Department of Health

Promoting professionalism, reforming regulation

Questionnaire

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1. Summary of the questions

Q1: Do you agree that the PSA should take on the role of advising the UK governments on which groups of healthcare professionals should be regulated?

Response:

Yes

Q2: What are your views on the criteria suggested by the PSA to assess the appropriate level of regulatory oversight required of various professional groups?

Response:

As a starting point, all groups that are currently regulated should remain subject to regulation. To currently registered professions, registration reflects the importance of professional standards. To the public, registration provides confidence that standards are maintained and enforced. Registrants are rewarded with the privilege of practising, and status. Conversely, the removal of mandatory registration would undermine public confidence in practitioners, and detract from the importance of professional standards. The suggested PSA criteria are very complex. Regulatory oversight should be extended to any group of healthcare practitioners where the maintenance and enforcement of professional standards is necessary to protect the public and patients.

Q3: Do you agree that the current statutorily regulated professions should be subject to a reassessment to determine the most appropriate level of statutory oversight? Which groups should be reassessed as a priority? Why?

Response:

In general, no. All groups that are currently regulated should remain subject to regulation. To currently registered professions, registration reflects the importance of professional standards. To the public, registration provides confidence that standards are maintained and enforced. Conversely, the removal of mandatory registration would undermine public confidence in practitioners.

Q4: What are your views on the use of prohibition orders as an alternative to statutory regulation for some groups of professionals?

Response:

The process sounds unnecessarily cumbersome, especially in the case of regulators with a Fitness to Practise Committee that has the power of interim suspension and the power to impose conditions of practice. Rather than introducing a new concept, it would make more sense to extend the power to impose an interim suspension to those regulators who do not currently have such a power.

Q5: Do you agree that there should be fewer regulatory bodies?

Response:

Yes, in general.

Q6: What do you think would be the advantages and disadvantages of having fewer professional regulators?

Response:

Consistency in standards and in the application of fitness to practise sanctions across the healthcare professions.

Q7: Do you have views on how the regulators could be configured if they are reduced in number?

Response:

Our particular area of expertise is in the pharmacy sector, and our comments relate specifically to this sector.

The pharmacy sector comprises, amongst other things, pharmacists who practice in community pharmacy, the hospital sector and the pharmaceutical manufacturing sector. This spread of practice does not easily lend itself to merging the regulation of pharmacists and pharmacy technicians with the regulator of any other healthcare profession.

Except perhaps because of its size, there is no compelling reason to merge the regulation of pharmacists and pharmacy technicians with the regulation of other healthcare professions. On the contrary, there are reasons why the pharmacy profession should retain its discrete regulation, as we explain below.

The pharmacy sector is already heavily regulated. The General Pharmaceutical Council is a modern regulator (established as recently as 2010) with modern powers. The GPhC:

- **Maintains a statutory register of pharmacists**
- **Maintains a statutory register of pharmacy technicians**
- **Maintains a register of premises**
- **Has a statutory duty under section 108(6C) of the Medicines Act 1968 to enforce certain provisions of the Act, including powers to bring prosecutions**
- **Has inspectors with rights of entry and powers of search and seizure in sections 109 to 112 of the Act, and Articles 8 to 12 of the Pharmacy Order 2010**
- **Has powers in relation to premises standards (see, for example) Articles 13 and 14 of the Pharmacy Order 2010**

The General Pharmaceutical Council's inspectorate has expert understanding of the practice and standards of the pharmacy profession, There is a risk that this would be lost or diluted if pharmacy regulation was merged with other healthcare professions, and the risk outweighs the possible benefits of efficiencies through size.

