January 2018

Pharmacists' Defence Association Response to the Department of Health's Consultation on Promoting Professionalism, Reforming Regulation

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the pharmacists' defence association

Contents

About the Pharmacists' Defence Association

The Pharmacists' Defence Association (PDA) is a not-for-profit organisation which aims to act upon and support the needs of individual pharmacists and, when necessary, defend their reputation. It currently has more than 27,000 members. The PDA Union was inaugurated in May 2008 and achieved independent certification in 2011.

The primary aims of the PDA are to:

- Support pharmacists in their legal, practice and employment needs
- Represent the individual or collective concerns of pharmacists in the most appropriate manner
- Proactively seek to influence the professional, practice and employment agenda to support members
- Lead and support initiatives designed to improve the knowledge and skills of pharmacists in managing risk and safe practices, so improving patient care
- Work with like-minded organisations to further improve the membership benefits to individual pharmacists
- Provide insurance cover to safeguard and defend the reputation of the individual pharmacist

Summary of Department of Health's (DoH's) proposals

The DoH is consulting from 31 October 2017 to 23 January 2018 on proposals to reform healthcare regulation in the UK, including reducing the number of regulators from nine to three or four.

Foreword

The PDA takes the view that the priority in reforming regulation should be the benefit to patients. Better regulation – we agree – could help to transform healthcare services and meet future challenges.

We would welcome fee reductions for pharmacists, if it is possible to ensure the same or better standards of regulation at the same time as reducing regulatory costs (the fee is currently £250 per year). However, in respect of registered pharmacies, we would be like to see better regulation (our reasons will be apparent from our responses to the questions) and do not agree that there should necessarily be a fee reduction for the registration of pharmacy premises (the fee is currently £241 per year).

We also take the view that professional bodies should have a key role in setting the standards for the profession – working in partnership with the regulator and the public – and regulators should enforce these. To use the DoH's phraseology from the consultation document, regulators should be "policing the conduct, performance and behavior" of registrants. To maintain the status of a profession, a professional leadership body would need to set increasingly high standards for practitioners to meet; in this respect, the interests of the profession would be aligned to those of the public. The pharmacy regulator has considerably less knowledge and understanding of the profession than professionals and so appears to have great difficulty in setting appropriate standards for them. [1] Professionals who have undertaken a university degree in order to serve patients are in the best position to define standards which care for and protect those patients. To allow a regulator whose council comprised non-professionals to attempt to define standards – even if it receives input from the profession but retains a decision-making capacity – could risk deprofessionalizing those subject to the standards, since the expectations may be too simplistic, misplaced or "set the bar too low".

It must also be noted that the Department of Health uses the term 'professional' too loosely; registration with a regulator does not mean that a group of people can necessarily be described as 'a profession'. For example, pharmacists are professionals, but pharmacy technicians may mostly aptly be characterized as an occupational group. Various factors determine whether a group of individuals constitutes a profession. [2]

There is significant concern that in pharmacy at least, the phrases 'acting professionally' and 'being a professional' are being used almost interchangeably and are thought of as such by some. This is not at all helpful. The use of the word 'professional' as an adjective (being professional) is altogether different to its use as a noun (being a professional) and the word carries different meanings in each case. A sixteen-year-old receptionist or fast food server with no qualifications whatsoever, can, with good manners and a little organisational knowledge, seem to act professionally in a relatively simple customer transaction – but the majority of objective commentators would not describe the person as being 'a professional' or part of a profession.

It is hoped that any staff member of a pharmacy in the UK would be able to act professionally when facing a patient or customer, but this does not mean that it would be appropriate to describe him or her as 'a professional' or the group as 'professionals'.

What exists in pharmacy is one profession, formed by pharmacists over many generations and in the traditional way, and one register of pharmacy technicians that was created recently on a particular date by government edict. Consequently, many of those on the pharmacy technician register are separated by great differences in training, experience, capability, appreciation of their accountabilities and, most importantly of all, widely differing ambitions. The majority of pharmacy technicians on the register were grandparented on to it. They did not join a profession in the common sense of the word; they came to work as usual and on one particular day, it became a requirement for their names to be entered onto a register; as such, the register 'joined them'.

The PDA's recommendations are:

