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Was the exclusion of health care from the Services Directive a pyrrhic victory?

A proportionality test on regulation of health professions

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Executive Summary

In January 2017, the European Commission launched a proposal for a directive laying down a general obligation for Member States to conduct an ex-ante proportionality assessment before introducing new or modifying existing provisions restricting access to or the pursuit of regulated professions. According to the proportionality principle, it must be proven that the measure is necessary to protect a public interest objective, that it does not exceed what is necessary to attain this objective and that the result cannot be achieved by a less restrictive measure. The bulk of the measures under scrutiny concern the regulation of health professionals.

The regulations referred to in the Commission proposal include the following issues: continuous professional development; language knowledge; reserving specific activities for professionals with a particular professional title; rules relating to the organisation of the profession, professional ethics and supervision; compulsory chamber membership, registration or authorisation schemes; requirements limiting the number of authorisations to practice, or fixing a minimum or a maximum number of employees, managers or representatives holding particular professional qualifications; and finally territorial restrictions, in particular where the profession is regulated in a different manner in different parts of a Member State.

Some of the requirements to be assessed under the proportionality test closely recall the provisions of Article 15 of the Directive on Services in the internal market, which was adopted in 2006. This article too obliges Member States to engage in a major screening exercise of their regulation of services. Its application to health services, in the same way as to any commercial service, was highly controversial because it did not take into account the specificity of the health care sector. Indeed, in this sector extensive regulation is needed to redress market imperfections and to guarantee universal access to care. Furthermore, it was feared that this measure would lead to considerable legal uncertainty for public authorities, providers and patients. This finally led to health care being excluded from the scope of application of the adopted Services Directive.

This paper shows that the concerns that led to the exclusion of health services from the scope of application of the Services Directive apply in the same way to the 2017 Proposal for a Directive on a proportionality test before adoption of new regulation of professions. It furthermore analyses why a proposal that is very similar to the proposal that provoked strong reactions a decade ago, now seems to pass without much animosity. Several factors can explain this low-level political reaction today. *First*, in 2004, when the Commission adopted the proposal for the Services Directive, there was barely any awareness of the potential impact of EU law on health providers, beyond the issue of patient mobility. Therefore, the proposed Services Directive came as a shock, and a much-needed eye-opener. Since then, policy debates have been more intense and case law has evolved. *Second*, the disagreement surrounding the inclusion of health care in the 2004

proposal for the Services Directive was part of a broader controversy as to the proposal, including disagreement on the country of origin principle and the provisions on posted workers. It thus affected actors in many sectors, which increased the potential for widespread protest (with 'the Polish plumber' as its symbol), beyond the health care concerns. *Third*, the 2004 proposal was used by domestic actors to further their political agendas. In particular, it was a key topic in the debates in the run up to the French referendum on the European Constitution. *Fourth*, since the exclusion of health care from the Services Directive, health authorities have been considering how to adopt a specific approach for the application of the internal market rules to health care and have been unable to reach a consensus, mainly because any legal proposal addressing this issue would inevitably encroach upon national powers over the organisation of health systems. *Fifth*, the European Commission also learned from its failures with regard to the Services Directive. Instead of coming up, out of the blue, with a proposal, it has now carefully built up the policy process. A mutual evaluation process involving Member State authorities and stakeholders was established, while the Competitiveness Council provided the Commission with a clear political mandate. In its mutual evaluation exercise, the Commission analysed professions on which there is little consensus across the Member States, such as psychologists and opticians, and avoided analysing those professions that are best organised at European level, such as doctors and dentists.

The analysis shows that a specific approach is needed for the application of the free movement rules to national regulation of health professions. The Opinion paper therefore advocates the exclusion of health professions from the scope of the current Commission proposal. To avoid a situation where health policies are defined by Courts instead of by policy makers, this exclusion should be accompanied by a specific legal framework applying the free movement rules to national regulation on health professions and health services. Such a legal framework should take into account the role of health professionals in protecting human life and health and their embeddedness in national publicly funded health systems. In this way, EU institutions and health authorities could seize the opportunity to fill the gap left by the Patients' Rights Directive, adopted in 2011.

Introduction ([1])

In January 2017, as part of the roadmap set out in the Single Market Strategy, the European Commission proposed several initiatives aiming to simplify procedures for cross-border service providers and to subject regulation in the services sectors to EU scrutiny ([2]). This package includes a proposal for a Directive on a proportionality test before adoption of new regulation of professions, hereafter 'Proposal for a Directive on a proportionality test' (European Commission 2017a). This proposal for a Directive lays down a general obligation for Member States to conduct an ex-ante proportionality assessment before introducing new or modifying existing provisions restricting access to or the pursuit of regulated professions falling under the Directive on the recognition of professional qualifications, hereafter 'Professional Qualifications Directive' (European Parliament and Council of the EU 2005) ([3]). The bulk of the regulated professions falling under the scope of both the Professional Qualifications Directive and the Proposal for a Directive on a proportionality test are health professionals.

