

Healthcare regulation: deciding when statutory regulation is appropriate - GMC Response

Questions 1. Do you agree or disagree that a qualitative and quantitative analysis of the risk of harm to patients is the most important factor to consider when deciding whether to regulate a health or care profession?

- 1** Yes, we agree that analysis of the risk of harm to patients is the most important factor to consider when deciding whether to regulate a health or care profession. This is reflected in our over-arching statutory objective of protection of the public and pursuit of the subsidiary objectives.

- 2** However, alongside any assessment of risk there must also be an assessment of whether the profession is ready to be regulated, and therefore meets certain conditions. For example:
 - there exists a defined body of knowledge and standards for that particular group
 - there are established training pathways for the education of future professionals
 - there is support within that group for the professional responsibilities that go with regulation
 - and, where relevant, there is infrastructure in place to support the delivery of the duties and responsibilities associated with a regulated profession

- 3 If a profession were to be brought into statutory regulation, solely based upon the risk posed to patients, and without consideration of whether the associated conditions for regulation are met, it is far more likely that individuals will fall short of any professional standards that are set.
- 4 We expand on these points below in answer to Question 2.

Question 2. Do you agree or disagree that proportionality, targeted regulation and consistency should also be considered in deciding whether to regulate a health or care profession?

- 5 While we agree that that proportionality, targeted regulation, and consistency should also be considered in deciding whether to regulate a health or care profession, it is important that these are not framed purely through the objective of reducing harm. There are wider aims and benefits of statutory regulation that go beyond this. For example, once a profession has evolved to the point of maturity, statutory regulation gives a level of assurance to employers about standards of practice and accountability that would not otherwise exist, particularly where there is a high level of risk associated with the activities. This in turn is likely to increase demand for the profession, as will the side effect of increased professional identity. The increased credibility and profile of a profession has the potential to attract more individuals to join a training pathway, thereby boosting workforce supply (though this is not, in itself, a reason for regulating).
- 6 In our response to the government's consultation on the regulation of Medical Associate Professions in 2017, we proposed the following criteria for assessing whether to regulate a new profession. As we set out below, these largely fall under the headings of proportionality, targeted regulation and consistency – but they provide additional factors to take into account. For ease, we have summarised these here:
 - i. The professional group must have a defined body of knowledge and standards
 - ii. The profession must be a clearly definable and differentiated group and have a clear role.
 - iii. Statutory regulation is necessary to perform functions associated with the role (for example prescribing).
 - iv. There is a high level of complexity associated with the role.

- v. There is a high level of risk associated with activities necessary to fulfil the role and therefore a need for accountability.
- vi. Professionals have a significant degree of autonomy.
- vii. Regulation is necessary to be able to command public confidence.
- viii. Regulation is necessary to provide assurance of quality and reliability to other professional groups or agencies using the services of the profession.
- ix. Statutory regulation must be supported by the proposed professional group and other key stakeholders.
- x. The professional group must be of sufficient size and maturity to be able to support the requirements of regulation (for example, an established educational and professional infrastructure and professional standards. This might be demonstrated through voluntary regulation).

Proportionality

- 7** We agree that proportionality should be considered when deciding to regulate a health or care profession and with the principle of applying the minimum intervention required to achieve the regulatory objective.
- 8** But it should be evident by the maturity of the profession and its supporting infrastructure that the next logical step in the profession's evolution is statutory regulation, rather than using statutory regulation as a means for establishing or 'jump starting' a new profession.

Targeted regulation

- 9** We agree that targeted regulation should be considered in deciding to regulate healthcare professionals. But as we set out in paragraph 6, targeting problems should extend beyond simply minimising harm but also address other challenges, for example, minimising variation in preparedness for practice, and the delivery of professional practice itself.

Consistency

- 10** It is imperative that a regulator be able to work in collaboration with other agencies as part of the wider regulatory system. Solutions to regulatory problems often do not rest within a single regulator's remit.
- 11** Rather, professional regulation is one element of a more complex picture which operates horizontally as well as vertically. It involves professional regulation, system regulation, employer regulation, regulation of the team, personal regulation by individuals of their own behaviour, and often international regulation. What matters most is how those various elements interact and are aligned within all four countries of the UK.
- 12** We therefore agree that consideration must be given to how statutory regulation complements the existing regulatory landscape to ensure that key risks at the margins of regulatory oversight are not overlooked.

Question 3. Do you agree or disagree that the currently regulated professions continue to satisfy the criteria for regulation and should remain subject to statutory regulation?

- 13** We agree that the currently regulated professions continue to satisfy the criteria for regulation, having not seen any evidence to the contrary.

Question 4. Do you agree or disagree that currently unregulated professions should remain unregulated and not subject to statutory regulation?

- 14** Don't know - This is not a question we are able to answer without having seen evidence either way relating to any unregulated professions. But we would suggest that it is a matter for Government to determine whether any currently unregulated professions should be brought into statutory regulation.