2012: 2; MDS 2012: 3; vdek 2012a: 12). The Bundesrat proposes to sign a letter of acknowledgement regarding any additional costs for treatment (IGeL), which should function as a reminder and thus secure the patient's decision-making (Bundesrat 2012: 9 f.). Additionally, EKD requires limiting liability of those payments, which considerably deviate from the earlier given prices (EKD 2012: 7).

The governmental proposal states that information shall be provided to the patient in an understandable manner. The dentists' chambers BZÄK and KZBV refuse this requirement as the medical practitioner shall not be given full responsibility regarding comprehensiveness of information, since the patient is able to further inquiry. Second, supposing communicative misunderstandings, the doctor would be forced not to conduct a possibly urgent treatment due to liability issues (BZÄK; KZBV 2012: 15). On the other hand, the comprehensiveness of information for non-German speaking patients is lacking legal codification and clarity as to the code of conduct (BÄK; KBV 2012a: 23 f.). Even though Deutscher Caritasverband (2012: 10) and EKD (2012: 6) agree, they further expect the costs for an interpreter to be borne by the health insurance fund and not the patient.

On the part of diverse associations and organisations, several aspects demand clarification and explicit formulation to foster clarity and legal certainty. The legislator should define and specify content and depth of information to be provided to patients (cf. AOK-Bundesverband 2012: 9f; BAG Selbsthilfe 2012: 9f; BÄK; KBV 2012a: 17, 21). From the presented proposal uncertainty concerns the type of risks and detailedness of information to be disclosed as well as the timing of explanation. It should be legally codified that some information, like on follow-up treatment, cannot be given beforehand, therefore a gradual information provision should be conducted (BZÄK; KZBV 2012: 14 f., 25 f.). Further on, it shall be clearly codified, which persons can undertake the duty to inform (BPtK 2012: 8 f.). On the one hand, limitation towards the treatment conducting doctor is demanded (Sozialverband VdK 2012: 8), on the other hand such a restraint is impracticable, especially in hospitals where explanation of treatment often happens by another medical practitioner (BÄK; KBV 2012a: 22 f.). Furthermore, since information coverage depends on the type of conducted treatment, the need for information shall be judged by the doctor on an individual case basis and therefore "if required" shall be added to the information paragraph (BÄK; KBV 2012a: 12). Besides, semantic clarity is demanded regarding the range of alternative treatment methods to be presented. Particularly exposure to new and unacknowledged methods (GKV-Spitzenverband 2012: 20 f.) and the presentation of all valid treatment options even if they cannot be conducted by the respective medical practitioner (cf. SoDV 2012: 5 f.; DGB 2012: 17; DPWV 2012: 6) shall be regulated.

Regarding the creation of a NCP, BÄK and KBV declare in a further joint statement that they will support the NCP by providing relevant information. Nonetheless, they object to the choice of DVKA as the leading NCP-organisation since it represents mainly the interests of specific, i.e.

compulsory insurance, organisations (BÄK, KBV 2012b: 2). As a NCP should be neutral in terms of interests and representation, it is proposed to establish the NCP within the Ministry of Health. Alternatively several NCPs should be created, each responsible for the respective field of competence (BÄK, KBV 2012b: 2 f.). Likewise, the Association of Substitute Insurance Funds (vdek) sees in the choice of DVKA not only a conflict of interests but also lack of competence, since it is viewed as primarily an administrative organisation instead of a communication entity for cross-border healthcare (vdek 2012b: 6 f.). As the NCP should be an information body to all German and EU-citizens (and not just the statutory insured), this societal task shall be performed by the German Patient's Commissioner (Patientenbeauftragter der Bundesregierung) (vdek 2012b: 6 f.).

As to costs for NCP, the KBV strictly refuses to contribute financially to the NCP, because the KBV and BÄK will perform additional tasks by providing information without being compensated. In a similar manner the DKG refuses cost-sharing. Thus both organisations demand that the additional financial burden be fully paid by public finances (BÄK, KBV 2012b: 3; DKG 2012: 14 f.).

The PKV-Verband disapproves of the governmental amendment introducing the NCP. The involvement of the PKV-Verband in the establishment and financing of the NCP will lead only to additional administrative and financial costs without bringing any gain for the privately insured citizens. The Association argues with the fact that the option of healthcare abroad for the privately insured has already been expanded on a contractual basis to the whole EU some decades ago. Thus the Directive is not relevant for PKV-Verband as a non-statutory insurance (PKV-Verband 2012b: 2). Information and reimbursement procedures for cross-border healthcare are also guaranteed services for privately insured. However, as it is given by an individual case study of the patient and determined by the respective insurance contract s/he has, the NCP cannot be an information body for the privately insured (PKV-Verband 2012b: 3). Since the NCP is neither a reliable instance for these patients, and since the private insurers cannot deliver the generalized information necessary for NCP, any financial contribution from the PKV-Verband would be unjustified and would raise constitutional doubts (PKV-Verband 2012b: 3 f.).

Following each country analysis, a summarizing table will be presented. It depicts all observations during national discourse as well as the number and name of the respective stakeholders uttering each observation. This visualization not only supports the comprehensiveness, but it is further the basis for the figures presenting the frequency of discussed articles and the most frequent remarks. Both are used for the intra- and inter-state comparison in the evaluation chapter.

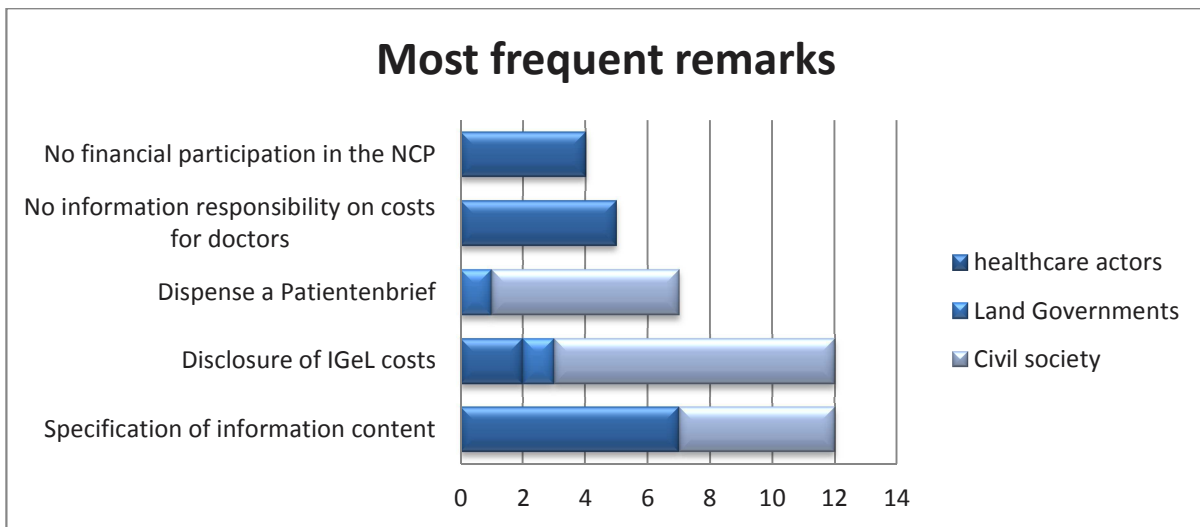


**Table 2: Summary of German Consultations on Directive 2011/24/EU**

Art. DIR	Observations	Healthcare actors	Civil society	Länder entity	No
<b>Art. 4(2)(b)</b>	Not all responsibility as to information comprehensiveness for the medical practitioner	BZÄK, KZBV			2
<b>Art. 4(2)(b)</b>	Private insurers shall be excluded from the scope of the Directive	PKV-Verband			1
<b>Art. 4(2)(b)</b>	Dispense a Patientenbrief for information purposes		EKD, BAG Selbsthilfe, SoDV, DGB, Sozialverband VdK, vzbv	Bundesrat	7
<b>Art. 4(2)(b)</b>	Mentally ill patients shall be offered a special treatment agreement	BPTK	APK, EKD	Bundesrat	3
<b>Art. 4(2)(b)</b>	Exhaustive (and minimal) list of exceptions from information duty	GKV-Spitzenverband	APK	Bundesrat	3
<b>Art. 4(2)(b)</b>	No exceptions regarding information provision		DGB		1
<b>Art. 4(2)(b)</b>	Specification and definition of information content; semantic clarity	BÄK, AOK- Bundesverband, KBV, BZÄK, BPTK, KZBV, GKV- Spitzenverband	BAG Selbsthilfe, Sozialverband VdK, SoDV, DGB, DPWV		12
<b>Art. 4(2)(b)</b>	The information duty for doctors on costs is to be refused	BÄK, KBV, BZÄK, KZBV, DKG			5
<b>Art. 4(2)(b)</b>	Clarity regarding foreigners or disabled person shall be codified	BÄK, KBV			2
<b>Art. 4(2)(b)</b>	Written refusal of information provision	PKV-Verband	vzbv		2
<b>Art. 4(2)(b)</b>	More security for patients regarding uncovered/additional costs (acknowledgement letter, withdrawal, retention period)	AOK- Bundesverband, PKV-Verband	Sozialverband VdK		3
<b>Art. 4(2)(b)</b>	Disclosure of IGeL costs and a right to withdrawal	vdek, GKV- Spitzenverband	SoVD, BAG Selbsthilfe, DGB, DPWV, MDS, vzbv, EKD, DKH, Deutscher Caritasverband	Bundesrat	12
<b>Art. 4(2)(b)</b>	Health Insurance Funds should bear the costs for interpreters		EKD, Deutscher Caritasverband		2
<b>Art. 6</b>	Objection to the choice of DVKA as the leading NCP-organisation	BÄK, KBV, vdek			3
<b>Art. 6</b>	Creation of several or one interest-neutral NCP	BÄK, KBV, vdek			3
<b>Art. 6</b>	No financial participation (cost sharing) in the NCP	BÄK, KBV, PKV- Verband, DKG			4

Source: Author

Figure 1: Most Frequent Remarks Made in German Consultations<sup>22</sup>



Source: Author

## 4.2 Poland

### 4.2.1 Information Provision

The Chamber of Physicians and Dentists (Naczelna Izba Lekarska – NIL) responded to public consultations claiming that it misses some clarification about rules for providing medical care to EU-foreign patients. The absence of a code of conduct, apart from the regulation on providing information to them, may result in interpretative doubts in practice (NIL 2013: 4). It is therefore recommended by the Chamber to regulate the provision of healthcare service to foreigners. Particularly specific rules shall apply as to the possibility of providing chargeable services as well as the procedure for public providers to treat foreigners. Moreover, clarification require the language of medical records and the required documents for incoming patient (NIL 2013: 4). Additionally, the governor of the voivodeship Opole (pol. marszałek województwa), as the only regional respondent, likewise points to a missing code of conduct for national healthcare providers regarding incoming patients (Sebesta 2013: 4).