Of particular concern, if pharmacy regulation was merged with the regulation of one or more other healthcare professions:

- **With one possible exception (see our answer to question 8), it is unlikely that new powers of regulation would be needed because the GPhC's powers are already modern (and have been used as a model to update the powers of other healthcare professions).**

- **It would be anomalous to have one profession that is (a) subject to a raft of criminal offences, for example under section 67 of the Medicines Act 1968 and regulation 255 of the Human Medicines Regulations 2012; and (b) the statutory powers of inspection and enforcement referred to above while another profession under the same regulatory umbrella was not subject to the same provisions (and that other profession(s) would presumably be subject to premises inspection by the Care Quality Commission with different standards and different reporting arrangements).**

We note that in order to achieve efficiencies, the Department believes that the optimal number of registrants for a regulator is between 100,000 and 200,000. We cannot see a good reason for retaining separate regulators in Great Britain and in Northern Ireland. If the GPhC and the Pharmaceutical Society of Northern Ireland were to become a single regulator:

1. **The aggregate number of registrants would only be a little below 100,000;**

2. **Compared to other healthcare regulators, the GPhC is already efficient in so far as only 25% of its total expenditure is devoted to fitness to practise;**

3. **Compared to other healthcare regulators, the Pharmaceutical Society of Northern Ireland is already efficient in so far as only 12% of its total expenditure is devoted to fitness to practise;**

4. **The GPhC is already efficient compared to other regulators, with a cost per registrant of £247, which is lower than all but two of the other 8 healthcare regulators**
5. **It is not possible to isolate the cost per registrant of the Pharmaceutical Society of Northern Ireland because the PSNI also has a professional leadership role which is reflected in its operational costs, but even with this role, there are other regulators with higher costs per registrant than the PSNI.**

6. **Although the consultation paper expresses general concern about delays in fitness to practise procedures, in the most recent report on the General Pharmaceutical Council by the Professional Standards Authority ("PSA"), the PSA found that the GPhC met its standard of dealing with fitness to practise cases as quickly as possible, taking into account the complexity and type of case and that delays did not result in harm or potential harm to patients and service users.**

Q8: Do you agree that all regulatory bodies should be given a full range of powers for resolving fitness to practise cases?

Response:

Yes. The modern powers available to the General Pharmaceutical Council could be (and have already been) a model for other healthcare professions. It would be beneficial if the GPhC had a power of consensual disposal of fitness to practise cases. This would allow cases to be dealt with faster, proportionately and cost-effectively.

Q9: What are your views on the role of mediation in the fitness to practise process?

Response:

It could be valuable, either enabling an aggrieved patient to gain an understanding direct from the practitioner of something believed to have gone wrong; or in enabling registrants to gain insight. Mediation may also have the advantage in appropriate cases of being speedier and less expensive than full fitness to practise proceedings, as well as facilitating remediation on the part of the registrant, while being less adversarial

Q10: Do you agree that the PSA's standards should place less emphasis on the fitness to practise performance?

Response:

We do not have a particular view about this, but we note the suggestion that "More **needs to be done to move to a more inquisitorial approach that seeks to establish 3.19.the circumstances of a case rather than an adversarial approach." We do not agree with this. There is no question in the consultation paper about an inquisitorial approach, so we are taking the opportunity to comment on it here.**

A balance has to be struck between the need to protect the public and the rights of a registrant. Naturally, the need to protect the public must outweigh the interests of the registrant. In all the healthcare professions, the standard of proof in fitness to practise cases is the balance of probabilities. In other words, an allegation of misconduct or deficient professional performance only has to be probably correct: a fitness to practise panel does not have to be sure, beyond reasonable doubt that the allegation is true. This is the case even if what is alleged involves what could be criminal behaviour. Given this low threshold, an adversarial system protects the rights of registrants. Moving to an inquisitorial system in combination with a low standard of proof would tip the balance too far against the rights of registrants.

Q11: Do you agree that the PSA should retain its powers to appeal regulators' fitness to practise decisions to the relevant court, where it is considered the original decision is not adequate to protect the public?

Response:

Yes. The PSA's powers aid consistency in decision making, especially among a multitude of different regulators. The High Court's decisions in PSA cases are a useful resource for all regulators.

Q12: Do you think the regulators have a role in supporting professionalism and if so how can regulators better support registrants to meet and retain professional standards?

Response:

Yes. Mentoring arrangements, especially in the early years of practice and in professions whose members often work in professional isolation would be beneficial, as would encouragement to participate in committees, as the GosC found (page 22 of the consultation paper).

