Response to the consultation: Future of Pharmacy Regulation in Northern Ireland

June 2016

1. Introduction

1.1 The Professional Standards Authority for Health and Social Care promotes the health, safety and wellbeing of patients, service users and the public by raising standards of regulation and voluntary registration of people working in health and care. We are an independent body, accountable to the UK Parliament. More information about our work and the approach we take is available at www.professionalstandards.org.uk.

1.2 As part of our work we:

- Oversee nine health and care professional regulators, including the Pharmaceutical Society of Northern Ireland (PSNI) and the General Pharmaceutical Council (GPhC), and report annually to Parliament on their performance
- Conduct research and advise the four UK governments on improvements in regulation
- Promote right-touch regulation and publish papers on regulatory policy and practice.

1.3 We welcome the opportunity to respond to this consultation about the future of pharmacy regulation in Northern Ireland (NI). We offer some general comments, but have not responded to the individual questions in the consultation document.

2. General comments

2.1 The Authority supports the proposals to separate professional regulation and professional leadership. In our view, this would be most efficiently and effectively achieved by transferring the regulatory powers of the PSNI to the GPhC (Option 3). The purpose of regulation is to protect the public, to maintain public confidence in the profession, and to uphold professional standards. Professional leadership works to promote the interests of the profession, and therefore should be separate from any regulatory arrangements.

2.2 We understand the concerns that some NI stakeholders might have about a four-country regulator being less in-touch with local issues. However, in our view, this risk could be mitigated by the governance measures suggested in the consultation document. Furthermore, we believe that the benefits in terms of cost-efficiency, effectiveness and workforce mobility of a UK-wide regulator by far outweigh this risk.

Removing professional interests from regulation

2.3 The separation of regulation from professional representation has been at the heart of modern thinking about professional regulation in the UK since it was recommended by Dame Janet Smith in the Shipman Inquiry report,[1] and taken forward by the UK Government of the day in the White Paper, *Trust, Assurance and Safety.*[2] We have echoed this sentiment in a number of our own publications, including *Right-touch regulation*,[3] and *Fit and Proper? Governance in the public interest.*[4] There is also support from the Law Commissions review (including the Northern Ireland Law Commission) of the United Kingdom, as is mentioned in the consultation document. It is interesting to note that the Royal Pharmaceutical Society of Great Britain (RPSGB) was similar to the PSNI, in that it combined the role of regulator with that of professional body. In 2010, the General Pharmaceutical Council was created to take on the regulation role while the RPSGB focuses on its sole remit of professional leadership.

A four-country or NI regulator?

2.4 Pharmacists are the only healthcare profession in the UK not to have a UK-wide regulator[5]. In our scrutiny of the seven UK-wide regulators we oversee, we have yet to identify any shortcomings in their ability to operate across jurisdictions, and in Northern Ireland in particular. The GPhC already operates across three of the four UK-countries, and we have no reason to believe that extending its remit to NI would have any adverse impact on its ability to effectively protect the public – particularly if the mitigation measures suggested in the consultation document (appointing an NI Director and Council Member at the GPhC) were implemented.

The costs of reform

2.5 In our view, Option 3 is the most cost-effective. Ensuring as cost-efficient a model as possible for registrants is a concern that is, rightly, explored in the consultation document. The document notes that larger regulators are more effective in their use of resources as there is greater '*shared knowledge, resource, expertise and experience*'. This belief echoes (and acknowledges) the findings of our paper in 2012 which explored the cost-efficiency and effectiveness of the nine regulators we oversee.[6] In addition, and in line with the

