



FACULTY OF LAW
Lund University

Pamela Finckenberg-Broman

The scope of the healthcare exemption in the Services Directive

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Supervisor: Jörgen Hettne

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Forewords

'Exceptions are not always the proof of the old rule; they can also be the harbinger of a new one.' - Marie von Ebner-Eschenbach

My work with this thesis has brought me revelations about EU law similar to scientists finally getting grasp of the Big Bang Theory¹. This revelation would not have been possible without help along the way. I want to thank the people who had an important role to play during this mental journey. First of all my supervisor, Jörgen Hettne, LL.D, who has been a valuable guide in making sure I would not get lost in the jungle of European internal market law.

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¹ Note – The theory behind the Universe and everything's beginning, not the TV-series.

Abstract

The goal for this thesis was to understand the scope of the healthcare exemption in the Directive 2006/123/EC on Services in the Internal Market (Services Directive) as it applies to national legislation/authorities of the membership states (MS) of EU.

The basis for this thesis is the Services Directive; this Directive has certain exceptions in regards to the subject matter. Therefore, for a deeper understanding of the exception of the rule, first the Services Directive being the main rule is studied in a detailed manner, then followed by an in depth analysis of the exception.

To understand the subject matter of this thesis I researched several different sources of *EU aquis* to establish EU's definition of the scope for the terms "healthcare", "pharmaceutical services", "healthcare professional" and "regulated professions". Several court cases from the European Court of Justice (ECJ) were used to establish how these terms were interpreted and applied in practice.

This led me to pick out *inter alia* the Services Directive, Directive 2005/36/EC on the recognition of professional qualifications (PQD) and Directive 2011/24 on the application of patients' rights in cross-border healthcare (PRD) to be the key ones for the purpose of this thesis to see what their effect is and how they interact and influence each other in practice.

My conclusions are that there are four main accumulative steps that have to be in place for the Healthcare exemption to apply. If these steps are not fulfilled the service provided will be fully under the SD, unless a *Venturini* situation amounting to a public health concern is present. It would be helpful with either further guidance from ECJ case law or guidelines from the Commission on the subject to confirm or deny the accuracy of the findings presented here.

Abbreviations

THE EUROPEAN UNION (EU)

AG	Advocate General
Charter	Charter of Fundamental rights of the European Union
EC	European Communities /European Commission
ECJ	European Court of Justice
ECR	Reports of the Court of Justice of the European Communities
EEA	European Economic Area
EU	European Union
IMI	Internal Market Information system
O.J	Official Journal of the European Union (previously of the EC)
ORRPI	Overriding Reasons Relating to the Public Interest
PQD	Directive 2005/36/EC on the recognition of professional qualifications
PRD	Directive 2011/24 on the application of patients' rights in cross-border healthcare
Services Directive/SD	Directive 2006/123/EC on Services in the Internal Market. SD will only be used in conjunction with references to an article or recital to get a better flow of the text.
TFEU	The Treaty on the Functioning of the European Union
TNCs	Third country nationals

SWEDEN

NBT	National Board of Trade
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GENERAL

Art/art/Arts/arts	Article/article/Articles/articles
e.g.	for example
MS/MS's	Member State/Member States
NA/NA's	National Authority/National Authorities
NC	National Court
NRT	Nicotine replacement therapy
p/pp	page/pages
para	paragraph
PB	Public Body
i.e.	that is
SMEs	small and medium-sized enterprises

1. Introduction

1.1 Background to the problem

Today, EU's internal market is the world's largest economy with a gross domestic product over 12.000 billion euro. The services sector covers approximately 70-80 percent of the overall production in European Union (EU).²

Of the four freedoms, the cornerstones of the internal market, the key articles (art) for the services sector are arts 49 and 56 of the Treaty on the Functioning of the European Union (TFEU)³, which prohibits restrictions to the freedom of providing services and the freedom of establishment. These guarantee the service providers within the EU the right to both establish themselves and to provide services in other Member States (MS's). As the character of these articles is that of a negative integration, i.e. they function by removing barriers existing between the MS's of the EU, they must be interpreted when applied in practice.

Under these circumstances, a unified interpretation of the primary law in different MS's is visionary, but proved hard to achieve in reality. In practice, the regulatory environment in the different MS's varies immensely.⁴ Thus, in the pursuit of a more integrated internal Market within the services sector, additional legal tools in form of positive integration was required to amend discrepancies of the application of the arts 49 and 56 TFEU. To meet this need, the Directive 2006/123/EC on Services in the Internal Market (Services Directive),⁵ codifying legislative and practical measures, was adopted in December 2006. The aim of the Services Directive was to remove legal and administrative barriers to trade within the single market by simplified and more transparent procedures for small and medium-sized enterprises (SMEs) and consumers when they either provide (on temporary or more permanent basis) or use services within EU. The Services Directive is fully transposed today in all the Member States (MS's) as the deadline for this was three (3) years from adoption of the directive. However, the development of a policy on quality of service does not end there.⁶

The Services Directive requires MS's to abstain from measures that can impede the good functioning of the internal market and to vigilantly review their legal acts. The dual purpose of this is to ensure that no conflict with the Services Directive remains and that no new barriers of trade are being created unless they can be objectively justified by *express derogations* in art 52.2⁷ or *overriding reasons relating to the public interest* (ORRPI) originating from the ECJ case-law.⁸ A special attention should also be paid to art 16.3, which

² Bank, 2012 <http://data.worldbank.org/country/EUU>.

³ Consolidated versions of the Treaty on the Functioning of the European Union, 2008.

⁴ See Commission, Report from the Commission to the Council and the European Parliament on the state of the internal market for services, 2002 p 70.

⁵ Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on Services in the Internal Market, OJ L376 of 27.12.2006 pp 36-68.

⁶ See, e.g. Commission, Single Market scoreboard, 2013.

http://ec.europa.eu/internal_market/scoreboard/performance_by_governance_tool/priority_areas/index_en.htm

⁷ See recital 41SD for a definition of public policy in context of the Services Directive.

⁸ See, e.g. C-55/94, Reinhard Gebhard v Consiglio dell'Ordine degli Avvocati e Procuratori di Milano [1996] ECR I-4165, para 37. See also for a non-exhaustive list the preamble recital 40 and art 4(8) SD.

expressly limits the possibility of a MS to impose requirements to four exemption grounds in the case of provision of cross-border services.⁹

This is markedly crystallized in the notification obligation to the Commission in arts 39.5 and 15.7 SD. The MS must continuously notify changes in requirements concerning cross-border provision of services and establishment. In practice this means that the designated National Authorities (NA's) must assess, on case by case basis, if '*requirements which affect access to or the exercise of a service activity*'¹⁰ issued by other NA's, whether existing or new, are non-discriminatory, justified by reasons mentioned above and proportionate as well as if they are within the scope of the notification obligation.¹¹ As the concept of requirement is extremely widely drawn, it catches an extensive range of requirements including the ones with a neutral effect on free movement of services and establishment.

The Services Directive covers a broad range of service activities; hence, to enable an efficient and correct evaluation, a clear understanding of the scope of the Directive and its exemptions is of vital importance for the NA's designated to perform this task.

The same is true in context of the notification obligation; to ensure that no relevant restrictive measures created by the MS's escape assessment, due to lack of proper demarcation, notification must take place. I.e., to be able to know what to notify, there must exist an accurate definition of what needs not to be notified. This may be tricky at times as the scope of the application of a particular exemption is not always known due to lack of relevant Jurisprudence from the Court and insufficient guidance from the Commission.

A good example of one of these exemptions is the provision of healthcare in art 2.2(f) SD, expressly mentioned by the Services Directive.¹² It is unclear whether the interpretation of the exclusion is constructed narrowly or broadly. I.e. is the entire healthcare sector and/or sectors related to it excluded? Can some division be drawn between the actual provision of healthcare and a service that is not actually healthcare but related to it by either the nature of the service or the profession providing the service?

Thus, every time specific demands somewhat related to healthcare are being introduced by a MS, the NA chosen to make the relevant assessment must raise the question if the requirements are covered by the healthcare exception. To perform this assessment can be quite a challenge. Individual legal analysts may have varying opinions regarding the relevant scope leading to an inability to have a clear standpoint within the NA.

The ECJ case law has systematically considered non-justified measures constituting a restriction of relevant areas on the freedom of establishment and services as incompatible with arts 49 or 56 TFEU.¹³ In July 2013 the Court finally discussed the exemption of art 2.2(f) SD

⁹ NBT, Justifications under the Services Directive, 2013 p 3.

¹⁰ See the 9th recital SD.

¹¹ See arts 15.3 SD and 15.7 SD regarding establishment and arts 16.1 SD, 16.3 SD and 39.5 SD in context of services.

¹² Art 2(2) SD.

¹³ See, e.g. C-372/04 Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health [2006] ECR I-4325, paras 86-87.

in detail in its judgment in *Fermabel*.¹⁴ Just three months later came another ruling, *Ottica*,¹⁵ which shed further light on the matter. According to these rulings the concept of “healthcare services” is to be interpreted broadly in EU legislation.¹⁶ These judgments contribute to an improved legal certainty in form of a clearer definition of the scope of the healthcare exemption by tackling the dilemma of how the hybrid operations, where a service provider provides both commercial and health services, should be assessed. Some uncertainty still remains though, particularly in the grey area of healthcare providers and the paramedical and how they should be assessed. Thus, the NA’s are still riding a tiger about some national requirements, as to whether they should be notified under the Services Directive or not.

1.2 Purpose and research question

The purpose of this study is to discuss and resolve the issues caused by this lack of legal certainty. In search of a possible solution which could work in the absence of a precise provision different Sources of Law are utilized to identify, scrutinize and finally resolve the practical problems at stake.

The thesis aims to build a bridge between an academic analysis and the implementation in practice by the NA’s of the matter by searching for a precise definition of the scope of the health exemption so that any suspect measures may be possible to assess in accordance with the notification requirement. Hopefully this will contribute to a solution of the problem that causes less legal uncertainty.

The author argues that a strict reading of art 2.2 (f) SD together with recital 22 SD does not necessary lead to a correct interpretation of the healthcare exemption. As a consequence unnecessary legal uncertainty possibly resulting in misunderstanding of the rule remains. This needs to be dealt with in more detail on an EU level in order to foster a correct and harmonized interpretation by all the MS’s. Ideas originating from this research for improved clarity, *de lege ferenda*, will be brought up for consideration where relevant.

The research question; *what is the precise scope of article 2.2(f) SD as can be defined within the current status of Union law?* will be used as a tool to achieve these objectives.

1.3 Delimitations

The focus of this thesis is the Services Directive.

Hence, even though arts 56 and 49 TFEU are explained and discussed, being the primary source for the free movement rights that the Services Directive codifies from the case law off the Court, the actual content of the Services Directive. To support the interpretation of arguments made, the relationship between other directives and particular parts of them, relevant to the interpretation of the healthcare exemption, will also be discussed and analyzed in depth. As the theme of this thesis is the exemption of healthcare, which according to art 2(2) (f) SD is not dependent of the way they are organized or financed, these latter aspects

¹⁴ C-57/12, *Femarbel ASBL v Commission*, paras 35-41.

¹⁵ C-539/11, *Ottica New Line di Accardi Vincenzo v Comune di Campobello di Mazara*, para 18 et seq.

¹⁶ See C-57/12, *Femarbel ASBL v Commission*, para 35 and C-539/11, *Ottica New Line di Accardi Vincenzo v Comune di Campobello di Mazara*, 2013 para 15 et seq.

will not be discussed. Reimbursements and prior authorization schemes are dealt with in other secondary legislation and also fall outside the scope of this thesis.

This thesis emphasis is particularly on the rules regarding services, i.e. art 2.2(f) SD. Thus, remedies and countervailing measures will not be debated much, albeit they are mentioned, since they have no actual value for the answer to the main question of this thesis. The same is true for competition law aspects. Moreover, due to the fact that free movement of services and establishment are applicable to nationals of the EU only, no third country nationals (TNCs) will be discussed.

Finally, to stay within the focus of this study, only provision of services in context of free movement of services and establishment are discussed. This means *inter alia* that the other freedoms, goods capital and persons except where they are intrinsically connected to the provision of services/establishment, will not be brought up. Also the Charter of Fundamental Rights of the European Union¹⁷ (Charter) is not discussed.

1.4 Method and material

The primary law being the supreme source of law in the EU, it is at the zenith of the European legal order. As such, the primary law takes precedence of all other sources of law. Thus, the secondary law must be perceived in the context of EU primary law. Intrinsically, the Services Directive must be interpreted and implemented in this context, particularly vis-à-vis the internal market freedoms.¹⁸ If any clashes occur the Treaties as *Lex superior* have the prerogative in regards to EU law and national law both.¹⁹ This is of particular relevance, due to the occasionally questionable quality of the legal text of the Services Directive; contradictions do occur within the Services Directive itself. A good example of a mismatch is the healthcare exemption that is the subject of this study: The art 2.2(f) SD of healthcare exemption does not mention pharmaceutical services, particularly cited in recital 22SD as part of healthcare.

The thesis utilizes the European legal method²⁰ and doctrine with a specific focus on the internal market *acquis*. I.e. the assessment of the current law is based on the *acquis communautaire*; primary Law,²¹ secondary law and jurisprudence from the EU Courts. Even some preparatory legal acts are investigated where/if they are important to the subject. Additionally, reports and notification decisions completed by the National Board of Trade

¹⁷ Charter of Fundamental Rights of the European Union (OJ 2000/C 364/01).

¹⁸ Especially in light of the art 3 TEU, arts 9 TFEU (the horizontal social clause), art 14 TFEU, Protocol No 26 annexed to the Treaties and the Charter. See Report form Opinion of the Committee on employment and social affairs on the Internal Market for Services: State of Play and Next Steps (2012/2144(INI)) p 2.

¹⁹ See Case 6/64 Costa v. ENEL [1964] ECR 585, Case 11-70 Internationale Handelsgesellschaft mbH v Einfuhr- und Vorratsstelle für Getreide und Futtermittel [1970] ECR 1125 and Case 106/77 Amministrazione delle finanze dello Stato v. Simmenthal [1978] ECR 629.

²⁰ Hettne, J. (2011). EU-rättslig metod. Stockholm: Norstedts juridik.

²¹ The Treaties Commission, Consolidated versions of the Treaty on the Functioning of the European Union, 2010 and the Charter of Fundamental Rights in the European Union (The Charter).

(NBT) as well as interviews and discussions with the personnel of NBT will be utilized. All the relevant data has been updated on the 16th of May 16, 2014.

The thesis has benefitted from an internship at the NBT which enabled and ensured a solid insight of the application of EU law in the day to day work by a NA designated to do this, as well as access to *empiri* on the notifications made within the services related to healthcare sectors by different MS's.

The *empiri* presented by this thesis encompasses inter alia actual notifications made by different MS's during the time period 2011-2013. Most specifically the Swedish notifications, including the decisions of the NBT (the Swedish designated NA), on whether the PA measures should be notified or not. The Swedish implementation of the Services Directive will furthermore be used as an example where relevant.

By pinpointing relevant benchmarks in context of the area of healthcare within the EU legislation this thesis strives to connect these as references to draw a comprehensible image of the scope of the art 2.2 (f) SD exemption. As a starting point the following assumption is made; since the services that fill the cumulative criteria of recital 22 of the Preamble and art 2.2(f) SD are outside of the scope of the Services Directive consequently, *e contrario*, if one of the criteria is not met the service is within the scope of the Services Directive.

The thesis starts by studying the Services Directive in detail since the author believes that the key for understanding an exception of a rule is to first understand the rule the exemption springs from. Only then can the, why, what and how of what is being excepted be explained appropriately. The relationship between the SD and other relevant secondary legislation is studied. ECJ case law will be researched for guidance on how the exemption should be interpreted and applied. The interpretation methods used are those governing the rulings of the ECJ, *inter alia* by text (literal Interpretation), context (contextual Interpretation) and purpose (teleological Interpretation).²² Also other integration methods will be applied if relevant.

The analysis will be initiated by a literal reading of art 2.2(f) SD together with recital 22 of the Services Directive, followed by an interpretation of the concept of 'healthcare services' based on its purpose and general structure. These are then put into the context of the scheme laid down by the SD in accordance with the formula presented by the Court in *Fermabel*.²³

1.5 Disposition

The thesis has six main chapters, each of them containing subchapters. To present the material as pedagogically as possible the material is demonstrated in a logical order.

Chapter one provides an introduction of the background, the purpose and the key research question and sets the framework and scope of this thesis. Also the method and material used are explained.

²² See Maduro, M. P. (2007, December 5). Interpreting European Law: Judicial Adjudication in a Context of Constitutional Pluralism. *The European Journal of Legal Studies*, Vol.1, Issue 2 art 8 p 4.

²³ See C-57/12 *Femarbel ASBL v Commission*, para 34.

Chapter two describes and explains the purpose and the function of the arts 49 and 56 TFEU as well as provides an overview of the Services Directive. In addition, the hierarchy of sources in EU Law and the context of the interpretation and implementation of the Directive are clarified.

Chapter three aims to sort out the scope of the Services Directive in detail. The purpose of the Directive is illuminated as well as the inherited risks. The Services Directive's distinct characteristics are shed light upon. The notification obligation will be explained to provide an insight into what part a proper assessment of the "restriction" plays in the whole monitoring process of the EU law application by different MS's.

Chapter four studies the exemption of the healthcare in context of the SD to establish a conceptual definition of the term. It aims to define and isolate the scope of the healthcare exemption by utilizing relevant jurisprudence from the European Courts for an increased understanding. The relationship to the Patients' rights Directive is scrutinized with the objective of establishing a proper demarcation for the healthcare exemption.

Chapter five seeks to identify the meaning of regulated professions. The link between the Services Directive and the Directive for Professional Qualifications is examined. The purpose of this is to identify the criteria necessary for the healthcare exemption.

Chapter six assembles, assimilates and analyses all elements, with argumentation about some of the inherent problems of the Services Directive in general and particularly regarding proper identification of the exclusion of healthcare followed by a conclusion which wraps up this thesis.

2. Free Movement of Services and the Services Directive

2.1 Free Movement of Services

Today EU is a service based economy. Services are found on all levels of economic, social and industrial infrastructure, covering more than 70% of economic activity and employment in the EU.²⁴ That is why services, and particularly ensuring their free movement, are crucial to the internal market of the EU.

The provision regarding the free movement of services is established by art 56 TFEU. Art 57 TFEU designates services as an economic activity, typically provided for remuneration, constituting “consideration” for the service in question.²⁵ In essence, the MS’s are prohibited from restricting; access to services for service recipients and for service providers to provision the services in cross-border situations within the internal market.

All type of movement of services provided on a temporary basis that have a cross-border element are included. Where either the service provider²⁶, or the service receiver²⁷, travels from one MS into another MS to provide/receive the service.²⁸ Art 56 even covers situations where the service itself moves²⁹ e.g. via internet services. *Internal Market aquis* is only appropriate where there is a cross-border element present. Art 56 TFEU covers performance of an activity or professions on temporary basis; else the relevant activities fall within the scope of art 49, free movement of establishment.

If a MS wishes to restrict the free movement it must justify the restriction by *express derogations* in art 52.2³⁰ or *ORRPI* set by the ECJ case-law. Restrictions are also subject to a proportionality test, i.e. they must be appropriate and not too far-reaching to achieve the objective they are intended for.

Art 56 TFEU applies to persons and covers both physical and legal persons, which are nationals of a MS of the EU. Hence, third Country nationals cannot invoke art 56 TFEU for their benefit.³¹ For judicial persons to be considered as nationals of a MS, the country of registration sets their nationality. It is also of importance to know that in a purely internal MS situation the Union law will not apply,³² even though this concept has been subject to some

²⁴ See Commission, A Single Market for Services http://ec.europa.eu/internal_market/top_layer/services/.

²⁵ See, e.g. case 263/86 Humbel [1988] ECR 5365, p 17.

²⁶ See, e.g. case 33/74 van Binsbergen v Bestuur [1974] ECR 1299 and C-341/05 Laval Un Partneri Ltd v Svenska Byggnadsarbetareförbundet [2007] I-11767, 2007.

²⁷ See e.g. joined Cases 286/82 and 26/83 Graziana Luisi and Giuseppe Carbone v Ministero del Tesoro[1984] ECR 377 and C-372/04 Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health [2006] ECR I-4325.

²⁸ See C-55/94 Reinhard Gebhard v Consiglio dell'Ordine degli Avvocati e Procuratori di Milano [1996] ECR I-4165.

²⁹ See C-384/93 Alpine Investments BV v Minister van Financiën [1995] ECR I-1141.

³⁰ See the recital 41SD for a definition of public policy in context of the Services Directive.

³¹ See e.g. case 136/78 Auer [1979] ECR 437, para 28.

³² See case 175/78 The Queen v Vera Ann Saunders [1979] ECR 1129, following a lead from case 115/78, J. Knoors v Staatssecretaris van Economische Zaken [1979] ECR 399.

erosion over the recent years.³³ The service must also be legal in the MS according to the laws in the MS where the service is being provided.

The area of services is characterized by a strong diversity. As demonstrated by ECJ practice, services do not only encompass temporary provision of services, but also acts as a general ‘gather-all’ for items³⁴ that cannot be covered by any of the other three free movement provisions. ECJ case law on the subject varies from matters regarding social objectives, *inter alia* delivery of welfare, to clearly technical issues like taxation and protection of intellectual property rights. There is also a decent level of harmonization within the area in form of directives.

Art 56 TFEU is vertically applicable, as it creates rights and access to legal remedies for a person vis-à-vis state actions, *in casu* service providers and receivers.³⁵ However, even after the Courts ruling in *Laval*³⁶ uncertainty remains in relation to whether the arts 56 and 49 TFEU have a horizontal direct effect. Consequently, at the current state of EU law it is not possible to draw a conclusion that a horizontal applicability in regards to the provisioning of services exist.

The Court applies a market access approach in relation to services i.e. the Keck doctrine is not really applicable in this context. Further there is no clear *de minimis* rule in the field of free movement of services. The Court in case *Säger v Dennemeyer*³⁷ set that quite firmly. However, later case law has in practice to some degree applied a type of *de minimis* to narrow down art 56 TFEU were it has been seen by the ECJ as necessary.³⁸

2.2 Free Establishment

Art 49 TFEU comes to play when Union citizens establish economic activities on a permanent basis in another MS than their own.³⁹ Self-employed and companies (art 54 TFEU) exercising economic activities are covered by this provision, vesting them with the ability to freely set up primary or secondary establishments under the same circumstances as nationals of the MS they are establishing in.⁴⁰ In line with other free movement provisions, all discriminatory restrictions on the free movement of establishment are prohibited, unless objectively justified

³³ See Sousa, P. C. (2011). Catch Me If You Can? The Market Freedoms’ Ever- expanding Outer Limits. European Journal of Legal Studies, 162-191 p 1, Advocate General Sharpston’s Opinion in Case C-34/09 Zambrano of 30 September 2010 in situations of reverse discrimination and joined Cases C-570/07 and C-571/07 Blanco Pérez and Chao Gómez [2010] ECR I-4629, paras 39-40. See also Case C-448/98 Criminal proceedings against Jean-Pierre Guimont [2000] ECR I-10663 and C-379/98 PreussenElektra [2001] ECR I-2099, para 52 and Joined Cases C-159/12 to C-161/12 Alessandra Venturini v ASL Varese and others.

³⁴ See C-452/04 Fidium Finanz AG v Bundesanstalt für Finanzdienstleistungsaufsicht [2006] ECR I-9521, para 32.

³⁵ See, e.g. case 33/74 van Binsbergen v Bestuur [1974] ECR 1299.

³⁶ See, e.g. C-341/05 Laval Un Partneri Ltd v Svenska Byggnadsarbetareförbundet [2007] I-11767.

³⁷ See, e.g. C-76/90 Manfred Säger v Dennemeyer & Co. Ltd. [1991] ECR I-4221, para 12.

³⁸ Waele, J. M. (2006). A Retreat from Säger? Servicing or Fine-Tuning the Application of Article 49 EC, Legal Issues of Economic Integration 33(3), 207–228 p 226 and Joined Cases C-544 and 545/03 Mobistar SA v Commune de Fléron [2005] ECR I-7723, 2005, para 31. For establishment see C-418/93 Semeraro di casa v Sindaco del Comune di Erbusco [1996] ECR I-2975, para 32 and C-379/92 Peralta ECR [1994] I-3453.

³⁹ See, e.g. C-221/89 The Queen v Secretary of State for Transport.v. Factortame (Factortame II) [1991] ECR-3905, para 20.

⁴⁰ See case 107/83 Ordre des avocats au Barreau de Paris v Onno Klopp [1984] ECR 2971.

by art 52 TFEU - express derogations or ORRPI. Even restrictions that can be considered non-discriminatory may be caught by art 49 TFEU.

Arts 49 and 54 TFEU can be used as defense against restrictions set up by either the home MS or the new host MS of the individual, self-employed or company.⁴¹

The Court's interpretation sets the scope of art 49 TFEU wide.⁴² Thus the concept of establishment catches a wide range of activities from religious groups to sportsmen.⁴³ Even a traineeship required to enter into a profession is covered.⁴⁴ Identical to the list of services in art 57 TFEU, the list of examples in art 49 TFEU is non-exhaustive.

As regards the self-employed, the MS that the EU nationals seek to establish themselves in should respect the mutual recognition principle.⁴⁵ The situation for companies is a bit more complex; as the national laws governing the treatment of a company as a national vary between "real seat" and "incorporation" theories.⁴⁶

Nevertheless, primary and secondary establishments both may move within the EU. The distinction between economic activities performed on stable or on temporary basis is not crystal clear as existence of some permanent infrastructure does not mean that establishment has taken place.⁴⁷

The vertical direct effect of free movement of establishment was affirmed by the ECJ in *Reyners*.⁴⁸ After the Courts ruling in *Viking* the horizontal effect of art 49 TFEU is slightly unclear. Private undertakings may evoke art 49 TFEU in their defense against Trade Unions. However, it has not yet been proven by the Court that this horizontal effect may be extended to even apply between private undertakings.

2.3 The Services Directive

Owing to the role as a driving force that the services have to the economy of the EU, the Services Directive was finally adopted in December 2006. Due to the herculean task of implementation into the national laws of the MS's it was allowed a lengthy transposition period which ended in December 2009. The current Directive is the final draft of three, which was finally adopted after serious teething troubles. Hitherto the two earlier versions, *the Bolkestein draft* of 2004⁴⁹ and the follow-up known as the *McCreevy draft*, both failed due to

⁴¹ See case 115/78 J. Knors v Staatssecretaris van Economische Zaken [1979] ECR 399.

⁴² See e.g. C-55/94 Reinhard Gebhard v Consiglio dell'Ordine degli Avvocati e Procuratori di Milano [1996] ECR I-4165, para 20.

⁴³ See e.g. C-415/93 ASBL&I UEFA v Jean-Marc Bosman [1995] ECR-4921 and C-196/87 Udo Steymann v Staatssecretaris van Justitie [1988] ECR I-6159.

⁴⁴ See C-313/01 Christine Morgenbesser v Consiglio dell'Ordine degli avvocati di Genova [2003] ECR I-13467.