Some of the requirements to be assessed under the proportionality test closely recall the provisions of Article 15 of the Directive on Services in the internal market (European Parliament and Council 2006), which was adopted in 2006, hereafter 'Services Directive'. This article too obliges Member States to engage in a major screening exercise of their regulation of services. The application of the initial proposal for this Directive ([4]), (European Commission 2004) and in particular of its Article 15, to health services as to any commercial service, provoked serious controversy. Many observers judged that this proposal did not take into account the specificity of the health care sector, where extensive regulation is needed to correct market imperfections and to guarantee universal access to care. Furthermore, it was feared that it would lead to considerable legal uncertainty for public authorities, providers and patients. This led to health care being excluded from the scope of application of the finally adopted Services Directive (Baeten 2005).

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1. An extended and updated version of this Opinion paper will be published in Vanhercke, B., Sabato, S. and Bouget, D. (Eds) Social Policy in the European Union: State of Play 2017, Brussels, European Trade Union Institute and European Social Observatory, forthcoming 2017.
2. http://europa.eu/rapid/press-release_IP-17-23_en.htm (accessed 15.02.2017).
3. Proportionality is a general principle in law intended to strike a balance between the restriction imposed by a measure and the severity of the nature of the prohibited act. As we will explain, in European law this principle has been interpreted by the Court of Justice of the EU. Three conditions apply: it must be proven that the measure is necessary to protect a public interest objective, that it does not exceed what is necessary to attain this objective and that the result cannot be achieved by a less restrictive measure.
4. Hereafter referred to as the 'Proposal for the Services Directive'.

It might come as a surprise that, ten years after the exclusion of health care from the scope of the Services Directive, the European Commission is again including health services in a horizontal Directive, on — professional — services, without providing a specific approach for health care providers.

In this Opinion paper, we look for answers to the question of why a proposal that is very similar to one which provoked serious reactions a decade ago, now seems to pass without much antagonism. We furthermore analyse whether the concerns voiced in 2004-2006 also apply to the current proposal. We first outline the legal context (Section 1), analysing how regulated health professions have so far been addressed in EU law. In Section 2 we discuss the EU level policymaking process dealing with regulated health professions. We outline the key elements of the Proposal for a Directive on a proportionality test in Section 3, before critically discussing the proposal in the concluding Section 4.

1. EU law and the regulation of health professions

According to the European Commission, over 6,000 professions are regulated across the EU, and the health and social services sector accounts for 42 percent of all regulated professions (European Commission 2015a). Regulation makes access to or the pursuit of a profession conditional upon the possession of specific professional qualifications, or protects the use of a specific title. It aims to reduce the information asymmetry between service providers and consumers and to protect the public from unqualified practitioners.

Health professions have long been regulated by the Member States, with the aim of protecting both patients and licensed health care professionals (De Bijl and Nederveen-Van de Kragt 1997; Healy 2012). Such nationally-set conditions can create de-facto barriers for professionals coming from another Member State. Since the variation in regulations across the EU potentially obstructs the free movement of health providers, the provisions of the Treaty on the Functioning of the European Union, hereafter 'TFEU' (European Union 2012), on freedom of establishment ([5]), or freedom to provide services ([6]), may apply. Given the role of health professionals in protecting human life and health, they have been singled out in the Treaty for special treatment (Lonbay 2000). Thus, Article 53 (2) of the TFEU specifies that 'in the case of the medical and allied pharmaceutical professions, the progressive abolition of restrictions shall be dependent upon coordination of the conditions for their exercise in the various Member States'.

5. Article 49 of the TFEU.
6. Article 56 of the TFEU.

The EU has therefore established a regulatory framework guaranteeing minimum qualifications to be met by health care professionals seeking to assert the right to practise their profession in other EU countries without discrimination. The currently applicable legislation is Directive 2005/36/EC on the recognition of professional qualifications (European Parliament and Council of the EU 2005).

Despite this specific legal framework, the fundamental freedoms enshrined in the TFEU continue to also apply directly. The direct application of the Treaty to health care provision is mainly driven by case law of the Court of Justice of the European Union (CJEU). Based on the case law, the principle of free movement does not only apply to regulation directly governing access to a national (health) services market, but also to regulation that governs the exercise of the health care activity itself. Furthermore, whereas the rules on free movement of services were originally thought to target discrimination against service providers by another Member State, the scrutiny of the Court gradually extended to measures that apply without distinction to domestic providers and providers from abroad (Gekiere *et al.* 2010). Consequently, almost any regulatory or institutional aspect of health care provision can be challenged as a potential obstacle to the free movement of services (Davies 2006). This is particularly important for the field of health care, which is characterised by a vast array of regulatory interventions, such as rules on professional behaviour, patient access, quality, effectiveness and pricing, which do not specifically relate to cross-border situations (Gekiere *et al.* 2010).

