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PGEU GPUE

Pharmaceutical Group of European Union

PGEU Comments on the proposal for a Directive on a proportionality test before adoption of new regulation of professions

PGEU GPUE Pharmaceutical

The Pharmaceutical Group of the European Union (PGEU) is the association representing community pharmacists in 32 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.

PGEU's comments to the Commission's proposal for a Directive on a proportionality test

We welcome opportunity to provide feedback to the Commission's proposal for a Directive on a proportionality test. Below we list arguments/points on behalf of the pharmacy profession namely:

1. Legal basis of the proposal;
2. Legal form of the proposal;
3. Procedural aspects;
4. Margin of appreciation;
5. Definition of public interest (particularly as far as protection of public health is concerned);
6. Specific reference to the Bersani reform.
7. Impact on Member States

In conclusion, PGEU strongly believes the scope of the proposal for a Directive on proportionality goes beyond the European legislator's competence under the Treaty and relevant EU legal framework (including the scope of Directive 2005/36/EC on the Recognition of Professional Qualifications). In light of the Treaty and of well-established Court of Justice case-law, it is indeed 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 national level, are taken into account.

Therefore, PGEU is convinced that neither the legal basis nor the instrument chosen by the Commission for this proposal are appropriate or comply with the principle of subsidiarity. PGEU is particularly concerned that the proposal will deter Member States from introducing restrictions which are necessary and justified on the grounds of public health and may have negative consequences to both individual patients and public health at large.

1. Legal basis

(1) We believe that the horizontally binding Directive exceeds the mandate of the European Union. The Commission relies on Article 46 (free movement of workers), 53(1) (free establishment of self-employed persons) and 62 of the Treaty of the Functioning of the EU (free provision of services) as the legal basis of the draft Directive. It is doubtful whether the scope of the draft Directive is

indeed covered by these articles. The existing Directives 2005/36/EC and 2006/123/EC clearly aim to address cross-border situations, where professionals and service providers want to exercise their occupation in other Member States. In contrast, the current draft Directive focuses on national regulations irrespective of a possible cross-border context. Furthermore, according to the Commission reasoning, the main impetus of the draft Directive is to boost economic growth. Both aspects do belong to other policy fields than those covered by the cited articles, and in those policy fields the European Commission has only an advocative and advisory role.

(2) We furthermore question the EU's competence for introducing harmonised criteria for Member States to assess the proportionality of the healthcare professions. We believe that with this proposal the Commission breaches the principle of subsidiarity and the principle of proportionality (Article 5 TFEU)[1] as well as Article 2(5) TFEU[2] given that the organisation and delivery of health services is an exclusive competence of Member States. Article 168 (7) of the TFEU clearly recognises 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".

(3) The Commission seems to disregard Article 53 (2) TFEU according to which *'in the case of the **medical and allied and pharmaceutical professions**, the progressive abolition of restrictions shall be dependent upon coordination of the conditions for their exercise in the various Member States'* (please note emphasises has been added). In our view, this provision means that while the EU can issue directives for the mutual recognition of diplomas, it can only encourage the (voluntary) coordination of the provisions related to taking-up and pursuit of activities of health care professions, which should remain a competence of Member States. In this respect, Article 168 (2) of the Treaty is also worth noting: "The Union shall encourage cooperation between the Member States in the areas referred to in this Article (i.e. public health protection) and, if necessary, lend support to their action. It shall in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas".

(4) We believe this proposal ignores the European Court of Justice's well established case-law which acknowledges that it is the right of Member States to determine the level of protection which they

[1] Under the principle of subsidiarity (Article 5.3 TFEU), in areas which do not fall within its exclusive competence, the EU shall act only if and insofar as the objectives of the proposed action cannot be sufficiently achieved by Member States but can rather be better achieved at Union level. Under the principle of proportionality (Article 5.4 TFEU), the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaty. (Paul Craig, 'EU Law text, cases and materials', sixth edition, 2015m p.96)

[2] Article 2(5) states 'In certain areas (which fall under Member States' competence, such as the protection of human health) and under the conditions laid down in the Treaties, the Union shall have competence to carry out actions to support, coordinate or supplement the actions of the Member States, without thereby superseding their competence in these areas. Legally binding acts of the Union adopted on the basis of the provisions of the Treaties relating to these areas **shall not entail harmonisation of Member States' laws or regulations**.' (Please note emphasises has been added).

wish to afford to public health and the way in which that level is to be achieved[3]. Member States are best placed to ensure that the country-specific considerations and objectives of general interest, which define how healthcare professionals are regulated at national level, are considered. Such national strategies take into account demographical, geographical and cultural realities. The regulation of healthcare professions serves indeed a public interest in terms of safeguarding the quality and availability of health care services and the protection of public health. Different approaches to regulating the healthcare professions have proven effective in achieving the public interest objectives described and must therefore be supported.