⁴⁵ See C-340/89 Irène Vlassopoulou v Ministerium für Justiz, Bundes- und Europaangelegenheiten Baden-Württemberg [1991] ECR I-2357.

⁴⁶ See e.g. C-81/87 The Queen v H. M. Treasury and Commissioners of Inland Revenue, ex parte Daily Mail and General Trust plc [1988] ECR 5483, 1988 and C-210/06 Cartesio Oktató és Szolgáltató bt [2008] ECR I-09641.

⁴⁷ C-55/94 Reinhard Gebhard v Consiglio dell'Ordine degli Avvocati e Procuratori di Milano [1996] ECR I-4165.

⁴⁸ See case 2-74 Jean Reyners v Belgian State [1974] ECR 631.

⁴⁹ Proposal for a Directive of the European Parliament and of the Council on services in the internal market [SEC(2004) 21]. (The Bolkestein draft, 2004)

too high ambition levels in context of mutual recognition and the insignificant margin for MS's to restrict provision of services.

The original draft, the *Bolkestein Draft*, already provided a legal framework for three main concepts by:

- Eliminating obstacles to free movement in regards to establishment for providers of services
- Eliminating obstacles to free movement in regards to providers of temporary services in accordance with the Country of Origin Principle (CoOP).
- Setting in-depth rules for both the establishment of 'points of single contact' and on mutual assistance between MS's.

It also, corresponding to the current Directive, gave rights and provided assistance to the service recipients of other MS's.⁵⁰ Yet, the dual key issues that drove a final nail in the coffin of the *Bolkestein Draft* were the CoOP which meant that the service providers would be subject solely to the laws of the MS of their establishment and the issue of posted workers⁵¹,

The *McCreevy Draft*, a pale follower of the original, to a large extent imitated the structure of the *Bolkestein Draft* but was narrower in scope. CoOP, healthcare 2.2(f) SD⁵² and social services 2.2(j) SD had been removed. Moreover, the list of forbidden requirements was chopped short.

The final draft of the SD, that became the currently applied Directive, bears several similarities to the second draft. The major differences being further exclusion of activities from the scope of the Services Directive and the 'points of single contact' obligations reduced.

Just like TFEU the Services Directive contains essential rules on both temporary provision of services and establishment. I.e. the way the Services Directive regulates trade in services varies, it is contingent on how the service is provided between MS's; on temporary basis (service) or by selling through the service firm which is established in the MS where the services are to be sold (establishment). The range of services the Services Directive covers is broad. It is applicable to individuals and companies alike, covering many services sectors with some particular sectors being excluded.⁵³

National red tape linked to these excluded services must meet the terms of other rules of EU law, especially arts 49 and 56 TFEU, the freedom of establishment and the freedom to provide services which the Services Directive replicates. The services excluded are the following:

- SGIs (Services of General Interest)
- Electronic communications services that are covered by other community legislation

⁵⁰ Commission, COM(2004) 2 final/3, 2004, art 21.

⁵¹ Barnard, C. (2008), Unravelling the Services Directive, Common Market Law Review 45, pp 328-329.

⁵² See Bolkenstein draft e.g. recital 8 and art 23 for assumption of healthcare costs.

⁵³ According to NBT 40.6% of the Services sectors are covered by the Services Directive.

- Audiovisual services
- Financial services
- Transport services within the scope of Title V TFEU.
- Healthcare services on condition that they are provided by healthcare professionals, recognized as such by the MS concerned, to patients to assess, maintain or restore their state of health.
- Staffing company services
- Services provided by private security companies
- Gambling services
- SSGIs (Social Services of General Interest), i.e. some social services that are based on solidarity. Those may be delivered by the State, by trustees of the State or by charities acknowledged as such by the State.
- Notaries and bailiffs services

If a MS wishes to hamper cross-border situation service transactions they must be able to justify that constraint objectively and stay within what is suitable and proportional to gain the effect wished for.

The Services Directive has vertical direct effect⁵⁴ as it provides legal remedies for individual rights under specific circumstances but is not limited to that. Even though the Services Directive is mostly about vertical relationships, there are also horizontal provisions which affect the actions of the service providers.⁵⁵ Service providers have therefore same horizontal obligations in regards to service recipients on the market.⁵⁶

When studying the Services Directive, five main areas of regulative provisions can be identified;

- the provisions on administrative simplification,
- freedom of establishment and
- the free movement of services activities,
- the rights of recipients,
- quality of services and administrative cooperation between MS's of the EU.⁵⁷

Structurally, the Directive itself is divided into eight chapters.

The first chapter contains general provisions; it establishes the purpose, area of application, the relationship with other EU legislation and offers relevant definitions.

The second chapter is about administrative simplification and points of single contact.

⁵⁴ See, e.g. C-41-74 Yvonne van Duyn v Home Office [1974] ECR 1337 and C-152/84 Marshall v Southampton & South West Health Authority [1986] ECR 723.

⁵⁵ Interpreting article 20(2) of the Services Directive. Stockholm, Sweden: National Board of Trade.p 1.

⁵⁶ Art 22 SD.

⁵⁷ Affairs, M. f. (2008), Genomförande av tjänstedirektivet Ds2008:75. Stockholm: Government Offices of Sweden.p 28.

The third chapter deals with the freedom of establishment, i.e., for a service provider to establish economic activities on a permanent basis in a MS other than the MS it is a national of.

The fourth chapter deals with the different facets of services; the rights the service providers and receivers have when offering/receiving cross-border services.

In chapter five, provisions on the quality of services can be found, whereas chapter six concentrates on the administrative procedures and cooperation with special attention to the Internal Market Information system (IMI).

The seventh chapter explains the convergence agenda of the Services Directive into NL. Chapter eight closes the Directive by final provisions.

2.4 The purpose of the Services Directive and inherited risks

In the words of the Commission Handbook:

' The objective of the Services Directive is to make progress towards a genuine Internal Market in Services so that, in the largest sector of the European economy, both businesses and consumers can take full advantage of the opportunities it presents. By supporting the development of a truly integrated Internal Market in Services, the Directive will help realise the considerable potential in terms of economic growth and job creation of the services sector in Europe. ' ...

Accordingly, the Services Directive is an important component of the renewed Lisbon Strategy, Europa 2020⁵⁸, for growth and employment. A genuine, truly integrated, internal market for services is the ultimate goal that the Directive strives for.

Beneath the stated surface motives the motivations for the SD are layered. On one hand, the SD aims for simplification of administration and enhanced cooperation, by improving the regulatory environment for service providers operating cross-border services on temporary basis.⁵⁹ To achieve this; the Services Directive specifies the “freedom to provide services” clause. Under the terms of this clause MS’s should, supposedly, not enact any national requirements on the service providers from other MS’s of the EU. As a result, the MS’s are not allowed to impose requirements upon those providers unless they meet certain conditions, i.e. express derogations or *OPRRI*.

Different codified obstacles for establishment by MS’s are categorized in a grey list, art 15 SD and a black list, art 14 SD. Black list requirements are simply prohibited, while grey list type of obstacles call for exceptional caution from MS’s if any of those are implemented. Services are dealt with separately in art 16 SD, the most far reaching provision of the whole Directive, prohibiting all type of restrictions as well as restricting the usage of justifications.

⁵⁸ See http://ec.europa.eu/europe2020/index_en.htm.

⁵⁹ These topics are reflections of smart regulation and 'Think Small' principle. See Commission, Smart Regulation , 2013 and Commission, Communication from the Commission“Think Small First”A .COM(2008) 394 final“Small Business Act” for Europe, 2008 p 3.

Ultimately, the obstacles for recipients wishing to enjoy cross-border services and all discriminatory requirements on grounds of nationality should be removed.⁶⁰ This duty of non-discrimination the MS's public administrations (i.e. the State, regional or local authorities) must abide by. The same applies to the general conditions of a MS's service providers for access to a service from another MS. The MS's are appointed guardians to ensure that the service providers will not discriminate recipients.⁶¹

On the other hand the Services Directive sends a message, not only to the providers or receivers of services, but to the legislators of the MS's. Art 9 SD is targeting the underlying issue of passive resistance of assimilating relevant EU jurisprudence in several MS's. This is unusual; other directives have not usually the same aim.⁶² In practice, the Commission drives the MS's on a quest to catalog and verify their national rules and their compatibility with EU law, thus enforcing the MS to adapt its legislation to the jurisprudence of the Court properly.

Since the Services Directive was originally intended for small companies, smart regulation⁶³ and the 'Think Small' principle⁶⁴ should be central topics for the Directive. Four points in particular should be in place before national rules are adopted at the EU level:⁶⁵ They must be clear, easily understood and unambiguous; void of any '*gold plating*'⁶⁶; mandatory procedures for companies and people ought to be doable swiftly and via electronic means; *guaranteed to provide* information and help as well as fast and effective redress if need be.

To augment the rights of service recipients, and reinforce their trust in the internal market, the Services Directive obliges MSs to implement the above mentioned '*points of single contact*', which function as one-stop-shops for service providers. All relevant information, as well as completion of all procedures and formalities at a distance and by electronic means, is offered by the '*point of single contact*' of each MS. These '*points of single contact*' will also offer advice on the legal requirements, especially on consumer protection rules.

The inherited risks about the Services Directive are numerous. For instance since the Services Directive merely provides the MSs with a framework aimed to harmonize their rules and standards, while leaving significant leeway as to the way of achieving those targets at the national level, considerable differences between the laws of the MSs across Europe may still occur.

⁶⁰ See Commission Handbook on implementation of the services directive, 2007 p 7.

⁶¹ Interpreting article 20 (2) of the Services Directive. Stockholm, Sweden: National Board of Trade.

⁶² Waele, H. d. (2009). The Transposition and Enforcement of the Services Directive: A Challenge for the European and the National Legal Orders, European Public Law 15 no.4, 523-531 p 526, referring to the respective national report by Kok, Facing the Challenge: The Lisbon Strategy for Growth and employment. E.g. Germany, the Netherlands and UK had not implemented the relevant provisions into the National laws.

⁶³ I.e. The rules ought to be tailored to effectively function for those they are targeted at. See the Commission communication "Smart Regulation in the European Union", COM (2010) 543 final and the Inter-Institutional Agreement on better law-making (2003/C 321/01).

⁶⁴ I.e. keeping the level of administrative burdens to the smallest possible. See, e.g. Commission Report "Minimizing regulatory burden for SMEs - Adapting EU regulation to the needs of microenterprises" COM (2011) 803 final.

⁶⁵ See COM(2012)259 - Better governance for the single market.

⁶⁶ For a definition of '*gold plating*' see 'Clarifying Gold Plating- Better Implementation of EU Legislation, Swedish Better Regulation Council 2012.

The devil being in the details; in the case of the Services Directive the issue is both in the details available and in the lack of them. The quality of the Services Directive is questionable; contradictions can be found in the Directive's wording as well as several ambiguities, this causes issues for the NAs.⁶⁷

This is especially true in context of art 16 SD, where the wording implies that 'requirements' catches even those that are non-discriminatory, irrespective of their form, purpose or effect on trade. I.e. art 16 SD seems to restrict the possibility to objectively justify any 'requirements' to the four specifically mentioned by the art. The narrowness of justifications expressed in art 16 SD has caused some confusion as the ground for justifications of restrictions mentioned by paras (1) and (3) are limited from what has been recognized by the case law of the Court as *ORPPI*.⁶⁸

Several MS's have indeed interpreted the specific mentioning of the four grounds for justification; public policy, public security, public health or the protection of the environment, as an exhaustive list.⁶⁹ Support for this interpretation has been lent by the official opinion of the Commission⁷⁰ which, even though lacking a legally normative value, is generally used as a guiding tool by NA's and scholars alike. Since ECJ jurisprudence is mostly absent in this matter, legal uncertainty remains. The only case shedding any light on the matter, *Commission v Portugal*⁷¹ is predating the closing date of the implementation of the SD.

In the ECJ's view the general obligations set out in art 16(1) stem directly from art 56 TFEU.⁷² Hence, by reason of deduction, also justifications deriving from those same rules should be included.⁷³

This is highly unsatisfactory for the providers and recipients of services, as well as for the NA's, who irrespectively of the legal status quo must address the issues raised concerning admissible justifications.

The NBT has made the call that *ORPPI*, beyond what is expressively mentioned in art 16 SD, will be accepted as justifications in Sweden until the appearance of relevant case-law from the Court.⁷⁴ This conclusion was reached through extensive research into the matter, using in particular the following;

⁶⁷ Ulrich Stelkens, *The Implementation of the EU Services Directive: Transposition, Problems and Strategies* (T.M.C. ASSER PRESS, The Hague) p 14.

⁶⁸ C-55/94 Reinhard Gebhard v Consiglio dell'Ordine degli Avvocati e Procuratori di Milano [1996] ECR I-4165.

⁶⁹ Ulrich Stelkens, *The Implementation of the EU Services Directive: Transposition, Problems and Strategies* (T.M.C. ASSER PRESS, The Hague) p 14 referring to reports from e.g. Denmark, the Netherlands, Germany and Lithuania.

⁷⁰ See Commission, Handbook on implementation of the services directive, 2007 p 36 and Commission, The Eu single Market, Services Directive Quick guide, 2013. http://ec.europa.eu/internal_market/services/services-dir/guide/index_en.htm.

⁷¹ See C-458/08 *Commission v Portugal* ECR [2010] I-11599, 2010 .

⁷² See C-458/08 *Commission v Portugal* ECR [2010] I-11599, 2010 paras 88-89.

⁷³ See Hatzopoulos, V. (2013). The Court's approach to Services (20062012): From case law to case load. *Common Market Law Review* 50, 459-502, p 462.

⁷⁴ See NBT, Justifications under the Services Directive, 2013 p 19.

- the wordings of recital 78SD and art 16SD⁷⁵
- the hierarchy of laws as confirmed by art 3.3SD,⁷⁶
- the origin of the Directive,⁷⁷
- considering both exclusive and subsidiary applications⁷⁸ as well as the opinions of the Advocate Generals.⁷⁹

There are still several areas where legal uncertainty remains, e.g. the scope of the healthcare exemption, if the SGEIs are within the scope of the SD and if so to which extent and the scope of the exclusion of labor law in art 1(6) SD. It is however clear that for services outside the scope of the Services Directive, either the primary EU law or other appropriate legislation for those types of services will apply.⁸⁰

As for further issues, the Services Directive might be applicable for purely internal situations based on its wording. Only chapter IV of SD explicitly links to cross-border services. Other chapters have no such references; hence there is room for interpretation if the other arts should be treated otherwise. In the doctrine, the opinion has been expressed that the SD is valid for cross-border situations only.⁸¹

Both the placement of the legal basis for the Services Directive, arts 53 and 62 TFEU, and the legal practice of the ECJ support transnational application.⁸² Rights of establishment are initiated in art 49, which especially concerns the situation of cross-border movement and has precedence over art 53, both being part of chapter 2 of the TFEU. So even though the context of the Directive provides no clear guidance for its sphere of application this does not mean that a conclusion can be drawn solely by the absence of such a provision.

In summary, the concept of the Services Directive and its lack of objectives observed together with art 53TFEU leads to the hypothesis that the SD is applicable for cross-border situations only. In practice, the difference is however marginal since the NA's screen all requirements imposed on service providers, no matter who they are targeted at, i.e. nationals of that MS or nationals of other MS's, to ensure that no hinder to free movement is taking place. I.e. even if the SD would not *de jure* be intended for purely internal situations, due to the way it is applied by NA's, its effect is *de facto* that it may be applicable without a cross border element having taken place.

2.5 Summary

The Services Directive is a horizontal legal instrument that gathers all service sectors not especially excluded from its scope in a collective regulatory system. Temporary provision of

⁷⁵ See NBT, Justifications under the Services Directive, 2013, p 3 et seq.

⁷⁶ Ibidem, p 9 et seq.

⁷⁷ Ibidem, p 7 et seq.

⁷⁸ Ibidem, p 12.

⁷⁹ Ibidem, p 13 et seq.

⁸⁰ The Posted Workers Directive 96/71/EC on the posting of employees in connection with the provision of services states that in situations where these two conflict the Directive 96/71/EC prevails.

⁸¹ Ulrich Stelkens, The Implementation of the EU Services Directive: Transposition, Problems and Strategies (T.M.C. ASSER PRESS, The Hague) p 68.

⁸² See Joined cases C-64/96 and C-65/96 Uecker and Jacquet, [1997] ECR I-3171 para16.

services and establishment are covered by the Directive which introduces rules on administrative simplification and cooperation of NA's, both between and within MS's. Its most distinguishing feature is the obligation for MS's to place at the disposal of foreign providers '*points of single contact*'. Service providers from other MS's can receive all necessary information and complete all compulsory procedures through a single point of access.

Authorization schemes are subjected to a test of non-discrimination, 'necessity' and proportionality. The same test applies to the requirements, an excessively wide concept, even catching non-discriminatory ones with no effect on trade. Notably, the black-list of national measures imposing on the freedom to provide services, art16 (2) SD, has only four tolerable restriction grounds. So, the lenience for objectively justified reasons to restrict cross-border temporary services is more stringent than for establishment.

A rule inventory of national laws and regulations vis-à-vis services took place as part of the implementation process of the Services Directive in order to ensure that they were in line with EU laws and jurisprudence. A separate ongoing notification procedure remains, when new or altered requirements are introduced by the MS's after the deadline of the adoption period, to ensure that no new non-justified hindrances to intra community trade on services arise.

Purpose

The Services Directive is intended to truly unify the services sector within the EU. Due to the Directive's inventive design, it is a staggering and fundamental shake-up of the single market. As a conventional legal instrument and governance device constituting control, the Services Directive is of a two-edged character.⁸³ The SD introduced a lot of different procedures and processes that are mandatory for the MS to adopt and follow.⁸⁴ Thus the MS had to truly assimilate the relevant jurisprudence after a long lingering period of resistance. This is a vital point as in a Community run by the rule of law, judgments of the Court must be fully complied with by the MS's in order to guarantee that the fundamental principles of the Union will not be compromised. The following principles deserve special attention;

- Individual rights,
- legal certainty,
- equal treatment of the diverse conditions under which market participants function in different parts of the EU,

The balance of rights and obligations of MS's under the Treaties are dependent on this.⁸⁵ One has to give credit where it is due; the Directive has accomplished this to certain extent as well as simplified the internal market both for providers and recipients of services.

⁸³ Neergaard, U. (2013). Wiberg, Maria: The EU Services Directive – Law or Simply Policy? *Europarättslig Tidskrift* nr 4/2013, p 881 referring to Wiberg, M. (2013) The EU Services Directive – Law or Simply Policy?, p 23.

⁸⁴ Wiberg, M. (2013, February 6). The EU Services Directive – Law or Simply Policy?, p 24 et seq.

⁸⁵ Commission, Europa.eu, 2005 p 1. [http://europa.eu/rapid/press-release MEMO-05-482_en.htm](http://europa.eu/rapid/press-release_MEMO-05-482_en.htm)

Risks

In order for the internal market to function in practice; its legal framework ought to be of great quality at both EU and national level. The Services Directive misses the mark a bit due to the poor quality of the legal text. It contains inconsistencies in relation to the internal market freedoms in the Treaties and within the Services Directive itself.

In case of uncertainties of interpretation and possible contradictions with the Treaties, the Directive must be interpreted and implemented in the context of the Internal Market freedoms. This may cause conflicts with Primary Law due to the many textual ambiguities within the Services Directive. Some problems are also caused by the fact that the Services Directive has been transposed into the national laws of the MS's by the method most suitable for each individual state. Therefore, differences between MS's national laws frequently occur.

3. Sorting out the Services Directive

3.1 The scope of the Services Directive

The Services Directive sets a general legal framework for how both cross-border provisions of services, either temporary or through establishment, should be dealt with by MS's of the EU and also European Economic Area (EEA). Service, within the meaning of the Services Directive, comprises '*any self-employed economic activity, normally provided for remuneration, as referred to in*' art 57 TFEU.⁸⁶ This definition is constructed of three parts;

- Self-employed
- Economic services: art 2(1) SD.
- Referred to in art 57 TFEU. Otherwise within the scope of art 57 TFEU.

First of all, the target of the Services Directive are self-employed, not really workers. Secondly, the services must be of an economic nature, characterized as offering services on the market for remuneration or consideration.⁸⁷ And finally, the definition of services in art 57 TFEU is mentioned as a reference. A non-exhaustive list explanatory in nature from art 57 TFEU is continued by the 33rd recital of the Services Directive.

A closer look at the Services Directive reveals that it has a material scope, personal scope and territorial scope.⁸⁸ For the sake of clarity the Directive will be dissected using these components.

The material scope

The material scope includes the following main parts:

1. Economic services
 - Services and goods

The borderline between goods and services can be quite fuzzy. Sale of goods on internet⁸⁹ as well as license's for a manufacture of goods fall under free movement of goods, not services. Usually tangibles are classified as goods and non-tangibles as services. Under certain circumstances this differentiation is not watertight.⁹⁰ When two freedoms relate to a matter at hand the deciding factor is the gradation of relevance between those two freedoms. The freedom which is of most relevance prevails.⁹¹ Retail, distribution and

⁸⁶ Art 4.1 SD.

⁸⁷ Barnard, C. (2008), Unravelling the Services Directive, Common Market Law Review 45, p 332.

⁸⁸ Barnard, C. (2008), Unravelling the Services Directive, Common Market Law Review 45, p 331.

⁸⁹ See e.g. C-322/01, Deutscher Apothekerverband eV v 0800 DocMorris NV and Jacques Waterval ECR I-14887, paras 65, 76 and 124 and C-108/09, Ker-Optika bt v ÀNTSZ Dél-dunántúli Regionális Intézete ECR[2010] I-12213.

⁹⁰ See e.g. C-275/92, Her Majesty's Customs and Excise v Gerhart Schindler and Jörg Schindler, 1994 and C-108/09, Ker-Optika bt v ÀNTSZ Dél-dunántúli Regionális Intézete ECR[2010] I-12213.

⁹¹ See C-108/09, Ker-Optika bt v ÀNTSZ Dél-dunántúli Regionális Intézete ECR[2010] I-12213, paras 43 and 46.

aftersales services ought to be treated as services, as long as goods *in casu* are subordinate to services.⁹²

2. Requirements, restrictions and barriers

○ Requirements

Requirements by MS's can be challenged by the Services Directive when they 'affect access to or the exercise of a service activity'.⁹³

○ Discrimination v market access

The Services Directive gives slightly conflicting signals on which approach should be used. Recitals 9 and 65 SD implies a discrimination approach, a removal of restrictions given that they are discriminatory. ECJ jurisprudence⁹⁴ as well as recital 69 SD argues in favor of a market access approach with the removal of all non-justifiable measures constituting a hindrance for cross-border movement of services.⁹⁵ Given some consideration, the market approach seems more likely having support in the Services Directive⁹⁶ as well as from the practice of the ECJ.⁹⁷

3. Exclusions, limitations and derogations

○ Exclusions

Additionally to non-economic services, goods and non-discriminatory hindrances, an assorted amount of general derogations have also been squeezed into the Services Directive. The main ones are assembled in arts 2(2) and 2(3) SD. These include, e.g., SGI's⁹⁸, temporary work agencies,⁹⁹ field of taxation,¹⁰⁰ official authority¹⁰¹ and the legal subject matter for this thesis, the healthcare exemption art 2(2) (f).

○ Limitations

More 'limitations' are spelled out in arts 1(2)-1(7). *Inter alia*, aspects of SGEI's are ruled out, as well as privatization of public service providers, state aid and ending of monopolies.¹⁰² Labor law, a sensitive area in light of *Viking*¹⁰³ and *Laval*¹⁰⁴, should

⁹² Recital 33SD and Barnard, C. (2008), Unravelling the Services Directive, Common Market Law Review 45, pp 334-335.

⁹³ 9th recital SD.

⁹⁴ C-76/90, Manfred Säger v Dennemeyer & Co. Ltd. [1991] ECR I-4221.

⁹⁵ Barnard, C. (2008), Unravelling the Services Directive, Common Market Law Review 45, p 339.

⁹⁶ E.g. art 9 (1) SD, 16(1) SD.

⁹⁷ Interpreting article 20(2) of the Services Directive. Stockholm, Sweden: National Board of Trade.

⁹⁸ Art 2(2) (a) SD.

⁹⁹ Art 2(2) (e) SD.

¹⁰⁰ Art 2(3) SD.

¹⁰¹ Art 2(2) (i) referring to art 45 TFEU.

¹⁰² Art 1(2)-1(3) SD.

¹⁰³ C-438/05, The International Transport Workers' Federation and The Finnish Seamen's Union [2007] ECR I-10779.

¹⁰⁴ C-341/05, Laval Un Partneri Ltd v Svenska Byggnadsarbetareförbundet [2007] I-11767.

also be mentioned as not supposed to be affected by the Directive.¹⁰⁵ According to art 3(2) SD private international law, particularly in regards to contractual and non-contractual obligations and consumer protection, is also outside of the scope of the Services Directive.

- Subordinate to other directives

There is a non-exhaustive list in art 3(1) SD that spells out the sub-ordinance of the Services Directive to other directives if clashes occur. Relevant for this thesis is ‘The Directive 2005/36/EC on the recognition of professional qualifications ‘(PQD).¹⁰⁶

- Additional derogations

There is also an assorted amount of supplementary derogations. These include, among other, chapter III on the subject of freedom of establishment and arts 17 and 18 SD on the subject of free movement of services.

The personal scope and the territorial scope

The legislative grounds for the Services Directive are arts 53 and 62 TFEU. Art 53.1 TFEU mentions particularly the implementation of directives in order to ease the embarkation and pursuance of activities of the self-employed in regards to establishment.

Art 62 TFEU covers all Treaty arts in regards of chapter 3, Services. Since the Services Directive applies to Service providers,¹⁰⁷ arts 4.1 and 4.1 SD definitions of ‘service’ and ‘providers’ melds the definition of service providers, being physical or legal persons offering or providing services, that are nationals of a MS of the EU.¹⁰⁸ An identical mechanism also functions for the recipients of services. As such, both consumers and businesses which use services in the course of their activities are encompassed by the definition.¹⁰⁹ All the twenty-eight EU MS’s as well as the EEA countries are within the territorial scope of the directive.

3.2 Discrimination prohibition

The concept of non-discrimination in EU Law means that similar situations should be dealt with in similar ways and situations that differ should not be treated equally.¹¹⁰ Discrimination may occur both directly and indirectly.

¹⁰⁵ Art 1(6) SD.

¹⁰⁶ Commission, Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (OJ 2005 L 255), 2005.

¹⁰⁷ Art 2.1 SD.

¹⁰⁸ The NA’s apply the SD widely without any concerns of the status of the employment. *Fermabel* gives a stamp of approval.

¹⁰⁹ Commission, The Eu single Market, Services Directive Quick guide, 2013.

http://ec.europa.eu/internal_market/services/services-dir/guide/index_en.htm

¹¹⁰ Interpreting article 20 (2) of the Services Directive. Stockholm, Sweden: National Board of Trade p 3, referring to C-80/94, G. H. E. J. Wielockx v Inspecteur der Directe Belastingen [1995] ECR I-02493, 1995 para 17.