Concerning the creation of a NCP, the governor of Opole reflects on creating several, regional NCPs which have appropriate local knowledge, since the information to be provided is detailed (Sebesta 2013: 3). Furthermore, the governor points out that due to the Directive two queues – for national and EU-foreign patients – may occur, therefore the legislation should prevent any possibility of abuse (Sebesta 2013: 4).

<sup>22</sup> Note, that for Germany no diagram regarding frequency of discussed articles is presented since a representation bias is already inherent in the debate.

#### 4.2.2 Access and Finances

NIL claims that part of the government's proposal does not achieve the objectives set by the Directive, i.e. the creation of a reimbursement mechanism and the abolition of migration barriers within the EU (NIL 2013: 1). Regarding refunds, the Chamber criticises the exclusion of drugs from the state's medication programme from reimbursement. This action is seen as incompatible with the Directive – especially Art. 1(3) defining limits of the Directive's scope – and thus as undermining its main goal (NIL 2013: 2). In addition, NIL considers the announcement "worrying" that cost reimbursement shall depend on the principle of economy and purposefulness, which is neither anticipated by the Directive nor a transparent criterion for refund (NIL 2013: 2). The most influential patient organisation in the public consultations named Porozumienie 1 czerwca (eng. 1st June Agreement), which associates numerous patients' groups, organisations and individuals, also notes that the proposed criteria for reimbursement (principle of economy and purposefulness) are neither transparent and objective categories, nor are they foreseen in the Directive's guidelines (1czerwca 2013: 3). Likewise, the association claims that the Directive's goal is to remove access barriers to EU-wide healthcare by an equal, non-discriminatory treatment of patients, which is partly not given by the transposition draft. The first objection refers to the exclusion of those drugs from reimbursement principle, which are part of the state's medication programme. This not only violates Art. 1(3) of the Directive, but also undermines the equality idea behind this EU act, as pharmacotherapy is an integral part of medical treatment and would deprive patients of access to effective healthcare (1czerwca 2013: 2). Likewise, the governor of Opole criticizes the drug exception from reimbursement (Sebesta 2013: 3).

A next observation of NIL reflects on the possibility of taking legal recourse if a negative reimbursement decision was made. An appeal should be filed with Common Courts, not as a complaint with regional administrative courts, as planned. Patients choosing recourse should also be relieved from any legal costs (NIL 2013: 3). Likewise, the governor of Opole suggests in cases of a negative reimbursement or treatment decision, to choose legal recourse via Common Courts. Requesting reconsideration and submitting complaints to the same authority which rejected the application in the first place is an inappropriate solution (Sebesta 2013: 2). Similarly, the association Porozumienie 1 czerwca calls for transparent judicial appeal mechanisms in case of authorisation denial as well as release from any legal costs (1czerwca 2013: 4).

Furthermore, NIL questions the calculation basis as the average cost of a medical service within a voivodeship. It will cause unequal treatment of Polish citizens, because they will receive different refund of cross-border healthcare, depending on their place of living, while medical treatment in another voivodeship would generate similar costs for them. Such a calculation method not only discriminates within the Polish territory, but also infringes upon Art. 7(6) regarding transparent calculation techniques (NIL 2013: 2). The association Porozumienie 1 czerwca remarks that the calculation basis for reimbursement bears the risk of a high refund discrepancy within the country. This risk increases in view of the planned healthcare reform in Poland by which regional NFZ would become more independent in their contracting policy and thus price-setting (1czerwca 2013: 2). It is therefore proposed to create a nationwide, uniform and periodically evaluated price list to meet the objectivity criterion in the Directive (1czerwca 2013: 2). Overall, the Association fears that the governmental proposal will discriminate against Polish patients and thus generate unequal treatment within the EU, especially regarding the right of patients to use cross-border healthcare (1czerwca 2013: 4 f.). Moreover, it notes, that

the draft reflects only interests of the NFZ and its budget, disregarding the main goals of the Directive (1czerwca 2013: 4).

The Association of Healthcare Managers (STOMOZ) questions the governmental calculation regarding the number of citizens willing to use healthcare abroad, and the financial burden for the NFZ – both are calculated too low and based on no practical evidence (STOMOZ 2013: 1 f.). It is further viewed as an "absurd situation" that Polish patients are reimbursed for a treatment abroad, disregarding the status of the provider, but get no refund for domestic treatment by a non-public (private) provider. Such a situation is a deliberate redirection of medical demand to other EU-countries (STOMOZ 2013: 3). STOMOZ, representing healthcare providers, assumes that the current healthcare system with financing based on contracting will further disadvantage Polish providers after the Directive is in place. They ask therefore for the abolishment of contracting and the introduction of unified tariffs among healthcare providers, otherwise the Directive will bring financial instability to the Polish healthcare sector (STOMOZ 2013: 1–4).

Furthermore, the governor of Opole proposes direct cost account mechanisms between NFZ and the respective EU-hospital. Costs would be then paid up to the limit that would have been assumed by the member state of affiliation, provided that the patient handed in necessary documents (Sebesta 2013: 2).

Regarding prior authorisation, the association Porozumienie 1 czerwca criticizes the right to deny it if the equivalent treatment can be delivered in Poland within a time not exceeding the maximum waiting time. This is not only an unforeseen criterion in the Directive (Art. 8(6) and Art. 7(8)) but also non-transparent since there is no mechanism in Poland which regulates the maximum waiting time (1czerwca 2013: 3). Moreover, as prior authorisation shall apply to all treatments except basic ambulatory care according to the governmental draft, the association would abandon or limit the list of treatments for which it is required (1czerwca 2013: 3). Since it derives from the governmental proposal that the whole limitation catalogue offered in the Directive will be used, its goals will not be met, i.e. access to EU-wide high-tech and highly specialized treatment methods (1czerwca 2013: 3). If the government publishes a list with treatments which require prior authorisation, social and patient organisations should be consulted in advance. More general, patient's organisations should be given voice in the decision-making process regarding governmental healthcare decisions. The association uses the Recommendation No. R(2000)5 of the Council of Europe<sup>23</sup> as a reference. It states that healthcare policy should be patient-oriented and therefore national politics should involve patient's organisations and other social groups into reform processes (1czerwca 2013: 3 f.).

Likewise, NIL considers the possibility to disallow prior authorisation as incompatible with the Directive, if the equivalent treatment can be delivered in Poland within a time not exceeding the maximum waiting time. Since any clear guidelines to measure 'maximum waiting time' are missing, such a criterion is non-transparent (NIL 2013: 3). Another observation is that costs of hospital care are missing in the government's calculation draft. This leads NIL to the conclusion

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<sup>23</sup> Recommendation No. R (2000) 5 of the Committee of Ministers to member states on the development of structures for citizen and patient participation in the decision-making process affecting health care, adopted by the Committee of Ministers on 24 February 2000 at the 699th meeting of the Ministers' Deputies, Council of Europe.

that the Polish legislators does not plan to allow hospital treatment abroad, which would violate the Directive's provisions (NIL 2013: 3).

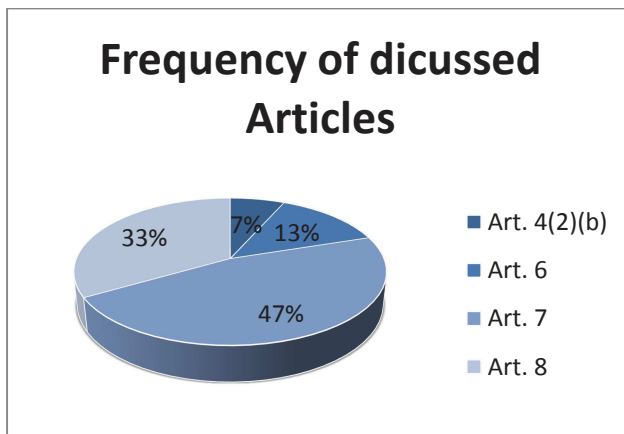
There are several patient's organisations which, although part of the association Porozumienie 1 czerwca, brought their own statements into public consultations. This applies to the Foundation "MY Pacjenci", the National Federation of Associations of Rheumatics (REF) and the Association of Suffering from Ankylosing Spondylitis and its Supporters (Stowarzyszenie ZZSK). All three make similar remarks as the main association, but include also a plea for an educational campaign and hotline for Polish patients (cf. REF 2013: 2) as well as a demand to include patients' organisations in decision-making, coordinating and monitoring bodies of the healthcare system (Stowarzyszenie ZZSK 2013: 3). Moreover, REF criticizes the lack of rules and standards regarding treatment of incoming patients. The organisation concludes that the proposed legislation will not bring any advantages for outgoing and incoming patients (REF 2013: 1 f.). It is further criticized by the Stowarzyszenie ZZSK that for reimbursement purposes a referral from a general practitioner is required, when aiming at a specialized treatment abroad. Since it is not clear whether other European healthcare systems demand such prerequisites, the patient shall be treated abroad by the respective domestic rules and still get reimbursed (Stowarzyszenie ZZSK 2013: 1 f.).