Hervey and Mc Hale (2015) list the CJEU rulings in which regulation that can impede professionals from accessing the market in another Member State, other than regulation of professional qualifications, is scrutinized. The Court rulings deal with requirements on the status of the directors or operators of an entity providing health services ([7]), the legal form of such an entity ([8]), the ban on a professional having more than one place of operation ([9]), the reserving of certain kinds of health services for professionals with particular qualifications ([10]), the restriction on the offering of private health services to only those who have been authorised to provide services within the national health insurance system ([11]), requirements for health professionals to have a bank account with a bank in a particular Member State ([12]), rules requiring that health

7. Case C-221/85, *Commission v Belgium (Clinical Laboratories)*, Case C-531/06, *Commission v Italy (Pharmacists)*.
8. Case C-70/95, *Sodemare*.
9. Case C-140/03, *Commission v Greece (Opticians)*.
10. Case C-108/96, *MacQuen*.
11. Case C-456/05, *Commission v Germany (Psychotherapists)*.
12. Case C-356/08, *Commission v Austria*.

professionals have sufficient language skills ([13]), and rules on the territorial distribution of health establishments ([14]).

Despite the fact that there is a low threshold for the application of free movement, the TFEU does not intend to create a completely deregulated internal market, nor does it give health care providers unconditional access to a particular domestic health care market (Gekiere *et al.* 2010). The Member States are allowed to maintain barriers to free movement provided that these are justified in the public interest. In this respect, three conditions — known as the proportionality test — apply: it must be proven that the measure is necessary to protect the public interest objective, that it does not exceed what is necessary to attain this objective and that the result cannot be achieved by a less restrictive measure.

Even though the Court tends to leave a wide margin of discretion to the Member States to substantiate that a national measure is necessary to protect a 'public interest' objective — such as the protection of public health or the safeguarding of the balance of the social security system — it will often be difficult for health regulators to provide evidence on the proportionality of the regulation in question (Spaventa 2004; Jorens *et al.* 2005). Member States' ability to regulate health service providers becomes subject to a general proportionality requirement. In doing so, they face a relatively high burden of proof. It may not only be a challenge to demonstrate the wider effect of an individual measure on the sustainability of the entire system — or on any other general interest objective it is pursuing — it also compels Member States to position the targeted measure within the broader context of related policies and alternative options (Gekiere *et al.* 2010). As an example, the Court ruled out a prior authorisation scheme for outpatient dental clinics. On the one hand the measure was considered not to pursue the general interest objective in a consistent and systematic manner, because group practices were not subject to a similar prior authorisation system to the dental clinics. On the other hand, the measure was found to not adequately circumscribe the exercise of national discretion, as decentralised authorities could apply different criteria for assessing the need for additional dental clinics ([15]). In other words: the grounds for exemption of the regulation of health professionals do not provide broad discretion to Member States to preserve national policies (Hervey and McHale 2015).

13. Case C-424/97, *Haim II.*
14. Cases C-570/07 and C-571/07, *Pérez and Gómez*.
15. Case C-169/07 *Hartlauer Handelsgesellschaft mbH/Wiener Landesregierung and Oberösterreichische Landesregierung*.

2. The policy process

The approach of the Court on the proportionality test has gradually been incorporated into secondary legislation. The Commission tried to codify the case law in 2004, through the inclusion of health services in the scope of the initial Commission Proposal for the Services Directive. This inclusion was one of the most controversial aspects of the proposal. The application of general rules on the free movement of services and the freedom of establishment, without any distinction, to health services, just as to any commercial service, was indeed considered inappropriate by policymakers and stakeholders alike. The controversy did not so much concern the stipulations with regard to the reimbursement of health care received in another Member State ([16]), but in particular the provisions of Article 15 applying the proportionality test to national regulation of services. These provisions obliged the Member States to engage in a major screening exercise of their regulation on health services. The requirements to be assessed under the Proposal for the Services Directive included ([17]):

(a) 'quantitative or territorial restrictions, in particular in the form of limits fixed according to population, or of a minimum geographical distance between service-providers;

(b) an obligation on a provider to take a specific legal form, in particular to be a legal person, to be a company with individual ownership, to be a non-profit making organisation or a company owned exclusively by natural persons;

(c) requirements which relate to the shareholding of a company, in particular an obligation to hold a minimum amount of capital for certain service activities or to have a specific professional qualification in order to hold capital in or to manage certain companies;

(d) requirements, other than those concerning professional qualifications or provided for in other Community instruments, which reserve access to the service activity in question to particular providers by virtue of the specific nature of the activity;

(e) a ban on having more than one establishment in the territory of the same State;

(f) requirements fixing a minimum number of employees;

(g) fixed minimum and/or maximum tariffs with which the provider must comply;

(…)

(i) requirements that an intermediary provider must allow access to certain specific services provided by other service-providers;

(j) an obligation on the provider to supply other specific services jointly with his service.'