The Discrimination prohibition in art 20 SD is divided into two parts. The first part in art 20(1) SD is of the traditional vertical nature, laying down an obligation for the MS's to ensure that no recipients of services is being discriminated on basis of nationality or residence. The second part, art 20(2), is of horizontal nature as it prohibits discrimination between the service provider and the recipient of the service. Different treatment by service providers of the recipients may be applied only to the extent that they are 'directly justified by objective reasons' e.g. a higher cost to the provider due to the service being provided in another MS.¹¹¹ The MS's are obliged to serve in the role of guardian in preventing that horizontal discrimination occurs.

The wording of the art 20(2) '*general conditions of access to a service*' is wide, offering no specifics on what requirements should be caught by the provision. No other EU law definition for this wording can be found.¹¹²

Most MSs seem to have interpreted art 20(2) SD as a market law provision, i.e. that the meaning of this clause is to ensure that the service is available to the public and that it is not a way to force the service providers to deliver a service.¹¹³ Consequently the article protects service recipients as a collective. They are represented by NA's that has a duty to address the issue with a service provider if need arises to cease discriminatory deeds. Depending on national laws, individuals may also seek redress from national courts. Other approaches, like a contract law approach, may compromise the freedom to enter contracts, due to the possibility of an *e contrario* reading leading to an obligation for the provider of the service to enter into contracts against their will. An antidiscrimination law approach may affect the possibility for a service recipient to claim damages.

According to NBT, a contract law approach would not be in line with recital 90 SD or the wording of the art 20(2) SD.¹¹⁴ There is also a possible breach of the spirit of arts 16 and 17 of the Charter.¹¹⁵ The line between access and delivery cannot be set in stone though, as some services intrinsically connected to the service already provided e.g. aftersales services. Further, an antidiscrimination law approach is also unlikely on the grounds that the legal basis for European anti discriminatory law is typically art 18 or 19 TFEU. This is not the legal basis for the Services Directive. The Services Directive also covers legal persons, not usually covered by anti-discrimination law.¹¹⁶ However as there is no case law in this matter which approach is the right one remains uncertain.

¹¹¹ Commission, Guidelines on the non-discrimination of service recipients under art. 20 of the Services Directive, 2010.

¹¹² SWD (2012) 146 Commission, Communication on the implementation of the Services Directive. A partnership for new growth in services 2012-2015 SWD(2012)146 final, SWD(2012) 147 final, SWD(2012) 148 final, 2012 final, p 9.

¹¹³ Interpreting article 20(2) of the Services Directive p. 15. Stockholm, Sweden: National Board of Trade referring to SWD (2012) 146 annex II.

¹¹⁴ Interpreting article 20(2) of the Services Directive, p 13. Stockholm, Sweden: National Board of Trade.

¹¹⁵ The non-Discrimination Clause in the Services Directive (a follow up on the National Board of Trade's interpretation of Article 20(2) of the Services Directive), p 3. Stockholm, Sweden: National Board of Trade

¹¹⁶ Interpreting article 20(2) of the Services Directive, p 14. Stockholm, Sweden: National Board of Trade.

3.3 The principles of Proportionality and Necessity

Proportionality is one of the legal principles of EU applicable to both EU and MS acts. It has a key role in constitutional review of public acts as its function is of a least restrictive means test. Not only is the principle of proportionality used as an instrument for market integration, according to some views in the doctrine it also has a function as a protection of individual rights.¹¹⁷

In the landmark case *Cassis de Dijon*¹¹⁸ the ECJ was of the opinion that requirements of minimum alcohol content for spirits enforced by German law were disproportionate as less restrictive means (LRM), as informing consumers by way of labelling could have been utilized.

The AG Van Gerven¹¹⁹ in *Grogan (Society of Unborn Children)*¹²⁰ elaborated further on the concept: to comply with the principle of proportionality, objective justifications should not have effect beyond that which is necessary. I.e. there is no alternative rule equally useful but less restrictive of the freedom to supply services that could be used instead. In *Gebhard*, even though the EJC does not use the term proportionality itself, further development of the principle occurred through the addition of a suitability dimension to the test. Hence, if a MS wishes to hinder or make less attractive one of the four freedoms, the measures in question must be non-discriminatory, justified by ORRPI, well suited to ascertain the attainment of the pursued objective and not go further than necessary in order to attain it.

The degree to which a proportionality test is to be applied on the actions of the MS's likely depends among other things on the level of harmonization achieved in the EU.¹²¹ The more harmonized a certain policy domain is, the less maneuvering space for independent action there seems to be for the MS's.¹²² *In casu*, the Services Directive requires a full LRM test, i.e. what is suitable and necessary, would be used to determine whether and/or to what extent MS's can limit the rights of service receivers/providers by governmental intervention motivated by public interests. Since all restrictive measures should be reviewed in light of their consistency with the Directive, especially in relation to art 16 SD, MS's are left with very little leeway to create them.

¹¹⁷ Tridimas, T. (2007). *The General Principles of EU Law* 2nd Ed . Oxford: Oxford European Union Law Library, pp 193-194 and Jan, J. H. (2000). *Proportionality Revisited*. Kluwer Law International, p 243.

¹¹⁸ See case 120/78 *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein (Cassis)* [1979] ECR 649.

¹¹⁹ AG Opinion, para 26, note 41 for *The Society for the protection of unborn children Ireland Ltd v Stephen Grogan et al* [1991] ECR I-4685.

¹²⁰ See *C-159/90, The Society for the protection of unborn children Ireland Ltd v Stephen Grogan et al* [1991] ECR I-4685.

¹²¹ See Sauter, W. (/2013). *Proportionality in EU law: a balancing act?* Utrecht: Nederlandse Zorgautoriteit, p 15 et seq., Tridimas, T. (2007). *The General Principles of EU Law* 2nd Ed . Oxford: Oxford European Union Law Library, p 193 and Graig, P. (2012). *EU Administrative Law*, 2nd Ed . Oxford: Oxford University Press, p 560 et seq.

¹²² Sauter, W. (/2013). *Proportionality in EU law: a balancing act?* Utrecht: Nederlandse Zorgautoriteit, p 16.

3.4 Requirements

The definition of requirements is set noticeably wide in an attempt to catch everything that may be interpreted as a requirement unless specifically excluded that might affect the exercising of free movement in regards to services and establishment.

According to the legal text in art 4.7 SD, “Requirements” mean

‘any obligation, prohibition, condition or limit provided for in the laws, regulations or administrative provisions of the Member States or in consequence of case-law, administrative practice, the rules of professional bodies, or the collective rules of professional associations or other professional organisations, adopted in the exercise of their legal autonomy; ...

No consideration is given to if there is a *de facto* effect on the service providers or not. And in case there is an effect no differentiation between positive or negative effect is made.

Herein lays the parallel to the vast *Dassonville-Cassis*¹²³ doctrine for goods, casting a net too wide to function properly, as it catches rules not intended to be caught. Recital 9 SD thrives to put in some breaks,¹²⁴ e.g. some types of national rules are presumptively legitimate. Nevertheless, if they affect free movement of services, they will be caught by the Services Directive. This is clearly demonstrated in art 16 SD of the Services Directive that gives the impression that only four types of justifications are acceptable.

However, in practice the broad range of possible methods described and covered, of a requirement being present, is appropriate. The requirements are rarely found in the national rules due to their generic nature. A quick glance will not reveal the true nature of requirements, nor the requirements themselves, as the requirements are unseen behind the screen of the generic rule. Thus identification of non-justifiable restrictions demands a wider and deeper scrutiny of a large and variable number of provisions in the form of different types of documents connected to the national rules concerning provision of services. Usually these requirements are found in appendixes, annexes or application forms,¹²⁵ e.g. a requirement of an interview demanding the physical presence of the person interviewed as part of the application process. Without doubt this type of obligation constitutes a hindrance for service providers from other MS’s for who it is more difficult and more expensive to participate than the nationals.

3.5 The notification obligation

A general notification obligation is set by the Notification Directive 98/34/EC¹²⁶ as *Lex generalis*. Based on Directive 98/34/EC (the Notification Directive) art 12.1 union acts that have specific notification procedure are considered as *Lex specialis*, i.e. the notification

¹²³ See case 8-74, *Procureur du Roi v Benoît and Gustave Dassonville* [1974] ECR 837 and case 120/78, *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein (Cassis)* [1979] ECR 649.

¹²⁴ See joined cases C-267/91 and C-268/91, *Criminal proceedings against Bernard Keck and Daniel Mithouard* [1993] ECR I-6097.

¹²⁵ According to Parinya Suvanavasin, jur kand, who did the evaluation process for the municipality of Umeå October 2012.

¹²⁶ Commission, Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998 amending Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulation.

procedure of these is independent of the Notification Directive.¹²⁷ This is relevant to art 39(5) SD consisting of a specific notification vis-à-vis the Services Directive when new, or changes in existing, requirements for services and establishment that might affect provision of cross-border services occur. Consequently requirements are notified by referring to 39(5) SD independently. Art 15(7) SD regarding establishment is a stand-alone rule, i.e. it does not rely on art 39(5) or on the Notification Directive. The form the notification procedure takes in regards of art 15(7) SD is optional to the extent that the MS notifying may choose to use the 98/34/EC procedure or the art 15(7) SD procedure. Arts 16(1) & 16(3) SD do not mention the notification obligation. This does not mean that requirements in regards to temporary provisions of services need not be notified; instead the obligation depends on the art 39(5) SD.

Due to the Services Directive arts 15(7) and 39(5) are both part of The Internal Market Information system (IMI),¹²⁸ for simplification as well as uniform approach and procedure, it is preferable to notify all by the IMI.

The notification method in practice is as follows; the designated NA makes an independent evaluation by looking first at a very specific requirement and then interpreting it in the context of the Directive as a whole, to make a correct evaluation if that requirement must be notified or not. Thereafter they send their evaluation of notification or non-notification to the NA that has imposed the requirement. The NA then downloads the notification in the Internal Market Information System (IMI) which has covered, since October 2013, the PQD and the Services Directive.¹²⁹ The designated authority¹³⁰ confirms the notification by pressing 'enter'.

3.6 The purpose of the notification obligation

The purpose of the notification obligation is preemptive; to adjust national measures potentially consisting non-justifiable restrictions on the freedom of provision of Services *ex-ante*, before EU internal market *aquis* is breached.

The information gathered from the MS's is also essential for the Commission to enable to set forth policy conclusions and evaluate what further initiatives should take place to improve the single market for the function of services.

Other central policy actions related to the Directive will also continue to be actively supported and developed, particularly in the areas of administrative cooperation, non-discrimination and assistance to service recipients.

¹²⁷ See also Commission, Riktlinjer den centrala kontaktpunkten för anmälningförfarandet 98/34 och för de anmälningförfaranden som föreskrivs i särskild EU-lagstiftning Part III p1.

¹²⁸ *Idebem*, part II, p5 and Commission, Regulation (EU) No 1024/2012 of 25 October 2012 on administrative cooperation through the Internal Market Information System and repealing Commission Decision 2008/49/EC ('the IMI Regulation'), 2012 Annex, Provisions on administrative cooperation in Union Acts that are implemented by means of IMI, referred to in art 3 p 1.

¹²⁹ Commission, European Commission Internal Market.

¹³⁰ See annex 2 for the designated authority in each MS.

The notification obligation even has a role to play as assessment example for the NA's from the different MS's to use as support and guidance on how to assess and justify similar restrictions if those arise.

It is important to apply the EC/EU directives correctly; as the same system of sanctions also covers incorrect application of directives.¹³¹ The consequences for a MS for this type of failure can be harsh, ultimately taking the form of both lump sums & penalty payments.¹³² It is therefore sensible to screen national measures in order to avoid unnecessary risks. Proceedings on some MS's, on the grounds of the improper adoption of the Services Directive have already been brought to the Court by the Commission, requesting the ECJ to impose penalty payments on those MS's.¹³³

In Sweden all NA's, including the Municipalities, are subject to the notification obligation. The Swedish transposition of arts 15.7 and 39.5(2) SD, take form in the Act of Services in the Internal Market 2009:1078 §2. According to §2 all new, or modification of existing, requirements directed at access to and exercise of a service activity must be notified to the NBT. The NBT does the interpretation of the National requirement while waiting for the answer from the Commission if it is in line with the provisions of the SD.

NBT in the role of supervisor for the notification procedures in Sweden-must be able to make an assessment of a proposed regulation and its eventual need for notification on its overall compliance with internal market rules. This assessment needs to be in a broad context that will cover all the individual cases, differing from the method of the preliminary rulings by the ECJ who's preliminary rulings are based on individual cases by or through a specific condition presented to the Court. The Court will hence do its assessment of how this National act has affected the imminent situation within the framework of rules the petitioner has invoked.

For a better understanding of how the NA's work, samples of what kind of requirements they have to assess and analyze in their daily work is summarized in charts 1-3 (see **annex 3**) which covers all the decisions related to the area of healthcare.¹³⁴

I.e. the major problem for the national authorities, working by guidance of preliminary rulings by the ECJ, is the difference in interpretation of the subject matter. To outline a rule covering all individual cases a practicable formula has to be created made up of elements based on benchmarks set forth by the ECJ in the preliminary rulings made. When these are put in a broader context the formula should be applicable for determining when the SD and thus the notification procedure for services are applicable.

¹³¹ See annex 2 for the designated authority in each MS.

¹³² See art. 260.3 TFEU read together with art 19.1 TEU 'to ensure that in the interpretation and application of the Treaties the law is observed' and C-304/02, *Commission v France (fisheries conservation)* [2005] ECR I-6263, paras 112-114.

¹³³ See e.g. Commission, Press releases database, 2011 http://europa.eu/rapid/press-release_IP-11-1283_en.htm.

¹³⁴ See annex 3 of this thesis.

Summary

In short, the Services Directive's target-group is self-employed and performing economic services for remuneration within the EEA countries. Nevertheless, in practice the Directive affects all service providers no matter their size or structure. Division into a material, a personal and a territorial scope is identifiable. The material scope covers the scope of economic services, requirements, and barriers. A market approach test seems to be the one applied by the Directive.

Further a bunch of exclusions, limitations and derogations that have been squeezed into the Directive are listed and explained, as well as its place in the order of precedence of EU horizontal instruments (chapter 1).

The Services Directive concept of requirements is extremely wide in a *Dassonville-Cassis* style. Even neutral and non-discriminatory requirements are caught by the web. The possibility of derogations is more limited with service providers who provide services on temporary basis, see art 16SD (chapter 3.4).

To ensure that as few un-justified requirements as possible slip through the system a notification obligation to the Commission was introduced by arts 39.5 and 15.7 SD empowering designated authorities to assess on a case-by-case basis that any requirements, put in place by other NA's, fulfill the non-discrimination principle, are justified, necessary and proportionate (chapters 3.5-3.6).

4. The exemption for healthcare according to the Services Directive

4.1 Motives for the exemption of healthcare

Initially healthcare was supposed to be part of the Services Directive. Art 23 in the *Bolkenstein Draft* was intended to codify and supplement the established case law of the ECJ on the free movement of services relating to healthcare: i.e. *Kohll and Decker*,¹³⁵ *Smits and Peerbooms*,¹³⁶ *Vanbraekel*,¹³⁷ *Müller-Fauré/vanRiet*,¹³⁸ *Inizan*¹³⁹ and *Leichtle*.¹⁴⁰

The proposal was aimed mainly at the patient's rights. Most MS's had been reluctant to or had not implemented the relevant jurisprudence of the ECJ. As a result patients encountering unjustified or disproportionate obstacles for reimbursement of costs¹⁴¹ increasingly brought cases before national Courts.¹⁴² The proposal sought to ensure that patients seeking cross-border healthcare would retain their rights to assumption of costs¹⁴³ from their own MS. This was to be achieved by barring all authorization schemes applied to health-care service providers of extramural care in other MS's by the patient's own MS.¹⁴⁴

Some issues which the jurisprudence of the Court had left unclear were intended to be clarified for increased legal certainty and transparency. This covered MS's and their social security systems as well as patients. Also, the European legislators would have been given the opportunity to deal with practical issues the jurisprudence had not dealt with.¹⁴⁵

However, since the content and scope of application of CoOP¹⁴⁶ was not clearly defined the MS's foresaw problems arising especially in relation to health services. There were serious concerns that the supervision of these services, to be carried out in accordance with the laws of the Member State of destination by the authorities of that Member State, would be at risk.¹⁴⁷ As regards to SGI's the scope of applicability of the Draft was perceived as unclear. Hence there was fear that the sovereignty of the NA's could be compromised, particularly by

¹³⁵ See e.g. C-155/96, *Kohll v. Union des Caisses de Maladie* ECR [1998] I-1931 and C-120/95, *Decker v. Caisse de Maladie des Employés Privés* [1998] ECR I-1831.

¹³⁶ C-157/99, *B.S.M. Geraets-Smits and Peerbooms v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Groep Zorgverzekeringen* [2001] ECR I-5473.

¹³⁷ C-368/98, *Abdon Vanbraekel and Others v Alliance nationale des mutualités chrétiennes* [2001] ECR I-5363.

¹³⁸ C-385/99, *V.G. Müller-Fauré and E.E.M. van Riet v. Onderlinge Waarborgmaatschappij ZAO* [2003] ECR I-4509.

¹³⁹ C-56/01, *Patricia Inizan/Caisse Primaire d'Assurance Maladie des Hauts de Seine* [2003] ECR I-12403.

¹⁴⁰ C-8/02, *Ludwig Leichtle and Bundesanstalt für Arbeit* [2004] ECR I-2641.

¹⁴¹ *Communities*, Commission Staff Working Paper of 28 July 2000 SEC(2003) 900, 2003.

¹⁴² See e.g. C-372/04 *Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-4325, *Jelinek v. National Social Insurance Board*, 2004 and *Stigell v. The National Social Insurance Board*, 2004.

¹⁴³ Inter institutional File:2004/0001(COD), General Secretariat of the Council, 2004 p 2.

¹⁴⁴ See The Bolkenstein draft, art 16 read together with art 17 para 18.

¹⁴⁵ Council, 2004 p 2.

¹⁴⁶ See The Bolkenstein draft, para 16 for CoOP.

¹⁴⁷ See e.g. The Committee of the Regions, 2004, Opinion on the Proposal for a Directive on services in the internal market p 1.7.

restricting their freedom to act in matters concerning healthcare¹⁴⁸ resulting in a unsatisfactory situation vis-à-vis market forces and public interest objectives.

As the original versions were proven to be a mission impossible for the European Parliament to agree on healthcare services were excluded from the Services Directive.¹⁴⁹ Codification of patient mobility was pushed forward in time and to be dealt with by separate legislation¹⁵⁰ which eventually resulted to the Patient's Rights Directive (PRD).¹⁵¹

4.2 Art 2(2) (f) SD and recital 22 SD

The Services Directive healthcare exemption was founded through art 2.2 (f) SD, which has the following wording:

'Healthcare services whether or not they are provided via healthcare facilities, and regardless of the ways in which they are organised and financed at national level or whether they are public or private.'

Quite obviously the phrasing tries to cover as wide a range of healthcare services as possible. From the wording of the art it can be read that the healthcare exemption covers all services that qualify as healthcare services.¹⁵² However, while the legal text of art 2(2) (f) SD is clear as day the Services Directive is not applicable to those services, i.e. the definition of *'healthcare services'* is left in the dark. To establish the definition one must follow the path shown by the Courts rulings in *Fermabel*¹⁵³ and *Ottica*,¹⁵⁴ that art 2(2) (f) SD must be understood in light of recital 22 SD.¹⁵⁵

By application of a teleological and contextual interpretation of the concept of *'healthcare services'* it can be determined whether, and to what extent, activities are excluded from the scope of the Services Directive. I.e. the matter is examined in the light of the context of the provision as well as its purpose and general structure.¹⁵⁶

First, in connection with the phrasing of art 2(2) (f) SD, attention should be called to the fact that the notion of *'healthcare services'* adopted by the EU legislature is somewhat wide-

¹⁴⁸ The Committee of the Regions, 2004, Opinion on the Proposal for a Directive on services in the internal market pp 2.17 -2.25.

¹⁴⁹ See e.g. McCREEVY SPEECH/05/148, 2005.

¹⁵⁰ See Commissions press release on the matter Commission, Services Directive: Commission puts forward amended proposal, 2006.

¹⁵¹ Commission, Directive 2011/24 of the European Parliament of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, 2011.

¹⁵² See Opinion of Mr Advocate General Cruz Villalón, C-57/12, p 20.

¹⁵³ C-57/12, *Femarbel ASBL v Commission*, para 34.

¹⁵⁴ C-539/11, *Ottica New Line di Accardi Vincenzo v Comune di Campobello di Mazara*, para 18.

¹⁵⁵ Commission, Handbook on implementation of the services directive, 2007 p 12 and C-57/12, *Femarbel ASBL v Commission*, para 36 and C-539/11, *Ottica New Line di Accardi Vincenzo v Comune di Campobello di Mazara*, para 18.

¹⁵⁶ See e.g. Fennelly, N. (1996). Legal Interpretation at the European Court of Justice. *Fordham International Law Journal* Volume 20, Issue 3, p 664 and Maduro, M. P. (2007, December 5). Interpreting European Law: Judicial Adjudication in a Context of Constitutional Pluralism. *The European Journal of Legal Studies*, Vol.1, Issue 2 art 8. See also C-283/ 81, *Srl CILFIT and Lanificio di Gavardo SpA v Ministry of Health* [1982] ECR 3415, para 20.

ranging. It covers services pertaining to health of humans, regardless of if provided via healthcare facilities or not. Neither the structure of organization and funding at national level, nor if it is state or privately owned makes any difference *in casu*.

Second, regarding the purpose and the overall structure of art 2(2) (f) SD, the fact that recital 22 SD points out that the scope of the healthcare exclusion should encompass;

'healthcare and pharmaceutical services provided by healthcare professionals to patients to assess, maintain or restore their state of health where those activities are reserved to a regulated health profession in the Member State in which the services are provided'

This recital deserves special attention.¹⁵⁷

Apparently, art 2(2) (f) SD read together with recital 22 SD sets two cumulative criteria that must be in place for the exemption to be applicable. Basically, the first criteria include both the 'healthcare' and 'pharmaceutical services'. Guidance for analysis of what those two services consist of is the wording, *'to assess, maintain or restore patient's state of health'*. The second cumulative criteria is that the services fall out of the scope of SD only if the provision of those services is by *healthcare professionals reserved to a regulated health profession in the Member State in which the services are delivered'*.

To create a better understanding of the healthcare exemption it is necessary to chart all of its building blocks. Assembled they constitute the exemption as a whole. The wording of art 2(2) (f) and recital 22, read together and broken down by the key meanings for individual assessment, results in the following criteria;

- healthcare
- pharmaceutical services (the prescription, dispensation and provision of medicinal products and medical devices)
- to assess, maintain or restore patients state of health
- to patients (this together with the above cannot be done without individual interaction between patient and the provider of the medical service)
- to be provided by healthcare professionals reserved to a regulated health profession.

4.3 Healthcare services in EU law

A natural starting point for a deeper understanding of what would most likely be covered by basic healthcare services in the MSs of the EU is to establish the meaning of health and public health on a level all the MSs have in common.

WHO defines health as *'a state of complete physical, mental and social well-being'*.¹⁵⁸ EU acknowledges this definition,¹⁵⁹ as the EU primary law has no similar simple definition of

¹⁵⁷ According to Opinion of Mr Advocate General Cruz Villalón, C-57/12, 2012 and confirmed by the ECJ in C-57/12, Femarbel ASBL v Commission.

health. Instead art 168 TFEU explains EU policy on public health. First, the subject of EU law in regards to public health is a human.¹⁶⁰ Further, mental as well as physical healthcare are healthcare in EU.¹⁶¹ Prevention of physical and mental illness as well as diseases and threats to health are also covered. Another primary law reference on the matter of healthcare is art 35 of the Charter which mentions both preventive healthcare and medical treatment. Notably, neither art 168 TFEU nor art 35 of the Charter mentions wellbeing.

In reality, the WHO definition is not overly useful as it is too wide in scope. It even covers activities not identifiable as particularly healthcare, e.g. water quality and genetics, which is hard to apply in practice. Albeit healthcare services are in place to upkeep the public and individual health, only selected areas of health are included.

The broad notion of healthcare services adopted by the Union legislature bears a likeness to the two faced god Janus. One face is aimed at art 168.7 TFEU, which lays down that it is the responsibility of the MS on a national level to organize and deliver healthcare. While the other face points at the several rulings by the ECJ, removing any doubt about the Treaty provisions concerning free movement *de facto* encompassing national laws (NLs) on healthcare schemes. Art 35 of the Charter guarantees right for everyone to access treatment *'under the conditions established by national laws and practices.'* Hence, EU law has had a strong impact on the organization of national healthcare. However, defining national health policies is within the exclusive competence of the MS's.¹⁶² Therefore healthcare schemes vary from MS to MS based on their political decisions, normative values and economic situations.

The Services Directive provides one of the most precise definitions of healthcare on EU level. However, similar to healthcare services in EU, the Services Directive also sends mixed signals. Recital 22 SD hints at a narrow interpretation of the rule while simultaneously widening the scope to cover pharmaceutical services as well.¹⁶³

Only activities strictly related to the state of a human patient fall within the healthcare exclusion related to the scope of the Services Directive.¹⁶⁴ Also, according to the Commission's handbook, services intended for enhancing well-being or to provide relaxation are left out of the exemption, e.g. sports or fitness clubs. Even though the Commission's Handbook lacks a normative value the ECJ in *Fermabel* supported this interpretation.¹⁶⁵ Thus, a line must be drawn between wellbeing and healthcare. Within this differentiation of concepts the prevention of disease must be fitted.

¹⁵⁸ Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19 -22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p 100) and entered into force on 7 April 1948.

¹⁵⁹ Commission, Green Paper - Improving the mental health of the population - Towards a strategy on mental health for the European Union /* COM/2005/0484 final */ , 2005 p 4.

¹⁶⁰ Art 168.1 TFEU and the Charter art 35.

¹⁶¹ Art 168.1 TFEU especially mentions mental illness.

¹⁶² See Commission, Europa http://europa.eu/legislation_summaries/public_health/index_en.htm and PRD recital 7 and the Charter art 35.

¹⁶³ See Barnard, C. (2008), Unravelling the Services Directive, Common Market Law Review 45, p 343.

¹⁶⁴ Art 168.1 TFEU.

¹⁶⁵ Art 168.1 TFEU and Commission, Handbook on implementation of the services directive, 2007, p 12.

The dilemma is, as genuine healthcare is ‘to assess, maintain or restore their state of health’, when does well-being become healthcare and vice versa? Some cases of the Court have discussed the differentiation of wellbeing and healthcare in detail. *Leichtle* was about a German national travelling to a health spa located in Italy to receive a health cure. His request for reimbursement of expenditure was rejected. The grounds for rejection was that the relevant German law allowed only for reimbursement where a medical officer had considered it to be absolutely necessary for the cure to take place outside Germany due to better odds of success. According to the German law the health spa where the cure took place had to be listed in a Register of Health Spas. According to the ECJ, German law did have the parameters in place for the treatment to be considered as healthcare on condition that it took place under medical supervision and is followed by drawing up a medical report.¹⁶⁶

Fermabel was a request for a preliminary ruling from the Court, on whether day- and night-care centers providing assistance and care to elderly persons was within the scope of the Services Directive. According to the Court, day- and night-care centers for elderly persons would be deemed as providers of “healthcare services” under the condition that their principal activities are ‘genuinely intended to maintain or restore the state of health of elderly persons’ and are provided by healthcare professionals.