**Table 3: Summary of Polish Consultations on Directive 2011/24/EU**

Art. DIR	Observations	Healthcare actors	Civil society	Voivodeship entity	No
<b>Art. 4(2) (b)</b>	Absence of a code of conduct for national providers to treat EU-patients	NIL	REF	Governor of Opole	3
<b>Art. 6</b>	Need for educational campaign and hotlines for Polish patients		REF		1
<b>Art. 6</b>	Creating regional NCPs with local knowledge for detailed information			Governor of Opole	1
<b>Art. 7</b>	Under-calculated amount of outgoing citizens and financial burden for NFZ	STOMOZ			1
<b>Art. 7</b>	Abolition of contracting systems for healthcare providers	STOMOZ			1
<b>Art. 7</b>	Exclusion of drugs from the state's medication programme from reimbursement – incompatible with Art. 1(3)DIR	NIL	1czerwca, MY Pacjenci, REF, Stowarzyszenie ZZSK	Governor of Opole	6
<b>Art. 7</b>	The calculation basis (average cost of medical service within a voivodeship) discriminates Polish citizens and is incompatible with Art. 7(6) DIR	NIL	1czerwca, MY Pacjenci, Stowarzyszenie ZZSK		4
<b>Art. 7</b>	Reimbursement shall not be depended on and thus limited by the principle of economy and purposefulness	NIL	1czerwca, MY Pacjenci, Stowarzyszenie ZZSK		4
<b>Art. 7</b>	Reimbursement for treatment abroad, but no refund for domestic treatment by non-public providers is inappropriate	STOMOZ			1
<b>Art. 7</b>	Create a direct account mechanisms between NFZ and EU-hospital			Governor of Opole	1
<b>Art. 8</b>	Inclusion of patients' organisations into decision-making and monitoring process		1czerwca, Stowarzyszenie ZZSK		2
<b>Art. 8</b>	Legal recourse: An appeal should be filed with Common Courts, not as a complaint with regional administrative courts: release from legal costs	NIL	1czerwca, MY Pacjenci, REF	Governor of Opole	5
<b>Art. 8</b>	Disallow prior authorisation if the equivalent treatment can be delivered in Poland within a time not exceeding the maximum waiting time	NIL	1czerwca, MY Pacjenci, Stowarzyszenie ZZSK		4
<b>Art. 8</b>	Abandoning or limiting the list of treatments for which prior authorisation is necessary		1czerwca, MY Pacjenci		2
<b>Art. 8</b>	Referral from a general practitioner to get reimbursement for specialized treatment abroad is inappropriate		Stowarzyszenie ZZSK		1

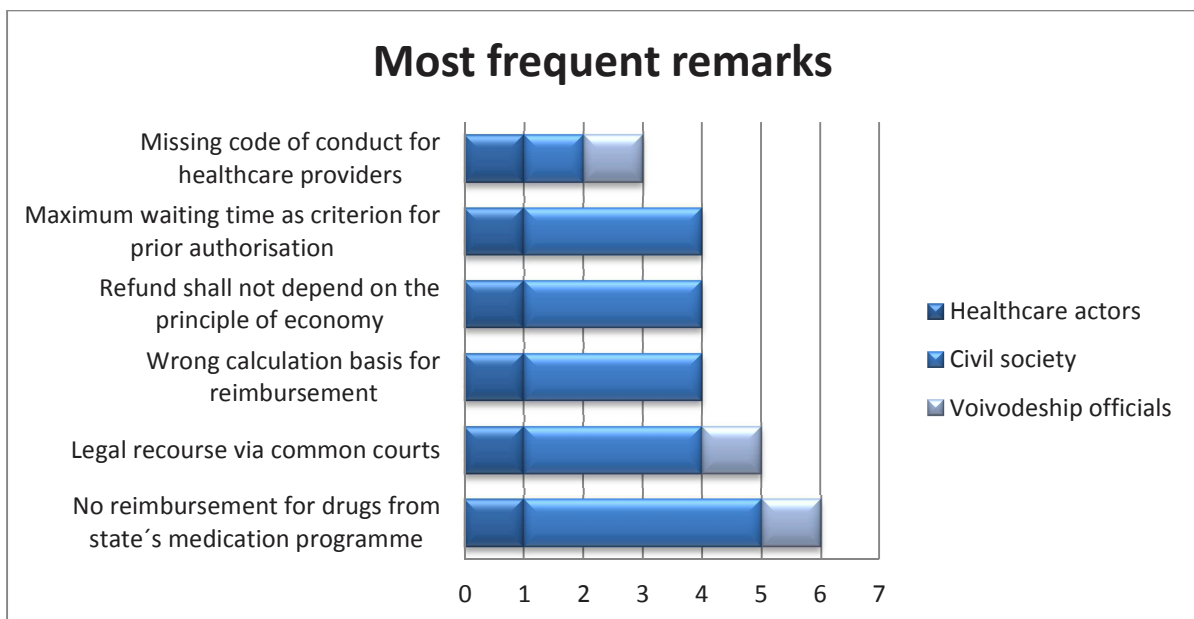
Source: Author

Figure 2: Frequency of Discussed Articles in Poland



Source: Author

Figure 3: Most Frequent Remarks Made in Polish Consultations



Source: Author

## 4.3 Austria

### 4.3.1 Information Provision

Regarding information provision, the Austrian Medical Association (ÖÄK) criticizes the proposal that information on prices and invoice issuance are required for all patients, including domestic treatments, which goes far beyond the Directive's cross-border character. The proposal includes a general information obligation and sets more data requirements than foreseen in the

Directive. It obliges doctors to inform patients about the costs before treatment (which might not be known in advance), whereas the Directive mentions fixed tariffs not all costs of treatment (ÖÄK 2013: 2–5, 8). The ÖÄK further questions the necessity and detailedness of information about professional liability insurance. On the one hand it is obvious that such is existing since it is a requirement when practicing medicine according to Austrian law; on the other hand the information requirements create legal uncertainty for doctors (ÖÄK 2013: 6 f.). The new provisions and duties for medical practitioners will cause additional work and expenditures, therefore the calculation that companies and thus medical practitioners will have no further costs is incorrect (ÖÄK 2013: 7).

Similar to the ÖÄK, the Austrian Dentists Chamber (ÖZÄK) criticizes the vague obligation for dentists to inform all patients about their liability insurance status. This is an incomprehensible proposal since it is too vague (dentists have often several insurances) and incompatible with the common procedure of treatment information (ÖZÄK 2013: 6 f.). Further, both chambers, doctors and dentists, criticize the obligation to issue an invoice for incoming patients which fulfils requirements to reimbursement in their home country. Such a demand is not tangible as medical staff is lacking information about the complex systems in the EU (ÖÄK 2013: 5, ÖZÄK 2013: 7 f.). The Land Government of Wien also calls for clarification on the required content of invoices, concurrently stating that no such demand is included in the Directive (Wiener Landesregierung 2013: 3).

Likewise, the Burgenland Hospital Company LLC (KRAGES) and the Central Federation of Health Insurance Funds (SV) remark that information provision for patients as to treatment costs raises the question of how detailed this obligation is to be defined, regarding changing circumstances and the 'follow up treatment' (KRAGES 2013: 1; SV 2013: 8). It shall be also specified what information about professional liability insurance are to be disclosed (KRAGES 2013: 2). Furthermore, the Land Government of Vorarlberg remarks that the duty to inform about costs outruns the requirements of the Directive. The latter demands only information on tariffs, not overall costs and only on patient's demand (Vorarlberger Landesregierung 2013: 2 f.). In like manner, the Land Government of Salzburg remarks that it is not possible to provide information on overall costs including follow-up treatment, only estimates are feasible (Salzburger Landesregierung 2013: 1 f.). Also the Land Government of Wien as well as the Land Government of Steiermark regard the overall cost information as an unspecific legal term which is furthermore not demanded by the Directive (Wiener Landesregierung 2013: 3; Steiermärkische Landesregierung 2013: 3). For the Austrian Industrialists' Association and the Austrian Economic Chamber (Wirtschaftskammer Österreich – WKÖ) precise information on any follow up costs are unconvertible into reality and also should be reduced to the minimum required (Industriellenvereinigung 2013: 2; WKÖ 2013: 2).

Concerning the creation of the NCP, GÖG, as the responsible institution for it, requires more clarified and detailed cooperation between GÖG and the regional and national bodies mentioned in § 15b(4). Especially with regard to the federal structure and self-administration principle in Austria, the GÖG requests coordinated action on form and functioning of the website. Further on, due to those structural circumstances information providing by phone should be limited to informing generally and to forwarding requests to regional bodies mentioned above (GÖG 2013: 1 f.). To create and maintain the NCP, GÖG pleads for more financial and personal resources then calculated by the Ministry (GÖG 2013: 3).



The patients' lawyers organisation ARGE and the Austrian Chamber of Employment (AKÖ) criticize the lack of quality assessment to be provided by the NCP according to the governmental proposal (ARGE 2013: 1; AKÖ 2013: 3). Next to the inclusion of such a provision into new legislation, this Directive should be taken as an opportunity to introduce in Austria concrete assessment models. Additionally, the NCPs information about enforcement and appeal possibilities should explicitly include not only legal recourses but also extrajudicial remedies (ARGE 2013: 1 f.). ARGE asks also for the inclusion of the organisation "ARGE Selbsthilfe" into the list of organisations closely cooperating with the NCP (ARGE 2013: 2). Likewise, the Austrian Industrialists' Association and the WKÖ demand participation and involvement in the NCP to guarantee high quality information and advice (Industriellenvereinigung 2013: 2; WKÖ 2013: 2). Also the umbrella organisation for organ transplant patients (Dachverband Organtransplantierte 2013: 2) demands the inclusion of patients' organisations into the adaptation of the NCP.

