

Professional Standards Authority response: consultation on developing the General Pharmaceutical Council (GPhC) approach to regulating registered pharmacies

August 2018

1. About the Authority

- 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 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 the nine health and care professional regulators and report annually to Parliament on their performance
 - Accredit registers of healthcare practitioners working in occupations not regulated by law through the Accredited Registers programme
 - Conduct research and advise the four UK governments on improvements in regulation
 - Promote right-touch regulation and publish papers on regulatory policy and practice.

2. General comments

- 2.1 We welcome the opportunity to comment on the GPhC's proposed changes to its approach to the regulation of registered pharmacies. We are pleased to learn that the GPhC has considered stakeholder feedback from the external evaluation it commissioned in 2015 and the focus groups in 2017 to inform some of the proposed developments.
- 2.2 We have previously addressed the disconnection between professional and system regulation. In our publication *Rethinking Regulation*¹, the Authority recommended that reform of the regulation of people and premises would be advantageous for patient safety by ensuring greater alignment of approach. In its dual role, the GPhC is in the beneficial position to apply the learnings from its regulation of premises to its regulation of professionals and vice versa. However, there is no reference in the consultation to how the proposed developments could be mutually beneficial for professional and system

¹ Professional Standards Authority.. *Rethinking regulation* (2015) pp13-15. Available at: <https://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/rethinking-regulation-2015.pdf>

regulation. We suggest that there should be further consideration of the learning that regulation of both people and premises can offer.

- 2.3 We welcome the GPhC's intention to continue to work with other enforcement agencies and to make referrals to other agencies when they are best placed to manage the concerns. We consider this to be a proportionate approach that adheres to the principles of right-touch regulation².
- 2.4 The Authority is currently consulting on the new Standards of Good Regulation³. One of the outcomes of the review of the Standards will be to express more explicitly that the Standards cover all aspects of the regulator's work, including in relation to the regulation of businesses or premises. Our comments below reflect the increased scope of the proposed revisions to the Standards. However, it should be noted that the Authority's response is in respect of proposed policy developments. We have not responded to proposed operational developments.

3. Detailed comments

Introduction of three types of inspection

- 3.1 We understand that the GPhC is proposing the introduction of three types of inspection to adopt a more proportionate approach to how inspections are carried out. We welcome this approach, which is consistent with the principles of right-touch regulation. We also support the stated approach that indicators of risk will determine which pharmacies are inspected as a priority. However, the GPhC will need to be assured that there is a transparent and consistent approach to the criteria that determines each type of inspection.

Moving to unannounced inspections

- 3.2 We do not have a view on the proposed move to unannounced inspections but support the GPhC's position, as detailed in the consultation, that they will continue to consider the impact on patients when undertaking inspections.

Changing inspection outcomes

- 3.3 In the consultation document the GPhC has addressed the responses to the commissioned external evaluation in 2015. It is reported that the responses included feedback about the lack of clarity and differentiation between the ratings given in the ratings model. We are of the view that there remains a lack of clarity in the proposed outcomes at the principle level, in that the factors determining an outcome of 'good practice' or 'excellent practice' remain unclear. We do not agree that the regulator's role is that of quality improvement and address this issue at 3.4 of this response. However, should the GPhC consider it essential to assess performance above that required to

² Professional Standards Authority. *Right-touch regulation (revised)* (2015). Available at: https://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/right-touch-regulation-2015.pdf?sfvrsn=eaf77f20_18

³ Details of the consultation on the revised Standards of Good Regulation available at: <https://www.professionalstandards.org.uk/news-and-blog/latest-news/detail/2018/06/14/reviewing-the-standards-of-good-regulation-second-consultation-launched>

meet its Standards, we suggest that revision to the good/excellent outcomes may be required to ensure consistency of approach and ease of understanding. It is important to ensure that the rationale behind outcomes, the outcomes themselves and the terminology used are clearly explained.

- 3.4 The GPhC states that the proposed approach, 'supports and drives continuous improvement in the quality of pharmacy services for patients and the public'. We are of the view that the role of the regulator is to ensure public protection, which is achieved by setting standards to be met by registrants and premises. The regulator's role is not one of quality improvement. As explained in *Rethinking regulation*⁴, 'It is the role of the regulators to help in the tasks of shaping the health and care systems in a way that facilitates achievement and maintenance of standards of care – not to be responsible for their achievement or for improvement.....Once a regulator becomes too intimately involved in putting improvement into effect it loses its objective and impartial advantage.'
- 3.5 We recognise there is a difference between regulation, inspection and quality improvement. We addressed this in *Rethinking Regulation*⁵, 'In system regulation the challenge also lies in a lack of an agreed theory of regulation to underpin their activities. Are system regulators improvement organisations, inspectors or regulators? These are different roles and not easily made compatible. Added to which, although generally referred to as 'system regulators', UK regulators' remits have focused on individual organisations with only passing reference made to the wider system in which they operate'. Whilst we recognise that the GPhC's role in this area differs somewhat from its role as a regulator of people, it will need to assure itself that the approach it takes is clear to patients and the public and it avoids the risks outlined above.
- 3.6 The foreword to the consultation explains that the aim of the proposed developments is to move away from a 'one-size-fits-all' approach to the regulation of pharmacies. We support the proposed revision to the standardised approach previously used for the regulation of pharmacies. However, moving away from the standardised approach may potentially present problems in describing good/excellent practice in a way that can be clearly understood by patients. This point further highlights the concerns we have identified at 3.3. Consequently, we suggest that assessing the level of practice above that required to meet the GPhC Standards could potentially cause confusion to registrants, patients and the public.

Requiring all standards to be met to receive an overall 'standards met' outcome

- 3.7 We do not have any comments.

⁴ Professional Standards Authority. *Rethinking Regulation* (2015) pp16. Available at: <https://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/rethinking-regulation-2015.pdf>

⁵ See footnote 4 pp13

Publishing inspection reports

- 3.8 We support the proposed development on the basis that it demonstrates increased transparency, which is one of the founding principles of right-touch regulation. It should be noted that the move to publish inspection reports contributes to the importance of consistent and transparent inspection outcomes.

Sharing examples of notable practice

- 3.9 We welcome the exchange of learning this will facilitate and suggest that this is a more appropriate method of encouraging learning and development/improvement than making a formal assessment of good and/or excellent practice as an inspection outcome. We hope that the feedback received will be used to benefit both the GPhC's regulation of professionals and its regulation of premises.

4. Further information

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

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