Thus for simplification, following in the footsteps of the Court in *Fermabel*,¹⁶⁷ from here on the term ‘genuine healthcare’ will be used to cover healthcare within the meaning of the Services Directive. Interestingly, the Court did not base the condition of healthcare professionals on the PQD like in *Ottica*, but on the PRD.

Ottica connects the protection of public health to healthcare services.¹⁶⁸ The preliminary ruling was about an optician’s right to establish freely within Italy. The Italian law enforces certain geographical placement and mandatory distances of minimum 300 meters between pharmacies, according to Italian authorities this also applies to opticians.¹⁶⁹

A division of hybrid operations in two categories based on different functions performed that are intrinsically linked was made and discussed;

- Opticians, who exercise an activity within the definition of healthcare and,
- Para-opticians, outside of the scope of healthcare, due to their practice being of a commercial nature.

AG Jääskeläinen in *Ottica*¹⁷⁰ discusses the problem of drawing the line in hybrid organizations covering healthcare and commercial services. He pinpoints as a possible yardstick the predominant part of a service operation. According to AG Jääskeläinen the rule

¹⁶⁶ See C-8/02, Ludwig Leichtle and Bundesanstalt für Arbeit [2004] ECR I-2641, paras 33 and 34.

¹⁶⁷ In C-57/12, Femarbel ASBL v Commission, para 41 the Court discusses of the genuine healthcare intentions.

¹⁶⁸ See C-539/11, *Ottica New Line di Accardi Vincenzo v Comune di Campobello di Mazara*, para 20. The Court referred to C-108/09, *Ker-Optika bt v ÀNTSZ Dél-dunántúli Regionális Intézete* ECR[2010] I-12213, 2010 para 64.

¹⁶⁹ See C-539/11, *Ottica New Line di Accardi Vincenzo v Comune di Campobello di Mazara*, para 7.

¹⁷⁰ See C-539/11, Opinion of Advocate General Jääskinen, para 19 et seq.

for treatment of the issue must be drawn up on a case by case basis in consideration of if the para-optical part of the operation may be the predominant one, as well as in terms of the applicable national legislation.

The ECJ confirms the above mentioned division of opticians into two sub-groups without any further elaboration.¹⁷¹ However the ECJ judged the healthcare exemption being relevant due to two facts: the opticians exercising activities covered by the protection of public health and the opticians in Italy being a regulated paramedical healthcare profession.¹⁷²

It is clear from these cases that the key to interpret healthcare services in EU Law is through the national laws in the MS's. The definitions provided by EU legislation are general enough to be applicable to any way the national healthcare system is organized.

4.4 The nature of healthcare

Traditionally the starting point of healthcare has been of a negative concept, focused on managing illness instead of achieving health.¹⁷³ The definition is a narrow concept of health, based on absence of sickness or injury healthcare. Hence healthcare seems to be mainly of a reactive nature, i.e. responsive to changes of health and focused on identifying these changes.¹⁷⁴ The positive aspect, prevention of disease in line of art 168 TFEU is also part of genuine healthcare, must be interpreted strictly as both the Commissions handbook and *Fermabel* implies. They exclude enhancement of wellbeing and provision of relaxation from *genuine healthcare*.¹⁷⁵

Wellbeing and relaxation are terms describing a positive condition linked to a state of being healthy. Thus, by logic, enhancing and providing a stable, positive health condition does not improve a person's *clinical health*, as the person is already regarded as clinically healthy. In the presence of, or with a suspicion of the presence of a negative condition the outcome is contrary and *genuine healthcare* comes into play. Under certain circumstances preemptive actions, such as halting the predicted occurrence of a serious negative condition to happen unless action is taken as part of *genuine healthcare*.

Genuine healthcare generally covers the following:

Assessing

Need for a checkup by a healthcare professional is either initiated by a medical condition of some kind or through a regular checkup to ensure that a healthy person remains that way. Typical examples of the regular checkups are the regular screening of small children to ensure that they are developing normally or the systematic screening of breast cancer for women

¹⁷¹ See C-539/11, *Ottica New Line di Accardi Vincenzo v Comune di Campobello di Mazara*, para 20.

¹⁷² See *ibidem* paras 20-22. The Court was referred to the PRD art 11 PQD Annex II.

¹⁷³ See Gillies, A. (2003). *What makes a Good Healthcare*. Oxon, United Kingdom: Radcliffe Medical Press, p 18 and Robert G. Evans, M. L. (1994). *Why are Some People Healthy and Others Not?: The Determinants of the Health of Populations*. Canada: Transaction Publishers, p 18.

¹⁷⁴ Robert G. Evans, M. L. (1994). *Why are Some People Healthy and Others Not?: The Determinants of the Health of Populations*. Canada: Transaction Publishers, p 28 and Gillies, A. (2003). *What makes a Good Healthcare*. Oxon, United Kingdom: Radcliffe Medical Press, p 18.

¹⁷⁵ C-57/12, *Femarbel ASBL v Commission*, para 37.

after they have reached a certain age.¹⁷⁶ Either way, no enhancement of a positive condition takes place, only an inspection to see if a possible negative condition is being present. If there is an ailment there will be also an evaluation of how it should be treated.

Maintaining

Maintenance of health and the stabilizing of a medical condition are two sides of the same coin; prevention of serious diseases and dealing with existing sickness. An example of the maintenance of health, as a preemptive action, is immunization against vaccine-preventable diseases.¹⁷⁷ Vaccination prevents catching the infectious disease and transmitting it to the rest of the population. Stabilization takes place where the condition must be stabilized in order for a cure to be possible. Or if there is no cure, treatment may still prevent a person's health from further deterioration, e.g. insulin treatment for diabetics or in the form of palliative care¹⁷⁸ e.g. for cancer or HIV patients, enable a persons to have a decent quality of life

Restoring

Restoration of health can only take place if the patient already has a treatable negative medical condition of some kind demanding a cure. Hence, a medical assessment, treatment or a restoration of health is always connected directly or indirectly to a negative medical condition of some kind, demanding activity of a professional healthcare service provider.¹⁷⁹

People's health is subject to changes over time. Persons do not seek healthcare unless there is a motivation behind it connected to a point in time: feeling ill, regular check up by pediatricians to ensure normal development of children, requirement of a health certificate from an insurance company etc. Interestingly enough, measures not seen as healthcare, e.g. in Sweden breast implants and *Botox* injections¹⁸⁰, may become healthcare if something goes wrong. For instance, when a patient gets sick as a result of a non-healthcare procedure, the public health concerns suddenly become valid.

Activity scope

It is currently unclear if there is some minimum level of activity and focus necessary for the exercising of the service to be considered *genuine healthcare*. The AG Villalon in *Fermabel* took the stand that activities that have no greater impact on the content or quality of the service, such as solely monitoring patients or issuing of certificates, should not be automatically considered to be '*healthcare*'. Thus, the effort of the relevant personnel must have taken place at a specific stage for '*genuine healthcare*' to be in place. Supervision is also included, the healthcare personnel must not necessary be the one performing the activity as long as they have a supervisory role.¹⁸¹

¹⁷⁶ At least Finland, Sweden and UK do this free of cost as part of their public health policy.

¹⁷⁷ See art 168.1 TFEU. See also PRD art 1. 3 (c); vaccinations are considered healthcare even though vaccination programmes are excluded from the scope of that Directive.

¹⁷⁸ For WHO Definition of Palliative Care see. WHO, 2013. <http://www.who.int/cancer/palliative/definition/en/>

¹⁷⁹ See Opinion of Mr Advocate General Cruz Villalón, C-57/12, paras 25-27.

¹⁸⁰ Affairs, M. f. (2008), Genomförande av tjänstedirektivet Ds2008:75. Stockholm: Government Offices of Sweden p 532.

¹⁸¹ Ibidem.

Summarized

Commonly the concept of genuine healthcare service is either directly or indirectly linked to a negative medical condition of a person at a relevant point of time. Some positive aspects also exist in form of prevention disease e.g. vaccinations even though the positive aspect is rather restricted excluding wellbeing on EU level. The range of what is considered to be healthcare varies from MS to MS. Even health cures in form of a spa treatment may be covered if it suits the parameters of healthcare set by national law.

4.5 Pharmaceutical services

The recital 22SD adds another dimension to the healthcare services; pharmaceutical services. However, the definition of ‘*pharmaceutical services*’ seems to be a carbon copy of the definition of ‘*healthcare*’. Both are therefore ambiguous with no guidance in the phrasing for a precise demarcation provided by the legal text. Accordingly, the arguments provided for the need to specify the basic components of the concept of ‘*healthcare services*’ are true also for ‘*pharmaceutical services*’.

Defining pharmaceutical services by logic involves provision of pharmaceutical care:

According to Hepler and Strand “*pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes which improve a patient’s quality of life.*”¹⁸² According to some doctrine¹⁸³ most European countries still rely on this definition in their approach to pharmaceutical care. However, a uniform definition of *pharmaceutical care* across EU is not possible due to the differences in language and healthcare systems between different countries.

Invaluable support for the definition of “*pharmaceutical services*” in Union law in context of the SD, as suggested by the AG Villalon,¹⁸⁴ is found in PRD¹⁸⁵ art 3.a) in the definition of ‘*healthcare*’. When read together pharmaceutical services within the meaning of the directives SD and PRD consist of ‘*prescription, dispensation and provision of medical products and devises*’.

4.6 To patients

One way of defining a healthcare system is as a collection of encounters between persons.¹⁸⁶ So, as healthcare is provided by a person, who is a healthcare professional, to a person, the patient, there must be a link (the state of health) between the healthcare professional and the patient. A *ratione personae* interpretation of recital 22 SD in context of *genuine healthcare* provides that the service activity can only be performed in actual connection with the individual patient.

¹⁸² Hepler CD and Strand LM. Opportunities and responsibilities in pharmaceutical care Am J Hosp Pharm. 1990; 47(3):533-43.

¹⁸³ Schulz, J. W. (2006). A Review of Pharmaceutical Care in Community Pharmacy in Europe. Harvard Health Policy Review Vol. 7, No. 1, p 156.

¹⁸⁴ See Opinion of Mr Advocate General Cruz Villalón, C-57/12, p 23.

¹⁸⁵ Commission, Directive 2011/24 of the European Parliament of the Council of 9 March 2011 on the application of patients’ rights in cross-border healthcare, 2011.

¹⁸⁶ Gillies, A. (2003). What makes a Good Healthcare. Oxon, United Kingdom: Radcliffe Medical Press, p 17.

At least healthcare is an encounter between the healthcare professional and the patient. In reality there occurs a series of encounters of different stakeholders.¹⁸⁷ The amounts of encounters vary, but they must all be connected to an individual patient's state of health. An encounter may be accessing and analyzing a patients' medical record. I.e. the healthcare provider has to have detailed individual information like the actual health condition of the patient, to assess, maintain or restore their state of health.

The wording of art 22 SD is aimed at a case-by-case assessment based on individual condition. This fits the Court's judgments in line of healthcare, e.g. *Watts*¹⁸⁸, *Elnicov*,¹⁸⁹ *Peerbooms*¹⁹⁰, *Fermabel* and *Ottica*. Basically, this type of healthcare can only be exercised at the end of a distribution chain, no matter if the service is connected to goods or is purely service based.

This means that supply, wholesale and delivery of medical products and devices is not *healthcare* but falls under the Services Directive.

To avoid any misunderstanding of what is meant by 'end of chain', two process pictures, picture 1 Concerning services mixed with goods and picture 2 Purely services are included in this paper to illuminate the definition. The picture of services mixed with goods is in four segments. They are symbolizing the following:

- i. The supply/production of a product, e.g. a pacemaker.
- ii. The distribution of the device to healthcare service providers.
- iii. The provision of the medical product by a healthcare professional to the patient.
- iv. The receiver of the medical healthcare service /medical device/ medicine.

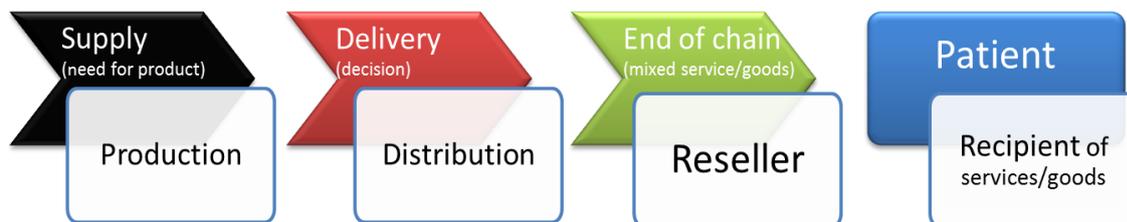


Figure 1 Generic supply chain example

Due to the more complex structure of the service sector, the process picture showing solely services has several layers. The end of the service chain may be realized in the three last boxes. There are four main process segments, and one receiver, the patient:

- i. Actual or possible medical issues or incidents initiating the need for healthcare services.

¹⁸⁷ Gillies, A. (2003). What makes a Good Healthcare. Oxon, United Kingdom: Radcliffe Medical Press, p 17.

¹⁸⁸ See C-372/04, Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health [2006] ECR I-4325.

¹⁸⁹ See C-173/09, Georgi Ivanov Elchinov v Natsionalna zdravnoosiguritelna kasa [2010] ECR I-8889.

¹⁹⁰ C-157/99, B.S.M. Geraets-Smits and Peerbooms v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Groep Zorgverzekeringen [2001] ECR I-5473.

- ii. Delivery; may be booking a time, calling an emergency number or just showing up at a providers emergency reception etc.
An evaluation of the patient’s status takes place. If one is made by a medical professional, a healthcare service occurs. This may be made by e.g. a nurse at a toxic center by phone or an ambulance medic when meeting the patient. If the decision is to not proceed with further healthcare the *end of chain is reached*. Otherwise the patient will be processed onwards.
- iii. The healthcare professional meets the patient for an assessment or analyses the personal data of the patient. Several relevant healthcare professionals may be included, e.g. the doctor examining, the radiologist x-raying, the lab specialist analyzing the patients’ blood sample. If the decision is to not proceed with further healthcare the *end of chain is reached*. Otherwise the patient will be processed onwards.
- iv. Medical treatment is applied by healthcare professionals; the *end of chain is reached*.

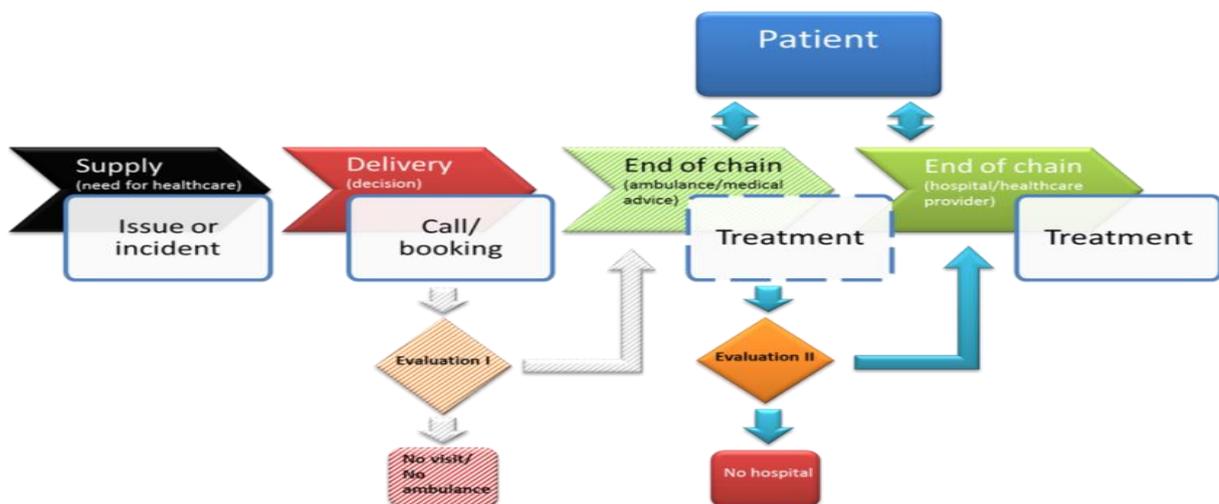


Figure 2 Example of a service supply chain

4.7 The relationship between art 2(2) (f) SD and PRD

After clarifying what the terms ‘healthcare’ and ‘pharmaceutical services’ implies, the next concept to tackle is ‘healthcare professionals reserved to a regulated health profession’. Here the Services Directive leaves its readers in a state of doubt as it does not provide an explanation of the definition to support a consistent interpretation.

The search for an answer leads to the PRD.¹⁹¹ At a first glance this might look like an odd choice since there is no explicit link between those two Directives. Both directives do share a partial scope, service receivers. Otherwise, their subject matter differs. The PRD is directed towards the *individual patients* receiving the healthcare and their rights. The SD, even though it also covers service recipients, has its main focus on the entire provision of services and all the requirements that may be targeted towards them.

¹⁹¹ See e.g. Opinion of Mr Advocate General Cruz Villalón, C-57/12, para 23 and C-57/12, FemarbelASBL v Commission, para 37.

De facto, art 2 PDR on the subject of relationship with other directives does not even mention the SD. It makes the impression that there are either no expected clashes between those two directives, or that the distinction between them is so quintessentially clear, that there is no need to separately establish an order of precedence. This is highly likely; after all the PRD is about healthcare, which is expressively outside the scope of the Services Directive. As such, there is no need to establish an order of precedence; SD and the PRD do not overlap. No mention of the PRD can be found in the Services Directive either. However, this is not surprising, considering the time sequence of their creation. It is important to remember that the first draft of the SD was supposed to include healthcare, but this was left out due to the heated arguments within the European Parliament, resulting in a lack of agreement between the MS's. Instead, there was a common understanding that the matter needed a specific directive.

Perhaps due to this connection through a common origin; the PRD being the *'phoenix'* raised from the ashes of the termination of the healthcare clause in SD, the wording of art 3(a) PRD reflects the wording in recital 22SD. Preamble recital 22:

"The exclusion of healthcare from the scope of this Directive should cover healthcare and pharmaceutical services provided by healthcare professionals to patients to assess, maintain or restore their state of health where those activities are reserved to a regulated health profession in the Member State in which the services are provided."

Art 3(a) in PRD's definition of *'healthcare'* is:

'healthcare' means health services provided by healthcare professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices;'

Noticeable similarities in the wording are also visible in other provisions of these two directives. As further example is the art 1(2) PRD ... *'to the provision of healthcare to patients, regardless of how it is organised, delivered and financed.'* which more or less echoes the contents of the legal text of the art 2(2) (f) SD.

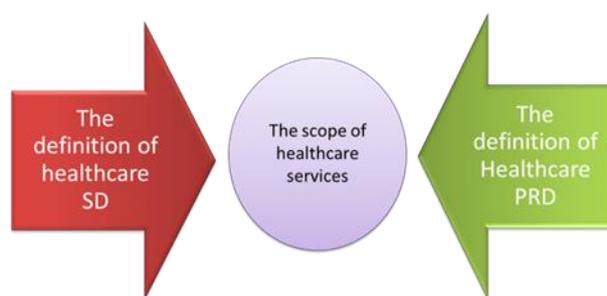


Figure 3 Definitions used for scoping healthcare services

Thus, the conclusion is that these two directives should be read together to patch the elements missing from the Services Directive. I.e. the PRD may be used as a complementary tool for the purpose of attaining a defined scope of the exemption of healthcare in the Services Directive.¹⁹² In *Fermabel* the Court compared the scopes and wording of the SD and PRD - if day-care and night-care centers for elderly persons are providers of *"healthcare services"* with their principal activities being *'genuinely intended to maintain or restore the state of health of elderly persons'* provided by

¹⁹² See picture 3.

a health professional they are within the scope of the healthcare exemption of art 2(2) (f) SD and land in the PRD.

PRD integrates social policy goals to hard free movement law measures in order to achieve social justice goals where SD concentrates on trade, i.e. purely economic values. *Ad valorem*, the social objectives based on solidarity as represented by the PRD supposedly precedes the purely economic objectives represented by SD.¹⁹³

Signs of an escalated effort towards social objectives have been seen lately by judgments of the Court and the modernization of secondary EU legislation in several areas.¹⁹⁴ Therefore it is rational that rights of the service receiver fall under the PRD instead of the Services Directive when healthcare is the object. Likewise, the healthcare service providers will be covered either by another directive, appropriate for the situation, or fall under Treaty arts 49 and 56 TFEU.

4.8 Hybrid operations

The categorization of an undertaking that operates services is defined by ‘*the principal part of the services offered*’. This means that a spillover effect takes place, thereby rendering other areas of operations by the service provider irrelevant. This was established by *Fermabel*¹⁹⁵ and confirmed by *Ottica* which extended the spillover effect by using the term ‘*predominant*’¹⁹⁶ element instead of ‘*principal*’¹⁹⁷. Explicitly, this type of wording is usually seen associated with competition law where predominance in one area affects the way the whole company is treated by EU legislation. The dominant part of the business operations may even spill over to another closely connected to it (think far-fetched analogically *Tetra Pack II*¹⁹⁸). It may therefore be possible to analogically use the large amount ECJ case-law in the area of competition to define what is meant by predominant.¹⁹⁹

An example shall be used to shed light on the idea: A person wants to buy catering services to a party. In this case the person is a service recipient and looking for a provider of catering services. The person will then look for different options offered to receive the service. The catering service can be provided by very different type of undertakings. Like department stores, cafeterias, restaurants and specific catering companies. All the same, the setting of where the service is offered does not affect the nature of the service or the type of service the consumer is receiving. I.e. it is *irrelevant* for the *type of the service itself* if the service

¹⁹³ See art 9 TFEU also called the Horizontal Social Clause. See also Auwers, T. (2010). Strengthening Social mainstreaming in the EU. Brussels: Federal Public Service Social Security, p 1. But then again see C-341/05 *Laval Un Partneri Ltd v Svenska Byggnadsarbetareförbundet* [2007] I-11767, 2007 where economic goals predominated.

¹⁹⁴ See e.g. C 34/09, *Gerardo Ruiz Zambrano v office national de l’emploi (ONEm)* [2011] ECR I-1177. See also the modernisation of the state aid for SGEIs and SGIs, the *Alumnia package* at Commission, European Commission, 2012. http://ec.europa.eu/competition/state_aid/legislation/sgei.html

¹⁹⁵ Para 53.

¹⁹⁶ According to Oxford dictionary ‘predominant’ means; the strongest, having or exerting control or power.

¹⁹⁷ According to Oxford dictionary ‘principal’ means the first in order of importance.

¹⁹⁸ I V/31043 - *Tetra Pak II*.

¹⁹⁹ See, e.g. case 27/76, *United Brands v Commission of the European Communities*[1978] ECR 207 and I V/31043 - *Tetra Pak II*.

provider *offers other services as well* that are not catering services as long as the predominant part of the activities performed are catering services. The classification of the business itself is not affected.²⁰⁰

This means that the entire operation of a hybrid company will be categorized depending on which is the predominant part of its operation. I.e. catering companies are caterers; small cafeterias whose major business in catering are caterers, restaurants whose business is mostly serving food at the restaurant are restaurants etc. What exactly is meant by predominant remains however unclear since the Court did not elaborate on this in any of the relevant cases.

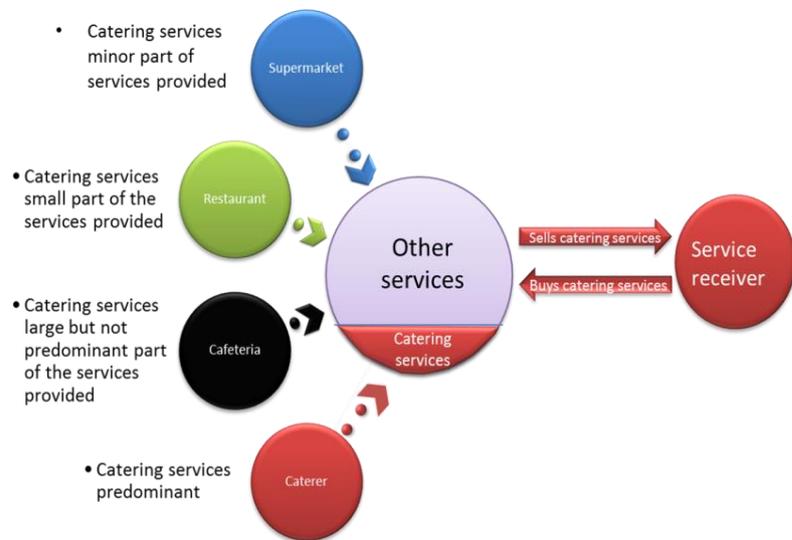


Figure 4 The establishment of predominant part of a service

4.9 Outsourcing and distribution

The formula applicable for categorization, of an undertaking operating services, is defined by *the principal part of its operations*. It needs to be established how far this principle influences different type of operations in relation to differences in structure, operation methods, purpose and the general context of the entire operations. The two main concerns arising are; the correct assessment of insourced services related to healthcare facilities and distribution services of medical products and medical devices.

Does the categorization as *'healthcare services'* cover situations where a worker of a third party outsourcer is brought in to work inside a company's facility on temporary basis, purely in a role other than healthcare? Three points can be put forward to argue that this is where the line should be drawn, i.e. the insourced working force should not be part of the healthcare exemption.

- Since it is the healthcare operation in this case that is the receiver of the service, by logic, the same structure as vis-à-vis hybrid operations should be valid.
- The fact that the people actually providing the service are hired by a commercial company other than the healthcare facilities. I.e. the work and time spent at the medical facility is not a main part of their work as a whole.
- The workers are not healthcare professionals regulated by NL in the MS where the service is being provided.

²⁰⁰ See picture 4.

One would think that these facts add up to the conclusion that they should be included within the scope of the Services Directive. This reasoning is also supported by the Commission Handbook²⁰¹ which explains that services which are not provided to the health professional or to a hospital are not covered by the exclusion of healthcare, i.e. they are within the scope of the SD.

The other question raised was, how the formula should be applied to the distribution of medical products and devices. I.e. if distribution of medical devices or products is '*genuine healthcare*', i.e. 'provided by healthcare professionals to patients to assess, maintain or restore their state of health'. In general, the 'hybrid logic' should also be valid *in casu*. On basis of the Commissions handbook the provision and maintenance of medical equipment as well as the services of medical research Centers is within the Scope of SD as well. In conclusion; distribution services do not fall within the exemption of healthcare, i.e. they are within the scope of the SD.