Furthermore, the organisation for organ transplant patients welcomes the choice of GÖG (BIQG) as the responsible institution for the NCP. Nonetheless, it criticizes the lack of a controlling body for the NCP. Further, the NCP should not only provide general information, but detailed information on treatment options, costs, effects, provider's safety and quality, at best in all EU-languages (or timely interpreted) or through easily understandable graphics. If required due to Länder-specific regulations in healthcare, several NCPs should be considered to guarantee enough competence (Dachverband Organtransplantierte 2013: 1 f.). Similar, the Land Government of Wien criticizes the limitation of the NCP to provide only general information, and suggests in contrast binding the NCP legally to grant information on all cross-border aspects in more detail (Wiener Landesregierung 2013: 1 f.).

The Austrian Trade Union Federation (ÖGB) criticizes the proposal of excluding NCP from liability regarding correctness and completeness of information. This should be cancelled particularly with respect to information on legal recourse and administrative procedures (Art. 6(3) Directive 2011/24/EU) (ÖGB 2013: 2). The Austrian Industrialists' Association, WKÖ and AKÖ make a similar argument, claiming that liability for provided information could increase its quality (Industriellenvereinigung 2013: 2; WKÖ 2013: 2; AKÖ 2013: 3).

Furthermore, the ÖÄK sees a duplication risk in the Ministry's proposal for NCP. Since ÖÄK manages the list of medical practitioners and collects the required data on doctors, its duties will overlap with the responsibility of NCP. For correctness and actuality purposes only the ÖÄK should publish information about doctors, therefore medical practitioners should be excluded from the NCP information scope (ÖÄK 2013: 1 f.). Likewise, the SV fears a creation of parallel structures regarding own duties and those of the NCP. Clarity should be provided to avoid duplication (SV 2013: 1 f.). Moreover, both, the ÖGB and the AKÖ seek to oblige the latter with delivering information to the NCP, since the proposed professional associations do not possess the relevant data (cf. AKÖ 2013: 3; ÖGB 2013: 1 f.).

#### **4.3.2 Access and Finances**

Regarding reimbursement, clarity should be given by the Ministry as to what possibilities the patients have, since there are currently too many parallel systems in place. Nonetheless, the division of refund amounts for ambulant treatment sounds reasonable to ÖGB (cf. ÖGB 2013: 2 f.). Similarly, the Austrian Industrialists' Association and the SV suggest working on a simplification of reimbursement procedures, as there are now three different available (Industriellenvereinigung 2013: 1, SV 2013: 3). The WKÖ makes a similar remark, attributing this

confusion to the parallel existing EU-legislations (WKÖ 2013: 1). Furthermore, the AKÖ doubts that the Austrian proposal to reimburse only 80 % of the ambulatory treatment abroad is in conformity with EU law. A 20 % deduction for administrative costs is neither foreseen in the Directive, nor compatible with the right to free movement and service (AKÖ 2013: 6).

In terms of cost calculation made by the government, the Land Government of Steiermark assumes a higher financial burden for public spending, especially for social assistance authorities (Sozialhilfeträger) dealing with reimbursement. Additional costs will arise because in the Austrian welfare system, both, the incoming EU-patient and outgoing Austrian may optionally apply for financial assistance in insolvent circumstances. Such situations will be critical, if patients use treatments under this Directive without being given prior authorisation (Steiermärkische Landesregierung 2013: 2 f.).

To prevent confusion and misunderstandings a concrete list of treatments requiring prior authorisation as well as standardised consideration periods on prior authorisation should be defined (AKÖ 2013: 5–7). Next to a treatment list, a clear definition of evaluation criteria for prior authorisation is needed; especially, whether the question of 'justifiable time within the country' refers to nationwide capacities or solely in the patient's neighbourhood (ÖGB 2013: 2 f.). Likewise the Land Government of Vorarlberg requests clarification regarding 'systemic failure', since it derives from the proposal that only highly specialized treatments are included, whereas it should apply to all ambulant healthcare (Vorarlberger Landesregierung 2013: 2). The Land Government of Wien also suggests the inclusion of all ambulant treatments for full reimbursement (Wiener Landesregierung 2013: 2 f.). Furthermore, 'ambulant' treatment shall be specifically defined, since a vague understanding will cause too many applications and thus very high administrative and financial efforts (AKÖ 2013: 5). Specification is needed whether ambulant means only treatments conducted by practitioners or also in hospital (Steiermärkische Landesregierung 2013: 1 f.). The WKÖ on the other hand demands clarification, that prior authorisation will not be granted if treatment can be provided domestically by public but also by private health providers (WKÖ 2013: 2).

ARGE points out that while considering prior authorisation, the risk level for patients should be evaluated by special risk-benefit-analysis, since a more risky treatment is sometimes most effective and helpful (ARGE 2013: 2). Further, the umbrella organisation for organ transplant patients warns against bureaucratically complicating dialysis treatments abroad for patients in need (Dachverband Organtransplantierte 2013: 1).

For reasons of legal clarity and certainty, the Land Government of Vorarlberg wishes to explicitly codify the option for health insurance funds to define prior authorisation cases (Vorarlberger Landesregierung 2013: 1 f.). GÖG further proposes a semantic change of § 7b SV–EG in order to ensure that the SV may only limit (not expand) the requirement for prior authorisation beyond the Directive (GÖG 2013: 2). Likewise, SV itself demands explanation of judicial and practical-technical nature, especially regarding reimbursement and prior authorisation procedures. The remarks refer to determining concrete criteria, giving explicit definitions and simplifying legal provisions (SV 2013: 4–8). Further codification is necessary regarding reimbursement principles, since the proposed calculation mechanism deviates – probably unintended by the Austrian government – from the already existing one (SV 2013: 5–7).

The AKÖ indicates that the governmental proposal regulates only treatments, which are part of the benefit basket of health insurance funds. Nevertheless, the Austrian social system knows further treatments possibly relevant for cross-border healthcare. This applies to benefit baskets

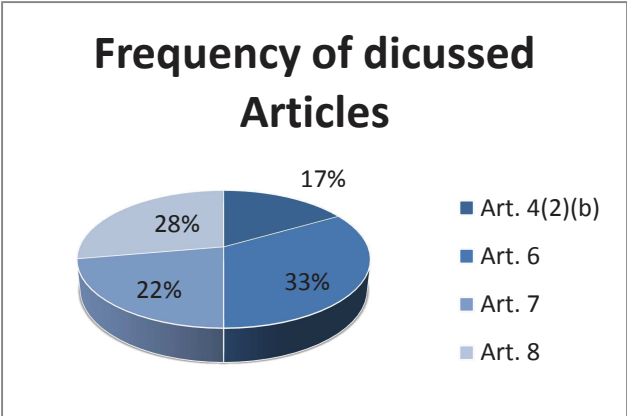
deriving from accident insurance and retirement pension insurance, both of which should be regulated in accordance with Directive 2011/24/EU (AKÖ 2013: 4). In this context the right for SV to deviate from prior authorisation is also insufficient, since this body only covers health insurance funds (AKÖ 2013: 5). The SV itself points to the fact, that under proposed legislation the right will only be given to members of the SV, not to all insurance bodies (SV 2013: 4).

**Table 4: Summary of Austrian Consultations on Directive 2011/24/EU**

Art. DIR	Observations	Healthcare actors	Civil society	Land Entities	No
<b>Art. 4(2) (b)</b>	Specification as to the detailedness of information on liability insurance	KRAGES, ÖÄK, ÖZÄK			3
<b>Art. 4(2) (b)</b>	Specification regarding the provision of information on treatment costs (tariffs or overall costs; only on demand; only for incoming patients or generalization)	KRAGES, ÖÄK, WKÖ, Industriellenvereinigung, SV		Vorarlberger, Salzburger, Wiener, Steiermärkische Landesregierung	9
<b>Art. 4(2) (b)</b>	Invoice for incoming patients fulfilling requirements to reimbursement in the home country is not tangible	ÖÄK, ÖZÄK		Wiener Landesregierung	3
<b>Art. 6</b>	More coordination and task-sharing and additional resources for the NCP	GÖG			1
<b>Art. 6</b>	Deepen and clarify the NCP information scope (include quality assessment and make it easily available)	AKÖ	Organtransplantierte, ARGE	Wiener Landesregierung	4
<b>Art. 6</b>	Change responsible institution for delivering information to NCP into AKÖ	ÖGB, AKÖ			2
<b>Art. 6</b>	NCP should be liable for correctness and completeness of information	ÖGB, WKÖ Industriellenvereinigung, AKÖ			4
<b>Art. 6</b>	No duplication and parallel structures as to the NCP and other bodies	ÖÄK, SV			1
<b>Art. 6</b>	Inclusion of further organisations cooperating with the NCP (ARGE Selbsthilfe; healthcare providers)	Industriellenvereinigung, WKÖ	Organtransplantierte, ARGE		4
<b>Art. 7</b>	Clarity on diverse mechanisms for reimbursement for cross-border healthcare in Austria	ÖGB, SV, Industriellenvereinigung, WKÖ			4
<b>Art. 7</b>	Division of reimbursement for ambulant treatment sounds reasonable	ÖGB			1
<b>Art. 7</b>	Reimbursement deduction for ambulatory treatment is not EU-Law conform	AKÖ			1
<b>Art. 7</b>	Higher financial burden for public spending (i.e. social assistance authority)	AKÖ		Steiermärkische Landesregierung	2
<b>Art. 8</b>	Definition of evaluation criteria for prior authorisation (defining 'systemic failure', 'ambulant' treatment, list of treatments, standardisation of consideration periods)	ÖGB, WKÖ, AKÖ		Vorarlberger, Wiener, Steiermärkische Landesregierung	6
<b>Art. 8</b>	Semantic change: Explicit clarification of prior authorisation and reimbursement	GÖG, SV		Vorarlberger Landesregierung	3
<b>Art. 8</b>	Evaluation of prior authorisation shall be scrutinized by a risk-benefit-analysis		ARGE		1
<b>Art. 8</b>	No bureaucratic complication regarding prior authorisation for dialysis patients		Organtransplantierte		1
<b>Art. 8</b>	Regulate benefit baskets deriving from accident insurance and pension insurance	AKÖ			1

