

April 2017

## Proportionality test before adoption of new regulation of professions

1. This position paper has been produced by the [Alliance of UK Health Regulators on Europe](#) (AURE) in response to the European Commission's proposal for a Directive on a proportionality test before adoption of new regulation of professions (COM(2016)0822).
2. AURE brings together nine health and social care regulators in the United Kingdom to work collaboratively on European issues affecting patient safety. Our purpose is to protect and promote patient safety through effective regulation and ensuring proper standards in the practice of health and social care.
3. As regulators for healthcare professionals, we welcome the proposal and support the European Commission aim of ensuring that regulation is necessary, proportionate and justifiable.
4. Health and social care regulators in the UK already apply the principle of proportionality when introducing or amending the legislation governing access to the professions and we welcome the recognition of the importance of this at EU level.
5. There are a number of areas where we call on the UK government and European Commission to provide clarity and to recognise the unique nature of the healthcare sector.

### *Patient safety as a public interest justification*

6. There is no specific reference in the draft Directive to patient safety as a public interest justification in recital 12 and article 5.
7. Patient safety must remain the principle consideration when assessing the proportionality of regulation in the healthcare sector and this must be reflected in legislation.
8. We thus call for patient safety to be added as a public interest justification in order to ensure that regulators are able to ensure the highest level of patient safety possible.

## AURE briefing

### *Administrative burden on regulators*

9. The administrative costs and burden incurred by conducting the proportionality test have yet to be identified. The Directive must not impose unnecessary administrative burden by being overly prescriptive about the way in which the proportionality test is undertaken.

10. We also seek clarification on the reference to “independent scrutiny bodies” in article 4.5 as this could add an extra layer of administrative burden. We suggest replacing this phrase with wording that allows for flexibility within our existing domestic structures. This would also avoid the need to add a new actor into the system where it does not currently exist.

11. The Directive should not act as a barrier to national regulatory reform by imposing additional bureaucracy.

### *Powers to impede legislative change*

12. It is unclear what would happen if a member state or other stakeholder challenged the introduction of a new national regulatory provision or the result of a proportionality test. The Directive does not contain provisions for this and we would not want UK implementing legislation to introduce such provisions as this would be disproportionate.

13. Additionally, we call on the Commission to clarify whether the proportionality test would need to be undertaken in the case of national legislation being amended to remove regulation or to reduce an identified regulatory burden. In this case, it would appear that a test would be superfluous as any move to reduce regulatory burden would automatically be in line with the aims of the draft Directive.

### *Impact of EU exit*

14. In view of the separate timelines envisaged for the UK exiting the EU and for the agreement and implementation of the Directive, we seek clarification from both the UK government and the European Commission on whether the Directive will apply to the UK before it leaves the EU, and, if so, for how long.

15. Further, as part of the EU exit negotiations, we seek clarification on whether any bilateral agreement regarding mutual recognition of professional qualifications (and



AURE

Alliance of UK Health Regulators on Europe

## AURE briefing

associated provisions, such as the proposed Directive) would form part of any free trade agreement between the UK and EU.

For further information on any of the issues in this briefing, please contact AURE at:

**Email: [aure@gmc-uk.org](mailto:aure@gmc-uk.org)**