Summary:

Political issues, one of them healthcare, were the downfall of the *Bolkenstein Draft* (see chapter 4.1). Hence, healthcare was excluded and is now codified in art 2(2) (f) SD that must be read in light of recital 22 SD to make any sense. Together they set two cumulative criteria which form the healthcare exemption: *healthcare* and *pharmaceutical services* which are provided by healthcare professionals assessing, maintaining or restoring a human patient's state of health (chapter 4.2). Healthcare resurfaced in the PRD, art 3(a) essentially repeating and then developing the definition for healthcare further (chapter 4.7) by e.g. providing an explanation that pharmaceutical services are prescription, dispensation and provision of medical products and medical devices (chapter 4.5).

WHO's definition of health demonstrates that the concept of health is a much wider notion than healthcare, as many values linked to good health are not healthcare in a traditional sense. The EU public health concept is codified in art 168 TFEU covering mental and physical health of humans. Art 168 TFEU is twofold, enforcing the MS's to deliver and organize healthcare while leaving the choice of method and content of those to the MS's (chapter 4.3). The purpose of this structure is to upkeep the health of the residents to the extent decided by the MS providing the healthcare based on the MS's socio economic values. Consequently, there is currently a large variation in which healthcare services each MS provides.

Healthcare services are, in accordance with the Services Directive and the PRD '*to assess, maintain or restore their state of health*'. Little case law exists for interpretation in this area, as the jurisprudence has mainly occurred within the healthcare system as recognized by the MS's. Of cases bringing light to the subject *Leicthe*,²⁰² *Fermabel* and *Ottica* stand out as benchmarks; the two latter ones concerns the Services Directive, clarifying that all service operators are to be categorized according to their principal part of operations. Hybrid companies will be deemed as healthcare services if the predominant part of the company

²⁰¹ Commission, Handbook on implementation of the services directive, 2007 p 12.

²⁰² C-8/02, Ludwig Leichtle and Bundesanstalt für Arbeit [2004] ECR I-2641.

while personnel providing services other than healthcare in healthcare companies that outsource should not, as they are within the sphere of the company that hires them out (chapter 4.3).

Healthcare is universally, either directly or indirectly, linked to a negative medical condition of a person at a relevant point of time. The concept does not cover enhancing wellbeing nor to provide relaxation. Some activity from the healthcare professional is required, at least by supervision of other personnel providing the service to be deemed as *genuine healthcare* (chapter 4.4).

Thus, even though the healthcare system must have a link between the patient and the care provider it is enough that it is based on individual data on the patients' health, no physical encounter is required. A purely manual function is not enough, thus healthcare will only occur at the end of distribution chain. Hence, distribution of medical products is not healthcare (chapters 4.6 and 4.7).

5. Healthcare professionals of a regulated profession

5.1 Healthcare professionals

After clarifying the meaning of *'healthcare professionals'* in context of the Services Directive, the next step is to delineate the meaning of the second cumulative requirement; *'healthcare professionals'*. This must be accomplished in a functional way to enable a systemic process that NA's may use in their work. Recitals in directives are not legally binding, however ECJ in *Fermabel*²⁰³ and *Ottica*²⁰⁴ confirmed that *in casu* recital 22SD is once again vital for interpretation of healthcare.

According to the Commission handbook and the meaning of recital 22SD the healthcare exemption solely includes activities reserved to a regulated health profession in the MS where the delivery of the services takes place.²⁰⁵ But what is meant by *'healthcare professionals'* and *'regulated profession'*?

The SD offers some help in this matter in regards to *regulated professions* by referring to the definition in PQD 3.1a).²⁰⁶ However, no clue can be found how to define *healthcare professionals*. Fortunately the Courts judgment in *Fermabel*, by some creative use of the PRD, offers an example for how to accomplish this. Since the definition of *'healthcare'* is incidentally reflected by art 3(a) PRD the definition of *healthcare professionals* in that directive may also be used. The PRD also has a definition of *health professional* in art 3.1(f) as well as an explanation of the meaning of the pharmaceutical services vis-à-vis SD and PRD.

'health professional' means a doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC, or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC, or a person considered to be a health professional according to the legislation of the Member State of treatment;

Not purely restricted to the PQD, this adds one more type of *health professional*. There are thus three different criteria or identifying traits:

The first and clearest way to categorize a *health professional* is that he/she exercises one of the *'sectorial'* medical professions which has professional qualifications that is automatically recognized in the whole EU.²⁰⁷

The second option is to identify a *'professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC'*.

The third option is a *'person considered to be a health professional according to the legislation of the Member State of treatment'*.²⁰⁸

²⁰³ C-57/12, *Femarbel ASBL v Commission*, para 36.

²⁰⁴ C-539/11, *Ottica New Line di Accardi Vincenzo v Comune di Campobello di Mazara*, para 18.

²⁰⁵ Commission, Handbook on implementation of the services directive, 2007 p 11.

²⁰⁶ Art 4.11SD.

²⁰⁷ E.g. doctors, nurses and pharmacists.

However, for a deeper understanding to what is meant by regulated professions, the relevant provisions in PQD must be studied in depth.

5.2 The relationship between the recital 22 SD and the PQD

Since recital 22SD and art 4.11SD establishes that the healthcare activity must be performed by a healthcare professional of a regulated profession, in accordance to PQD. The interplay of those two directives is of considerable importance.²⁰⁹ Those two directives are complementary instruments that regulate different issues; hence, they must often be read together.

The PQD is all about education and qualifications, whereas the Services Directive covers *inter alia* multidisciplinary activities, administrative simplification and authorization. In regards to the order of precedence, the Services Directive is subordinate to PQD by art 2.1(d) SD. The Services Directive addresses a ‘*service provider*’ (company or person) while the PQD addresses a ‘*person*’ as service provider. So, the subject matter of these two directives differ, the PQD being aimed at the individuals practicing a service, where SD looks at provision of services in general of all the branches within its scope and is aimed at requirements as a whole .

The PQD and SD converge and the importance of parallel reading is required when the SD addresses regulated professions. Some professions are harmonized at EU level, i.e. the sectorial professions, thus being regulated professions in all the MS’s by default.²¹⁰

Non-sectorial professionals are assessed by the ‘*generic system*’²¹¹ basically functioning by the mutual recognition principle. The generic system groups professional qualifications into five levels in art 11 PQD so that they may be compared. The art mechanically stipulates these levels of qualifications based on the type and duration of training/education. However, if a difference of more than two levels exists between the qualification of the professional and the qualification obligatory in the host MS, the PQD does not apply.

To understand what the concept of regulated profession contains for professionals of the ‘*generic system*’, the essential elements of the definition in art 3.1(a) PQD has to be unraveled. Art 3.1(a) PQD is divided in two main parts that each has relevant key elements for this. The legal text in the first part one is:

‘regulated profession’: a professional activity or group of professional activities, access to which, the pursuit of which, or one of the modes of pursuit of which is subject, directly or indirectly, by virtue of legislative, regulatory or administrative provisions to the possession of specific professional qualifications; in particular, the use of a professional title limited by legislative, regulatory or

²⁰⁸ Opinion of Mr Advocate General Cruz Villalón, C-57/12, para 25.

²⁰⁹ Commission, Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (OJ 2005 L 255), 2005.

²¹⁰ PQD ch III.

²¹¹ PQD ch I of title III.

*administrative provisions to holders of a given professional qualification shall constitute a mode of pursuit.*²¹²

Followed by part two;

*'Where the first sentence of this definition does not apply, a profession referred to in paragraph 2 shall be treated as a regulated profession;*²¹³

To begin with, the two main parts are distinct. Even though the second part is conditional on the first part not being applicable, both are independent in a way that each leads to an end result that the profession is de facto regulated. The first part of the art is complex. It can be divided in two segments, regulated professional in general and use of professional titles. These will be discussed separately.

The first segment is a general instruction on the different methods through which a profession can be regulated. The structure of its text can be further dissected for extraction of its essence to ease comprehension. The three components that cause legal uncertainty due to lack of precision of their meaning are;

- I. a professional activity or group of professional activities subject to (i.e. what is restricted)
 - a. access to which
 - b. the pursuit of which
 - c. or one of the modes of pursuit of which is subject
- II. requirement of possession of *specific* professional qualifications(i.e. what is required)
- III. restricted by virtue of legislative, regulatory or administrative provisions, directly or indirectly (i.e. how is the profession regulated)

Component I, a professional activity: This concept is the starting point for my interpretation. A professional is a person engaged or qualified in a profession.²¹⁴ Art 1 PQD provides that the *telos* of the Directive is to establish a framework of rules to regulate the methods MS's can restrict access to or pursuit of regulated professions.²¹⁵ It is also apparent from the art 2.1 PQD, that the Directive is supposed to be applicable to all nationals of a MS who desire to pursue a '*regulated profession*'.²¹⁶ The activity must be exercised for remuneration or recognition as it is one of the criteria of services in the context of EU-law. Also, the employment status is irrelevant; the activities can be exercised as self-employed or employee.²¹⁷

Thus, the transition to component II follows, as '*professional activity or group of professional activities*' by way of *internal market aquis* is the taking up or exercising of a professional

²¹² Art 3.1(a) PQD.

²¹³ Art 3.1(a) PQD.

²¹⁴ <http://www.oxforddictionaries.com/definition/english/professional>.

²¹⁵ See e.g. C-575/11, Eleftherios-Themistoklis Nasiopoulos v Ipourgos Igias kai Pronoias, para 3.

²¹⁶ See C-586/08, Angelo Rubino v Ministero dell'Università e della Ricerca [2009] ECR I-12013, paras, 4-6 confirmed by C-575/11, Eleftherios-Themistoklis Nasiopoulos v Ipourgos Igias kai Pronoias. See also Commission, Need help?, 2013 p 3. http://ec.europa.eu/internal_market/qualifications/docs/directive-in-practice/useful-documents/users_guide_en.pdf

²¹⁷ Art 2.1 PQD.

activity that is conditional of possessing some specific qualifications. As to what those qualifications might be, art 3.1(b) PQD offers guidance to the definition of *professional qualifications*, which is; ‘*qualifications attested by evidence of formal qualifications, an attestation of competence referred to in Article 11, point (a) (i) and/or professional experience...*’.²¹⁸

Relevant professional qualifications may have been obtained by means of;

- education/training,
- a specific examination confirming the competence where no training has taken place,
- professional experience within the field for three successive years or for an equal period on a part-time basis for the duration of the previous 10 years.²¹⁹

When combined with the word ‘*specific*’, regulated professions seem to be at the apex of the professional qualifications, as the ‘*requirement of possession of specific professional qualifications*’²²⁰ goes above and beyond what is expected of regular professional qualifications as there is a requirement of *specificity*.

Component III of the first segment of the art 3 (1) (a) PQD, asserts that the professions may be regulated in several ways, by legislative, regulatory or administrative means either directly or indirectly. This provides the means by which MSs, when choosing what professions to regulate and the way to regulate, may accomplish this within the framework that EU provides.

The second segment of the first part of art 3.1(a) PQD is about titles. The first and the second segments are not cumulative; the second segment merely provides an example of a mode of pursuit a regulated profession can take.

A title is a way to identify and legitimize, a form of visible diploma, a stamp of approval which is distinctive of a specific skillset, know-how or attributes achieved *a posteriori*, a certain type of training, education or practice. An analogy can be made by professional title and franchising e.g. ‘McDonald’s’. For restaurants to be able to use the name they must upkeep a certain quality, the “Prospective Franchisees” must initially pass training,²²¹ the workers must have certain training, the food has to have specific ingredients and certain qualities. Thus, franchising might be analogically close to a Barrister. Just like the franchising name, a title is a reserved and protected, since the access is conditional upon the possession of specific qualifications or for which the use of a specific title is protected, e.g. pharmacists or architects.²²²

The second part is explicit, in need of no further study as it refers to a list in Annex I PQD, which names the professions encompassed by the rule. The important dilemma here is to

²¹⁸ Art 3.1(b) PQD.

²¹⁹ Art 11, point (a) (i) PQD.

²²⁰ Art 3.1(a) PQR.

²²¹ See McDonald’s “World Class Training” webpage at;

http://www.aboutmcdonalds.com/mcd/franchising/us_franchising/why_mcdonalds/world_class_training.html

²²² See e.g. Commission, europa.eu, 2013. http://europa.eu/rapid/press-release_IP-13-897_en.htm

understand: What type of regulatory provisions, by the MS for a profession, step over the threshold so as to make the profession considered as regulated by EU *aquis*?

The deciding fact is if the interpretation should be wide or narrow. The key factor seems to be specificity.

5.3 The specificity of regulated professions

Currently, there is no general, clear criterion of distinction for/of ‘*regulated professions*’. A patchwork of pieces of negatives (non-harmonized professions) and positives (the sectorial professions) combined with the case law of ECJ-provide some pieces of the puzzle.

There are several examples of case law about specificity of requirements. *Inter alia*, the Court has held that activities that contain a practical training component as part of a training necessary to access a profession, is not to be held equivalent to a barristers regulated profession.²²³ I.e. the French ‘*maîtrise en droit*’, an awarded LBB legal diploma, is not to be seen as equivalent to an Italian University’s awarded or confirmed. The “gap” between the different diplomas and the absolute criteria for becoming a barrister cannot be replaced by practical training.

Further, professional duties do not by themselves found a ‘*regulated profession*’. In *Peñarroja Fa* the duties of court expert translators did not qualify as a ‘*regulated profession*’ set out in art 3 (1) (a) PQD.²²⁴ ‘*Provisions, whose sole purpose is to establish to facilitate recourse to the services of professionals, whether members of regulated professions or not, and not to lay down rules governing recognition of a particular qualifications...Do not by themselves establish a ‘regulated profession’.*’²²⁵

However, where there is a successful selection of a predefined number of individuals and a strictly time limited qualification is conferred, based a comparative assessment rather than absolute criteria this cannot be regarded within the meaning of art 3(1) (a) PQD as a professional qualification.²²⁶

The Court in *Rubino* interpreted the art 3(1)(a) PQD as meaning ‘...;’ *where the conditions for taking up or pursuing a professional activity are directly or indirectly governed by laws, regulations or administrative provisions requiring possession of certain professional qualifications, that activity constitutes a regulated profession.*’²²⁷ According to the ECJ the relevant qualifications can be, among other things, verifiable proof of formal qualifications or competence based on a specific examination short of prior training.²²⁸ Thus, the Court underlines the specificity requirement in situations of professional qualifications.

²²³ C-313/01 Christine Morgenbesser v Consiglio dell’Ordine degli avvocati di Genova [2003] ECR I-13467.

²²⁴ See joined Cases C-372/09 and C-373/09, Josep Peñarroja Fa [2011] ECR I-1785, para 32.

²²⁵ See, e.g. joined Cases C-372/09 and C-373/09, Josep Peñarroja Fa [2011] ECR I-1785, para 30 referring to, by analogy, to C-285/07, Burbaud [2003] ECR I-8219, para 91.

²²⁶ C-586/08, Angelo Rubino v Ministero dell’Università e della Ricerca [2009] ECR I-12013, para 32.

²²⁷ *Ibidem*, para 24.

²²⁸ *Ibidem*, para 25.

In *Ottica*²²⁹ the Court based the definition of a *regulated profession* on art 11(c) (ii) PQD. Hence, a natural link to regulated professions may be drawn to art 11(c) (ii) PQD.²³⁰

Accordingly, a ‘*professional of a regulated profession*’, has completed successfully a training of a specific structure which includes:

- Post-secondary level training of a minimum of one year, to which the entry has been conditional on meeting certain requirements.²³¹
- Additional mandatory training, if any, required.

That ‘*person*’ must also hold a diploma from competent authorities certifying a successful completion of that training.

Annex II PQD includes *inter alia* a non-exhaustive list of paramedical or child-care²³² courses recognized as being of the specific structure that makes a profession regulated. By mutual recognition if a MS has a requirement of a specific training it may require equivalent training from practitioners of the profession from other MS’s. However, the list is remarkably short, e.g. accordingly only eleven of the twenty-eight MS’s seem to have specific training that leads to a regulated paramedical or child-care professional. The Annex II p1 list includes e.g. opticians, a paramedical profession regulated by more than half of the MS’s of the EU according to the list. What catches the eye is that many MS’s are not present on that list at all, e.g. Sweden.

However, as demonstrated in Annex II of this thesis, the optician is a regulated profession in Sweden. Thus, Annex II of PQD cannot be relied on as a complete list of regulated professions. Nevertheless, that does not mean that the definition itself cannot be utilized, as it provides a final and important piece to the puzzle of a more general definition of the ‘*regulated profession*’ as a whole, the specificity.²³³

Based on the content of art 11 PQD, the Annexes of the Directive and the

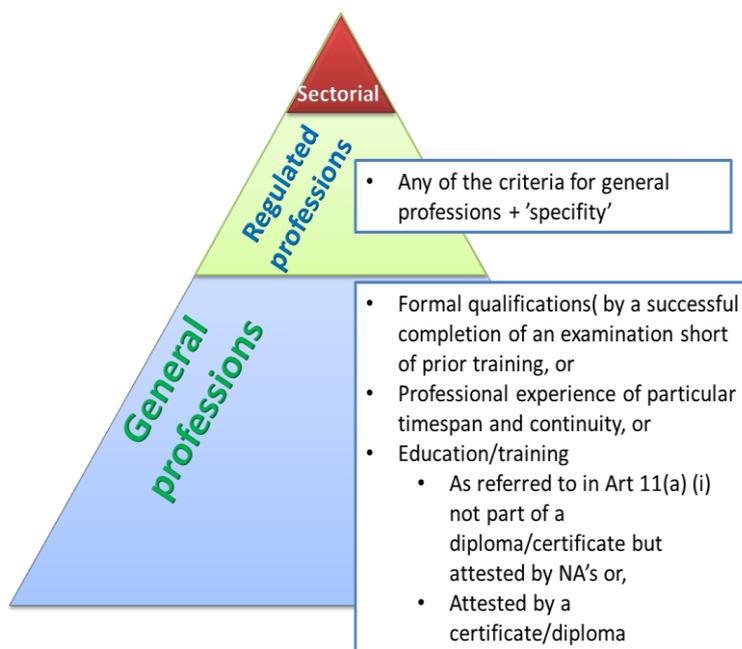


Figure 5 Segmentation of the ‘*profession*’ definition

²²⁹ C-539/11, *Ottica New Line di Accardi Vincenzo v Comune di Campobello di Mazara*.

²³⁰ See C-539/11, Opinion of Advocate General Jääskinen, p 28 and C-539/11, *Ottica New Line di Accardi Vincenzo v Comune di Campobello di Mazara*, para 21. Even though the Court does not develop this concept further they clearly accept the concept.

²³¹ See art 11(c) (i) referring to points (d) and (e) of the same art for detailed information.

²³² See art 11(c) (ii) PQD and annex III p 1 PQD.

²³³ See picture 5. The picture is not drawn in proportion of the different types of professions presented due size it would take.

general structure of the PQD, the *specificity* of training/education seems to be of major importance and usually the key to the regulated profession. The notion of specificity creates a link through art 13.2 PQD to art 3(i) (e) PQD, defining the notion of ‘*regulated education and training*’ as specifically geared to a certain profession and adds one more non-exhaustive list to look into. Art 13.2 PQD refers to Annex III PQD for regulated education and training at the level described in art 11 p(c) PQD.

It can be established that “regulated profession” addresses the education/qualification necessary to actually perform the activity (“know how” - e.g. electrician, doctor, etc.). Also it is a matter of a regulated activity rather the circumstances under which the activity is executed.²³⁴

Not all the particular details on how those criteria will be achieved are covered by jurisprudence as the choice of methods for regulation is mainly within the competence of national Law as long as they do not clash with EU law. As the Court has proclaimed in several cases the definition of ‘*regulated profession*’, for the purposes of the PQD, is a matter of EU law.²³⁵ As a result the healthcare exemption is formed not only by the SD and the PRD, but also by the PQD.²³⁶

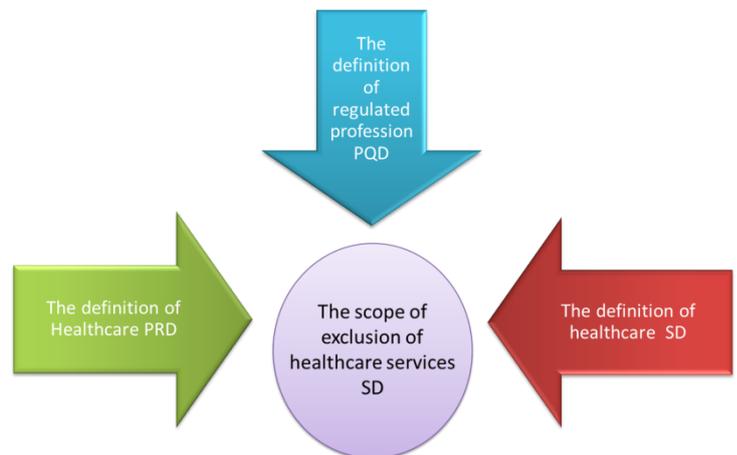


Figure 6 Definitions providing scope for healthcare exemption

5.4 Paramedical

During the course of this thesis it has been established that according to jurisprudence, mainly *Fermabel* and *Ottica*, healthcare exemption can only exist if the healthcare services are provided by a healthcare professional. Hence, a non-regulated professional selling a medical product or a medical device, e.g. Nicotine replacement therapy outside of a pharmacy is not healthcare but trade, i.e. not exempted on basis of art 2(2) (f).

Chapter 5.3 above set that healthcare professionals (of a regulated profession) can be divided into two main categories, *sectorial* and those recognizable by generic evaluation.

The healthcare professionals that belong to the *sectorial* professions are seen as *medical professions proper* (e.g. pharmacists), a term used by the Court in *Eleftherios*.²³⁷ The paramedical professionals, e.g. opticians are subject to the *generic evaluation*.

In *Ottica* AG Jääskeläinen discussed the matter of paramedical professionals in relation to opticians at length. According to the Court opticians can be either regulated or not, but Italian

²³⁴ Bernhard Zaglmayer, Deputy Director, Internal Market Affairs Oslo, 29 November 2011.

²³⁵ See C-164/94 Arantitis, C-313/01 Christine Morgenbesser v Consiglio dell'Ordine degli avvocati di Genova [2003] ECR I-13467, C-234/97 Bobadilla and C-285/07, Burbaud [2003] ECR I-8219.

²³⁶ See picture 6.

²³⁷ A term used by the Court in C-575/11, Eleftherios-Themistoklis Nasiopoulos v Ipourgos Iglas kai Pronoias.

law regulates opticians in general making it a regulated profession, therefore the court did not elaborate the matter further.

In *Venturini*²³⁸ the similarities between para-pharmacies and regular pharmacies were compared and assessed. If a paramedical service provider is too similar to pharmacies they will fall outside the scope of SD. I.e. the seller of a medical product must be clearly commercial and the services must be separable enough not to be ‘interchangeable’ with pharmacies, run by professionals of sectorial profession.

This raises the question of; if and under which circumstances paramedical should be deemed to be healthcare professionals. As can be understood from the above the regulatory dealing of paramedical seems to vary between different MS’s so no unison EU wide rule exist.

The paramedical sector is extensive and covers a broad range of different activities, e.g. physiotherapist and optician, and does not fall within the sector of *medical professions proper*.²³⁹ Thus, unlike the *medical professions proper* they do not automatically benefit of the sectorial rules automatically providing the status of a regulated profession. However, this does not mean that paramedical by definition avoid the system of mutual recognition of *regulated professions* as established by EU law.²⁴⁰

5.5 Issues due to differences in how MS’s define regulated professions

Four different types of approaches for the MS’s to regulate professions are acknowledged by the Commission Communication SWD(2013) 402 final;²⁴¹

- Regulated professions associated with reserved activities
- Professional activities regulated through mandatory certification (the qualification requirement is not exclusively linked to a profession as such but to a specific activity).
- Protected professional titles
- Voluntary certification schemes

With voluntary certification schemes it is slightly unclear where one should draw the line.²⁴² Private regulation has been assessed by the court and the signals can be slightly confusing. Obviously where the certification schemes are connected to bodies appointed or effectively controlled by the State it is considered regulatory.²⁴³ But, there is also a possibility that

²³⁸ Joined Cases C-159/12 to C-161/12 *Alessandra Venturini v ASL Varese and others*.

²³⁹ C-575/11, *Eleftherios-Themistoklis Nasiopoulos v Ipourgos Igiias kai Pronoias*, para 28 draws a clear line between paramedical. C-539/11, *Ottica New Line di Accardi Vincenzo v Comune di Campobello di Mazara*, confirmed optician as a paramedical. See also PQD Annex II. Spa treatment can also be healthcare, C-8/02, *Ludwig Leichtle and Bundesanstalt für Arbeit* [2004] ECR I-2641.

²⁴⁰ C-575/11, *Eleftherios-Themistoklis Nasiopoulos v Ipourgos Igiias kai Pronoias*, para 28.

²⁴¹ Communication from the Commission evaluating national regulations on access to professions {SWD(2013) 402 final}, 2013 Annex I, p 12.

²⁴² Feedback from internship at the NBT.

²⁴³ See e.g. C-136/12, *Consiglio nazionale dei geologi v Autorità garante della concorrenza e del mercato*, paras 42-44 where the membership is required by law of the MS.

measures by private bodies intended to regulate an activity in a collective way is included. This has occurred in the field of professional services.²⁴⁴

Lastly, the ‘*effect rationale*’, i.e. that voluntary certification schemes, even though they do not fall under the system of recognition in PQD, may affect the market. This happens by them creating a necessity of certification to access some professional activities by favoring dominant professional associations.²⁴⁵

Due to the difference of regulatory methods and choices regarding which professions to regulate some cross-border services might be deemed as healthcare in some MS’s and covered by the Services Directive in others. As an example, the Swedish system permits a person to exercise the activities of an optician without having an actual license²⁴⁶, granting the applicants do not call themselves licensed while performing their work. This system accounts for all regulated medical professions in Sweden except the following licensed professions: pharmacists, midwives, medical doctors, dentists and prescriptionist due to their sole right to the profession.

A certain amount of confusion may arise from a strict reading of art 14.4 PQD, when a professional, who is not part of the sectorial professions of one MS, moves/establishes “business” in another MS. This is due to the wording of art 14.4 of the PQD, that ‘*substantially different matters*’ means matters of which knowledge is essential for the pursuit of the profession. It may then be interpreted as; none of the regulated professions where only the use of the title is regulated would then be possible to subject to compensation measures if the pursuit of the profession is not considered as regulated in the new host MS.²⁴⁷

This type of uncertainties could amount to a severe disregard of the mutual recognition principle of the profession that a person has training for, resulting in a restriction to the exercising of a profession. This would most likely be disproportionate in line with the ECJ’s reasoning in *Eleftherios*.

Partial hindrance, may however be justified under certain circumstances by *ORRPI*, consumer protection and health protection. That is why a MS can restrict access to the title (being a mode of regulated profession) but not to the exercise of professional activities the service provider has competence for and has proof of it from competent authorities.²⁴⁸ Sectorial professions function in a similar way.

In *Ministero per i beni e le attività culturali*²⁴⁹ the exercise of professional activities that fall under the title of architect was discussed in depth. The Court made two things rather clear.

²⁴⁴ See C-506/04, Graham J. Wilson v Ordre des avocats du barreau de Luxembourg ECR[2006] I-8613, paras 51-58 and joined Cases C-94/04 and C-202/04, Federico Cipolla and Others v Rosaria Fazari, née Portolese and Roberto Meloni [2006] ECR I-11421.