(5) The scope of the proposal for a Directive on proportionality goes beyond the scope of Directive 2005/36/EC on the Recognition of Professional Qualifications (the Article 2 of the proposal, says that the proposal complements the Directive of Recognition of Professional Qualifications ('RPQD'), and therefore falls within the same scope[4]) in particular in the case of regulation of the pharmacy profession. Indeed, Recital 26 of RPQD states: *"This Directive does not coordinate all the conditions for access to activities in the field of pharmacy and the pursuit of these activities. In particular, the geographical distribution of pharmacies and the monopoly for dispensing medicines should remain a matter for the Member States".* In addition, we would like to remind of the Court of Justice's ruling in the case Blanco Pérez y Chao Gómez in this context, which stated the following in paragraph 45: "*Secondly, neither Directive 2005/36 nor any other measure implementing the fundamental freedoms lays down rules, concerning access to activities in the pharmacy field, which seek to set the conditions for opening new pharmacies in Member States."*[5] Therefore, within the pharmacy sector, territorial restrictions, which was the issue of discussion in this case, are not included in the scope of Directive 2005/36. More generally, one can conclude that the conditions to open pharmacies fall outside the scope of such Directive. The same principle might apply by extension to the conditions to manage and operate the pharmacies.

2. Legal form

(1) The choice of a horizontal legally binding instrument in an area of Member States' competence does not seem justified and proportionate. As it has been previously mentioned, according to the Treaty of the Functioning of the EU, the EU legislator can issue directives for the mutual recognition of diplomas, certificates and other evidence of formal qualifications. However, as it regards medical and pharmaceutical professions, we understand that **the EU can only coordinate the provisions related to the access to and the exercise of activities of such professions**. On the

[3] 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.

[4] *'The Directive shall apply to requirements under the legal systems of the Member States restricting access to a regulated profession or its pursuit, or one of its modes of pursuit, including the use of professional titles and the professional activities allowed under such title, falling within the scope of Directive 2005/36/EC'.*

[5] Court of Justice's ruling of 1 June 2010 in joint cases C-570/07 y C-571/07, paragraph 45.

basis of this as well as in line with our comments above (Article 168 and 53.2 TFEU), PGEU believes that a EU directive is not the appropriate means for the EU to set a proportionality test for the regulation of healthcare professions.

(2) Should the EU legislator deem necessary to introduce some clarity in relation to the existing obligations on how to assess the proportionality of national regulations, which we doubt, the adoption of guidance in the form of recommendations or best practices would be more suitable and appropriate and in line with the subsidiarity and proportionality principles set by the Treaty.

(3) When the Services directive was discussed, the European legislator excluded health professions from its scope explicitly stating that such a horizontal instrument was not appropriate for health services. In particular, when the first proposal for a Services Directive (including all professions) was discussed at the European Parliament, the IMCO report recognised the following: "Health services are fundamentally distinct from other services of general interest. **A horizontal framework directive of this nature is not an appropriate instrument to deal with Health services."**

3. Procedural aspects

(1) We would like to highlight the lack of transparency with regard to the decision-making process for the adoption of this proposal. According to the Impact Assessment Report, the results of the consultation pointed to a general preference for the option of the EU Directive, however, the outcome of such a consultation is not yet publicly available (only a summary thereof is included in the Impact Assessment as an annex). We question the appropriateness of a decision to publish a legislative proposal without having previously made the outcome of the preparatory public consultation public. This hinders a well-informed discussion and does not constitute good practice.

4. Margin of discretion

(1) The need to respect Member States' margin of discretion when assessing whether the principle of proportionality has been observed in the field of public health and has been confirmed in well-established case-law of the Court of Justice. According to a ruling of the Court of Justice of 11.09.2008, *"In accordance with settled case-law of the Court, 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 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*** *(…) 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".***[6]

(2) Furthermore, in case C-171/07 (Apothekerkammer des Saarlandes) the Court stated: *"it is important that, where there is uncertainty as to the existence or extent of risks to human health, a*

[6] Judgement of the Court of 11 September 2008 in Case C-141/07 Commission v Federal Republic of Germany (paragraph 51).

