

Proportionality and Commission Proposal for a Directive on a proportionality test for adoption of new regulation for professions (COM(2016) 822 final)

A. Background

- What is proportionality?
- What is the aim of the Proportionality Test Directive (“the Proposal”)?
- What is the scope of the Proposal?
- How is proportionality assessed currently?
- How will the proportionality test work if the Proposal is adopted?

1. What is proportionality?

Proportionality is a general principle of EU law, which follows from the European Court of Justice’s case law. It requires Member States to strike the right balance between preserving the **fundamental freedoms** guaranteed by the Treaty (such as the freedom to provide services) and Member States’ margin of discretion to decide on how to protect a **public interest** objective (such as public health)¹. How to strike the right balance was summarised as follows: “National measures liable to hinder or make less attractive the exercise of fundamental freedoms guaranteed by the Treaty must fulfil four conditions:

- they must be applied in a non-discriminatory manner;
- they must be justified by imperative requirements in the general interest;
- they must be suitable for securing the attainment of the objective which they pursue;
- and they must not go beyond what is necessary in order to attain it”².

Proportionality is also a common general principle of the national constitutions and laws of the Member States, though the respective conditions may differ in certain details.

2. What is the aim of the Proportionality Test Directive (“the Proposal”)?

The Proposal forms part of the **Services Package** which was adopted in January 2017. It includes three other initiatives linked to the Services Directive (a regulation for new European Services e-Card, guidance for national reforms in regulation of professions and a directive on a Services Notification Procedure). The goal of the package is to simplify procedures for cross-border service providers and to subject regulation in the services sectors to EU scrutiny. The package aims to improve the functioning of the **Single Market** and to boost the services sector, by increasing professionals’ **mobility**, while generating **economic growth** and **job creation** in Europe.

¹ In EU law-making, see Article 5(4) of the Treaty of the European Union (TEU) and Protocol No. 2.

² *Gebhardt*, C-55/94, paragraph 37 and paragraph 6 of the judgement.

According to the European Commission, the objective of the Proposal is to improve the quality of the proportionality assessments to be undertaken at Member State level. It introduces an **EU level test** harmonising and streamlining the proportionality assessments at Member State level building on:

- Article 59(3) of the Directive on the recognition of professional qualifications 2005/36/EC³ (“RPQD”) and on
- Case law of the European Court of Justice on proportionality of professional regulation⁴.

3. What is the scope of the Proposal?

The proportionality test shall apply to any legislative, regulatory or administrative **provisions restricting** access to or pursuit of **regulated professions**, which are

- new or
- under revision.

The proportionality test shall apply to **regulated professions** falling within the scope of the RPQD such as cooks, hairdressers, tourist guides, real estate agents, engineers and health professions (i.e. doctors, nurses, midwives, pharmacists and dentists⁵).

4. How is proportionality assessed currently?

Complying with the general principle of proportionality (see 1.) and with Article 59 of the RPQD (see 2.), before adopting new or amending existing regulation for professions, Member States already follow national proportionality tests and are to consider whether such regulation is justified, necessary and proportionate. Member States justify the regulation at stake with respect to protecting any public interest concerned, such as in the case of health professions, **public health** and the **organisation of national health systems**. This exercise allows them to consider national and regional specificities in each legislative process. Proportionality assessment is also an important part of national and EU court procedures.

5. How will the proportionality test work if the Proposal is adopted?

Member States have to apply an *ex ante* assessment mechanism before adopting new or amending existing regulation with regard to access to or exercise of a profession. Therefore, competent authorities, have to fulfil the following obligations:

- Give **justifications** on grounds of public interest objectives (such as public health)⁶;

³ Directive 2005/36/EC as amended by Directive 2013/55/EU.

⁴ According to the Commission the applicable case law includes: *Gebhardt*, C-55/94, paragraphs 35 and 37 (see also *Säger*, C-76/90, paragraph 15 and *Kraus*, C-19/92, paragraph 32); *van Leuken*, C-197/06, paragraph 41 ; *Cipolla*, C-94/04, paragraph 68; *Deutsche Parkinson*, C-148/15, paragraph 34; *Doc Morris NV*, joines cases C-171/07 and C-172/07, paragraph 42; *Hartlauer*, C-169/07, paragraphs 55 and 63; *Watts*, C-372/04, paragraph 106; *Price*, C-149/05, paragraph 55; *Säger*, C-76/90, paragraph 18; *Payroll Data*, C-79/01, paragraph 34; *Servizi Ausiliari Dottori Commercialisti*, C-451/03, paragraphs 39-43; *Ramrath*, C-106/91; *Admiral Casinos*, C-464/15, paragraph 32; *Corsten*, C-58/98, paragraph 38; *The Scotch Whisky Association*, C-333/14, paragraph 29; *Libert a.o.*, C-197/11, paragraphs 51-52; *Ottica New Line di Accardi Vincenzo*, C-539/11, paragraph 47;

⁵ Article 3 (a) of Directive 2011/24/EU of the European Parliament and the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare

⁶ Articles 4(1) and 5.