²⁴⁵ Commission, Communication from the Commission evaluating national regulations on access to professions {SWD(2013) 402 final}, 2013 Annex I, p 13.

²⁴⁶ See <http://www.optikerforbundet.se/index1.asp?siteid=1&pageid=3>.

²⁴⁷ One of issues faced by the NBT, source Ola Valois, legal analyst at NBT.

²⁴⁸ See C-575/11, Eleftherios-Themistoklis Nasiopoulos v Ipourgos Igiias kai Pronoias, paras 22-24.

²⁴⁹ C-111/12, Ministero per i beni e le attività culturali v Ordine degli Ingegneri di Verona e Provincia et others.

1. It is the national legislation of the host MS that defines the field of activities enclosed by architects.²⁵⁰ However, the principle of mutual recognition in regards to the sectorial professions requires automatic recognition of persons having the qualifications and proof of this in a form of diploma by relevant authorities in the MS of Origin.
2. If there are variations on the specifics, those persons must be allowed to pursue the activities of an architect even though the use of the title can be refused, until 'equivalence' has been reached by the person in question by additional education or training. During that time period the person may either use the title from the MS he/she originates from or a title the host MS considers suitable.²⁵¹

Interestingly enough the Court actually used a likely cross-border situation, which was not the matter at hand, to analogically apply the rule for Italian engineers having the right qualifications and a legitimized proof of it by relevant authorities even though they did not bear the title architect but that of an engineer²⁵² wanting to practice activities of an architect in Italy. To be precise, since the cross-border element was only theoretical, the case was about a purely internal situation. Motivation behind this judgment was to address the issue of reverse discrimination, as the Court explicitly mentions.²⁵³

Since a person currently cannot claim any regulated professional title without fulfilling some form of education, accreditation or other professional requirement it logically follows that the training in itself cannot be seen as exclusive. I.e. the title, even when regulated, is only provided after an individual fulfills the criteria for achieving it. The horse goes before the cart.

Access to training for certain required qualifications for an individual may be restricted by national authorities by law or fact. Lawyers, not a regulated profession in Sweden will be an excellent sample. Law in Sweden can be studied at different type of faculties, *inter alia*;

- Business Law, at the institutes of Economy and Management,
- Administrative Law (förvaltningsrätt), institutes for Social Science and Faculty of Law
- Law, at the Faculty of Law.

These educations may take form of programmes or freestanding courses. But, only a successful completion of the programmes offered solely by the Faculties of Law²⁵⁴ give access to LBB which is compulsory to be able to access the title of a barrister or to pursue certain professions, e.g. judge of a national court. Several of the courses are offered only within the programme (e.g. criminal and process law) and cannot be accessed as free standing

²⁵⁰ C-111/12, Ministero per i beni e le attività culturali v Ordine degli Ingegneri di Verona e Provincia et others, para 42.

²⁵¹ Ibidem, para 47.

²⁵² See Commission, Council Directive 85/384/EEC on the mutual recognition of diplomas, certificates and other evidence of formal qualifications, including measures to facilitate the effective exercise of the right of establishment and freedom to provide serv, 1985 arts 10 and 11.

²⁵³ C-111/12, Ministero per i beni e le attività culturali v Ordine degli Ingegneri di Verona e Provincia et others, para 38.

²⁵⁴ There are only six of these Universities in Sweden, Uppsala, Lund, Stockholm, Umeå, Göteborg and Örebro. See Högskoleverket. Rapport 2007:18 R.

courses in Sweden. So, the only way to access the LLB is by finishing one of the specific programmes aimed at providing access to the regulated Barrister title. Thus, there is a *de facto* exclusivity on some qualifications.

Further, due to the restrictive way the definition of ‘*regulated education*’ in the PQD is constructed²⁵⁵ closing out even education and training recognised by a MS as relevant for a regulated profession, without the specific aim of pursuing that profession, can be deemed as nonspecific. This means that persons possessing similar/same skills can be categorised differently.

Additional issues may be caused by part of the legal text of the PQD being lost in translation. This can be demonstrated by the Swedish and German language versions, differing in a relevant aspect from the others; they seem to be the only ones where the word ‘*or*’ is changed to ‘*and*’. Also the whole aspect of administrative provisions is left out from these two versions. In the text of eleven languages compared (English, French and Italian, Polish, Dutch, Estonian, Danish, Spanish and Finnish), the method of regulation is by virtue of legislative, regulatory or administrative provisions. Since the definition of method of regulating professions is not complete, there is a risk that a healthcare professional could be wrongly assessed as not regulated.

5.6 The public health concerns

Health professions have a special role from several aspects. Public health concerns seem to have a heavy duty role to play as regards the economic means test, i.e. in connection with mixed nature of paramedical activities; the rulings of the ECJ intricately point toward a preference to assess the activities at hand under the Treaty regulations instead of the SD. So far the cases concerning activities of a mixed nature, healthcare and commercial, have either had no mention of the Services Directive,²⁵⁶ have been deemed as healthcare²⁵⁷ or the Court has left it for the National Courts to decide.²⁵⁸

Fermabel mentions, in reference to recital 7SD, that due to the wide range of services covered by the Services Directive, a careful balancing should be made with insight into the distinct feature of the activity and general interest objectives, particularly mentioning those linked to public health,²⁵⁹ when evaluating if activities are healthcare or not.

Ottica clearly marks this link with activities of assessing, maintaining or restoring the state of patient’s health and the protection of public health. Accordingly, these activities should be performed by *healthcare professionals proper* or *paramedical*. Thus paramedical of a more commercial nature are subject to a nudge towards the genuine medical healthcare where assessments are being made.

²⁵⁵ 3(i) (e) PQD.

²⁵⁶ See, e.g. Joined Cases C-159/12 to C-161/12 *Alessandra Venturini v ASL Varese and others*.

²⁵⁷ See C-539/11, *Ottica New Line di Accardi Vincenzo v Comune di Campobello di Mazara*, referring analogically to C-108/09 *Ker-Optika bt v ÀNTSZ Dél-dunántúli Regionális Intézet* ECR[2010] I-12213, 2010.

²⁵⁸ See C-57/12, *Femarbel ASBL v Commission*.

²⁵⁹ C-57/12, *Femarbel ASBL v Commission*, para 39.

In *Venturini*, the persons performing the services being pharmacist providing services in form of retail sales of medicines in para-pharmacies, strengthens this link further.²⁶⁰

Recapitulated, the main idea is that ‘*end of distribution chain*’ activities, which may raise issues of public health, connected intrinsically to the performance of the service itself, would usually not be assessed under the Services Directive. That is why those services are usually (in many MS) connected to requirements targeted at the person providing the service possessing certain qualifications. Here however the line between services and goods can become a little vague as the classification of the goods, let's say, a medical x-ray device, reflects to nature of the service, the operation of X-ray apparatus being reserved for professional radiographers. The mentioned setting does not however lead to the service necessary being healthcare. I.e. sale of painkillers in supermarkets, for that to be considered healthcare the person engaged in the activity must be a healthcare professional.

Some countries are even of the opinion that there should not be a partial access to health professions as there is greater risk posed in relationship to the service provided. As well as the possibilities of misinformation regarding the professional activities’ restricted nature to the patients, public in general and other service users.²⁶¹ Consequently, for the providers of the healthcare services, if any lack of clarity of the nature of the service exists and there are public health concerns involved the Services Directive is unlikely applicable.

5.7 Reflections and Demarcations

Health services should be provided by healthcare professionals according to recital 22SD or the 3.1(f) PRD in accordance with *Fermabel* and *Ottica*. However, neither the Services Directive, the PRD or the PQD specify what formal skills health care professionals should have.

That is why a case-by case assessment has to be done. In the case of a regulated profession, the provisions relating to the regulation demonstrate whether it is a health-care profession or not. *Fermabel* extended the coverage of healthcare professional to a larger group. Accordingly, if the profession is not regulated by virtue of PQD, but the person is nevertheless recognized as a health professional in accordance to the legislation of MS where the treatment is provided, consideration must be taken to the occupational description of the relevant MS and to the services that are provided by the professional group as a whole, which requires a special evaluation of the activities they conduct.²⁶² (Chapter 5.1 and chapter 5.2)

Lacking a clear general criterion in the current state of EU law, the key to regulated professions seems to be ‘specificity’.²⁶³ I.e. a person must have a certain specific

²⁶⁰ Joined Cases C-159/12 to C-161/12 *Alessandra Venturini v ASL Varese and others*, paras 51-54.

²⁶¹ UK, D. o. (2011). European Commission Green paper: UK Government response - Modernising the Professional Qualifications Directive. London, United Kingdom: Department of Business innovations and skills UK, p 11.

²⁶² C-57/12, *Femabel ASBL v Commission*, para 53 and Opinion of Mr Advocate General Cruz Villalón, C-57/12, para 25.

²⁶³ See e.g. C-586/08, *Angelo Rubino v Ministero dell’Università e della Ricerca* [2009] ECR I-12013, C-539/11, *Ottica New Line di Accardi Vincenzo v Comune di Campobello di Mazara*, C-575/11, *Eleftherios-Themistoklis Nasiopoulos v Ipourgios Igiias kai Pronoias*.

education/qualification necessary to actually perform the activity (“know how”) and has to be able to prove it. On top of the ‘iceberg’ are the sectorial professions benefiting from automatic mutual recognition. It seems absolutely clear that the definition falls under EU’s competence, but just as regarding healthcare, it is the MS’s who choose which professions to regulate. Thus, the variety of regulated professions within EU is wide (chapter 5.3). Currently four types of ways to regulate professions are deployed by the MS’s of the EU: by protected titles, activities regulated through mandatory certification, regulated professions associated with reserved activities and certification schemes that are voluntary. There are several issues connected to the way the rules are written in combination with some strict reading of the rules potentially causing professionals of regulated professions not to be categorized as such (chapter 5.5). The Directive 2005/36/EC however is being updated.²⁶⁴ The updates most relevant for healthcare professionals linked with the Services Directive is that they will be automatically excluded from the SD.²⁶⁵ The deadline for implementation to national laws is 18 November 2016.

Differences of classification are at a zenith for paramedical, as *Ottica* visualizes by discussing different types of opticians (chapter 5.4). If opticians would have not been a regulated profession in Italy they might have fallen under the Service Directive. Then again, a link with public health concern seems to have resulted in quite the opposite, corresponding to *Venturini* (chapter 5.6). As these concerns are of great weight in assessment of healthcare activities in regards to public health concerns, when such a link exists, the case will most likely be assessed under the relevant Treaty art instead of the Services Directive.

²⁶⁴ Commission, Directive 2005/36/EC – policy developments.

²⁶⁵ Commission, DIRECTIVE 2013/55/EU of 20 November 2013 amending Directive 2005/36/EC on the recognition of professional qualifications and Regulation (EU) No 1024/2012 on administrative cooperation through the Internal Market Information System, 2013 recital 30.

6. Reflections, analysis and conclusion

6.1 Reflections

6.1.1 The Services Directive and its purpose

The Services Directive is a joint regulatory system that covers all service sectors that are not specifically excluded from it. The Directive addresses both temporary provision of services and establishment. Rules on administrative simplification and cooperation of NA's, between and within MS's are introduced. An excessively wide scope for the requirements, bound to catch non-discriminatory requirements with no effect on the trade, are subjected to a test of non-discrimination, 'necessity' and proportionality.

The tolerance for objectively justified reasons to restrict cross-border temporary services is narrower than for establishment. (See Chapter 2.4)

The Services Directive is a legal instrument and a tool for control, forcing the MS's of the EU to undertake a continuous review of national laws and regulations to make certain that they are not in a contradiction with EU law and practice. With the implementation of the Directive the MS's had to truly assimilate the relevant jurisprudence after a long lingering period of resistance. This was a vital matter, as the Community is run by the rule of law and the judgments of the Court must be fully complied with by the MS's so as fundamentals of the Union will not be compromised. Individual rights, legal certainty, equal treatment of the diverse conditions under which market participants function in different parts of the EU, also the balance of rights and obligations of MS's under the Treaties are dependent on this.²⁶⁶

The Directive has accomplished this to a certain extent as well as simplified the internal market for both for providers and recipients of services.

A separate ongoing notification procedure, when new or altered requirements are introduced by the MS's after the deadline of the adoption period remains, to ensure that no new non-justified hindrances to intra community trade on services arise.

6.1.2 Risks

In order for the internal market to function in practice, its legal framework ought to be of great quality at both EU and national level. In the blink of an eye it can be deemed that the Services Directive stumbles a bit there due to the sometimes poor quality of the legal text; inconsistencies occur both in relation to the internal market freedoms and within the Services Directive itself. In case uncertainties of interpretation and possible contradictions with the Treaties occur, the Services Directive must be interpreted and implemented in context of the internal market freedoms. This situation may well take place due to the textual ambiguities within the Services Directive. Some problems are also caused by the fact that the Services Directive has been incorporated into the National Laws of the MS's by the method most suitable to them from a national perspective. This leads to differences in interpretations and implementation in national laws between the MS's.

²⁶⁶ Commission, Europa.eu, 2005 p 1. [http://europa.eu/rapid/press-release MEMO-05-482_en.htm](http://europa.eu/rapid/press-release_MEMO-05-482_en.htm)

A good example of a contradiction is the healthcare exemption that is the subject of this study. The art 2.2(f) SD only mentions healthcare, however recital 22SD adds pharmaceutical services to healthcare, thus, they do not match. Even though a certain amount of ambiguities are most likely intentional with the purpose of providing a certain scope for interpretation based on normative differences between MS's national legislations,²⁶⁷ though in regards to the Services Directive the number has overstretched.

6.1.3 The Services Directive healthcare exemption

Provision of healthcare in EU is a huge service sector, and on the rise as the population is aging. However, due to its nature, social objective as well as *inter alia* public health concerns, it was left out from the Services Directive. The exemption for healthcare is founded by art 2(2) (f) SD, which lists what the exemption covers, but lacks any kind of definition for what constitutes healthcare services.

Art 2(2) (f) SD specifies the circumstances where the Services Directive is not applicable. Recital 22 addresses what '*healthcare*' is in context of the Services Directive, and it recognises that both '*healthcare and pharmaceutical services*' are covered by the exemption. This is followed by an explanation that the concept of 'healthcare' is conditional on that those service should be '*provided by healthcare professionals to patients*'. Also specific circumstances for the exemption to stand are added; '*to assess, maintain or restore their state of health*' and '*reserved to a regulated health profession in the Member State in which the services are provided*'. These terms must be interpreted first autonomously and then together as a whole in a wider context.

6.1.4 Healthcare services in EU law

Healthcare can be found in art168 TFEU, covering mental and physical health. The data collected points to the concept of healthcare covering human health only. (Chapter 4.2) Since the concept does not cover enhancing wellbeing or the provisioning of relaxation healthcare, it is either directly or indirectly linked to a negative medical condition of a person at a relevant point in time. Provision of healthcare is provided by a person to a patient and is divided in three categories:

- Assessment - an inspection of a negative condition either being or not being present. If needed, evaluation of possible treatments is included. (Chapter 4.4)
- Maintenance - Maintenance of health or stabilizing a medical condition. Also actions with a preemptive purpose are covered e.g. vaccines. (Chapter 4.4)
- Restoration - treatment of a negative medical condition of some kind. (Chapter 4.4)

For "*pharmaceutical services*" no EU level definition was found. Thus they are deemed to be prescription, dispensation and provision of medical products and devices in line with the PRD art 3.a).

²⁶⁷ Maduro, M. P. (2007, December 5). Interpreting European Law: Judicial Adjudication in a Context of Constitutional Pluralism. *The European Journal of Legal Studies*, Vol.1, Issue 2 art 8, p 9.

6.1.5 Patients' Rights Directive (PRD)

To understand the “*healthcare*” concept in a wider context one must read the healthcare exemption in light of the PRD which contains specific provisions regarding healthcare.²⁶⁸

As explained earlier (Chapter 4.7) even though the PRD only covers recipients of healthcare services on a temporary basis, the remarkably similar wording of recital 22SD and art 3.a) PRD can be used to unravel the healthcare exemption of the Services Directive. This was done in *Fermabel*, which did not even mention the PQD. However *Ottica* does mention PQD and since SD and PRD both mention PQD it is of essential value.

PRD also provides the explanation for ‘*pharmaceutical services*’ as well as ‘*healthcare professionals*’. For the final piece of the puzzle, the PRD just like the SD refers to the PQD for a definition of a healthcare professional of a regulated profession.

6.1.6 Professional Qualifications Directive (PRQ)

The last legal instrument relevant to healthcare exemption in SD is the PQD. If the healthcare services are not provided by members of a health profession regulated nationally by the relevant MS they will be covered by the Services Directive. Art 4(11) SD refers to the art 3(1) (a) PQD for the definition of regulated professions. The PQD addresses the person providing the services and the qualifications that person possesses. Both the object of restriction ‘*regulated profession*’ and the different type of regulative methods that are deemed to be as ‘*regulated*’ are covered by the art 3(1) (a) PQD. The definition of ‘*regulated profession*’ for the purposes of Directive 2005/36 is a matter of Union law.²⁶⁹ The MS’s decide which activities are reserved to a regulated health profession within their jurisdiction. I.e. which professions they at least partially regulate. There is not a clear criterion of what really is a ‘*regulated profession*’ but from EU jurisprudence the requirement of *specificity* of the acquired skills is the key feature as have been presented in chapter 5.3 of this thesis and case law- e.g. *Ottica*, *Rubino*, *Perranoja Fa*.

The new amended PQD recital 30 puts an end to the legal uncertainty in regards to what is adjudged regulated healthcare professionals by clearly stating that healthcare professionals (notice the absence of the word regulated) are not covered the Services Directive.²⁷⁰

6.2 Discussion and analysis

Janus, the god of transitions looking at the same time both into the future and he past, does not only symbolize the normative plural nature of the EU law in general, the same pluralism is very much present in the exemption of healthcare.

It is the EU that defines the definitions applicable to healthcare as a ‘*regulated profession*’, but it is the MS’s that regulate which healthcare is appropriate and what type of ‘*healthcare professionals*’ are regulated. This legal pluralism reflects how the legislative tools are

²⁶⁸ Opinion of Mr Advocate General Cruz Villalón, C-57/12, para 23.

²⁶⁹ C-586/08, Angelo Rubino v Ministero dell’Università e della Ricerca [2009] ECR I-12013, para 23.

²⁷⁰ Commission, DIRECTIVE 2013/55/EU of 20 November 2013 amending Directive 2005/36/EC on the recognition of professional qualifications and Regulation (EU) No 1024/2012 on administrative cooperation through the Internal Market Information System, 2013.

applicable in the MS's, and indubitably leads to national differences in treatment of the scope of the Services Directive. This is of course how the EU works due to different legal cultures and the choice each MS makes in to what extent different aspects of health services are being regulated. An attempt for a more unified viewpoint on what is the correct legal tool applicable for healthcare professionals is reflected in the Draft of the PQD recital 30 which puts the cat on the table²⁷¹ by exclaiming that '*healthcare professionals*' are not covered by the Services Directive.

It is no wonder that the MS's could not agree to the *Bolkenstein* Draft's healthcare legislation; the wide coverage of cross border extramural care for consumer concept was too far reaching for the MS to sign. Eventually the healthcare boomeranged back in form of the PRD which now also may be used as an interpretation tool for the healthcare exemption in the art 2.2(f) SD in support of recital 22 SD.

6.2.1 Interpretation of Art 2.2(f) SD

Art 2(2) (f) SD must be read in light of recital 22 SD. These establish two cumulative criteria of the healthcare exemption. After *Fermabel* and *Ottica*, both the PRD and the PQD must be studied where relevant. Their interaction with the Services Directive as well as the order of precedence of these horizontal legal instruments must be established.

The scope of the exemption of healthcare exists on three planes; SD, PRD and PQD, as well as three different levels; material, personal and territorial, simultaneously. For a deeper understanding the three directives, Services Directive and PRD need to be read together with the definitions in PRD, as was suggested by the AG and done by the Court in *Fermabel* and *Ottica*.

6.2.2 Healthcare services in EU law and the nature of healthcare

Art 168 TFEU mentions mental and physical health as part of public health. Also prevention of diseases is mentioned. Nevertheless, it is not nearly as wide as either the WHO concept of health or what many people would consider as health. Genuine healthcare in EU Law is '*to assess, maintain or restore their state of health*'²⁷² taking place at a specific stage. Even some sort of activity level from the healthcare professional providing the healthcare must exist or the service is not '*genuine healthcare*'. (Chapter 4.4) Even prescription, dispensation and provision of medical products are included. (Chapter 4.5) What exactly is covered by healthcare is set by the national law of each individual MS.

Instead of concentrating on health, the traditional healthcare has taken a contrary approach by focusing on dealing with illness and disease. (Chapters 4.3- 4.4) A more positive medical view, the prevention of disease, has been gaining an increased foothold in healthcare systems.²⁷³ Thereby adding an aspect of positive focus to the assessment of as well as widening the concept of healthcare.

²⁷¹ 'Putting the cat on the table' is a Finnish expression that refers to speaking frankly and honestly about difficult subjects. See <http://catonthetable.com.wordpress.com/2011/02/06/hello-world/>.

²⁷² See recital 22SD.

²⁷³ Gillies, A. (2003). What makes a Good Healthcare. Oxon, United Kingdom: Radcliffe Medical Press, p 21.

The Commission handbook²⁷⁴ partially reflects the traditional narrow concept of healthcare as it closes out wellbeing in the form of fitness clubs even though it is well documented that good physical condition helps prevent diseases of affluence such as cardiovascular diseases,²⁷⁵ diabetes and obesity.²⁷⁶ Most likely this is to stay politically on the safe side. This narrow view is commonly shared among the MS's, while the biggest variation of healthcare will be found on the positive approach.

To what extent the MS's apply positive aspects of healthcare policy is the outcome of the interaction of values and drivers, varying largely from MS to MS and culture to culture. It is crucial to be aware of the fact that assessment of the scope of healthcare must be done individually by each MS as the Commission's handbook is not normative.

Nonetheless, "*genuine healthcare*" is a part of the healthcare exemption formula. Its explicit key is *the nature of the service* and activity level at a given point in time based on an explicit need.

6.2.3 The link between healthcare professional and patient

Since the state of human health does not remain constantly unchanging, but is subject to at times even rapid changes, the timing is a fundamental component of healthcare. The missing ingredient of the healthcare exemption is the aspect of time.

So to say, it is not possible to cure a patient who is already dead. Connected to the timing is the action, which classifies as healthcare. For that action to transpire at the correct time there must be some sort of direct link with the provider of the healthcare and the health status of the receiver of the healthcare. It is not possible to take into account... '*each individual case of the medical circumstances and the clinical needs of the person concerned*'²⁷⁷ unless the healthcare professional assessing, maintaining or restoring the patients state of health has access to specific data relating to the specific patient at a specific point of time. This data can of course be accessed by different methods, individual medical reports or personal contact of some kind with the patient. This removes the middlemen of healthcare sector from being part of the exemption 2.2(f). This line of thought gains support from ECJ case law.²⁷⁸

A common factor in all cases studied in (Chapter s.4.3, 4.4 and 4.6) is that the exercise of a healthcare activity always occurs at the '*end of the distribution*' chain as presented by pictures 1 and 2 since it is directly linked to the patients state of health at a specific point in time.

²⁷⁴ Commission, Handbook on implementation of the services directive, 2007 p 10.

²⁷⁵ Majid Ezzat, S. V. (2005). Rethinking the "Diseases of Affluence" Paradigm: Global Patterns of Nutritional Risks in Relation to Economic Development. Plos Medicine May 2005 | Volume 2 | Issue 5 | e133, 0404-0412, p 0404. www.plosmedicine.org.

²⁷⁶ Hu, M. J. (2001). Diet, lifestyle, and the risk of type 2 diabetes mellitus in women. The New England Journal of Medicine 345 (11), p 796.

²⁷⁷ See C-372/04, Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health [2006] ECR I-4325, para 75.

²⁷⁸ See e.g. C-372/04, Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health [2006] ECR I-4325, paras 62 and 75 and C-173/09, Georgi Ivanov Elchinov v Natsionalna zdravnoosiguritelna kasa [2010] ECR I-8889, para 66 referring to C-56/01, Patricia v Caisse primaire d'assurance maladie des Hauts-de-Seine [2003] ECR I-12403, para 46.

Where that link to the patient is established is crucial for a correct evaluation of genuine healthcare. Is it for instance enough to provide healthcare within the meaning of the Services Directive in a situation where the healthcare professional only has access to an individual's medical data, without any physical contact with the patient.

In this evaluation, keen attention should be paid to numerous healthcare cases that lay it down clearly, that in order to determine an effective *treatment for the patient, all the circumstances of each specific case must be taken into account. This includes the degree of pain the patient is in or the nature of the patient's disability as well as the patients' medical history.*²⁷⁹ This indicates that processing or analyzing a totally isolated part, not linked to the state of the health of the patient, and with no contextual regard to the individual patient's actual state of health as a whole, would not be healthcare within the meaning of the healthcare exemption. Thus, a pure processing of data, e.g. a lab analyzing a batch of blood samples without connecting it any further to a specific patient, should not be deemed as healthcare. The situation is different if the lab's analysis is done to determine a person's medical condition, i.e. genuine healthcare occurs.

An entirely different question is if there should be differential dealing by EU law, vis-à-vis on how that overall assessment of the medical condition of the patient is done, i.e. must there be a physical contact with the patient; is information submitted by phone or e-mail enough or even an analysis of a medical record of the actual patient. It should be adequate enough that there is a personal contact by phone, as e.g. information and assessment provided by the medical personnel at poison information centers, emergency centers and medical on-call services as healthcare. However, in lack of special know-how in the medical area, to ensure a proper call, this criterion should be refined by the specialist in the area.

The main finding relevant for the NA is that they do not however need to assess what the specific link is; it should be enough to establish that such a link exists provided the link is related to the establishing of health status. Basically, even though natural or legal persons of the MS's are considered as service providers or receivers, the ones who actually perform and receive the healthcare service are always physical persons.

6.2.4 The personal link (end of distribution chain) PRD+SD

ECJ left unmentioned a very important factor, *the personal link* in *Fermabel* but touched upon it in *Ottica*. The AG's opinions had an elaborated discussion around this link even though they did not use the exact wording. Since healthcare occurs as a transaction involving the patient and healthcare professionals in a manner that the professional must always be aware of the patients individual medical condition, healthcare service will always occur at the end of distribution chain. (Chapter 4.6) This is an important part of the formula for the healthcare exemption and should actually be the starting point of the whole - healthcare or not healthcare assessment.

²⁷⁹ Ibidem. See also C-157/99, B.S.M. Geraets-Smits and Peerbooms v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Groep Zorgverzekeringen [2001] ECR I-5473, para 104 and Müller-Fauré and Van Riet [2003] ECR I-4509, 2003, para 90.

6.2.5 The principal part (*Ottica* and *Fermabel*)

It is true that the ruling in *Fermabel* clarified several issues regarding the scope of 2.2(f). But by doing so, several new questions arose.