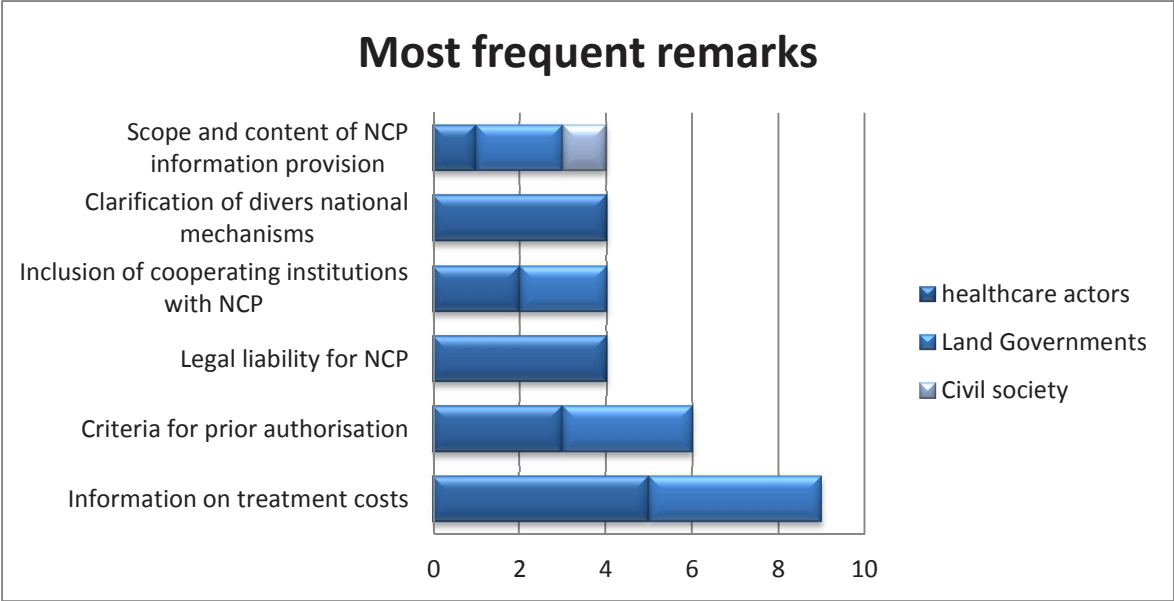
Source: Author

Figure 4: Frequency of Discussed Articles in Austria



Source: Author

Figure 5: Most Frequent Remarks Made in Austrian Consultations



Source: Author

#### 4.4 Discourse Evaluation

The above presented national discourses in Germany, Poland and Austria depict some patterns regarding intra- and inter-state behaviour and processes. Although it is not possible to give an account of the complete public consultations, the type and wording of arguments presented draw a national picture of the debate’s intensity, scope and content regarding the Patients’ Rights Directive. Even if official hearings and public consultations are only one part of the overall domestic debate, they are an optimal tool for analysis since their aim is to

critically reflect on the proposed reform, here the transposition process. In the following, a short domestic picture of each country shall be drawn as part of the process-tracing.

### **Process-tracing of the national transposition discourse**

In Germany, the 22 analysed statements were strictly related to Art. 4(2)(b) and Art. 6 of the Directive. This is in accordance with the analysis conducted in Table 1, concluding that Germany already had transposed the part on access and finance, i.e. Art. 7 and Art. 8. The first observation refers to the number of comments from healthcare actors and civil society. A balanced picture of stakeholders evolved in Germany, with respectively 10 and 11 organisations. The most frequent comment called for a specification of duties, rights and explicit formulation of legal concepts (mentioned 12 times). The other referred to disclosure of costs on IGeL-services and the right to a retention period or withdrawal (mentioned 12 times). Adding the other comments on prevention of unprecedented costs, the latter is a clear demand of civil society towards more rights for patients. Several further claims, including the one on dispensing a Patientenbrief (mentioned 7 times), press for more patients' safety and privilege. On the other hand, the second demand regards semantic clarity of the legal concept and its practical implications for healthcare actors and patients. This shows that one of the most critical points in the German discourse is connected with only some details and minor conceptual aspects of legal certainty. Further, a clear division between German healthcare providers and civil society appeared in the debate, showing that the first insist on less self-responsibility (e.g. regarding cost information or its comprehensiveness), whereas the latter push for more patients' rights. Although opposite positions resulting from each organisation's needs might appear logical, such behaviour was not observable to this extent in other countries. Moreover, some stakeholders representing specific social groups express demands closely connected with the interests of their members (see pleas for enforcement of mentally-ill or exclusion of private insurance funds). Interesting is also the lack of a NCP discourse, as the greatest novelty in Germany, which can be traced back either to seemingly non-public debates on the NCP or the unexplainable tardiness in its presentation (cf. Appendices). Germany is also the only country, where costs for the NCP should not be covered by public spending, but by a group of healthcare actors. Summing up, in Germany the discursive struggle was mostly limited to self-interest driven demands or the questioning of few provisions from the governmental draft.

As for Poland, the discourse was characterised by the predominant focus on access and finances (Art. 7 and Art. 8 together comprised 80 % of arguments), even though all provisions of the Directive had to be implemented domestically. The most frequent argument, uttered by 6 of 7 stakeholders, criticized the exclusion of drugs from the state's medication programme from reimbursement. The accusation that the Polish proposal infringes upon Art. 1(3) Directive 2011/24/EU and is thus incompatible with EU-law was complemented by the plea for a broader refund scope, including this medication. Regarding reimbursement, critiques as to the (wrong) calculation basis for refund and its conditioning on the principle of economy were often stressed (each mentioned 4 times). Next to the evident problems concerning reimbursement, the possibility to appeal against a negative authorisation or reimbursement decision was frequently remarked, where legal recourse instead of a complaint procedure shall be provided. This should serve not only as a patient right, but also guarantee legal certainty for Polish and incoming patients. Overall, the discourse in Poland

was shaped by intrinsic questioning of the governmental proposal. Moreover, the critique expressed by the stakeholders was not simply semantic in nature, aiming to clarify parts of the provisions. The discussion opposed the legal and practical foundation of the Polish implementation draft, claiming incompatibility with the Directive. Such accusations of improper transposition or under-implementation indicate how serious and contested the proposed legislation and the idea behind it are. The government's behaviour suggests unwillingness towards appropriate transposition, which would be in accordance with the Polish vote against the Directive in the EC (cf. Appendix B). A further interesting observation resulting from the analysis is the lack of discussion on the NCP and information provision. This possibly emanates from the assumption that access to information is subordinate if admittance and finances of healthcare are not (or inappropriately) regulated. Nonetheless, such non-discussion clearly does not stimulate improvement and further development of those provisions. Beside the possibly grounded critiques, several demands are either patient-friendly pleas for more privileges and rights, or claims going beyond the Directive's provisions. Exemplary thereof is the demand of STOMOZ to re-evaluate and reform the Polish contracting system in healthcare. In sum, the Polish discourse evidently reveals intrinsic shortcomings in the Polish transposition process.

Concerning Austria, the discourse of articles regarding information provision on the one hand, and access and finances on the other, was very balanced (at a ratio of 50:50 %). The most frequent remark (mentioned 9 times) criticized the obligation for healthcare providers to inform all patients on occurring treatment costs. Reasons for this critique were first its impracticability, and second its rulings far beyond the Directives requirements. Several other comments (like invoice issuance and information on liability insurance) reflected the same argumentation. Austria's stakeholders take a very critical stance towards the Directive and, unlike in other compared states, reproach the government for over-implementing its provisions. Regarding the type of arguments, it becomes evident that the discourse is very self-interest driven. Associations make far more comments on their own or their members behalf than elsewhere, demanding the inclusion of specific tasks, the exclusion from particular responsibilities or privileges for members. Next to such pleas, several comments regard definition, clarification and semantic specification for the provisions. As in Germany, those demands are only as critical as the draft is unspecific to the depth and scope of some aspects, but they do not question the overall transposition proposal. Furthermore, unlike in both prior countries, the NCP is more debated, specifically its legal status (liability), formation (cooperating partners) and information scope (more detailed provision). Interestingly, Austria is the only country in the sample, where more healthcare actors expressed critique towards the governmental draft than civil society. This explains the prevalent demands of minimizing the responsibilities for healthcare actors. Also regional entities, i.e. the governments of the Länder, were more prominent in this debate than in other countries. Their active participation in this process is congruent with the finding that Austria voted against the Directive based on the opposition of the subnational level (cf. Kostera 2013). The Länder's discursive presence and focus on treatment costs and prior authorisation confirms their prior fears of not being allowed to fully charge foreign patients and thus bearing financial burden. Their participation also indicates that one factor influencing the Austrian discourse is its federal character with extensive self-administration rights for the Länder in the healthcare area (cf. Kostera 2013).