16. Article 23 of the Proposal for a Services Directive.
17. Article 15 (2) of the Proposal of the Services Directive.

If the listed requirements were found to be discriminatory, or if their necessity and proportionality could not be justified, Member States were required to simplify or remove authorisations and licensing procedures. According to the proposal for a Services Directive, Member States had to notify to the Commission of any new laws, regulations or administrative provisions which set requirements listed above, together with the reasons for those requirements. The Commission would then communicate the provisions concerned to the other Member States. When the Commission considered a national requirement not in line with the Directive, it would request the Member State in question to refrain from adopting it or to abolish it.

All these types of requirements are important in national health policies, for example in planning facilities, setting tariffs, establishing care pathways, setting up referral systems and ensuring quality of care. Generally, Member States implement these requirements to safeguard the accessibility, sustainability and quality of health care services in their territory. A systematic and pre-emptive screening of all regulations in health care was considered undesirable by many stakeholders, as it would lead to legal uncertainty; it could turn out to be difficult in some cases to sufficiently substantiate certain measures and therefore could disrupt the consistency of the health system as a whole (European Health Policy Forum 2005). The provisions contained in the Proposal for a Services Directive were deemed too drastic and unfit to reflect the complexity and specific nature of health care systems. This finally led to health care being excluded from the scope of application of the Services Directive. The exclusion covers 'healthcare and pharmaceutical services provided by health 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' ([18]).

As a result of the policy debates provoked by the inclusion of health services in the initial Proposal for the Services Directive, policymakers and stakeholders had become aware that health care is not sheltered from the application of the EU internal market rules. It was feared that the removal of unjustified restrictions on the free movement principles could cripple the steering instruments used by health authorities and could lead to the Member States losing control over areas such as health care priority setting and capacity planning (Gekiere *et al.* 2010). Member States asked for more clarity on how much room for manoeuvre they had to justify regulations - in the general interest - even if they present an obstacle to free movement. Since 2005, several policy initiatives have been tabled in an attempt to provide policy responses to the legal uncertainty and the pressure on the regulatory powers of health authorities. Thus, the Council of the EU adopted

18. Recital 22 of the Proposal for a Directive on a proportionality test.

Conclusions on the common values and principles of EU health systems, urging that the overarching social values of universality, access to good quality care, equity and solidarity be protected when drafting an EU-level legal proposal (Council of the European Union, 2006). Furthermore, the Council urged the Commission to put forward a broad framework that would go beyond the patient mobility issue (Council of the European Union, 2007).

The policy processes eventually led to the adoption in 2011 of the Directive on the application of Patients' Rights in Cross-border Healthcare, hereafter the Patients' Rights Directive (European Parliament and Council of the EU 2011). Despite the concerns voiced by the health authorities, this Directive only deals with patient mobility and carefully avoids addressing the potential deregulatory effect of the application of the free movement principles to providers wishing to temporarily or permanently provide services in another Member State. There was indeed no agreement within the Commission to bring forward a proposal presenting a broader framework. At the same time, the Member States were equally unable to find a consensus on this sensitive topic, mainly because any legal proposal addressing this issue would inevitably encroach upon national powers in relation to the organisation of health systems. Strikingly, the policy debate on these controversial issues has fallen completely silent since the Commission presented its proposal for a Patients' Rights Directive (Baeten and Palm 2011). Consequently, the Treaty provisions on free movement of services have continued to be interpreted by the CJEU on a case-by-case basis.

Relevant elements of the case law have gradually been incorporated into the Professional Qualifications Directive. A revision of this Directive in 2013 introduced an Article 59, which obliges Member States to list the professions they regulate, and to explain why the regulation is necessary. This process required Member States to enter all the professions they regulate into an EU Database alongside all the regulatory measures implemented for each profession notified. Using this information, they were then required to review the impact of such measures and to consider their value in protecting legitimate public interests. Member States had to examine whether their regulatory requirements are compatible with the principles of non-discrimination, necessity and proportionality. This exercise culminated in a requirement for Member States to submit 'National Action Plans' (NAPs) by early 2016 with the outcome of the proportionality assessment, and to justify any decisions taken as a result of this analysis to maintain or amend professional regulations ([19]). Other Member States were invited to submit their observations on these reports in a mutual screening exercise. To this end, the Commission organised a public consultation (27 May to 21 August 2016) ([20]) and a conference (on 18 May 2016) ([21]) to discuss

19. http://ec.europa.eu/DocsRoom/documents/20581 (accessed 8.02.2017).
20. http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8827 (accessed 7.04.2017).
21. http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8592&lang=en (accessed 7.04.2017).

the action plans. Article 59 of the amended Professional Qualifications Directive furthermore requires Member States to submit any new requirements they intend to introduce subsequently to the same procedure. Every two years Member States have to report to the Commission on requirements which have been removed or made less stringent.