- Assess planned legislative changes as to whether these are **necessary and suitable** for securing the attainment of the objective which they pursue and do not go beyond what is necessary to attain that objective⁷ by:
 - Considering **criteria** such as nature of the risk, complexity of the tasks and different routes to obtain the qualification, scientific and technological developments reducing the asymmetry of information, economic impact of the measure, availability of less restrictive means, and the cumulative effect of restrictions⁸, accompanied by a detailed statement⁹;
 - Examining the **cumulative effect** of restrictions when introducing **requirements** such as reserved activities, continuous professional development, chamber membership, quantitative and territorial restrictions, legal form, incompatibility rules, insurance cover, and language knowledge requirements¹⁰, accompanied by a detailed statement¹¹;
- Present planned measures substantiated by '**qualitative** and, wherever possible, **quantitative evidence**' including its **economic impact**¹²;
- Monitor the proportionality of provisions restricting access to or pursuit of regulated professions in view of e.g. new scientific and technological **developments**¹³;
- Involve an **independent scrutiny body**¹⁴.

B. Legal Setting: Union role in health

- What is the Union role in organising health systems and health policies?
- Why is Member State regulation of health professions necessary?
- What is the status of health professions in EU law?

1. What is the Union role in organising health systems and health policies?

Article 168 of the Treaty of Functioning of the EU (TFEU) establishes the need for a high level of human health protection to be ensured in the definition and implementation of all Union policies and activities. Therefore, the Union role is limited to a complementary and coordinating function and to a sharing function when it comes to common safety concerns in public health matters. What is more, Article 168 TFEU highlights that the definition of health policy and the organisation and delivery of health services and medical care, including all the laws and regulations relating to the exercise of health professions, are a **Member State responsibility**.

2. Why is Member State regulation of health professions necessary?

European health systems are continuously ranked among the top performing in the world and are recognised for providing high quality and accessible healthcare services to citizens¹⁵. This is also thanks to

⁷ Articles 4(1) and 6 (1).

⁸ Articles 4(1) and 6(2).

⁹ Article 4(2).

¹⁰ Articles 4(1), Articles 6(2)(k) and 6(4).

¹¹ Article 4(2).

¹² Articles 4(3) and 6(4)(i).

¹³ Article 4(4) and 6(2)(h).

¹⁴ Article 4(5).

the fact that health systems as well as the access to and the practice of health professions are highly regulated at national level. For instance, all EU countries have reserved certain activities for health professions. This is crucial to pursue policy objectives such as patient safety and quality of care, as certain activities of health professionals require specialised education and training in order to ensure the highest public health standards are attained. Other examples of professional regulation affecting health professions include professional ethics such as confidentiality, or the obligation to undergo continuous professional development to maintain fitness to practise.

Furthermore, health professionals operate in situations in which there is a high degree of risk to human health and an asymmetry of information between service provider and the recipient. The health professional has a level of competence which is very much higher than that of the recipient so that the latter is not in a position to make a genuine assessment of the service¹⁶. In addition, patients cannot always freely exercise 'consumer choice' as they could in a commercial context. The decision where and what services to seek may not only be subject to their preferences, nor is their capacity to refrain from using services e.g. due to the organisation of health services, insurance policy, or price always given. In this context Member State regulation is key to guaranteeing **patient safety, high quality healthcare, safe and accessible services** and public health in general.

3. What is the status of health professions in EU law?

While the requirements defining professions remain a **Member State prerogative**, healthcare professions, such as dentists, doctors and pharmacists¹⁷, have a special status under the RPQD as the latter allows for **automatic recognition of their qualifications**. This means that the authorities of the country in which a health professional wants to work can only check whether the qualifications awarded by the home Member State are in line with the minimum training and education requirements described in the Directive. Such a special status under the RPQD allows a high degree of professional mobility.

Moreover, the services provided by health professionals cannot be equated with business/commercial services and were thus **exempted from the Services Directive 2006/123/EC**.

C. Effects: Health Professions' Opinion on Commission Proposal

- The Proposal equates health with business/commercial services.
- The Proposal conflicts with the precautionary principle.
- The Proposal anticipates results in testing health professional regulation.
- The Proposal is likely to increase costs causing a regulatory chill.
- The Proposal lacks evidence on the effects of (de-)regulation of health professions.
- The Proposal is not likely to increase professional mobility.

¹⁵ Ryan M Barber et al. Healthcare Access and Quality Index based on mortality from causes amenable to personal health care in 195 countries and territories, 1990–2015: a novel analysis from the Global Burden of Disease Study 2015, *The Lancet* (2017). DOI: 10.1016/S0140-6736(17)30818-8.

¹⁶ See Advocate General Opinion in case *Procureur du Rois v Ioannis Doulamis*, C-446/05, paragraphs 114 and 115

¹⁷ Article 3 (a) of Directive 2011/24/EU of the European Parliament and the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare

1. The Proposal equates health with business/commercial services.

The economic drivers of the Proposal are not compatible with health professions and their services. The Proposal forms part of the 'Services Package' and reflects both in rationale and approach, the economic objectives of the Services Directive¹⁸. This is not compatible with the rationale of regulating health professions, which is why health professions and their services are exempted from the Services Directive.

