



**PGEU Response to the consultation  
on proportionality in the regulation of  
professions**



**PGEU GPUE**

Pharmaceutical Group of European Union  
Groupement Pharmaceutique de l'Union Européenne

*The Pharmaceutical Group of the European Union (PGEU) is the association representing community pharmacists in 33 European countries. In Europe over 400.000 community pharmacists provide services throughout a network of more than 160.000 pharmacies, to an estimated 46 million European citizens daily.*

*PGEU's objective is to promote the role of pharmacists as key players in healthcare systems throughout Europe and to ensure that the views of the pharmacy profession are taken into account in the EU decision-making process.*

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The Pharmaceutical Group of the European Union (PGEU) welcomes the opportunity to comment on the European Commission's consultation on the regulation of professions and the need for an EU proportionality assessment framework ("proportionality test"). However, the PGEU is concerned that the horizontal approach adopted in the consultation and further strategy proposed by the Commission does not take due account of the special nature of the activities carried out by healthcare professionals.

Article 168 of the Treaty of the Functioning of the EU establishes the need for a high level of protection of human health to be ensured in the definition and implementation of all Union policies and activities. Furthermore, the European legislator has repeatedly highlighted the **special nature of healthcare professions**.

Healthcare professions, namely doctors, pharmacists, nurses and midwives are subject to the Recognition of Professional Qualifications Directive (Directive 2013/55/EU). This directive paves the way for the automatic recognition of a limited number of professions, mainly healthcare professions including pharmacists, across Europe on the basis of minimum qualifications and training requirements. Healthcare professions, including the pharmacy profession, are therefore subject to specific rules under this Directive, for instance it introduces a specific alert mechanism for healthcare professionals with a view to ensure a high level of health and consumer protection (article 56a of Directive 2013/55/UE).

Article 168 of Treaty of the Functioning of the EU also 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**. It is especially notable in this regard that the scope of the Services Directive excludes "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" (recital 22 and article 2 of Directive 2006/123/EC on Services in the Internal Market).

Member States organise their healthcare systems on the basis of local needs and national strategies aimed at ensuring a certain level of safety and quality in health services. Such national strategies take into account demographical, geographical and cultural realities. Community pharmacies are a key element of healthcare systems in Europe – they are actually very often the first contact point with a healthcare system



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for EU citizens. The regulation of the pharmacy profession serves indeed a public interest in terms of safeguarding the quality and availability of pharmaceutical services and protects public health.

Furthermore, the Court of Justice's well established case-law dealing with pharmacies acknowledges that **it is the right of 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 that level may vary from one Member State to another, Member States must be allowed discretion<sup>1</sup>. The European legislator enhanced this principle in relation to pharmacy regulation on many occasions, including in the Professional Qualifications Directive (recital 26) and the Falsified Medicines Directive (Directive 2011/62/EU) (recital 22)<sup>2</sup>.

***In light of the Treaty and relevant EU legal framework, it does not seem appropriate to address the proportionality assessment of regulation of healthcare professions, including pharmacists, in a general manner, together with other professions that perform professional activities of varying natures, which are subject to different legislative rules and have completely different safety implications. It is a competence of Member States to ensure that the country-specific considerations and objectives of general interest, which define how healthcare professionals are regulated at a national level, are taken into account. Therefore, PGEU is convinced that regulation of healthcare professionals should be excluded from any potential EU-wide framework for the 'proportionality test'.***

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<sup>1</sup> See, inter alia, judgement of the Court of 19 May 2009 in joint cases C-171/07 and C- 172/07 Apothekerkammer des Saarlandes and Others v Saarland, judgement of the Court of 19 May 2009 in Case C-531/06 Commission v Italian Republic and judgement of the Court of 11 September 2008 in Case C-141/07 Commission v Federal Republic of Germany.

<sup>2</sup> The Court of Justice of the EU has also recognised the very particular nature of medicinal products, whose therapeutic effects distinguish them substantially from other goods. This was reiterated in the Falsified Medicines Directive.