To complete the mutual evaluation, 12 professions were chosen as examples of different regulatory approaches for discussion, including four health professions: physiotherapist, psychologist, dental hygienist and optician. The Commission published sector reports on each of these professions (European Commission 2015b, 2016a, 2016b and 2016c), drawing on information communicated by the Member States and discussions which took place during a meeting in 2015 on mutual evaluation for each sector. The sector reports present an assessment of the justifications. They invite the Member States to assess in more depth the necessity and proportionality of specific requirements, most of which have subsequently been listed in the Proposal for a Directive on a proportionality test. The Commission insists that assessments should be more based on the concrete and real impact of the measures, showing the exact interlinks between benefits (such as the improvement of oral health) and the regulation. It also asks Member States to provide concrete data justifying the effects of the regulatory measures. Member States are requested to take into account experiences gained in other countries with no or less restrictive measures. The sector reports were endorsed by the Member States before their publication (European Commission 2017c).

Additionally, an increasing number of Member States are urged in the context of the European Semester and Memoranda of Understanding to reduce the restrictions on access to professional services, including health professions in some countries (European Commission 2017c).

3. Proposal for a Directive on a proportionality test on regulation of professions

The launch of the Proposal for a Directive on a proportionality test on regulation of professions by the Commission in January 2017 should be seen in the light of the developments presented above. The proposal stems from the Commission's assessments of the mutual evaluation process and is one of the follow-up initiatives referred to in Article 59 (9) of the revised Professional Qualifications Directive, where the Commission is requested to submit, where appropriate, proposals for further initiatives.

According to the Commission's impact assessment on the Proposal for a Directive on a proportionality test, Member States, in the mutual evaluation exercise, did not provide sufficient arguments as to the proportionality of their professional regulations and produced only scarce evidence to suggest that regulatory decisions are currently being based on sound and objective analysis. The Commission claims that the exercise was often subject to the will of strong interests (European Commission 2017c). The Commission suggests that it needs better instruments to enforce compliance with the proportionality principle, arguing that it is often difficult to initiate infringement procedures against non-compliant Member States. Given the huge number of professional regulations across the EU, the proportionality test should provide the Commission with the necessary information to assess regulations in their national context (European Commission 2017c).

The Proposal for a Directive on a proportionality test requires Member States, when reviewing existing rules on regulated (health) professions or considering the introduction of new ones, to assess whether the provisions are necessary to attain a public interest objective, are suitable for securing the attainment of the objective pursued and do not go beyond what is necessary to attain that objective (the proportionality principle). It sets out the main criteria to be considered by the competent authorities. This assessment has to be substantiated by 'qualitative and, wherever possible, quantitative evidence' ([22]). Where the measure is justified, the authorities 'have to assess in particular whether the objective can be attained by a protected professional title without reserving activities' ([23]). Reserved activities are defined as 'a form of regulating a profession where the access to a professional activity or group of professional activities is reserved to members of a regulated profession, including where the activity is shared with other regulated professions' ([24]).

22. Article 4 of the Proposal for a Directive on a proportionality test.
23. Ibid, Article 6 (3).
24. Ibid, Article 3 (b).

The assessment of proportionality should be carried out 'in an objective and independent manner, including through involvement of independent scrutiny bodies' ([25]).

According to the proposal, requirements linked to professional qualifications 'should be considered as necessary only where existing measures, such as consumer protection law, cannot be regarded as being suitable or genuinely effective to achieve the aim pursued' ([26]). The proposal points to the following elements as being of most relevance and to be taken into account when assessing the necessity and proportionality of provisions ([27]):

(d) 'the link between the scope of activities covered by a profession or reserved to it and the professional qualification required;

(e) the link between the complexity of the tasks and the necessary possession of specific professional qualifications, in particular as regards the level, the nature and the duration of the training or experience required, as well as the existence of different routes to obtain the professional qualification;

(f) the scope of the professional activities reserved to holders of a particular professional qualification, namely whether and why the activities reserved to certain professions can or cannot be shared with other professions;