Q13: Do you agree that the regulators should work more closely together? Why?

Response:

Yes. It would save costs. In cases of dual registration, it would also be more efficient.

Q14: Do you think the areas suggested above are the right ones to encourage joint working? How would those contribute to improve patient protection? Are there any other areas where joint working would be beneficial?

Response:

Yes. Generic standards and a single adjudicator would be a sensible way forward. This would enable consistent decision making and consistent sanctions. Consideration also needs to be given to the different powers and systems regulators have. For example, the General Pharmaceutical Council has statutory inspectors who have inspection and occasionally investigatory functions. In the case of other professions, premises are, in effect, regulated by the Care Quality Commission.

Q15: Do you agree that data sharing between healthcare regulators including systems regulators could help identify potential harm earlier?

Response:

: **Yes**

Q16: Do you agree that the regulatory bodies should be given greater flexibility to set their own operating procedures?

Response:

No. There would be a risk of inconsistency in procedures and consequently downstream.

Q17: Do you agree that the regulatory bodies should be more accountable to the Scottish Parliament, the National Assembly for Wales and the Northern Irish Assembly, in addition to the UK Parliament?

Response:

Neutral

Q18: Do you agree that the councils of the regulatory bodies should be changed so that they comprise of both non-executive and executive members?

Response:

Yes

Q19: Do you think that the views of employers should be better reflected on the councils of the regulatory bodies, and how might this be achieved?

Response:

Yes. In some professions, especially in pharmacy, employers are a significant stakeholder. Also, the type of employer in community pharmacy is different, because community pharmacy businesses are often significantly larger than other types of business in the health sector. A proper balance needs to be struck.

Q20: Should each regulatory body be asked to set out proposals about how they will ensure they produce and sustain fit to practise and fit for purpose professionals?

Response:

Yes. There are wide varieties of practice, and currently variations in inspection and enforcement.

Q21: Should potential savings generated through the reforms be passed back as fee reductions, be invested upstream to support professionalism, or both? Are there other areas where potential savings should be reinvested?

Response:

Both. It seems hard to justify the level of fees in some healthcare professions when they are so much higher than in other professions.

Q22: How will the proposed changes affect the costs or benefits for your organisation or those you represent?

- an increase
- a decrease
- stay the same

Please explain your answer and provide an estimate of impact if possible.

Response:

A single Fitness to Practise tribunal for all healthcare professions could be desirable but, as pointed out in answer to question 7, pharmacy regulation is already relatively cost-efficient. Merging pharmacy regulators with other healthcare regulators may make them less cost efficient, not more so. Regulation itself may be more complex because a regulator that is not dedicated to pharmacy may struggle to get to grips with the raft of regulation and criminal offences that are unique to pharmacy.

Q23: How will the proposed changes contribute to improved public protection and patient safety (health benefits) and how could this be measured?

Response:

For largely historical reasons, community pharmacy is already very heavily regulated – probably more heavily than other healthcare professions because, amongst other things (1) the principal regulator, the GPhC, is responsible for regulation of both registrants and premises; (2) the GPhC has a statutory inspectorate, unlike other healthcare professions; (3) unlike other professions, there are numerous statutory provisions governing pharmacy practice breach of which is a criminal offence; and (4) other regulators such as the MHRA, NHS England and the CQC also have regulatory roles.

A single fitness to practise tribunal for all healthcare professions would give the public reassurance through more transparent arrangements.

Q24: Do you think that any of the proposals would help achieve any of the following aims:

- Eliminating discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010 and Section 75(1) and (2) of the Northern Ireland Act 1998?

- Advancing equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it?

- Fostering good relations between persons who share a relevant protected characteristic and persons who do not share it?

If yes, could the proposals be changed so that they are more effective?

Response:

Not in the pharmacy profession. Professional standards in pharmacy already address these aims.

If not, please explain what effect you think the proposals will have and whether you think the proposals should be changed so that they would help achieve those aims?

Response:

To the extent that any profession does not already address Equality Act requirements in its standards, these can be included in its professional standards.