

Exempting healthcare professions from the Proportionality Directive is justified and appropriate.

Exempting health professions from the future Directive is justified, because the EU legal framework foresees a specific approach to proportionality testing health professions.

<p>The protection of human life and health is a primary objective of EU law.</p> <p>→ The regulation of health professions has direct bearing on human health and life, the protection of which is a primary objective of EU law. To treat their regulation as a restriction and require proof of regulations' effects on economic objectives ignores the value allocated to human health in EU law.</p>	<p>“When assessing whether that obligation has been complied with, account must be taken of the fact that the health and life of humans rank foremost among the assets and interests protected by the Treaty. [...]”</p> <p><i>Joined Cases C-171/07 & C-172/07 Apothekerkammer des Saarlandes, paragraph 19</i></p>
<p>The protection of health justifies restrictions on free movement.</p> <p>→ In the regulation of health professions, there are numerous overriding reasons in the public interest which have been acknowledged by case law as justifying restrictions on the freedom to provide services, ranging from the protection of public health to the protection of the dignity of the profession.</p>	<p>“It must be noted, in that regard, that the protection of the health is one of the objectives which may be regarded as overriding reasons in the public interest capable of justifying a restriction on the freedom to provide services (see, to that effect, judgments of 10 March 2009, Hartlauer, C-169/07, EU:C:2009:141, paragraph 46, and of 12 September 2013, Konstantinides, C-475/11, EU:C:2013:542, paragraph 51).</p> <p>In addition, with regard to the importance of the relationship of trust which must prevail between a dentist and his patient, the protection of the dignity of the profession of dentist may also be regarded as being capable of constituting such an overriding reason in the public interest.”</p> <p><i>Case C-339/15 Vanderborght, paragraphs 67 and 68</i></p>
<p>The precautionary principle warrants the regulation of health professions including in cases in which evidence is scarce.</p>	<p>“Furthermore, where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of</p>



<p>→ Regulating health professions has direct impact on quality and safety of healthcare. Therefore action can be taken without conclusive evidence on the effects of regulation, in line with the precautionary principle, as confirmed by case law.</p>	<p>the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures, provided they are non-discriminatory and objective (see <i>Gowan Comércio Internacional e Serviços</i>, paragraph 78 above, paragraph 76 and the case-law cited).”</p> <p><i>T-333/10 Animal Trading Company (ATC) BVK, paragraph 81</i></p>
<p>The protection of health allows for regulation to occur before risks materialise.</p> <p>→ To protect health, case law acknowledges that it is justified to regulate health professions without waiting for risks of non-regulation to materialise.</p>	<p>“Furthermore, it is important 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. In particular, a Member State may take measures that reduce, as far as possible, a health risk, including, more specifically, a risk to the reliability and quality of the provision of medicinal products to the public (see <i>Apothekerkammer des Saarlandes and Others</i>, paragraph 30, and <i>Blanco Pérez and Chao Gómez</i>, paragraph 74).”</p> <p><i>Joined Cases C-159/12 to C-161/12 Venturini, paragraph 60</i></p>
<p>Member States have the competence to organise their healthcare systems.</p> <p>→ In the regulation of health professions, Member States have discretion.</p>	<p>“None the less, the Court notes that it is for the Member States to decide on the degree of protection which they wish to afford to public health and on the way in which that protection is to be achieved. Since the level may vary from one Member State to another, Member States should be allowed a margin of discretion (see, to that effect, <i>Apothekerkammer des Saarlandes and Others</i>, paragraph 19, and <i>Blanco Pérez and Chao Gómez</i>, paragraph 44).”</p> <p><i>C-539/11 Ottica New Line di Accardi Vincenzo, paragraph 44</i></p>
<p>Different national approaches to regulating health professions are explicitly permitted by EU law.</p> <p>→ Health professions may be subject to</p>	<p>“[...]when assessing whether the principle of proportionality has been observed in the field of public health, account must be taken of the fact that a Member State has the power to determine the degree of protection which it</p>



different degrees of regulation, as it is in the Member States' competence to assess how to protect public health. Case law confirms that this does imply that different approaches, e.g. cumulative requirements, are disproportionate per se.

wishes to afford to public health and the way in which that degree of protection is to be achieved. Since that degree of protection may vary from one Member State to the other, Member States must be allowed discretion (see, to that effect, Case C-41/02 Commission v Netherlands [2004] ECR I-11375, paragraphs 46 and 51) and, consequently, the fact that one Member State imposes less strict rules than another Member State does not mean that the latter's rules are disproportionate (Case C-262/02 Commission v France, paragraph 37, and Case C-443/02 Schreiber [2004] ECR I-7275, paragraph 48)."