## Key aspects of domestic debates and cross-country trends

This section will be dealing with the question of what were the key aspects of domestic debates on the Patients' Rights Directive, including observations on inter-state trends and conclusions from the cross-national discourses. Key aspects reflected on prior authorisation, reimbursement, information provision and National Contact Points, but the intensity of discourse depended on the type of misfit (see hypothesis below). The type of critiques expressed by stakeholders was in all states a mix of demands for correct transposition, legal certainty, semantic clarity and detailedness, patient-friendly development and self-interest. Besides, in each debate various perspectives were used for argumentation. The discursive story line of various discourse coalitions was a mix of economic, social, practical and legal arguments. Tactics of individualisation and generalisation were assumed by using self-impact or abstraction to make a valid point (cf. Bechmann 2007: 33 f.). Interestingly, discourse coalitions, as organisations claiming similar arguments, were not only formed within the group of healthcare actors or civil society. Arguments with support from various groups may indicate the importance of such claims, as they are uttered by several different societal representatives. Furthermore, what can be deduced from cross-national discourse is that access and finances (Art. 7 and Art. 8) are most critical in the Directive, which can be seen by looking at the intensity of discussion in the respective countries and academic literature. In Germany no debate occurred since the two most controversial provisions were already implemented before the Directive. In Austria they were partly existent, thus controversies on the remaining parts were present. In Poland, these "new" provisions were most intensely debated and contested. This finding is in congruence with the statement of Legido-Quigley et al. (2011:366), that already during negotiations between the EC and Parliament, the most controversial issues have been: "prior authorisation, prepayment, treatment of rare diseases, the definition of quality and safety standards, and e-health". Aside from the aspects not relevant for transposition, it is evident that Art. 7 and Art. 8 of the Directive were, and still are, most disputed and problematic in implementation. The logic that the most controversial issues are the most frequently debated, might also explain for why it appears that Poland faces the most frequent accusation of infringing upon Directive 2011/24/EU.<sup>24</sup> Reverse, the National Contact Point was surprisingly little contested, although some debate on its practical functioning occurred. In the context of its practical conducting, it is to mention that the Commission mandated PWC to conduct a feasibility study as to approaching the NCP websites.<sup>25</sup> Either this recommendation limited the discussion, or the NCP is seen as an issue to be just dealt with in practice.

Moreover, one can deduce from the sense and language of the arguments that intensity of controversy varies among the countries. It was most critical in Poland, followed by Austria which can be described as modest, and lastly by Germany, where minor criticism was voiced. Evidently, in every member state stakeholders made remarks according to their interests, nonetheless the degree of change proposed fluctuates from semantic change in Germany (and somewhat Austria) to completely remodelling provisions in Poland. The content of

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<sup>24</sup> Even if one assumes that such accusation was partly used as an argumentative tactic.

<sup>25</sup> The PWC recommendation is available on the EU website:

[http://ec.europa.eu/health/cross\\_border\\_care/docs/pwc\\_national\\_contact\\_points\\_website\\_en.pdf](http://ec.europa.eu/health/cross_border_care/docs/pwc_national_contact_points_website_en.pdf).



debates varies considerably among the member states, but nevertheless similar trends are observable. A visible behavioural pattern in all states is the division between healthcare providers and patient organisations. The latter demand often more than is foreseen in the Directive. They are pushing the government to implement a wider range of rules or to loosen the set of requirements, but it cannot be said that those claims all derive from the Directive. On the other hand, healthcare providers plea for minimal regulations and obligations, in order to stay as close as possible to status quo. Legislative changes would probably only give them more duties and thus restrict their discretionary power.

A further conclusion from the cross-national comparison of discourse contents concerns the degree of implementation. It is stated by several organisations in Germany that the PRG is a codification of patients' rights, but goes no further than the judicial rulings (cf. GKV-Spitzenverband, 2012:4; BAG Selbsthilfe 2012: 2; DKG 2012: 4; SoVD 2013: 2). On the other hand, the Polish proposal is being criticized for incompatibility with and incorrect transposition of the Directive (cf. NIL 2013; 1czerwca 2013; REF 2013; Stowarzyszenie ZZSK 2013). In contrast, Austria faces criticism of implementing too many provisions and generalizing the Directive's obligations towards all healthcare recipients (cf. ÖÄK 2013; ÖZÄK 2013; Wiener Landesregierung 2013; Vorarlberger Landesregierung 2013). In sum, Austria's transposition draft is to be described as over-implementation, Poland's as under-implementation and Germany's as balanced implementation, codifying judged law. It is to note in this context, that German representatives pushed already during negotiations on the Patients' Rights Directive for a very narrow scope of the Directive, closely aligned with the ECJ rulings. Thus, not much transposition effort was required (cf. Appendix A). On the other hand, Poland and Austria voted against Directive 2011/24/EU in the EC. The positioning during negotiations can explain Poland's reluctant transposing attitude and the widely criticized draft. However, in the case of Austria the accusation of over-implementation is surprising, taking into account its voting behaviour. Then again, as Kostera concludes, the subnational Länder Governments persuaded the federal Government to a negative vote (Kostera 2013: 154). Thus, Austria's legislative transposition draft might not be a full reflection on the regional, rather the federal position. Recapitulating, key aspects of domestic debates have been indentified, even if their presence and intensity varied among the countries. Though analogies in stakeholder's behaviour and national patterns of transposition were singled out, differences prevail over similarities in the cross-country comparison. Further, explanations for the respective domestic variations of transposition were presented.

### **Testing the three hypotheses**

The last section of discourse analysis will focus on testing the three hypotheses. The goodness of fit approach is an optimal explanation model regarding the scope of transposable provisions and thus the scope of discourse. As derives from Table 1 and the intermediary results presented in section 2, misfit is a necessary, but not sufficient condition for domestic changes and the affiliated debate. Since Germany had already implemented most of the Directive's provisions, the domestic reform and consultations were narrow and less controversial. Austria is an example of medium misfit, where obligations resulting from the Directive are domestically in place, but require optimization to fully comply with EU law. Poland has a high misfit level between national and European rules, thus it requires most domestic change in legislation. Thus, it is valid that adaptational pressure is higher, if the compatibility of policies is lower. As in misfit approach policy change is a result of interaction

between national government and affiliated stakeholders, the degree of goodness of fit determines the discursive scenery. Nonetheless, as Treib (2003: 3) points out, misfit explains only part of the transposition process and domestic adaptational patterns. In this study it illustrates the content and intensity of discourse as well as the severity of arguments and disputes, but not the volume of participation; neither can this approach clarify on which aspects interest groups focus and what motivates them. Further, it is evident from the cross-country analysis, that the quantity of stakeholders is not correlated with the number of transposable provisions. In German consultations the number of participants was highest, even though the scope of articles relevant for implementation was lowest. In Poland the observation is opposite, whereas Austria is positioned in between. To explain this phenomenon, one should review not the misfit approach, but civil participation, corporatism and advocacy theories. Moreover, a sociological analysis of the country-specific culture towards decision-making and involvement of stakeholders in the formal legislative process may give insights into the nation's individual structure and behavioural patterns. As Bechmann (2007: 24) remarks, discourse is constituted by the country-specific societal codification of reality ("gesellschaftsspezifische Kodierung der Wirklichkeit").

The second hypothesis expected the Directive to give not only cross-border rights, but general patients' rights (cf. Peeters 2012). Similar assumptions as to benefits for domestic healthcare recipients and a higher impact on national policies than mere cross-border care can be found in academic literature (cf. Palm, Beaten 2011: 273; Delnoij; Sauter 2011: 271). All are validated by the findings in Table 1 as well as the discourse analysis. In the German case, the *Patientenrechtegesetz* embraced from the beginning all patients treated domestically, including foreign and German citizens. The aim of the legislative act was to strengthen patients' rights, irrespective of their member state of affiliation, even though one can assume that the ulterior motive of PRG were German patients (or insured in Germany). This is in congruence with the fact that the PRG was originally a general healthcare reform act, where just some provisions from the Directive had been incorporated, nonetheless leaving the predominantly universal approach (e.g. information right, right to medical records etc). As to Poland, it is not specifically mentioned by the legislator how wide the application scope will be understood. But by deducing from the draft changes, the term "patient" is used. Since in other provisions it explicitly referred to incoming patients (cf. MZ 2013: 22 f.), this may be an indicator for the universal application of the information rights. As respective articles of the Directive were not an important part of public consultations, it can only be deducted from the governmental proposal. In Austria special rights for outgoing or incoming patients are included in the proposed legislation, like to reimbursement or to specific invoices. Nevertheless provisions regarding information obligations towards patients are formulated in a general manner. This suggests – and is a point of criticism from healthcare providers – that the information duties for costs and treatment details are to be provided to each patient, including Austrian insured. Concluding, the Patients' Rights Directive on cross-border healthcare indeed includes obligations applicable to all patients. In other words, the Directive was interpreted in the analysed countries as more than a non-discriminatory right, by translating privileges and obligations towards universally valid national acts. However, this finding is particularly accurate for "new" patients' rights included in this Directive. As Delnoij and Sauter (2011: 271) put it, the Directive include "old" rights, which codify the ECJ rulings regarding reimbursement and prior authorisation, and "new" rights concerning information provision, transparency and accountability. Domestic patients benefit from the "new" rights,

inasmuch as detailedness and legal certainty regarding information on treatment is improved.