(g) the degree of autonomy in exercising a regulated profession and the impact of organisational and supervision arrangements on the attainment of the objective pursued, in particular where the activities relating to a regulated profession are pursued under the control and responsibility of a duly qualified professional;

(h) the scientific and technological developments which may reduce the asymmetry of information between professionals and consumers;

(i) the economic impact of the measure, with particular regard to the degree of competition in the market and the quality of the service provided, as well as the impact on the free movement of persons and services within the Union;'

The proposed Directive furthermore lists elements to be in particular taken into account when examining the cumulative effect of all the existing measures restricting access to or pursuit of professions ([28]):

(a) 'reserved activities, existing alongside protected professional title;

(b) continuous professional development requirements;

25. Ibid, Article 4 (5).
26. Ibid, Recital 15.
27. Ibid, Article 6 (2).
28. Ibid, Article 6 (4).

(c) rules relating to the organisation of the profession, professional ethics and supervision;

(d) compulsory chamber membership, registration or authorisation schemes, in particular where those requirements imply the possession of a particular professional qualification;

(e) quantitative restrictions, in particular requirements limiting the number of authorisations to practice, or fixing a minimum or a maximum number of employees, managers or representatives holding particular professional qualifications;

(f) specific legal form requirements or requirements which relate to the shareholding or management of a company (…);

(g) territorial restrictions, in particular where the profession is regulated in parts of a Member State's territory in a different manner;

(h) requirements restricting the exercise of a regulated profession jointly or in partnership, as well as incompatibility rules;

(i) requirements concerning insurance cover or other means of personal or collective with regard to professional liability;

(j) language knowledge requirements to the extent necessary to practise the profession.'

Before introducing a measure, all interested parties have to be informed and should be given the possibility to express their views ([29]). The information should also be exchanged with the competent authorities of other Member States ([30]). Member States have to record the justifications for considering a provision in the database of regulated professions, created pursuant to the Professional Qualifications Directive, and these will be made publicly available by the Commission ([31]). Other Member States and interested parties may submit comments to the Commission or to the Member State which has notified the provisions.

Furthermore, Member States have to monitor the proportionality of their regulation on a regular basis to take into account developments that have occurred since the measure concerned was adopted ([32]).

29. Ibid, Article 7.
30. Ibid, Article 8.
31. Ibid, Article 9.
32. Ibid, Article 4 (4).

4. Discussion and conclusions

The requirements to be assessed under the Commission Proposal for a Directive on a proportionality test are almost copy-pasted from Article 15 of the Proposal for the Services Directive'. In its impact assessment, the Commission clarified that this proposal is complementary to the Services Directive and in particular that, 'in terms of scope the Services Directive relates to only legal persons and does not cover the medical professions' (European Commission 2017c). This suggests that an important driver for the current proposal is to extend the principles enshrined in Article 15 of the Services Directive to health services.

Whereas 13 years ago the inclusion of health in the initial Proposal for the Services Directive provoked fierce reactions in both the Council and the European Parliament, today there appears to be much less political controversy on the proposal. In the European Parliament, the ENVI Committee (Environment, Public Health and Food Safety) initially decided not to issue an Opinion on the Proposal for a Directive on a proportionality test ([33]). The Council gave the Commission a mandate to provide an analytical framework for a comprehensive proportionality assessment of professional regulations (Council of the EU 2016). Perhaps ironically, the proposal introducing a European services e-card (European Commission 2017d), adopted by the Commission in the same services package, appears to provoke more controversy in the Council than the proposal to organise a proportionality test for regulated professions (Bulletin Quotidien Europe 2017).

The most important stakeholder reactions to the proposal have come so far from the EU-level organisations of some key health professionals. According to the Standing Committee of European Doctors (CPME), the Pharmaceutical Group of the European Union (PGEU) and the Council of European Dentists (CED), regulation of health care professionals should be excluded from any potential EU-wide framework for a proportionality test. The three organisations are concerned about the lack of specificity in addressing the overall issue of health profession regulation, and are convinced that health professions should be considered distinctly from other professions. They argue that policy decisions relating to the regulation of the health professions must serve the objective of attaining the best possible quality of care for every patient and that under no circumstances may quality of care, access to care or patient safety be put at risk by decisions driven by other agendas, in particular economic concerns ([34]).

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33. Whilst writing this paper, this decision has been revoked and the ENVI Committee decided to appoint a rapporteur on 5 April 2017, http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?lang=&reference=2016/0404(COD) (accessed on 12.04.2017).
34. http://doc.cpme.eu:591/adopted/2017/CED_PGEU_CPME_joint_PR_January_2017.pdf (accessed on 13.03.2017).