Member State should be able to take protective measures without having to wait until the reality of those risks becomes fully apparent. Furthermore, a Member State may take the measures that reduce, as far as possible, a public-health risk (see, to this effect, Case C-170/04 Rosengren and Others [2007] ECR I-4071, paragraph 49), including, more specifically, a risk to the reliability and quality of the provision of medicinal products to the public".

5. Definition of public interest and public health is a competence of Member States.

(1) The Commission's proposal disregards the Member States competence to define their respective public health policies and introduces binding criteria which Member States must use when introducing any legal or administrative provision which may restrict access to or the exercise of regulated professions on public health grounds. This principle (as mentioned before) is established by the Article 168 (7) TFEU and further explained by the European Court of Justice's case-law.

(2) **PGEU is particularly concerned that Directive may delay or even dissuade the adoption of necessary health regulations and may result in unintended negative consequence to quality of care and patient safety**. We strongly believe the expertise of healthcare professionals, such as pharmacists' in dispensing medicines and providing advice on their safe use, is crucial to ensure patient safety. The aim of introducing regulatory requirements for access to and exercise of such professions is precisely to protect patients and public health in general. Therefore, it is not 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 are unlikely to have implications for patient safety. The European legislator has repeatedly highlighted **the special nature of healthcare professions**, for instance in the Professional Qualifications Directive (recital 26) and the Falsified Medicines Directive (Directive 2011/62/EU) (recital 22). It is also worth noting 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). The European legislator enhanced this principle on many occasions, including in the Professional Qualifications Directive and the Falsified Medicines Directive[7].

6. Reference to Bersani report

(1) We challenge the appropriateness of reference to Bersani reform and suggest it is misleading.

(2) According to the Explanatory Memorandum of the proposal, in Italy the Bersani reform of 2006, which covered a number of sectors and professions, brought new entrants into the market for retail distribution of non-prescription medicinal products (NPMPs), leading to a higher overall employment of young pharmacists. This is mentioned as an example of benefits that have been brought by the reform of regulation in some Member States.

[7] 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.

(3) With regard to the pharmacy profession, the Bersani reform liberalised the market regulation for distribution of NPMPs, by opening it up to new entrants. As a result, parapharmacies and supermarkets could enter the market and compete directly with existing pharmacies. This measure resulted in an increase in the demand of (mainly young) pharmacists because, as it is mentioned in the report itself, a pre-existing provision, applicable also to new entrants, required that such retail establishments still needed to hire pharmacists to sell NPMPs in their shops. However, higher pharmacists employability was not linked to the lifting of any professional regulation contrary to what it is suggested in the Memorandum.

(4) The demand for pharmacists to work in the new retail stores in addition to the enlargement of outlets offering NPMPs led to an increase of overall employment of pharmacists. The effect was therefore a result of the liberalisation of the distribution channel of NPMPs together with maintaining the 'reserved activity' of dispensing medicines to pharmacists.

7. Impact of the proposal on Member States

(1) The Commission's Impact Assessment estimates the costs of the new proposal at the amount of 700 EUR per profession per Member State. This itself is costly and highly unrealistic, particularly given the type of evidence national authorities would need to provide. In addition, this would be a very time-consuming process which even involves control by an independent body**.** We are concerned this proportionality test will demotivate Member States from introducing new, or amending existing requirements which may be necessary to adapt the access and pursuit of the pharmacy profession to the evolution of the market or the specific national circumstances on the grounds of public health.

(2) In addition to the current procedural steps that Member States have to comply with when a regulation is proposed (for instance the verification of the competence of the legislative power by the government and budgetary control), the proposal will introduce many additional administrative steps which may endlessly delay the whole regulation process.

(3) Furthermore, it is unclear whether the negative assessment by the European Commission or failure to comply with the requirement will mean an automatic annulment of the measure. This proposal generates a significant degree of legal uncertainty with regard to the adoption of new requirements for the access to and exercise of regulated powers while creating a veto power from the European Commission with no legal basis.

(4) Finally, it is unclear whether the rational of the proposal would apply the same methodological assessment to new regulations eliminating existing restrictions. We would like to stress the impact, in terms of patient safety, of deregulating healthcare professionals without assessing the potential risks, particularly if established on the grounds of public health.

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