Lastly, Legido-Quigley et al. (2011) concluded from the negotiation and formation phase of the Directive that most problematic areas will remain administrative, conceptual and practical issues – during and after the implementation process. An intra- and inter-state comparison of debated aspects indeed reveals that the most critical issues correspond with the above. In Poland the comments on administrative problems regarding prior authorisation, reimbursement and cost calculation are especially evident. In all fields problems with the transposition of the Directive's goals are visible. Likewise, Austria's parallel reimbursement mechanisms cause not only confusion but are also viewed as administratively non-operable.<sup>26</sup> Another questionable area concerns clear definition of vague concepts, for example the specification of a medically justifiable waiting time. As appears from the discourse, the assumption is valid for this example, as well as many other provisions of the Directive. In Poland and Austria stakeholders demand clarification regarding the scope and understanding of 'waiting time'. Moreover, interest groups from all three countries criticise the partly vague and unspecific legal proposals, which leave too much room for interpretation. As indicated by each summary table, semantic clarity was a frequent demand as to how and to what extent specific provisions apply. It appears that only after public consultations did legislators become aware of the conceptual problems in their drafts. This is further valid for the practical execution of the Directive's obligations. Questions of pragmatic and functional nature were brought up by experts and professionals, which deal with the Directive's provisions in daily practice. Those questions vary depending on diverse national laws, which are to be adjusted to the requirements of the Directive. Although these problems are more by-products than specific obligations deriving from the Directive, they need clarity in order to be applied. Nonetheless, it is noteworthy that despite those problematic areas discussed in consultations, the discourse is shaped also by demands driven by self-interest, criticism as to the correct transposition of specific articles and proposals going beyond the Directive's implications. As for the latter, comments unrelated with the Directive are perceivable where stakeholders take the opportunity to place own claims during discussions on a certain policy field. Regardless of the variety of argumentation types, the hypothesis postulated by Legido-Quigley et al. was confirmed by the case study analysis. Likewise, as she assumed, the different interpretation and transposition of the Directive may cause differences between member states (cf. Legido-Quigley et al. 2011: 366). These regard the benefit basket, prior authorisation procedure and information scope. Next to these obvious fields, differences may also occur regarding practical and legal aspects, which will become apparent only after implementation.

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<sup>26</sup> The argument referring to administrative problems with reimbursement and prior authorisation does not apply to Germany for obvious reasons of misfit (i.e. already implemented).

## 5 Conclusion

The Patients' Rights Directive, as "the first harmonization Directive concerning health care" (Delnoij, Sauter 2011: 271), was implemented on national level on October 25<sup>th</sup> 2013. Before each final national transposition act was adopted, a domestic discourse regarding the Directive took place in the countries. The discourse analysis, undertaken from an actor-centred perspective, already allows for conclusions regarding the most critical points of the Directive and transposition patterns in the member states. The intra-country study and cross-national comparison revealed considerable differences among a small sample of three EU-states, with only some analogies regarding stakeholder and governmental behaviour. This results not only from the difficult and debated area of health policy, but also from country-specific characteristics. By analysing the discourse content, partly national viewpoints, preferences and mind-sets can be identified. Those indicate what problems and difficulties the Directive's provisions generate, and how it will not succeed in overcoming existing differences among states.

The transposition picture drawn in this paper results from the voting position of member states, the misfit study, the governmental transposition proposals as a discursive starting point and statements of stakeholders in domestic consultations. The last figures as a critical examination of the implementation draft, which broadly inspects the national legislative act. Process-tracing shows significant differences regarding scope and content of the transposition discourse. In Germany, overall 22 statements commented on the draft, while the content of discussion on the provisions of the Directive was only limited towards Art. 4(2)(b). Only 4 comments were given regarding the NCP in the public consultations, which can be partly explained by the delayed incorporation into the transposition draft. In contrast, the Austrian Ministry received 15 statements, which included remarks on all four articles. A balanced debate on the information provision but also access and finances occurred. The most intense discussion took place in Poland, even though only 7 stakeholders took part. This discrepancy between participation and discourse intensity can be explained by a country-specific culture towards decision-making and the approach to formal legislative processes, as well as the corporate structure in the respective country (e.g. see participatory approaches in political theories). Next to those approaches, the fact that European policies are decided by a qualified majority, forces individual countries to sometimes "download" inconvenient policies. "Finally, information asymmetries or incomplete information about the costs of compliance may also explain why states accept norms and rules that constitute a serious misfit" (Börzel, Hofmann, Sprungk 2004: 13).

An interesting but diversified picture evolved from the cross-country discourse analysis. Germany supported the Directive in the EC, but tried to channel its form in the German legislative direction. This successful advocacy and the already implemented aspects of the Directive caused merely a minor controversial public discourse. However, Poland disapproved the Directive and this opposing attitude persisted, influencing the transposition draft and process. It is the country in the sample, where not only minor aspects but the fundament, i.e. the core idea behind a transposition proposal, was questioned. Several provisions were doubted by stakeholders as to their compatibility with the Directive. On the other hand, though Austria voted against the Directive in the EC, it transposed the necessary provisions accurately, even being accused of over-implementation. Although in the domestic

debate stakeholders also criticized the governmental draft and demanded changes as to the scope of responsibilities, clarification and adjustment of legislation, it seems that its initial voting position did not influence its implementing behaviour. Yet, the very late transposition start – with consultations from July till mid-August 2013 – may indicate a more reluctant position. One can deduce from this case study analysis, that it is not critical any more that Europeanization influences member states. "The issue is no longer whether Europe matters but how it matters, to what degree, in what direction, at what pace, and at what point of time. [...] Most studies draw on several mechanisms to explain the domestic change they observe" (Börzel, Risse 2003: 60). This paper showed how diverse the transposition picture is and what factors should be scrutinized, to understand the different patterns in order to improve the EU's coordination efforts.

Lastly, this paper scrutinized three hypotheses regarding transposition of EU directives in general (goodness of fit) and the content of the Patients' Rights Directive in particular. It was shown, that misfit demonstrates a valid approach explaining the scope of transposition and its affiliated discourse. Nonetheless, this approach is a necessary, but not sufficient explanatory variable. The next hypothesis proved that Directive 2011/24/EU offered rights for patients beyond their the cross-border character. This is particularly valid for the "new" rights connected with information provision, transparency and accountability. The legal certainty improved in those areas is a universal benefit for all healthcare recipients. Finally, the hypothesis of Legido-Quigley et al. regarding the problematic areas of the Patients' Rights Directive was validated. Next to other, nationally specific difficulties and differences, the problematic fields were of administrative, conceptual and practical nature.

Recapitulating, the analysis reveals considerable discrepancies among European states in the transposition process of the EU Patients' Rights Directive. The contrast occurred in the number and type of stakeholders, the emphasis in the discourse and frequency of discussed articles. Moreover, also the general approach towards implementation, including national voting position in the EC, the goodness of policy fit, accurateness of implementation and timing of public consultations, varied immensely among the member states. This diversity shall motivate academics to further observe and scrutinize the evolvement and development of this Directive, especially its effectiveness and harmonization effect of EU-wide transposition. More generally, if cross-border healthcare is to be improved by this Directive, an accurate and akin implementation has to be guaranteed. This analysis thus indicates how important the process of transposition, as part of EU law-making, is for the correctness and success of European politics. A stronger emphasis on the implementation phase is required to closely understand, analyse and improve the functioning of the *Acquis Communautaire*.

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## 7 Appendices

Statement from the Ministry of Health, Department Z 32: General Affairs of the EU; EU-Coordination. Questions were asked in two Emails, on August 23<sup>th</sup> and August 29<sup>th</sup> 2013. The responses were received on August 29<sup>th</sup> and September 3<sup>rd</sup> 2013. To guarantee legibility of the correspondence, in the reply Emails from the Ministry my questions were included [italics in square brackets].

### Appendix A: Reply Email from August 29<sup>th</sup> 2013

Liebe Frau Goscinska,

einer Antwort auf Ihre Fragen bezüglich der Umsetzung der Richtlinie Patientenmobilität möchte ich zunächst vorausschicken, dass die Bundesregierung schon bei den Richtlinienverhandlungen darauf geachtet hat, dass die Richtlinie sich möglichst eng an die bis dahin ergangene einschlägige EuGH-Rechtsprechung hält und in Deutschland möglichst wenig Umsetzungsbedarf auslösen soll. Richtlinienkonforme Regelungen zur Kostenerstattung und Vorabgenehmigung sind in § 13 Abs. 4 und 5 SGB V bereits seit 2004 enthalten.

Demgemäß gibt es in Deutschland kein einheitliches, zusammenhängendes und in der Öffentlichkeit als solches wahrnehmbares Umsetzungsgesetz, sondern die noch fehlenden Elemente werden punktuell durch einzelne Regelungen geschaffen. Vgl. zum Ganzen auch BT-Drs. 17/12896 (Kleine Anfrage).

zu den einzelnen Fragen:

*1. [Art. 7 der Richtlinie - Nationale Kontaktstelle - was gab es da für Überlegungen, kritische Punkte, Einwände usw. Wie war die Kommunikation mit dem GKV-Spitzenverband?]*

Da die Richtlinie es den Mitgliedstaaten offen lässt, eine oder mehrere nationale Kontaktstellen einzurichten, und da Deutschland ein föderal organisierter Staat ist, stand zum einen die Überlegung im Raum, ob eine Kontaktstelle auf Bundesebene eingerichtet wird oder ob die Aufgabe den Ländern zufallen soll. Von Länderseite wurde deutlich gemacht, dass die Einrichtung von 16 Kontaktstellen in 16 Ländern nicht zielführend und sinnvoll sei und die Einrichtung einer einzigen Stelle auf Bundesebene zu bevorzugen sei.

Ausgangspunkt der Überlegungen zur Einrichtung einer einzigen Stelle war, eine bereits bestehende Einrichtung mit einschlägigen Vorerfahrungen und Kompetenzen zur nationalen Kontaktstelle auszubauen. Die teure Schaffung einer völlig neuen Struktur sollte vermieden werden. Auf der Basis dieser Überlegungen wurde bald deutlich, dass sich die DVKA am besten eignet.