One relevant question is: what legislative tool should be applied to the personnel working at Healthcare providers that are not providing any healthcare at all (e.g. cleaners, auditors)? If the SD is not the correct one do they fall under the Treaties even though the area and the services are particularly mentioned as commercial activities being within the scope of SD by the Commissions handbook? Does this mean that the people working within those settings are not covered by the notification obligation? After *Fermabel* and *Ottica* the classification of in-house non-healthcare personnel is effected by the spillover effect. If they are outsourced personnel, they should fall within the scope of the Services Directive. (Chapter 4.9)

However the extension of the spillover effect is ambiguous. The situation for the in-house, non-healthcare personnel, remains uncertain since the subject matter for the question placed with the Court in *Fermabel* was if the entire operation of the service provider (day and night care centers) was considered to be healthcare or not.

The Court's preliminary ruling provides a criterion for interpreting and assessing healthcare activities; if the predominant part of the services offered can be identified as health care services, it establishes the service provider as a health care service provider.

The Court only mentions “*care staff*” and paramedical staff.²⁸⁰ What is left unmentioned is the legal situation of the individual's not providing healthcare. AG Villalon discusses personnel other than healthcare professionals only in conjunction with care personnel working under the supervision of healthcare professionals. Thus the role of specific individuals that work for the healthcare service providers in a role other than healthcare and not under the supervision of the healthcare professionals (i.e. auditors etc.) are not covered directly by the relevant case law. Consequently, as the Commissions handbook still stands as the only guide for these types of activities, these individual's activities should fall under the scope of the Services Directive.

Another relevant question in this area is; If the classification of ‘*genuine healthcare*’ activities is defined by what constitutes the main part of the service providers operation and thus outside the scope of SD, as the Court judged; what does that mean when the predominant part of those services are commercial?

By the same logic, *e contrario*, the whole operation is considered as commercial and hence falls under the SD. Controversially this would even cover the part of operation that is genuine healthcare provided by a *health professional* of a *regulated profession* by the MS where the service is being delivered. One might draw the conclusion that the ‘spillover effect’ of *Fermabel* is a one way street, i.e. only predominance in healthcare does spillover not vice versa. To play devil's advocate; one of the purposes of the healthcare exemption is to ensure a high level of public health. A vice versa situation could be seen as rendering this purpose of the exemption hollow. I.e. what happens to the public health concern where the healthcare

²⁸⁰ See C-57/12, *Fermabel ASBL v Commission*, para 41.

service is not predominant part of the operations of the company, but healthcare services are still part of the services offered? Public health considerations should protect healthcare service receivers. However, the AG in *Fermabel* discussed and affirmed that also an *e contrario* interpretation is the correct way of applying the spillover effect in accordance to the ‘*spillover effect*’ of *Fermabel* in points 29-36 of his opinion. *Venturini* provides a solution.

6.2.6 Public health concerns

What if a commercial service is not separable from public health concerns? Then the service will likely be outside of the Services Directive in line with *Venturini* and *Ottica*. *Venturini* does not even mention the Services Directive. Both *Ottica* and *Fermabel* talk about public general interest objectives, naming especially public health concerns and link this to the healthcare exemption of SD. Thus activities that may raise issues of public health, being connected to a provision of services or the performance of the service itself, should be assessed as healthcare. Combined with the fact that one of the reasons healthcare was exempted from the SD on basis of inter alia the same concerns this makes sense.²⁸¹ Here however the line between services and goods become a little fuzzy. It seems that the classification of the goods, *in casu* a medical device or medical product, reflected in the classification of the service. This does not however lead to the service necessary being healthcare. For that to be the outcome the person engaged in the activity must be a healthcare professional.

The question is if this can be guaranteed by a directive with the commercial character of the Services Directive, which also covers the receivers and providers of a variable and wide range of services and concentrates of requirements as a whole instead of the relevant concerns of a patient.

The answer must be that activities, even closely related to healthcare services or public health concerns, will be assessed by the relevant Treaty articles like *Venturini*. Here a paramedical operation bore sufficient resemblance to pharmacies, being *genuine healthcare*, even though they were of a commercial nature. This allowed Italy to restrict the establishment of these para-pharmacies.

When the Courts reasoning in *Venturini* is compared with sales of some non-description medicine in food stores and supermarkets is acceptable by some MS’s,²⁸² an example of the level of independence the NA’s have of deciding where the line of public health concern is drawn at national level.²⁸³

Therefore, by logic of *Venturini*, the *Fermabel* spillover doctrine cannot be interpreted too widely, as the public health considerations become relevant. The two-way spillover effect must have been put in place by the Court purely for the sake of coherence, to enable an easier

²⁸¹ See e.g. C-57/12, *Fermabel ASBL v Commission*, para 39.

²⁸² *Affairs, M. f.* (2008), *Genomförande av tjänstedirektivet Ds2008:75*. Stockholm: Government Offices of Sweden p 536.

²⁸³ *Affairs, M. f.* (2008), *Genomförande av tjänstedirektivet Ds2008:75*. Stockholm: Government Offices of Sweden p 536.

and more unified assessment and application of the healthcare exemption in the different MS's.

6.2.7 Qualifications required of the people providing the service (PQD)

As it is clear that even though the service itself does not change, the classification of it seems to do so based on the predominant part of the nature of the service (of services provided), the next question to answer is the *qualifications required of the people providing the service* leading to one more *element of the formula of healthcare exemption*.

As has been established so far by this thesis, for healthcare services to be excluded from the Services Directive they must be provided by members of a health profession regulated nationally by the relevant MS. Reference to what a regulated profession means is given in art 4 (11) SD, which defines '*regulated profession*' as '*professional activity or a group of professional activities as referred to in Article 3(1) (a) of PQD*'. There is not a clear criterion of what really is a regulated profession, but from EU jurisprudence the requirement of *specificity* of the acquired skills is the key feature. Further, due to the restrictive definition of '*regulated education*' in the PQD²⁸⁴, covering only educations aimed specifically at pursuing that profession, healthcare professionals passing through the general assessment may be not categorised as such.

Remarkably the Court in *Fermabel* did not refer to the PQD regarding the matter of healthcare professionals. Instead they added a new dimension for the healthcare professionals by viewing only the PRD. This interpretation does patch the issue created by '*regulated education*' mentioned above.

Thus the SD, PRD and PQD may be melded to '*healthcare professionals recognized as such by the Member State concerned*'.²⁸⁵ A direct consequence of this decision was that the designated NA's were given the additional burden of establishing a method for identification of the people who belong to the group of healthcare professionals.

6.2.8 Healthcare performed by regulated professions

This can be provided in three different ways, by:

- Automatic recognition when a doctor of medicine, a nurse when responsible of general care, a dental practitioner, a midwife or a pharmacist in accordance to PQD(sectorial professions)
- a practitioner of healthcare activities which are reserved to regulated profession in accordance to the definition in PQD art 3.1(a)(EU)
- or a person considered to be a health professional according to the legislation of the Member State of treatment (if not covered by the definition of PQD art 3.1(a)(EU))

²⁸⁴ 3(i) (e) PQD.

²⁸⁵ C-57/12, *Fermabel ASBL v Commission*, para 53 and C-539/11, *Opinion of Advocate General Jääskinen*, para 28.

The definitions are a matter of Union law²⁸⁶ but the actual application, i.e. what to regulate and the choice of which professions to regulate is the choice of the MS as long as they stay within the framework of the PQD.

One of the functions of the exemption of healthcare from the SD is to ensure a high quality of healthcare services. As a result, MS's have relatively wide leeway in asserting restrictions based on public health concerns. Thus paramedical activities are more likely than not to be assessed under the Treaty regulations, not the Services Directive.

6.3 Conclusion

The subject matter of the SD differs from the system by which ECJ operates. The Courts decisions regarding operations of undertakings are made on a case-by case basis, whereas the SD is aimed at requirements as a whole. Thus, the purpose of this thesis was to find a solution for the existing legal uncertainty concerning the healthcare exemption in art 2(2) (f). By defining the scope of the health exemption as precisely as possible, suspect measures can be properly assessed for the purpose of the notification requirement. Further, the intention was to develop easily applicable model for the analysis process to enable a smooth unified implementation in practice by the NBT on the subject.

My starting point was to argue that a strict reading of art 2.2(f) SD read together with recital 22SD, the only tool available for the NA's until the recent rulings, does not necessary lead to a correct interpretation of the exemption. As a consequence unnecessary legal uncertainty remains, possibly resulting in misinterpretation of the rule. This needs to be dealt with in more detail on an EU level for a correct and harmonized interpretation in the MS's. My key research question was *'What is the precise scope of Article 2.2(f) as can be defined within the current status of Union law?'* My starting point was correct. But the study took me on a legal path more profound than I had anticipated.

Due to the uninformative nature of art 2(2) (f) SD, it must be read in light of recital 22 SD. These together establish two cumulative criteria of the healthcare exemption that needed to be defined as clearly as possible. Another aspect is brought in by the necessary criteria of *regulated healthcare professionals* by art 4.11 SD, targeting the person performing the service and the know-how, i.e. the professional requirement, that specific person has as well what activity that person performs at a specific point of time linked directly to the patients (service receivers) state of health. *Fermabel* introduced the PRD as one more legal instrument that affects the scope of the healthcare exemption. *Ottica* confirms the link between the SD and the PQD.

Healthcare seems to be divided in *medical proper* and paramedical. The paramedical are considered as healthcare, not wellbeing, if they are either linked to the *medical proper* as a part of the treatment of in some cases as standalone paramedical as was demonstrated by *Eleftherios*. (Chapter 5.4) In regards to standalone paramedical, either their medical nature

²⁸⁶ C-586/08, Angelo Rubino v Ministero dell'Università e della Ricerca [2009] ECR I-12013, para 23 referring to C-234/97, Fernández de Bobadilla [1999] ECR I-4773, para 14 and C-285/07, Burbaud [2003] ECR I-8219, para 43.

must be impeccably clear-cut, like the opticians measuring sight etc. like in *Ottica*, or they should be sufficiently similar to *medical proper* to be considered at least as partially 'substitutable' to the medical sectorial professions like in *Venturini*. Sectorial professions, e.g. pharmacist are always a regulated healthcare professional in the MS, as it is one of the harmonized professions by EU rules.

Thus the requirements for the service itself, the person performing the service and the direct personal link connected to a specific point of time of the patient's (service receivers) state of health are just different layers of the same thing, healthcare. Variable factors due to differences between MS's are territorial;

- Legislation
- Healthcare services provided
- Requirements for the service provider
- Requirements for the person performing the service

Territorial – i.e. the territory (MS) decide what healthcare is appropriate and under what circumstances they are provided as well as what formal qualifications are required of the persons to allow them to perform the service. Paramedical are covered to the extent of national treatment. A regulatory provision on goods, requiring a mandatory authorization of the person performing a service linked with a requirement of certain know how the person must possess the good, outcome is that that person is of a regulated profession.

Where public health concerns arise in line with *Venturini*, even activities of a commercial nature that are not healthcare, will most likely fall outside of the Services Directive. *Venturini* also supports that the key for public healthcare is the nature of the service, the professional status of the provider of that service and how strongly it affects to the rest of the service activities offered by the same provider.

Here is where the subject matter of the SD, PRD and PQD meet and meld to encompass the different aspects of different requirements in a three dimensional model.

The formula must be of four parts

- the nature of the service provided,
 - healthcare
- the predominant part of the service
- the persons providing the service
 - healthcare professionals
- the direct link

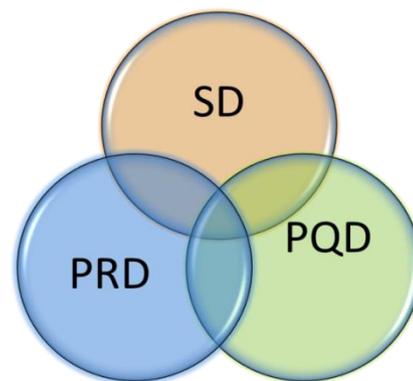


Figure 7 Directive overlap

For a whole picture of the exemption of healthcare in SD the three Directives must be read together, as demonstrated by picture 7 and in light of each other. Only this way is the true nature and the scope of the exemption of healthcare within the meaning of the Services

Directive revealed. The area where all those three meet is the healthcare exemption in 2.2(f) SD.

The NA deal with requirements aimed at provision of services in some form. To identify and assess the presence of a 2.2(f) SD healthcare exemption in a service/services, the author of this thesis recommends taking the following steps.

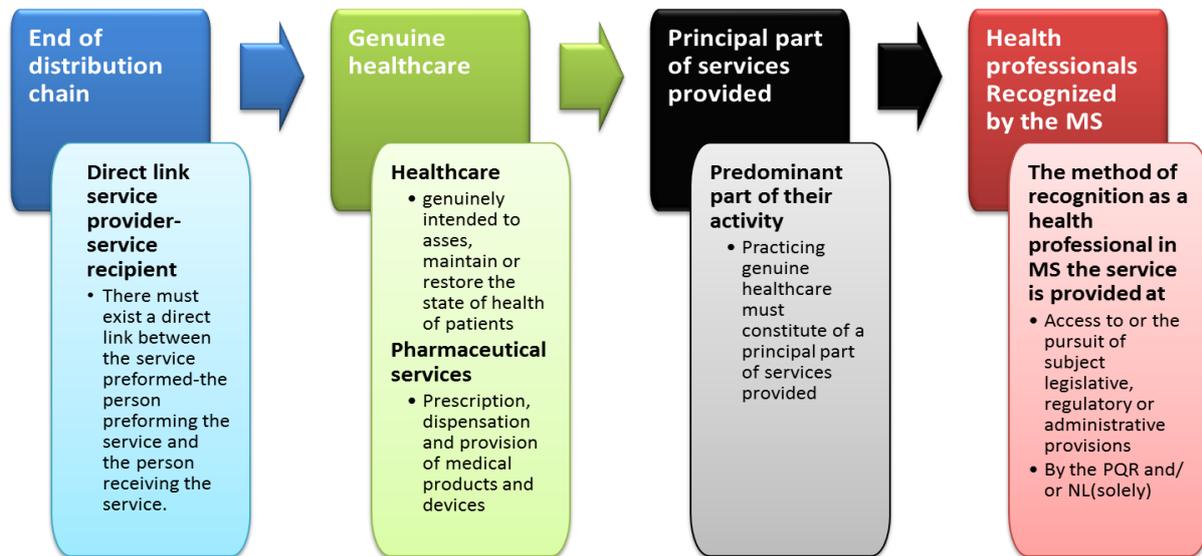


Figure 8 A step-by-step guide for the healthcare exemption

The steps are cumulative; all must be in place for the exemption of healthcare to be in place. Otherwise, the Services Directive will be fully applicable for the service provided, unless a *Venturini* situation amounting to a public health concern is present. Further guidance in form of case law from the ECJ or at least as guidelines from the Commission on the subject would however be extremely useful to confirm or to point out errors in this reasoning.

Even though the different MS's are bound to have a large variation in implementation of the healthcare exemption based on the level they regulate professions, the matter seems to be dealt with to some extent on an EU level by the implementation of the new PQD. With an automatic exclusion of healthcare professionals from the Services Directive a correct and harmonized interpretation in the MS's of the exemption will be more realistic. This is likely to cause a domino effect; if healthcare professionals will automatically be outside the scope of the Services Directive it will be enough to establish that a service is being performed by a healthcare professional. This would reduce the need for complicated analysis. However, until the draft of the new PQD is fully implemented and we have more cases from the ECJ as regards this matter, it is difficult to predict the exact path the future rulings will take.

What is unlikely to change are the issues of classification of paramedical due to the different views the MS's have regarding them, as either healthcare professionals or purely pursuers of commercial activities. This is unfortunate; an EU level recognition of paramedical as healthcare professionals would simplify the whole assessment process as well as fix the mutual recognition issues. There might be no remedy for this situation, as it is based on the

cultural values varying from state to state within EU. This is a complicated matter constituting a dilemma for the legislators, but it is also the nature and richness of EU.

Bibliography

Official publications

- Auwers, T. (2010). *STRENGTHENING SOCIAL MAINSTREAMING IN THE EU*. Brussels: Federal Public Service Social Security.
- Charter of Fundamental Rights of the European Union (2000/C 364/01) *Official Journal of European Communities (OJ2010C83/02)*, 1-22.
- Commission, E. (1985). Council Directive 85/384/EEC on the mutual recognition of diplomas, certificates and other evidence of formal qualifications in architecture, including measures to facilitate the effective exercise of the right of establishment and freedom to provide serv. *Official Journal of the European Community*, (OJ L 223, p 15).
- Commission, E. (1993, June 14). Council Directive of 14 June 1993 concerning medical devices. *Official Journal of European Communities (OJ L 169, 12.7.1993, p.1)*, 1-60.
- Commission, E. (1998,). Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services. *Official Journal of European Communities (OJ L 204, 21.7.1998, p. 37)*, 18-80.
- Commission, E. (2001). Directive 2001/83/EC of November 2001 on the Community code relating to medicinal products for human use. *Official Journal of the European Communities L 311*, 67-128.
- Commission, E. (2002). *Report from the Commission to the Council and the European Parliament on the state of the internal market for services*. Brussels, Belgium: European Commission.
- Commission, E. (2004, March 5). COM(2004) 2 final/3. *Proposal for a Directive of the European Parliament and of the Council on services in the internal market*. Brussels, Belgium: European Commission.
- Commission, E. (2005). *Green Paper - Improving the mental health of the population - Towards a strategy on mental health for the European Union* /* COM/2005/0484 final */. Brussels: European Commission.
- Commission, E. (2005). Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (OJ 2005 L 255). *Official Journal of European Communities*.
- Commission, E. (2006). Directive 2006/123/EC on Services in the internal market. *Official Journal of the European Communities*, 36-68.
- Commission, E. (2006, 4 6). Services Directive: Commission puts forward amended proposal. *Services Directive: Commission puts forward amended proposal IP/06/442 04/04/2006*. Brussels.
- Commission, E. (2007). *Handbook on implementation of the services directive*. Luxembourg:: Office for Official Publications of the European Communities.
- Commission, E. (2008, June 25). Communication from the Commission “Think Small First”A .COM(2008) 394 final“Small Business Act” for Europe.
- Commission, E. (2008, May 9). Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union. *Official Journal of the European Union*, C:2008:115:TOC.

- Commission, E. (2010, June 9). Guidelines relating to the application of the Council directive 93/42/EEC on medical devices. *MEDICAL DEVICES: Guidance document-Classification of medical devices*. Brussels, Belgium: European Commission.
- Commission, E. (2010, October 8) Smart regulation in the European Union. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. COM (2010) 543 final. Brussels, Belgium: European Commission.
- Commission, E. (2011). Directive 2011/24 of the European Parliament of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare. Official Journal of the European Union 4.4.2011, 45-65. Brussels, Belgium: European Commission.
- Commission, E. (2012, June 8). COM(2012) 259-Better Governance for the Single Market. *Communication from the Commission to the European Parliament, the Council, the European economic and social committee and the committee of the regions*. Brussels, Belgium: European Commission.
- Commission, E (2012, October 24) Riktlinjer den centrala kontaktpunkten för anmälningsförfarandet 98/34 och för de anmälningsförfaranden som föreskrivs i skärskil EU-lagstiftning. Brussels, Belgium: European Commission.
- Commission, E. (2012, October 25). Regulation (EU) No 1024/2012 of 25 October 2012 on administrative cooperation through the Internal Market Information System and repealing Commission Decision 2008/49/EC ('the IMI Regulation'). *Official Journal of European Union OJ L 316, 14.11.2012*, pp. 1–11.
- Commission, E. (2012, November 23). COM(2011) 803 final-Minimizing regulatory burden for SMEs Adapting EU regulation to the needs of micro-enterprises. *Report from the Commission to the Council and the European Parliament*. Brussels, Belgium: European Commission.
- Commission, E. (2013). *Communication from the Commission on evaluating national regulations on access to professions [SWD(2013) 402 final]*. Brussels, Belgium: European Commission.
- Commission, E. (2013). Directive 2013/55/EU of 20 November 2013 amending Directive 2005/36/EC on the recognition of professional qualifications and Regulation (EU) No 1024/2012 on administrative cooperation through the Internal Market Information System. *Official Journal of European Union L 354 Volume 56, 132-170*.
- Communities, C. o. (2003, 7 28). Commission Staff Working Paper of 28 July 2003 SEC(2003) 900. *Commission Staff Working Paper: Report on the application of internal Market rules to health services Implementation by the Member States of the Court's Jurisprudence*. Brussels.
- Communities, C. o. (2004, March 5). The Bolkenstein Draft. *Proposal for a Directive of the European Parliament and of the Council on services in the internal market [SEC(2004) 21]*. Brussels: Commission of the European Communities.
- Council, G. S. (2004, July 16). Explanatory note from the Commission Services on the provisions of the proposed Directive on services in the Internal Market relating to the assumption of healthcare costs . *Interinstitutional File:2004/0001(COD)*. Brussels: General Secretariat of the Council.
- EDQM, D. D. (n.d.). *Pharmaceutical Care – Policies and Practices for a Safer, More Responsible and Cost-effective Health System*. Strasbourg, FRANCE: Directorate for the Quality of Medicines & HealthCare of the Council of Europe (EDQM).
- McCREEVY, C. (2005, May 9). SPEECH/05/148. *Verbatim of discussion in the European Parliament Plenary – Commissioner McCreevy on the Services Directive*. Strasbourg.

Parliament, E., the Council of the European Union and the Commission of the European Communities(2003, December 31). Interinstitutional agreement on better law-making (2003/C 321/01). *Official Journal of the European Union C 321* , 31/12/2003 P. 1-5.

Parliament, E. (2006). *Improving the mental health of the population - towards a strategy on mental health for the EU P6_TA(2006)0341*. Strasbourg: The European Parliament.

Parliament, T. E. (2013). *European Parliament resolution of 11 September 2013 on the Internal Market for Services: State of Play and Next Steps (2012/2144(INI))*. Strasbourg: The European Parliament.

Protection, T. C. (2013). *OPINION of the Committee on Employment and Social Affairs (20.6.2013)*. Strasbourg: The European Parliament.

Regions, T. C. (2004, October 22). Opinion on the Proposal for a Directive on services in the internal market. *Opinion of the Committee of the Regions on the Proposal for a Directive of the European Parliament and of the Council on services in the internal market COM(2004) 2 final – 2004/0001 (COD)*. Brussels.

UK, D. o. (2011). *European Commission Green paper:UK Government response - Modernising the Professional Qualifications Directive*. London, United Kingdom: Department of Business innovations and skills UK.

Court cases

European Court of Justice

Case 26/62 (February 5, 1963), Van Gend en Loos v. Administratie der Belastingen [1963] ECR 1.

Case 6/64 (July 15, 1964) Costa v. ENEL [1964] ECR 585.

Case 11-70 (December 17, 1970), Internationale Handelsgesellschaft mbH v Einfuhr- und Vorratsstelle für Getreide und Futtermittel [1970] ECR 1125.

Case 2-74 (June 21, 1974), Jean Reyners v Belgian State [1974] ECR 631.

Case 8-74 (July 11, 1974), Procureur du Roi v Benoît and Gustave Dassonville [1974] ECR 837.

Case 33/74 (December 3, 1974), van Binsbergen v Bestuur [1974] ECR 1299 .

C-41-74 (December 4, 1974), Yvonne van Duyn v Home Office [1974] ECR 1337.

Case 27/76 (February 14, 1978), United Brands v Commission of the European Communities [1978] ECR 207.

Case 106/77 (March 9, 1978), Amministrazione delle finanze dello Stato v. Simmenthal [1978] ECR 629.

Case 136/78 (February 7, 1979), Auer [1979] ECR 437.

Case 115/78 (February 7, 1979), J. Knoors v Staatssecretaris van Economische Zaken [1979] ECR 399.

[1979] ECR 649 , Case 120/78 (February 20, 1979), Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein(Cassis).

Case 175/78 (28 March 1979), The Queen v Vera Ann Saunders [1979] ECR 1129.

C-283/ 81 (October 6, 1982), Srl CILFIT and Lanificio di Gavardo SpA v Ministry of Health [1982] ECR 3415.

Joined Cases 286/82 och 26/83 (January 31, 1984), Graziana Luisi och Giuseppe Carbone mot Ministero del Tesoro [1984] ECR 377.

Case 14/83 (April 10, 1984.), Van Colson and Kamann v Nordrhein - Westfalen [1984] ECR 1891.

Case 107/83 (July 12, 1984), Ordre des avocats au Barreau de Paris v Onno Klopp [1984] ECR 2971.

C-152/84 (February 26, 1986), Marshall v Southampton & South West Health Authority [1986] ECR 723.

Case 263/86 (March 15, 1995), Belgian State v René Humbel and Marie-Thérèse Humbel née Edel [1988] ECR 5365.

C-81/87 (September 27, 1988), The Queen v H. M. Treasury and Commissioners of Inland Revenue, ex parte Daily Mail and General Trust plc [1988] ECR 5483,.

C-196/87 (October 5, 1998), Udo Steymann v Staatssecretaris van Justitie [1988] ECR I-6159.

Case 186/87 (February 2, 1989), Ian William Cowan v Trésor public [1989] ECR 195.

C-106/89 (November 13, 1990) Marleasing SA v. La Comercial Internacional de Alimentación SA [1990] ECR I-4135.

C-340/89 (May 7, 1991), Irène Vlassopoulou v Ministerium für Justiz, Bundes- und Europaangelegenheiten Baden-Württemberg [1991] ECR I-2357.

C-76/90 (July 25, 1991), Manfred Säger vs. Dennemeyer & Co. Ltd [1991] ECR I-4221.

C-221/89 (July 25, 1991), The Queen v Secretary of State for Transport, ex parte Factortame Ltd and others. (Factortame II) [1991] ECR-3905.

C-159/90(4 October 1991), The Society for the protection of unbor[1991] ECR I-4685, n children Ireland Ltd v Stephen Grogan et al.

Joined Cases C-6/90 and C-9/90 (November 19, 1991), Andrea Francovich and Others v. Italian Republic [1991] ECR I-5357.

Joined cases C-267/91 and C-268/91 (November 1993, 1993), Criminal proceedings against Bernard Keck and Daniel Mithouard [1993] ECR I-6097.

C-275/92 (March 24, 1994 Her Majesty's Customs and Excise v Gerhart Schindler and Jörg Schindler) [1994] ECR I-1039.

C-379/92 (July 14, 1994), Peralta [1994] ECR I-3453.

C-384/93 (May 10, 1995), Alpine Investments BV v Minister van Financiën [1995] ECR I-1141.

C-80/94. (August 11, 1995), G. H. E. J. Wielockx v Inspecteur der Directe Belastingen [1995] ECR I-02493.

C-415/93 (December 15, 1995), ASBL&l UEFA v Jean-Marc Bosman [1995] ECR-4921.

C-55/94 (November 30, 1995), Reinhard Gebhard v. Consiglio dell'Ordine degli Avvocati e Procuratori di Milano [1996] ECR I-4165.

C-418/93 (June 20, 1996), Semeraro di casa v Sindaco del Comune di Erbusco [1996] ECR I-2975.