Several reasons could explain this low-profile political reaction, at least so far. *First*, in 2004, when the Commission adopted the Proposal for the Services Directive, stakeholders and health authorities were aware of the impact of the free movement principles on patient mobility, based on case law. However, there was barely any awareness of the potential impact of EU law on health providers, apart from the issue of patient mobility. Therefore, the Proposal for the Services Directive came as a shock. Since then, policy debates have been more intense and case law has evolved. Or, as formulated by Davies (2006), 'Laying down broad principles which are then slowly, perhaps over decades, realized and enforced in the Member States is a common Court of Justice technique. By the time Member States realize their implications (…) they have been around long enough to seem established'. *Second*, the controversy surrounding the inclusion of health care in the 2004 Proposal for the Services Directive was part of a broader dispute on the proposed Services Directive, including disagreement on the country of origin principle and the provisions on posted workers. It thus affected actors in many sectors, and increased the potential for broad protest (with 'the Polish plumber' as its symbol). *Third*, the 2004 proposal was used by domestic actors to further their political agenda. In particular, it was a key topic in the debates in the run up to the French referendum on the European Constitution. *Fourth*, since the exclusion of health care from the Services Directive, health authorities have been considering how to adopt a specific approach for the application of the internal market rules to health care, but have so far been unable to reach consensus, mainly because any legal proposal addressing this issue would inevitably encroach upon national powers in relation to the organisation of health systems. Since Member States seem unable to formulate an alternative to the Court's case-by-case approach, they are in a weak bargaining position to (radically) oppose the Commission's initiatives to include health services in general horizontal secondary legislation. *Fifth*, the European Commission has also learnt from its failures with regard to the Services Directive. Instead of coming up, out of the blue, with a proposal, it has now carefully built up the policy process. The 2013 revision of the Professional Qualifications Directive established a mutual evaluation process involving Member State authorities and stakeholders, in addition to a mandate to come up with further proposals. The Competitiveness Council also provided the Commission with a clear political mandate, whilst the involvement of health authorities has so far been avoided. In its mutual evaluation exercise, the Commission analysed professions on which there is little consensus across the Member States, such as psychologists and opticians, and avoided analysing the professions that are best organised at European level, such as doctors and dentists, whilst stating that the principles underlying its analysis should apply to all professions.

This does not mean that the concerns voiced in the debates on the inclusion of health care in the Services Directive, and the calls for a specific approach for health services, are now irrelevant. Indeed, some specific features of the health sector require strong regulatory frameworks. *First*, health and access to health care are generally acknowledged as fundamental human rights. To guarantee these, public intervention and financing are considered necessary. *Second*, from an

economic perspective the health care sector is characterised by significant externalities and market failures which make it impossible to achieve an efficient market for health care (Hsiao and Heller 2007). Indeed, patients in general lack the necessary background knowledge to make an informed decision about the care they need and the quality and effectiveness of the service they receive. Since health care providers may have other interests than their patients, this information asymmetry makes the relationship very precarious. Health care providers have unique power to induce demand and to set prices. It is therefore widely acknowledged that the activities of health care providers require regulation to bring them fully in line with the goals of public health and social policy. Furthermore, since health care in the EU is mainly publicly financed, both patients and health providers might seek to respectively receive and supply more health care (moral hazard), due to the fact that the cost is mainly borne by a third public party. For these reasons, health care is a field with extensive regulation, aiming to address the important market failures in this sector and to ensure the most cost-effective use of the limited public financial means.

It should nevertheless be acknowledged that regulation can also be subject to regulatory capture. Regulatory capture is the phenomenon whereby regulation or regulatory bodies set up to safeguard the public interest may instead be 'captured' by the interest groups that dominate the sector it is charged with regulating, to protect specific corporate or private interests. Health care providers may thus use regulation to avoid competition and sustain their incomes, which may result in scarcity of certain necessary services and inefficiencies. This is especially the case where the regulation of entry criteria is the responsibility of health professional groups (Dubois et al 2006). As a derivative of regulatory capture, Member States may also use regulation to favour their own providers and protect their health care markets from any influx of foreign competitors.

A general proportionality test could therefore potentially be used to improve the general interest objectives of regulation of health providers, whilst countering corporatist private interests as well as protectionist national interests. However, in the proposal for a Directive on a proportionality test, as in European law in general, the regulation of health professionals, rather than being seen as a way of protecting patients, or inherent to the proper functioning of national health care systems, is viewed as an obstacle to the operation of the market (Hervey and McHale 2015). In this sense, the Commission proposal is yet another example of the constitutional asymmetry between weak EU-level powers on social policies and strong powers in the economic field, aiming for market and monetary integration. National welfare states are legally and economically constrained by European rules on economic integration, whereas efforts to adopt European social and health policies are politically impeded by the diversity of national welfare states (Scharpf 2002), which is maintained by the principle of subsidiarity.

