



European Network of Medical
Competent Authorities

ENMCA position paper on the proposed directive on proportionality test before adoption of new regulations of professions

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1. The European Network of Medical Competent Authorities (ENMCA) was first convened at the behest of the European Commission (EC) in spring 2010 and brings together organisations responsible for recognising medical qualifications. As doctors are one of the most mobile professions in Europe, ENMCA participants have significant experience with both the benefits and challenges of high levels of mobility and recognition procedures.
2. On 10 January 2017 the European Commission published a "Proposal for a directive of the European Parliament and of the Council on a proportionality test before adoption of new regulation of professions" (COM (2016) 822) as part of a package of measures intended to facilitate the provision of services for professionals.
3. The proposal stipulates that Member States must conduct proportionality assessments before introducing new or modifying existing legislative, regulatory or administrative provisions restricting access to or the pursuit of regulated professions, and must make a detailed statement explaining these considerations.

While the competent authorities in ENMCA support the European Commission's aim of ensuring that regulation is necessary, proportionate and justifiable, we have concerns about whether the proposed directive is in line with the principle of subsidiarity under Article 168 TFEU.

We also have serious doubts about whether the proposed directive is necessary for the medical profession which is among the most mobile professions in Europe. The suggested proportionality assessment could delay the implementation of measures necessary to protect patients and result in additional costs and administrative burden for Member States.

4. The proposal must respect the responsibilities of Member States for health policy and for the organisation and delivery of health services and medical care as outlined in Article 168 TFEU.
5. The Commission has stated that the proposed directive aims at the codification of established case law of the European Court of Justice, ENMCA participants believe that the proportionality assessment goes beyond the jurisprudence of the ECJ and introduces a new set of criteria for assessing proportionality.
6. We call for the Commission to recognise both the principle of subsidiarity and the unique nature of the healthcare sector. In the past, this unique nature has been recognised by the Commission, for example in the services directive (2006/123/EC) where the healthcare sector was excluded, and the consumer rights directive (2011/83/EU) in which the Commission acknowledged that healthcare requires special regulation. In addition, the recognition of professional qualifications directive also allows authorities to require additional evidence (such as language knowledge and

good standing) for health professionals where it is acknowledged that there is a greater public protection risk.

Administrative burden

7. ENMCA participants question the necessity of the proportionality assessment. Article 59 of the modernised recognition of professional qualifications directive already includes a provision for a proportionality test. We question whether the introduction of an additional proportionality assessment is necessary so soon after implementation of the directive or whether it simply imposes an additional administrative burden on competent authorities.

Patient safety

8. Patient safety must remain the principal consideration when assessing the proportionality of regulation in the healthcare sector and this must be reflected in legislation. However, the draft directive contains no specific reference to patient safety as a public interest justification in articles 5 and 12. We therefore call for patient safety to be added as a public interest justification above and beyond economic and market access considerations.
9. Performing a proportionality assessment and completing additional administrative procedures before introducing regulation could result in delays to the introduction of regulation aimed at improving patient safety. Any delays to the introduction of reforms to address regulatory gaps could have substantial consequences for patient safety.

Conclusion

10. In light of the above concerns, ENMCA remains concerned about the proposed directive and calls for further justification as to its necessity. We also call for an amendment of the draft directive to include the important patient safety exemptions mentioned above.

To discuss our position, please contact: [Nicola While](#), General Medical Council (+44 161 250 6954); [Alexander Jäkel](#), German Medical Association (+49 30 400 456-369); [Marie Colegrave-Juge](#), French Medical Council (+33 1 53 89 33 61) or visit the ENMCA [website](#) for more information.