C-96/95 (March 20, 1997), Commission v Germany [1997] ECR I-1653.

Joined cases C-64/96 and C-65/96 (June 5, 1997), Uecker and Jacquet [1997] ECR I-3171.

C-120/95 (April 28, 1998), Decker v. Caisse de Maladie des Employes Privés [1998] ECR. I-1831.

C-155/96 (April 28, 1998), Kohll v. Union des Caisses de Maladie [1998] ECR I-1931.

C-234/97 (July 8, 1999), Fernández de Bobadilla [1999] ECR I-4773.

Case C-448/98 (December 5, 2000) Criminal proceedings against Jean-Pierre Guimont [2000] ECR I-10663.

C-379/98 (March 13 2001) PreussenElektra AG v Schleswag AG, in the presence of Windpark Reußenköge III GmbH and Land Schleswig-Holstein [2001] ECR I-2099.

C-368/98 (July 12, 2001), Abdou Vanbraekel and Others v Alliance nationale des mutualités chrétiennes [2001] ECR I- 5363.

C-157/99 (July 12, 2001), B.S.M. Geraets-Smits and Peerbooms v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Groep Zorgverzekeringen [2001] ECR I-5473.

C-322/01 (March 11, 2003), Deutscher Apothekerverband eV v 0800 DocMorris NV and Jacques Waterval [2003] ECR I-14887.

C-385/99 (May 13, 2003), V.G. Müller-Fauré and E.E.M. van Riet v. Onderlinge Waarborgmaatschappij ZAO [2003] ECR I-4509.

C-285/01 (September 9, 2003), Isabel Burbaud v Ministère de l'Emploi et de la Solidarité [2003] ECR I-8219.

C-56/01 (October 3, 2003), Patricia Inizan/Caisse Primaire d' Assurance Maladie des Hauts de Seine [2003] ECR I-12403.

C-313/01 (November 13, 2003), Christine Morgenbesser v Consiglio dell'Ordine degli avvocati di Genova [2003] ECR I-13467.

C-8/02 (March 18, 2004), Ludwig Leichtle and Bundesanstalt für Arbeit [2004] ECR I-2641.

C-304/02 (Grand Chamber) July 12, 2005), Commission v France (fisheries conservation) [2005] ECR I-6263.

Joined Cases C-544 and 545/03 (September 8, 2005), Mobistar SA v Commune de Fléron [2005] ECR I -7723.

C-372/04 Grand Chamber 8 May 16, 2006), Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health [2006] ECR I-4325.

C-506/04 (Grand Chamber) September 19, 2006), Graham J. Wilson v Ordre des avocats du barreau de Luxembourg [2006] ECR I-08613.

C-452/04 (Grand Chamber) October 3, 2006), Fidium Finanz AG v Bundesanstalt für Finanzdienstleistungsaufsicht [2006] ECR I- 9521.

Joined Cases C-94/04 and C-202/04 Grand Chamber (December 5, 2006), Federico Cipolla and Others v Rosaria Fazari, née Portolese, and Roberto Meloni [2006] ECR I-11421.

C-438/05 Grand Chamber, (December 11, 2007), The International Transport Workers' Federation and The Finnish Seamen's Union [2007] ECR I-10779.

C-341/05 Grand Chamber (December 18, 2007), Laval Un Partneri Ltd v Svenska Byggnadsarbetareförbundet [2007] I-11767.

C-210/06 ((Grand Chamber) December 16, 2008), Cartesio Oktató és Szolgáltató bt. [2008] ECR I-09641.

C-586/08 (December 17, 2009), Angelo Rubino v Ministero dell'Università e della Ricerca [2009] ECR I-12013.

Joined Cases C-570/07 and C-571/07 (June 1, 2010) Blanco Pérez and Chao Gómez [2010] ECR I-4629

Case C-173/09 8 Grand Chamber (October 5, 2010), Georgi Ivanov Elchinov v Natsionalna zdravnoosiguritelna kasa [2010] ECR I-8889.

C-458/08 (November 18, 2010), Commission v Portugal [2010] ECR I-11599.

C-108/09 (December 2, 2010), Ker-Optika bt v ÀNTSZ Dél-dunántúli Regionális Intézete [2010] ECR I-12213.

C-34/09 (Grand Chamber) March 8, 2011), Gerardo Ruiz Zambrano v office national de l'emploi (ONEm) [2011] ECR I-1177.

Joined Cases C-372/09 and C-373/09 (March 17, 2011), Josep Peñarroja Fa [2011] ECR I-1785.

C-575/11 (June 27, 2013), Eleftherios-Themistoklis Nasiopoulos v Ipourgos Iglas kai Pronoias ECR not yet published.

C-57/12 (July 11, 2013), Fédération des maisons de repos privées de Belgique (Femarbel) ASBL v Commission ECR not yet published.

C-136/12 (July 18, 2013), Consiglio nazionale dei geologi v Autorità garante della concorrenza e del mercato. ECR not yet published,

Joined Cases C-159/12 to C-161/12, (December 5, 2013), Alessandra Venturini v ASL Varese and others ECR not yet published.

C-111/12 (February 21, 2013), Ministero per i beni e le attività culturali v Ordine degli Ingegneri di Verona e Provincia et others ECR not yet published, .

C-539/11 (September 26, 2013), Ottica New Line di Accardi Vincenzo v Comune di Campobello di Mazara ECR not yet published.

Opinion of Advocate General

Opinion of Advocate General Sharpston, C-34/09 (September 30, 2010).

Opinion of Advocate General Cruz Villalón Pedro Cruz Villalón, C-57/12 (March 14, 2012).

Opinion of Advocate General Jääskinen , C-539/11 (January 30, 2013).

European Commission

Tetra Pak II, (IV/31043 - Tetra Pak II (Commission Decision July 24, 1991).

Sweden

Jelinek v. National Social Insurance Board, case nr. 5595-99 (Swedish Supreme Court 1 30, 2004).

Stigell v. The National Social Insurance Board, case nr. 6790-01 (Swedish Supreme Administrative Court 1 30, 2004).

Doctrine

Affairs, M. f. (2008). *Genomförande av tjänstedirektivet Ds2008:75*. Stockholm: Government Offices of Sweden.

Barnard, C. (2008). Unravelling the Services Directive. *Common Market Law Review* 45, pp. 323-394.

Fennelly, N. (1996). Legal Interpretation at the European Court of Justice. *Fordham International Law Journal* Volume 20, Issue 3.

- Gillies, A. (2003). *What makes a Good Healthcare*. Oxon, United Kingdom: Radcliffe Medical Press.
- Graig, P. (2012). *EU Administrative Law, 2nd Ed*. Oxford: Oxford University Press.
- Hatzopoulos, V. (2013). The Court's approach to Services (2006/2012): From case law to case load. *Common Market Law Review* 50, 459-502.
- Hettne, J. (2011). *EU-rättslig metod*. Stockholm: Norstedts juridik.
- Hu, M. J. (2001). Diet, lifestyle, and the risk of type 2 diabetes mellitus in women. *The New England Journal of Medicine* 345 (11), 790–797.
- Iain Paterson, M. F. (2003). *Economic impact of regulation in the field of liberal professions in different Member States (Regulation of Professional Services)*. Vienna: Institute for Advanced Studies.
- Jan, J. H. (2000). Proportionality Revisited. *Kluwer Law International*, 239–265.
- Jané-Llopis, E. &. (2006). *Mental health promotion and mental disorder prevention across European Member States: a collection of country stories*. Luxembourg: European Communities: European Communities.
- Kok, R. f. (2004). *Facing the Challenge: The Lisbon Strategy for Growth and employment*. Belgium: Office for Official Publications of the European Communities.
- Maduro, M. P. (2007, December 5). Interpreting European Law: Judicial Adjudication in a Context of Constitutional Pluralism. *The European Journal of Legal Studies, Vol.1, Issue 2 art 8*.
- Neergaard, U. (2013). Wiberg, Maria: The EU Services Directive – Law or Simply Policy? *Europarättslig Tidskrift nr 4/2013*, pp. 881-885.
- Robert G. Evans, M. L. (1994). *Why are Some People Healthy and Others Not?: The Determinants of the Health of Populations*. Canada: Transaction Publishers.
- Sauter, W. (/2013). *Proportionality in EU law: a balancing act?* Utrecht: Nederlandse Zorgautoriteit.
- Schulz, J. W. (2006). A Review of Pharmaceutical Care in Community Pharmacy in Europe. *Harvard Health Policy Review* Vol. 7, No. 1,, 155-168.
- Sousa, P. C. (2011). Catch Me If You Can? The Market Freedoms' Ever- expanding Outer Limits. *European Journal of Legal Studies*, 162-191.
- Trade, N. B. (2012). *Possible Effects of the Services*. Stockholm: National Board of Trade.
- Trade, N. B. (2013). *Intrepreting article 20(2) of the Services Directive*. Stockholm, Sweden: National Board of Trade.
- Trade, N.B. (2013). *The non-Discrimination Clause in the Services Directive (a follow up on the National Board of Trade's intrepretation of Article 20(2) of the Services Directive*. Stockholm, Sweden: National Board of Trade.
- Trade, N. B. (2013). *Justifications under the Services Directive*. Stockholm: National Board of Trade.
- Tridimas, T. (2007). *The General Principles of EU Law 2nd Ed*. Oxford: Oxford European Union Law Library.
- Ulrich Stelkens, W. W. (2012). *The Implementation of the EU Services Directive: Transposition, Problems and Strategies*. (T.M.C. ASSER PRESS, The Hague)
- Waele, H. d. (2009). The Transposition and Enforcement of the Services Directive: A Challenge for the European and the National Legal Orders. *European Public Law* 15, no.4, 523-531.

Waele, J. M. (2006). A Retreat from Säger? Servicing or Fine-Tuning the Application of Article 49 EC. *Legal Issues of Economic Integration* 33(3), 207–228.

Wiberg, M. (2013, February 6). The EU Services Directive – Law or Simply Policy? *The EU Services Directive – Law or Simply Policy?* Uppsala: Department of Law, Uppsala University.

Internet sources

Bank, T. W. (2012, December 2012). *Data European Union*. Retrieved January 21, 2014, from The World Bank: <http://data.worldbank.org/country/EUU>

Commission, E. (2005, December 14). *Europa.eu*. Retrieved November 12, 2013, from Press releases database: [http://europa.eu/rapid/press-release MEMO-05-482_en.htm](http://europa.eu/rapid/press-release_MEMO-05-482_en.htm)

Commission, E. (Aug, 2010) Guidelines on the non-discrimination of service recipients under art. 20 of the Services Directive, 2010. Retrieved May 5, 2014 from: http://ec.europa.eu/smart-regulation/impact/planned_ia/docs/2011_markt_023_service_recipients_en.pdf

Commission, E. (2011, October 27). *Press releases database*. The Commission refers Germany, Austria and Greece to the Court over incomplete transposition of the Directive Retrieved November 19, 2013, from Europa.eu: http://europa.eu/rapid/press-release_IP-11-1283_en.htm

Commission, E. (2012, June 8). *Communication on the implementation of the Services Directive. A partnership for new growth in services 2012-2015 SWD(2012)146 final, SWD(2012) 147 final, SWD(2012) 148 final*. Retrieved May 5, 2014 from: http://ec.europa.eu/internal_market/services/docs/services-dir/implementation/report/SWD_2012_146_en.pdf

Commission, E. (2012, October 1). *European Commission*. Retrieved December 9, 2013, from Competition, legislation: http://ec.europa.eu/competition/state_aid/legislation/sgei.html.

Commission, E. (2013, October 2). *Press releases database*. European Commission and Member States to assess barriers restricting access to regulated professions Retrieved April 6, 2014, from Press releases database: http://europa.eu/rapid/press-release_IP-13-897_en.htm

Commission, E. (2013, December 13). *European Commission, Eurostat*. Retrieved March 19, 2013, from Population structure and ageing: http://epp.eurostat.ec.europa.eu/statistics_explained/index.php/Population_structure_and_ageing

Commission, E. (2013, November 8). *Need help?* Retrieved March 5, 2013, from European Commission: http://ec.europa.eu/internal_market/qualifications/docs/directive-in-practice/useful-documents/users_guide_en.pdf

Commission, E. (2013, May 10). *Single Market scoreboard*. Retrieved November 11, 2013, from The EU Single Market: http://ec.europa.eu/internal_market/scoreboard/performance_by_governance_tool/priority_areas/index_en.htm

Commission, E. (2013, November 13). *Smart Regulation* . Retrieved December 17, 2013, from European Commission: <http://ec.europa.eu/smart-regulation/>

Commission, E. (2013, November 8). *The EU single market*. Retrieved November 29, 2013, from Automatic recognition: http://ec.europa.eu/internal_market/qualifications/directive_in_practice/automatic_recognition

- Commission, E. (2013, November 8). *The Eu single Market, Services Directive Quick guide*. Retrieved November 9, 2013, from European Commission: http://ec.europa.eu/internal_market/services/services-dir/guide/index_en.htm
- Commission, E. (n.d.). *A Single Market for Services*. Retrieved November 26, 2013, from The EU Single Market: http://ec.europa.eu/internal_market/top_layer/services/
- Commission, E. (n.d.). *Directive 2005/36/EC – policy developments*. Retrieved November 19, 2013, from European Commission, The EU Single Market: http://ec.europa.eu/internal_market/qualifications/policy_developments/index_en.htm#maincontentSec3
- Commission, E. (n.d.). *European Commission Internal Market*. Retrieved November 27, 2013, from about IMI: http://ec.europa.eu/internal_market/imi-net/about_en.html
- Commission, E. (n.d.). *Europa*. Retrieved March 7, 2014, from Summaries of EU legislation > Public health: http://europa.eu/legislation_summaries/public_health/index_en.htm
- Commission, E. (n.d.). *Europe 2020*. Retrieved March 7, 2014, from Europe 2020: http://ec.europa.eu/europe2020/index_en.htm
- Education, S. C. (2012, December 28). *Universitets- och högskolerådet*. Retrieved November 27, 2013, from Reglerade yrken i Sverige: <http://www.uhr.se/sv/Bedomning-av-utlandsk-utbildning/Utlandsk-utbildning/Arbeta-i-Sverige/Reglerade-yrken-i-Sverige/>
- Institutions, E. (2010, August 12). *The decision-making process and the work of the institutions*. Retrieved February 3, 2014, from Europa: http://europa.eu/legislation_summaries/institutional_affairs/decisionmaking_process/114530_en.htm
- McDonald's, *World Class Training*. Retrieved March 13, 2014, from: http://www.aboutmcdonalds.com/mcd/franchising/us_franchising/why_mcdonalds/world_class_training.html
- Majid Ezzat, S. V. (2005, May). *Rethinking the "Diseases of Affluence" Paradigm: Global Patterns of Nutritional Risks in Relation to Economic Development*. *Plos Medicine May 2005 | Volume 2 | Issue 5 | e133*, 0404-0412. Retrieved March 21, 2014, from Plos medicine: www.plosmedicine.org
- Riksförbunds, S. H. (2010). *Svenska Homeopater Riksförbunds ,SHR-Auktorisation*. Retrieved May 4, 2014 from: <http://www.svenskahomeopater.se/SHRAuktorisation/tabid/63/language/sv-SE/Default.aspx>.
- Optikerförbundet, *Svenska Optikerförbundet*. Retrieved May 4, 2014 from: <http://www.optikerforbundet.se/index1.asp?siteid=1&pageid=3>.
- Oxford Dictionaries, *Language matters*. Retrieved May 13, 2014 from: <http://www.oxforddictionaries.com/definition/english/professional>
- Swedish Better Regulation Council (2012). *Clarifying Gold Plating- Better Implementation of EU Legislation*. Retrieved May 14, 2014 from Regelrådet: <http://www.regelradet.se/wp-content/uploads/2012/03/Clarifying-Gold-Plating.pdf>
- WHO. (2013). *Cancer, Who Definition of Palliative care*. Retrieved May 13, 2014, from World Health Organisation: <http://www.who.int/cancer/palliative/definition/en/>

Annex 1

Contact details of bodies designated to assist service recipients

(Article 21 Bodies)

15/07/2013

Member State	Body designated (for providing information to consumers)	Body designated (for providing information to businesses)
Austria	Europäisches Verbraucherzentrum Österreich(European Consumer Centre Austria)	Wirtschaftskammer Österreich (Austrian Federal Economic Chamber)
Belgium	SPF Economie, PME, Classes moyennes et Energie (DG Contrôle et Médiation - Coopération internationale)	SPF Economie, PME, Classes moyennes et Energie (DG Contrôle et Médiation - Coopération internationale)
Bulgaria	Point of Single Contact in cooperation with the European Consumer Centre	Contact details of bodies designated to assist service recipients (Article 21 Bodies)
Croatia	Croatia European Consumer Center Croatia (ECC-Net)	Point of Single Contact Croatia
Cyprus	Cyprus European Consumer Centre (Cyprus) (ECC-Net)	Point of Single Contact Cyprus
Czech Republic	Czech Republic Points of Single Contact(Ministry of Industry and Trade)	Czech Republic Points of Single Contact(Ministry of Industry and Trade)
Denmark	Denmark Forbruger Europa (ECC-Net)	
Estonia	Estonia EUROPEAN CONSUMER CENTRE ESTONIA (ECC-Net)	Ministry of Economic Affairs and Communications
Finland	The Finnish Competition and Consumer Authority (FCCA)	Point of Single Contact (The Finnish Competition and Consumer Authority)
France	Centre Européen des Consommateurs France(European Consumer Centre France (ECC-Net)	Enterprise Europe Network Paris Ile-de-France Centre (PIC ²) Paris Chamber of commerce and industry (CCIP)
Germany	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (Federal Office of Consumer Protection and Food Safety)	Germany Trade & Invest - Gesellschaft für Außenwirtschaft und Standortmarketing mbH (Bonn Office (Trade))
Greece	Ombudsman for Consumers	Enterprise Europe Network – Hellas Help – Forward Network
Hungary	European Consumer Centre Hungary (ECC-Net)	Enterprise Europe Network ITD Hungary Zrt.
Iceland	Neytendastofa (Consumer Agency)	Efnahags- og viðskiptaráðuneytið (Ministry of Economic Affairs)
Ireland	European Consumer Centre Ireland	Galway Chamber of Commerce

	(ECC-Net)	
Italy	ECC-Net Italy	Unioncamere (Chambers of Commerce) through points of single contacts:
Latvia	European Consumer Centre Latvia ECC-Net (ECC Latvia)	Investment and Development Agency of Latvia
Liechtenstein	Amt für Handel und Transport (Fachbereich Konsumentenschutz, Urheberrecht und unlauterer Wettbewerb)	Einheitlicher Ansprechpartner/ Point of Single Contact (Amt für Volkswirtschaft / Office for Economic Affairs)
Lithuania	Europos vartotojų centras (ECC-Net) European Consumer Centre in Lithuania	Public Institution Enterprise Lithuania Point of Single Contact for Services and Products
Luxembourg	European Consumer Centre Luxembourg (ECC-Net)	Espace Entreprises de la Chambre de Commerce de Luxembourg
Malta	European Consumer Centre (MALTA) (ECC-Net)	Malta Enterprise, Enterprise Centre, Industrial Estate
Norway	The European Consumer Centre (ECC-Net)	Enterprise Europe Network Innovation Norway
Poland	Point of Single Contact Ministry of Economy	Point of Single Contact Ministry of Economy
Portugal	Centro Europeu do Consumidor (European Consumer Centre ECC-Net)	Instituto de Apoio às PequeNA's e Médias Empresas e à Inovação – IAPMEI (Institute of Support to Small and Medium Enterprises and Innovation)
Romania	European Consumer Centre Romania (ECC-Net)	
Slovakia	European Consumer Centre Slovakia (ECC-Net)	Ministry of Economy of the Slovak Republic
Slovenia	Evropski potrošniški center (European Consumer Centre Slovenia (ECC-Net))	Obrtno-podjetniška zbornica Slovenije (Chamber of craft and small business) Gospodarska zbornica Slovenije (Chamber of commerce and industry)
Spain	European Consumer Centre (Spain) (ECC-Net) Instituto Nacional de Consumo	Ministerio de Industria, Turismo y Comercio Dirección General de Política de la PYME
Sweden	The Swedish Consumer Agency (ECC-Net)	The National Board of Trade
The Netherlands	The Consumer Authority Consumentenautoriteit (BackOffice Consumentenautoriteit)	Antwoord voor bedrijven ("Dutch Point of Single Contact") Ministerie van Economische Zaken
United Kingdom	The European Consumer Centre for Services Trading Standards Institute (TSI)	Point of Single Contact: Business Link Department for Business, Innovation and Skills

Annex 2 Regulated professions in Sweden²⁸⁷

- Advokat, kontakta Sveriges advokatsamfund
- Apotekare, kontakta Socialstyrelsen
- Arbetsterapeut, kontakta Socialstyrelsen
- Audionom, kontakta Socialstyrelsen
- Auktoriserad tolk, kontakta Kammarkollegiet
- Auktoriserad translator, kontakta Kammarkollegiet
- Barnmorska, kontakta Socialstyrelsen
- Biomedicinsk analytiker, kontakta Socialstyrelsen
- Brandskyddskontroll, kontakta Myndigheten för samhällsskydd och beredskap (MSB)
- Dietist, kontakta Socialstyrelsen
- Djursjukskötare, kontakta Jordbruksverket
- Elinstallatör, kontakta Elsäkerhetsverket
- Fastighetsmäklare, kontakta Fastighetsmäklarnämnden
- Hovslagare, kontakta Jordbruksverket
- Kiropraktor, kontakta Socialstyrelsen
- Logoped, kontakta Socialstyrelsen
- Läkare, kontakta Socialstyrelsen
- Lärare och förskollärare i det offentliga skolväsendet, kontakta Skolverket
- Naprapat, kontakta Socialstyrelsen
- Optiker, kontakta Socialstyrelsen
- Ortopedingenjör, kontakta Socialstyrelsen
- Patentombud, kontakta Patentombudsnämnden
- Psykolog, kontakta Socialstyrelsen
- Psykoterapeut, kontakta Socialstyrelsen
- Receptarie, kontakta Socialstyrelsen
- Röntgensjuksköterska, kontakta Socialstyrelsen
- Sjukgymnast, kontakta Socialstyrelsen
- Sjukgymnast inom djurens hälso- och sjukvård, kontakta Jordbruksverket
- Sjukhusfysiker, kontakta Socialstyrelsen
- Sjuksköterska, kontakta Socialstyrelsen
- Sjuksköterska inom djurens hälso- och sjukvård, kontakta Jordbruksverket
- Tandhygienist, kontakta Socialstyrelsen
- Tandläkare, kontakta Socialstyrelsen
- Tandläkare inom djurens hälso- och sjukvård, kontakta Jordbruksverket
- Trafiklärare, kontakta Transportstyrelsen
- Veterinär, kontakta Jordbruksverket
- Väktare, kontakta Länsstyrelsen i Stockholms län (avdelningen för rättsliga frågor)

²⁸⁷ Education, 2012 <http://www.uhr.se/sv/Bedomning-av-utlandsk-utbildning/Utlandsk-utbildning/Arbeta-i-Sverige/Reglerade-yrken-i-Sverige/>

Annex 3 Notifications & decisions made in Sweden concerning 2.2(f) SD

2011 Notifications	Amendment of existing rules		New rules
Subject-matter	2011/01478	Appointment and provision of pharmaceuticals and other products.	Supply of hospital drugs
Case no	MPA	2011/00381-3	2011/01514
NA behind the measure	Change of MPA rules (LVFS 1997:13) regarding prescribing certain products.	MPA	MPA
Restriction	Change of MPA rules (LVFS 1997:13) regarding prescribing certain products.	Proposed amendment to the MPA rules (LVFS 2009:13) for the appointment and provision of medical products and industrial alcohol.	Draft on hospital drug supply regulations
Decision by NA	No notification obligation.	No notification obligation.	Partial notification obligation
Grounds of exemption of notification	Art 2(2)(f)SD	Art 2(2)(f)SD	
Grounds of notification requirement			

2012 Notifications			New rules			
Subject-matter	Supply and delivery of pharmaceuticals and other products	Amendment of MPA rules	Supply and delivery of pharmaceuticals and other products	Pharmacovigilance	Provision of medicinal products for human use	Esthetical surgery
Case no	2012/01832	2012/01560	2012/01819	2012/00550	2012/01534	2012/01250-2
NA behind the measure	MPA	MPA	MPA	MPA	MPA	National Board of Health and Welfare
Restriction	Proposal of amendment in the MPA rules over supply and delivery of some medical products	Draft rules (2013: xx) on the operation of active substances intended for human use and modification of LVFS(2004:6) and LVFS(2006:11)	MPA rules over supply and delivery of medical products containing isotretinoin.	The Swedish MPA's rules on the pharmacovigilance of medicinal products for human use.	The Swedish MPA's proposal for new regulations on provision of medicinal products for human use	The National Board of Health and Welfare rules on esthetic surgery.

Decision by NBT	No notification obligation	Notification obligation	No notification obligation	Notifiable to the part which does not relate to pharmacy.	Several requirements are notifiable in accordance with art 39.5. Health exception does not appear to be applicable.	At least partially notifiable. Needs further assessment when the bill and the appurtenant rules have been remitted.
Grounds of exemption of notification	Art 2(2)(f)SD		Art 2(2)(f) SD due to covering doctors and pharmacies			
Grounds of notification requirement.		2013: xx:is about inter alia distributors, not exempted by art 2(2)(f) medical exception because not a regulated profession. A new notification is a requirement that is notifiable.		(24.5) the implementation of the amending Directive (and old directive).		Esthetical surgery is most likely not healthcare.

2013 Notifications	Amendment of existing rules	Kolumn1	New rules	Kolumn2	Kolumn3
Subject-matter	Change of fees	Appointment and provision of pharmaceutical and other products.	Retail sales	Compensation and environmental concerns.	Distance trade by pharmacies.
Case no	2013/00459	2013/00715	2013/00357	2013/00894	2013/00910
PA behind the measure	MPA	MPA	MPA	Ministry of Health and Social Affairs	MPA
Restriction	Proposal of amendment of fees to Apotekens Service AB.	Proposed amendment to the MPA rules (LVFS 2009:13) for the appointment and provision of medicinal and industrial alcohol.	MPA rules over pharmacies retail.	Compensation for drug injury and environmental concerns regarding pharmaceutical benefits. SOU 2013:23	The MPA's rules regarding distance trade by pharmacies.
Decision by NA	Recommendation of notification.	Notification obligation if the MPA estimates that pharmacy operations are not restricted to regulated healthcare professions. Otherwise exempted on grounds of art 2(2)(f)SD.	The legal situation is unclear. The MPA determines to notify or not according to art 39(5) on grounds whether a pharmacy can be operated on temporary basis.	No notification obligation.	No notification obligation.
Grounds of exemption of				Art 2(2)(f)SD	Art 2(2)(f)SD

notification					
Grounds of notification requirement	Recommendation to notify since the fees can be claimed to affect the pharmacy service providers.	See above.	Unclear whether the operation of pharmacies is covered by At 2(2) (F) SD exemption due to "restricted regulated healthcare profession." The lack of clarity has been reported.		