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[1] The Shipman Inquiry (2004). Fifth Report – Safeguarding Patients. Lessons from the past, proposals for the future. Cm 6394. The Stationery Office.
[2] Department of Health (2007). *Trust, Assurance and Safety: The regulation of healthcare professionals in the 21st Century.*
[3] Professional Standards Authority, 2015, Right-touch regulation, pg. 9. Available at: http://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/right-touch-regulation-2015.pdf?sfvrsn=12
[4] Professional Standards Authority, 2013. *Fit and Proper? Governance in the public interest.* Available at: http://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/fit-and-proper-2013.pdf?sfvrsn=2
[5] Regulation of social workers is devolved.
[6] Professional Standards Authority, 2012, Review of the cost effectiveness and efficiency of the health professional regulators. Available at: http://www.professionalstandards.org.uk/docs/default-source/publications/special-review-report/cost-effectiveness-and-efficiency-review-health-professional-regulators-2012.pdf?sfvrsn=4

principles of *Right-touch regulation,* we recommend that the NI Government considers making full use of existing mechanisms before opting to create a new body. [7] For these reasons, we support the proposal for a four-country regulator for pharmacists in the UK, in the shape of the GPhC. The GPhC has performed consistently well against our Standards of Good Regulation, and we would have no concerns about its ability to take on the additional registrants from the PSNI.[8]

2.6 On page 18, the consultation document explains that to deliver Option 2 (a Northern Ireland based regulator) would require a *'significant and resource intensive legislative programme*'. We mention in our paper *Right-touch Regulation* the need to keep regulatory solutions simple and to 'build on existing approaches where possible'.[9] The NI Government may wish to consider whether such expenditure would be necessary, when transferring the register to the GPhC (Option 3) could provide an effective and less onerous solution. As long ago as 2008, we recommended that '*the GPhC [be] set up in such a way that at a logistical level it is a straightforward matter [for it to] register Northern Ireland's pharmacists and pharmacy technicians, should the Minister decide in future that this is [their] wish*.'[10]

Further benefits for the public and professionals

2.7 It is critical for healthcare economies to make the best use of a mobile workforce, to ensure that communities across the UK have access to the healthcare they need. Having one regulator for all UK-registered pharmacists would allow freer movement of professionals around the UK. It would also bring consistency of professional standards and fitness to practise processes, and would be likely to make decisions about registration, removal, and other sanctions fairer and more equitable. This consistency would provide greater clarity for the public, and help to increase public confidence in the regulator and the profession.

2.8 Further, in previous reports we have mentioned that time spent by registrants complying with regulatory requirements should be a factor in decision making about the effectiveness of regulators.[11] Under Options 1 and 2, there would be an increase in the burden of regulation on professionals as they would have to

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[7] Professional Standards Authority, 2015, Right-touch regulation, pg. 9. Available at: http://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/right-touch-regulation-2015.pdf?sfvrsn=12

[8] In 2014-15, it met all but one of our Standards of Good Regulation. See our Performance Review report, available at: http://www.professionalstandards.org.uk/docs/default-source/publications/performance-reviews/performance-review-report-2014-2015.pdf?sfvrsn=10

[9]Professional Standards Authority, 2015, *Right-touch regulation,* g. 7. Available at: http://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/right-touch-regulation-2015.pdf?sfvrsn=12

[10] Professional Standards Authority (formerly the Council for Healthcare Regulatory Excellence), 2008. *Advice to the Department of Health and the Pharmacy Regulation and Leadership Oversight Group on aspects of the establishment of the General Pharmaceutical Council*. Available at: http://www.professionalstandards.org.uk/publications/detail/establishing-the-general-pharmaceutical-council.

[11] Professional Standards Authority, 2012, Review of the cost effectiveness and efficiency of the health professional regulators, pg. 14. Available at: http://www.professionalstandards.org.uk/docs/default-source/publications/special-review-report/cost-effectiveness-and-efficiency-review-health-professional-regulators-2012.pdf?sfvrsn=4

adhere to the requirements of multiple jurisdictions when moving from one to the other. Having a four-country regulator would remove this additional burden.

2.9 If either Option 2 or Option 3 were to go ahead, the Northern Ireland Department of Health would need to explain clearly to the public why the change was necessary – particularly with regard to the benefits that would be achieved by the new arrangements. This is important as regulation needs to maintain public confidence in itself, as well as in the profession.

3. Further information

3.1 Please get in touch if you would like to discuss any aspect of this response in further detail. You can contact us at:

Professional Standards Authority for Health and Social Care
157-197 Buckingham Palace Road
London SW1W 9SP

Email: michael.warren@professionalstandards.org.uk
Website: www.professionalstandards.org.uk
Telephone: 020 7389 8030