Two elements of the proposal illustrate this asymmetry:

- When assessing the necessity and the proportionality of their provisions, the relevant competent authorities have to consider in particular 'the economic impact of the measure, with particular regard to the degree of competition in the market and the quality of the service provided, as well as the impact on the free movement of persons and services within the Union' ([35]), This suggests that health objectives should be weighed up against economic objectives.
- The fact that a great majority of the professions under scrutiny are health professions is not mentioned once in the proposal, and no specific approach is proposed for these professions.

For many of the requirements under scrutiny, it is unclear to what extent it will be possible for Member States to justify their regulation. Health authorities are thus yet again on the defensive. Some examples taken from the provisions of the proposed Directive illustrate this:

- The proposal asks for account to be taken of 'scientific and technological developments which may reduce the asymmetry of information between professionals and consumers' ([36]). In the health sector, this could refer to access to health information via the internet and other sources. However, it is highly debatable whether such developments could reduce the information asymmetry between the patient and the health professional. Indeed, it is usually impossible for patients to assess the reliability of the sources they consult and the interests behind them. Moreover, medical knowledge is increasingly complex.
- The proposal insists on assessing 'whether the objective of the regulation could be attained by the protection of the professional title without reserving activities' ([37]). The sector reports on selected health professions discussed above, drafted by the Commission, do not invite Member States to remove regulation on reserved activities, but to align the training requirements with the scope of reserved activities and the level of responsibilities (European Commission 2016b and 2015b). This suggests that reserved activities in health care could be justified under certain conditions, but this is not clear from the proposal ([38]).
- Requirements on continuous professional development (CPD) should be assessed ([39]). The sector report on physiotherapy drafted by the Commission suggests that CPD requirements could be problematic, by inviting Member States to reassess the relationship of mandatory CPD requirements with, and their possible effect on, initial education requirements (European Commission 2016a). At the same time, the European Commission's Directorate General for

35. Article 6 (2) of the Proposal for a Directive on a proportionality test.
36. Ibid, Article 6 (2).
37. Ibid, Article 6 (3).
38. This would also be in line with the case law of the CJEU, stating that 'in so far as there is no Community definition of medical acts, the definition of acts restricted to the medical profession is, in principle, a matter for the Member States', Case C-61/89 *Bouchoucha*.
39. Article 6 (4) of the Proposal for a Directive on a proportionality test.

Health and Food Safety (DG SANTE), published a report confirming that 'There is widespread recognition of the importance of CPD and life-long learning (LLL) of health professionals' ([40]). The extent to which CPD requirements can be justified is therefore unclear, and the DG SANTE report could even be read as an attempt to provide evidence to counterbalance the approach calling into question the desirability of CPD requirements, based on the free movement principles.

These examples illustrate that it is not so much the assessment of the proportionality of the requirements in itself that could pose problems, but rather the lack of clarity as to the extent to which a specific approach for health professionals could be justified. This thus leads to substantial legal uncertainty on regulation that can be crucial to preserve high-quality health services and universal access to care.

In this context, it is also significant that the CJEU did accept a specific approach when risks to human health are involved. The Court noted that where there is uncertainty as to the existence or extent of risks to human health, a Member State should be able to take protective measures without having to wait until the reality of those risks becomes fully apparent ([41]), for instance without having to wait for the shortage of health professionals to materialise. The Court also takes the view that, when there is uncertainty about the efficacy of alternative or less restrictive measures to protect public health, the inherent risks can be invoked to justify the maintenance of a measure ([42]). These lines of reasoning are not incorporated into the Proposal for a Directive on a proportionality test.

The concerns that led to the exclusion of health services from the scope of application of the Services Directive apply in the same way to the Proposal for a Directive on a proportionality test. The exclusion of national regulation on health care professionals from the scope of the current proposal would therefore be advisable. This would be fully in line with Article 168 (7) of the TFEU, which states that 'Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them.' To avoid a situation where health policies are defined by Courts instead of by policy makers, the exclusion of health professions from a horizontal Directive on professional services should be accompanied by a specific legal framework applying the free movement rules to national regulation on health

40. https://ec.europa.eu/health/workforce/key_documents/continuous_professional_development_en (accessed on 17.03.2017).
41. Case C-531/06 *Commission v Italy*, Joined Cases C-570/07 and C-571/*07 José Manuel Blanco Pérez and María del Pilar Chao Gómez*, Case C-73/08 *Bressol and Chaverot.*
42. See also Case C-531/06 *Commission v Italy.*

services and professionals. Such a legal framework should take into account the role of health professionals in protecting human life and health and their embeddedness in national publicly funded health systems. In this way EU institutions and health authorities could take the opportunity to fill the gap left by the Patients' Rights Directive.

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