C-141/07 Commission v Germany (hospital pharmacies), paragraph 51

"In addition, it must be recalled that rules of a Member State do not constitute a restriction within the meaning of the FEU Treaty solely by virtue of the fact that other Member States apply less strict, or economically more favourable, rules to providers of similar services established in their territory (see Commission v Italy, paragraph 49 and the case-law cited)."

C-475/11 Konstantinidis, paragraph 47

"When assessing whether that obligation has been complied with, account must be taken of the fact that the health and life of humans rank foremost among the assets and interests protected by the Treaty and that it is for the Member States to determine the level of protection which they wish to afford to public health and the way in which that level is to be achieved. Since the level may vary from one Member State to another, Member States must be allowed discretion (see, to this effect, Case C-322/01 Deutscher Apothekerverband [2003] ECR I-14887, paragraph 103; Case C-141/07 Commission v Germany [2008] ECR I-0000, paragraph 51; and Hartlauer, paragraph 30)."

Joined Cases C-171/07 & C-172/07 Apothekerkammer des Saarlandes, paragraph 19



Exempting health professions from the future Proportionality Directive is appropriate based on the policy context and objectives.

The economic drivers of the Directive are not compatible with health services.

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

"A deeper and fairer internal market is a top priority of the Commission: "to put policies that create growth and jobs at the centre of the policy agenda". [...] There is considerable potential to enhance the creation of growth and jobs by Member States through increasing the transparency of their regulated professions and completing a more thorough analysis of their proportionality before adopting any new rules while simultaneously completing reforms in their regulated professions to modernise their requirements. As described in the impact assessment accompanying this proposal, numerous studies show how poor regulatory choices are liable to distort competition by restricting market entry and thus may result in substantial lost employment opportunities, higher prices for consumers and hinder free-movement. In terms of job creation alone, an academic study suggests around 700 000 more jobs could be created in the EU through addressing unnecessary and disproportionate regulations."

Explanatory memorandum of proposal for a Directive on a proportionality test before adoption of new regulation of professions

There is no robust evidence on the effects of (de-)regulation of health professions and its impact on economic growth or quality of services. The risk of 'regulatory chill' cannot be excluded.

→ There is no evidence that health professions, which are not affected by the same competitive market forces as professions providing commercial services are, will in any way benefit from the Directive and not rather be negatively affected by a higher administrative burden leading '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 product market reforms in Italy which



	<p>affected the pharmacists' profession was not able to measure the reform's effects on quality of services or benefits to patient care.</p>
<p>Health professions are already highly mobile.</p> <p>→ Health professions enjoy a high degree of cross-border mobility, greatly thanks to the 'automatic recognition' regime of the Professional Qualifications Directive 2005/36/EC, featuring prominently among the ten most mobile professions. 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.</p>	<ol style="list-style-type: none"> 1. Doctor of Medicine (120286) 2. Nurse (104850) 3. Secondary school teacher (79291) 4. Physiotherapist (33124) 5. Electrician / Senior electrician /Specialised electrician (22367) 6. Dental Practitioner (21926) 7. Second level nurse (20030) 8. Primary school teacher (14672) 9. Veterinary Surgeon (10897) 10. Pharmacist (10496) <p><i>DG GROW Database of regulated professions, Ranking: the most mobile professions for establishment, DG GROW, http://ec.europa.eu/growth/tools-databases/regprof/index.cfm</i></p>
<p>Health professions widely oppose the draft Directive.</p> <p>→ Across all health professions, European and national organisations have voiced their opposition towards this Directive.</p>	<ul style="list-style-type: none"> ▪ Standing Committee of European Doctors (CPME) ▪ Council of European Dentists (CED) ▪ Pharmaceutical Group of the European Union (PGEU) ▪ Federation of European Dental Competent Authorities and Regulator ▪ European Region of the World Confederation for Physical Therapy / Physiotherapy ▪ European Public Service Union (EPSU)

CPME therefore calls for health professions to be exempted from the Proportionality Directive.

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The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

For more information, please visit www.cpme.eu

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CPME comments on proposal for a Directive on a proportionality test before adoption of new regulation of professions (COM(2016)822 final)