





PGEU, CED and CPME statement on proportionality in professional regulation

Setting the rules for assessing the proportionality of regulation concerning healthcare professions should remain a competence of Member States. The Pharmaceutical Group of the European Union (PGEU), the Council of European Dentists (CED) and the Standing Committee of European Doctors (CPME) are convinced that regulation of healthcare professions should be excluded from the proposal for a Directive on a 'proportionality test'¹ for the following reasons:

- 1. 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 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. The European legislator has repeatedly highlighted the **special nature of healthcare professions**. Healthcare professionals, namely doctors, dentists, pharmacists, nurses and midwives are subject to the Recognition of Professional Qualifications Directive. Furthermore, 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".
- 2. Article 168 of the Treaty of the Functioning of the EU 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 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. 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. Dentists, doctors and community pharmacists are key for healthcare systems in Europe they are actually very often the first contact point with a healthcare system for EU citizens. The regulation of these professions serves indeed a public interest in terms of safeguarding the quality and availability of health care services and protects public health. Different approaches to regulating the healthcare professions have proven effective in achieving the public interest objectives described and must therefore be supported.
- 3. The European Court of Justice's well established case-law 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 achieved². The European legislator enhanced this principle on many occasions, including in the Professional Qualifications Directive and the Falsified Medicines Directive.
- 4. **Policy decisions** relating to the regulation of the professions must serve the objective of attaining the best possible quality of care for every patient. 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.

¹ See Proposal for a Directive of the European Parliament and of the Council on a proportionality test before adoption of new regulation of professions of 10 January 2017, COM(2016)822.

² 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.

CPME, CED and PGEU are extremely concerned that such a legal framework will deter Member States from introducing new or reforming existing professional regulation which is necessary and justified on the grounds of public health. Ultimately, this may be detrimental for patients and public health.

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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.

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 institutions and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

- We believe the best possible quality of health and access to healthcare should be a reality for everyone.
- We see the patient-doctor relationship as fundamental in achieving these objectives.
- We are committed to interdisciplinary cooperation among doctors and with other health professions.
- We strongly advocate a 'health in all policies' approach to encourage cross-sectorial awareness for and action on the determinants of health.

The **Council of European Dentists (CED)** is a European not-for-profit association representing over 340,000 dental practitioners across Europe through 32 national dental associations and chambers in 30 European countries. Established in 1961 to advise the European Commission on matters relating to the dental profession, the CED aims to promote high standards on oral healthcare and dentistry with effective patient-safety centred professional practice, and to contribute to safeguarding the protection of public health. The CED is registered in the Transparency Register with the ID number 4885579968-84.