2. The Proposal conflicts with the precautionary principle.

The Proposal bypasses the precautionary principle. The precautionary principle, as applied by the European Court of Justice, entitles Member States to pro-actively introduce measures to prevent harm to human health before a risk manifests, even in cases in which the evidence as to the existence or extent of that risk is limited¹⁹. However, Recital 9 and Articles 4(3) and 6(4)(i) of the Proposal reverse this principle by shifting the burden of proof to Member States when carrying out the proportionality test. Thereafter, Member States are required to provide 'qualitative and, wherever possible, quantitative evidence' including its economic impact, on professional regulation serving the public health interest of ensuring patient safety and quality of care. This raises questions as to which type of evidence is needed and how to anticipate the economic impact. When it comes to patient safety, economic concerns are secondary.

3. The Proposal anticipates results in testing health professional regulation.

The Proposal has the potential to anticipate results of a proportionality test at national level. According to Article 6(4) Member States have to examine the cumulative effect of restrictions when introducing requirements such as reserved activities, continuous professional development, chamber membership, quantitative and territorial restrictions, legal form, incompatibility rules, insurance cover, and language knowledge requirements (see **A. 5.**). With the definition of such a catalogue as a test scale for proportionality, Member States' discretion can be considerably narrowed implying a certain result of the assessment. Given that health professions have to be highly regulated (see **B. 2.**), typically, all requirements listed in Article 6(4) are cumulatively applied in health professional regulation.

4. The Proposal is likely to increase costs causing a regulatory chill.

The proportionality test is likely to become a time- and cost-consuming exercise at Member State level given the additional administrative burden (such as elaborating detailed statements, collecting quantitative and qualitative evidence, carrying out an economic assessment and involving independent scrutiny bodies, see **A. 5.**) in order to comply with the specific criteria and process that is prescribed. It may delay the regulatory process thus. In view of the administrative burden, the Proposal might trigger political unwillingness to adopt new or amend existing professional regulation which is justified on the grounds of public health, necessary and proportionate. Delay or a regulatory chill put quality of care and patient safety at risk.

5. The Proposal lacks evidence on the effects of (de-)regulation of health professions.

¹⁸ Rita Baeten, OSE, Opinion Paper 'Was the exclusion of health care from the Services Directive a pyrrhic victory? A proportionality test on regulation of health professions', April 2017, page17.

¹⁹ See *Commission v Italian Republic*, C- 531/06, paragraph 54, joined cases C-171/07 and C-178/07 *Apothekerkammer des Saarlandes*, paragraph 30, Joined cases C-570/07 and C-571/07 *Blanco Pérez and Chao Gómez*, paragraph 74, Joined Cases C-159/12 to C-161/12 *Venturini* para.60, Case T-333/10, *ATC and others v European Commission*, paragraph 81.

There is no evidence that health professions, which are not affected by the same competitive market forces as professions providing commercial services, will in any way benefit from the Directive and not rather be negatively affected by a higher administrative burden leading to a 'regulatory chill'. The majority of evidence on which the proposal is based, focusses on commercial, legal, accounting and engineering professions, with very little research looking at any health professions in specific. The Impact Assessment [quotes](#) regulated professions' impact on wages, job creation, mobility, skills and consumer information as key findings on which the proposal is based. In none of these categories do health professions face the same conditions as other professions. Nor were factors such as patient safety or quality of services measured. For example, the [analysis](#) of the impact of the operational retail restrictions reforms in Italy targeting the distribution of non-prescription medicines, which indirectly affected the pharmacists' profession, was not able to measure the reform's effects on quality of services or benefits to patient care. Furthermore, this study is irrelevant in this context since it did not involve any changes to the regulation of the pharmacy profession.

6. The Proposal is not likely to increase health professional mobility .

Health professions enjoy a high degree of cross-border mobility, greatly thanks to the 'automatic recognition' regime of the RPQD, featuring prominently among the ten most mobile professions²⁰. At the same time, they often see low levels of unemployment to the point of acute workforce shortages. There is therefore no systemic obstacle to either access to the profession or cross-border mobility. Furthermore, pharmacists and nurses were among the first professions using the European Professional Card, which was introduced by the modernisation of the Directive in 2013 with the aim to further increase mobility²¹.

D. Way forward: Exempt health professions

There is no evidence that the application of a binding EU proportionality test will generate any benefits with regard to the healthcare sector. On the contrary, in view of potential pitfalls (see **C.**) there is the necessity to exclude health professions from the Proposal.

Instead of introducing an additional layer of EU legislation (next to the general principle of proportionality and Article 59 RPQD) the European Commission should focus on enforcing the implementation of the RPQD where necessary. Furthermore, the European Commission should improve and modernise other aspects of the RPQD which may have an added value for mobility. For example, Annex V of RPQD listing the basic criteria to achieve qualifications has not been properly reviewed for some health professions for decades and thus ignores evolution of scientific developments that has happened since.

²⁰ http://ec.europa.eu/growth/tools-databases/regprof/index.cfm?action=stat_ranking&b_services=false.

²¹ http://ec.europa.eu/growth/single-market/services/free-movement-professionals/european-professional-card_lt.