*2. [Art. 4(2)(b) - die Informationspflicht für Gesundheitsdienstleister - sind alle Vorgaben der Richtlinie diesbezüglich bereits im deutschen Recht verankert? Gab es hier keinen Umsetzungsbedarf?]*

Die Informationspflichten der Gesundheitsdienstleister nach Art. 4 Abs. 2b) der Richtlinie sind teilweise durch das Patientenrechtegesetz vom 20. Februar 2013 in § 630c) als

vertragswesentliche Elemente des zivilrechtlichen Behandlungsvertrags geregelt worden: Die erforderliche Information über Diagnose, gesundheitliche Entwicklung, Therapie und nach der Therapie zu ergreifende Maßnahmen nach § 630c Abs. 2 erfüllt die Anforderungen der Richtlinie bzgl. der Information über "Behandlungsoptionen". Darüber hinaus ist in § 630c Abs. 3 BGB eine Kostenaufklärungspflicht normiert, wenn der Behandelnde weiß oder den Umständen nach erkennen kann, dass eine vollständige Kostenübernahme durch Dritte nicht gesichert ist. Damit ist die Pflicht zur Erteilung von klaren Kosteninformationen aus der Richtlinie erfüllt.

Die übrigen Pflichten der Gesundheitsdienstleister aus Art. 4 Abs. 2b) der Richtlinie (Information über Verfügbarkeit, Qualität und Sicherheit, klare Rechnungen, Zulassungs- und Registrierungsstatus, Versicherungsschutz) werden von den Ländern im Rahmen ihrer Zuständigkeit für die Berufsausübung der Gesundheitsberufe geregelt. Entsprechende Gesetzgebungsaktivitäten in den Ländern laufen.

3. *[Kurze Begründung, warum aus deutscher Sicht eine öffentliche Debatte nicht nötig war]*  
öffentliche Debatte - s.o.: nur noch punktuell bestehender Umsetzungsbedarf; die dazu erforderlichen Regelungen wurden teils -wie die Regelung zur nationalen Kontaktstelle oder die Regelung in § 20 Abs. 3 der Apothekenbetriebsordnung - in anderweitige Gesetzesvorhaben (Patientenrechtgesetz) eingegliedert und machten in diesem Zusammenhang keinen Debattenschwerpunkt aus. Sie waren Gegenstand des ordentlichen Gesetzgebungsverfahrens / Verordnungsgebungsverfahrens. Darüber hinaus wurde im Februar 2012 vom BMG eine Konferenz zur Richtlinienumsetzung durchgeführt; Anlässlich des Besuches der Kommission im Dezember 2011 hatten interessierte Beteiligte die Gelegenheit zum Informationsaustausch mit BMG und Kommission.

4. *[Gibt es Dokumente über die Umsetzung (Aufzählung der bereits existierenden Gesetze und Verweis auf die Umzusetzenden usw.) - in diesem Zusammenhang: wie bereits erwähnt, habe ich ein Dokument des Bundestages gefunden (Drucksache 17/8637, vom 10.02.2012) wo Frau Widmann-Mauz darauf hinweist, dass "derzeit geprüft wird, ob und ggf. inwieweit die gegenüber dem Rechtsstand von 2004 erweiterten Möglichkeiten der Mitgliedstaaten, eine Vorabgenehmigungspflicht für Auslandsbehandlungen vorzusehen, genutzt und im SGB V verankert werden sollen" (S. 72, Frage 104). Gibt es ein solches Dokument bzw. eine Stellungnahme die eine solche Evaluation beinhaltet?]*

Legislative Umsetzungselemente:

- Patientenrechtgesetz (Patientenakte; Informationspflichten der Gesundheitsdienstleister (z.T.), Schaffung der gesetzlichen Grundlage für die nationale Kontaktstelle in § 219a und § 219d SGB V
- 4. Verordnung zur Änderung der Apothekenbetriebsordnung: Normierung der Pflichten für Apotheker aus Art. 4 Abs. 2b) in § 20 Abs. 3 der Apothekenbetriebsordnung
- Verordnung zur Umsetzung der Regelungen der Europäischen Union über die Anerkennung von in anderen Mitgliedstaaten ausgestellten ärztlichen oder zahnärztlichen Verschreibungen von Arzneimitteln und Medizinprodukten (Bundesrats Drucksache 615/13) zur Umsetzung des Art. 11 der Richtlinie sowie der Durchführungsrichtlinie 2012/52/EU (Zustimmung des Bundesrates steht noch aus).

(-Umsetzungsgesetze der Länder bzgl. der Pflichten der Gesundheitsdienstleister aus Art. 4 Abs. 2b) und d)

5. *[Gibt es seitens der EU Kommission, die den Umsetzungsprozess unterstützt (bzw. "überwacht"), Stellungnahmen und Hinweise für Deutschland zur Umsetzung der einzelnen Artikel?]*

Unterstützung der Kommission:

Die Kommission war in jedem Mitgliedstaat, um dort die Ausgangsvoraussetzungen und Notwendigkeiten der Umsetzung zu besprechen, in Deutschland im Dezember 2011. Des Weiteren wurde zur Richtlinie - da sie an verschiedenen Stellen den Erlass von Durchführungsrechtsakten vorsieht - ein "Komitologieausschuss" eingerichtet ("Cross Border Healthcare Committee"), in dem auch Deutschland vertreten ist und den die KOM teils auch nutzte, um Hinweise zur Richtlinienumsetzung zu geben, z.B. durch Vorstellung einer bei Pricewaterhouse in Auftrag gegebenen Machbarkeitsstudie zum Informationsangebot der nationalen Kontaktstellen oder durch die Übermittlung von "Benchmarking Papers"

6. *[Gab es Stimmen, die eine öffentliche Debatte verlangt haben oder die im Kontext der Richtlinienumsetzung die bisherigen Regelungen abändern wollten? Würden Sie sagen, eine Debatte hätte die deutsche Umsetzung verzögert?]*

öffentliche Debatte: s.o.; keine Verzögerungen dadurch

7. *[Haben Sie mit anderen Ländern kommuniziert? Gab es einen Erfahrungsaustausch?]*

Kommunikation/Erfahrungsaustausch mit anderen Ländern:

- bei der Konferenz im Februar 2012 in Berlin waren Vertreter aus UK und Polen eingeladen, die ihren Umsetzungsansatz erläuterten
- In Brüssel wurden von der KOM Workshops der Mitgliedstaaten-Vertreter initiiert, die dem gegenseitigen Austausch über einzelne Richtlinien-Themen dienten, z.B. Einrichtung der nationalen Kontaktstelle.

8. *[Was waren die kritischen Punkte bei der deutschen Richtlinienumsetzung?]*

Kritische Punkte bei der Richtlinienumsetzung:

Es sind keine grundlegenden Kontroversen aufgetreten. Die Herausforderung der Richtlinie besteht darin, dass ihre Regelungen in verschiedene Rechtsmaterien hineinwirken und auch die Länder mit betreffen.

9. *[Gibt es Statistiken für Deutschland die zeigen, wie viele Patienten seit 2004 (seit dem GMG) die Möglichkeiten der grenzüberschreitenden Gesundheitsversorgung genutzt haben?]*

Detailliertes Datenmaterial über das Ausmaß und die Art der grenzüberschreitenden Gesundheitsversorgung ist kaum vorhanden. Die KOM will die Erkenntnislage auf der Grundlage des Art. 20 der Richtlinie verbessern. Allerdings sind die Mitgliedstaaten nur verpflichtet, verfügbare Informationen zu liefern. Die Einführung neuer Datenerhebungen ist in Deutschland nicht vorgesehen.

## Appendix B: Reply Email from September 3<sup>rd</sup> 2013

Liebe Frau Goscinska,

1. *[War Deutschland im Ministerrat für oder gegen die Patientenrichtlinie?]*

Deutschland hat im Rat --für-- die Richtlinie gestimmt (dagegen waren Polen, Portugal, Rumänien und Österreich; enthalten hat sich die Slowakische Republik.) Polen, Portugal und Rumänien haben eine Erklärung zu Ihrer Haltung abgegeben, s. beigefügtes Dokument.

2. *[Den Stellungnahmen des Bundesrates zum Gesetzesentwurf habe ich entnommen, dass dieser sehr "patientenfreundliche" Vorschläge zu Patientenrechtegesetz gemacht hat. Dies hatte mich etwas überrascht, würde ich doch durch die föderalistische Struktur eher von Streitigkeiten bzw. Kommentaren dieser Natur ausgehen. Wissen Sie, warum die Bundesrat-Stellungnahme so ausgefallen ist?]*

Zur Meinungsbildung innerhalb des Bundesrats zum Patientenrechtegesetz bin ich nicht auskunftsfähig; auch zum Gesetzgebungsverfahren aus 2003 (GMG) habe ich die von Ihnen angefragten Informationen nicht.

3. *[Warum wurde die Nationale Kontaktstelle erst mit einem Änderungsantrag in das Patientenrechtegesetz mit rein integriert und nicht direkt mit anderen Maßnahmen?]*

Da es kein eigenes Umsetzungsgesetz zur Richtlinie Patientenmobilität gibt, mussten die notwendigen gesetzlichen Änderungen im Zuge eines anderweitigen Gesetzgebungsvorhabens in die Wege geleitet werden - das Patientenrechtegesetz war von der Thematik und vom Verfahrensstadium her geeignet.

4. *[Welche Aspekte des Patientenrechtegesetzes setzen noch die Richtlinie um, ohne dass darauf hingewiesen wird (neben § 630h zu Kosteninformationen, auch § 13a SGB V?) - eine Liste dieser Umsetzungsparagrafen wäre eine riesen Unterstützung.]*

s. die Aufzählung der legislativen Umsetzungselemente in meiner e-mail vom 29. August.

Abschließend noch der Hinweis auf die von der KOM bei PWC in Auftrag gegebene Machbarkeitsstudie zur Informationserteilung durch Nationale Kontaktstellen:  
[http://ec.europa.eu/health/cross\\_border\\_care/docs/pwc\\_national\\_contact\\_points\\_website\\_en.pdf](http://ec.europa.eu/health/cross_border_care/docs/pwc_national_contact_points_website_en.pdf).

Ich hoffe, damit auch Ihre e-mail vom 21.8.2013 beantwortet zu haben.

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