- The work to evaluate whether a group of people should be regulated should be led at a government level – to help ensure it reflects the interests of the public – rather than by the PSA.
- Where consideration is being given to the regulation or deregulation a group of healthcare staff, a public consultation about the proposals – specifically in relation to that group – should be held.
- The 'impact of the controls provided through regulatory sanctions including removal from the register', considering the salaries of the regulated group, should be among the criteria used to assess whether an occupational group or profession needs regulatory oversight.
- The current need for statutory regulation of community pharmacy technicians should be reviewed, alongside the training standards for becoming a pharmacy technician.
- A wholesale comprehensive review should be conducted of the roles that pharmacists – and consequently pharmacy technicians – have, with a view to establishing career frameworks for each group with accompanying skills and salary escalators. Appropriate standards of training for pharmacy technicians should be established to enable them to more effectively support the roles of pharmacists and establishing them as a group which needs and is able to be effectively regulated; currently it is not.
- Pharmacy premises inspection and regulation should not be conducted by the same regulator as that which regulates pharmacists and/or pharmacy technicians. It requires different expertise and should be conducted by a regulator which does not fall under the remit of the PSA. The PSA's focus solely on the regulation of individuals could then be justified. In principle, consideration should be given to transferring the regulation of pharmacy premises to a dedicated premises regulator. In our view, this would improve public safety and protection.
- Detailed analyses should be conducted and consulted upon separately in respect of each occupational group where consideration is being given to subjecting it to prohibition orders.
- The Department of Health should consider introducing a plea-bargaining system to allow regulated registrants to enter a plea for a particular finding, where he / she recognises and has learned from his / her error and wishes to avoid a protracted process.
- The PSA must be given powers to investigate complaints about regulators, to compel them to take action where shortcomings are identified and to issue sanctions to employees of the regulator.
- Changes to the operating practices of the regulators should continue to require changes to primary and secondary legislation as at present.
- Employers must not be represented on the councils of regulatory bodies or be "working in partnership" with the regulators. Regulators may rely on them for input in to consultations, for example, but they must not be established as partners in deed or in practice.

These recommendations are also repeated in the relevant section of this document.

Consultation Response

1: 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?

NO

Which groups of healthcare professions are regulated is a matter of public interest and national healthcare policy. It should be subject to public consultation by the Department of Health, in to which the PSA should provide input.

The PSA's role is to regulate the regulators within a defined framework, rather than to reform and set healthcare policy. Part of the PSA's funding comes from the Department of Health and part comes from the regulators it oversees. [3] This means there would be some potential for self-interest, or the perception thereof, in increasing its own budget by extending regulation to additional groups of people.

> **Recommendation**
> The work to evaluate whether a group of people should be regulated should be led at a government level – to help ensure it reflects the interests of the public – rather than by the PSA.

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

NO

We agree with the criteria set out on page 14 of the consultation document. For reference (from page 14):
"[The PSA] has proposed a two stage assessment. The first stage considers evidence of risk of harm in three key areas. These are:

- *the complexity of the activities/intervention undertaken;*
- *where the intervention occurs (for example in a hospital or someone's home); and*
- *the vulnerability/autonomy of the patient and their ability to make an informed choice about their care.*

The second stage considers wider external policy factors. These could include:

- *the scale of the risk – the size of the professional group or number of patients who are treated;*
- *means of assurance – the range of different ways in which the risk of harm can be reduced;*
- *sector impact – the impact that regulation (or other means of oversight) would have on cost and supply of the workforce;*
- *risk perception – the effect that regulation (or other means of oversight) would have on the confidence levels for the relevant profession; and*
- *unintended consequences of the preferred form of oversight."*

However, it is not possible to make an assessment of any individual health profession or occupation as a desktop exercise. It is a matter which is subject to subtle nuances which would not reveal themselves in the PSA's high-level approach. To determine the appropriate level of regulatory oversight required of a particular group of practitioners, a public consultation would be required in respect of that group – seeking opinions from professional and leadership bodies, trade associations, unions, employers and the public.

> **Recommendation**
> Where consideration is being given to the regulation or deregulation a group of healthcare staff, a public consultation about the proposals – specifically in relation to that group – should be held.

3. 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?

YES, we agree with this as a general principle, but have restricted our comments principally to pharmacy-related matters.

Pharmacy technicians

We are supportive of the part that pharmacy technicians play, but there is a need in pharmacy for a wholesale comprehensive review of the roles that pharmacists – and consequently those of pharmacy technicians – have, with a view to establishing career frameworks for each group with accompanying skills and salary escalators and appropriate standards of training for pharmacy technicians to enable them to more effectively support the roles of pharmacists. At the moment, however, the role of a pharmacy technician is essentially the same as that of a dispensing assistant in community pharmacy. [2] Whilst regulation of community pharmacy technicians may be necessary in the future, it may not be so at this point in time. The registration requirement for pharmacy technicians has been questioned in academic research commissioned by the GPhC – but thus far, the GPhC has not acknowledged this or taken any discernible action as a result. [4]

The pharmacy sector could learn much from the dental sector in this regard, which appears to lead the way in skill mix through the development of healthcare technicians. With all dental roles registered since 2007 and now divided into one of seven groups, each with its own training requirements and career structure, the dental sector makes good use of skill mix and the skills and salary escalator to ensure all its registrants have clearly defined roles and responsibilities. The career structure and associated salaries facilitate regulatory traction. [2]

The average salaries of the occupations or professions being regulated are an important factor in determining whether or not they should be regulated. This is particularly important in the case of pharmacy technicians, where the typical salary of those working in community pharmacy is comparable to that of window cleaners, vehicle valeters and general retail roles. Whilst that is the case, registrants know that there will be little practical consequence to the ultimate regulatory sanction of being removed from the register; they can simply find a job elsewhere with much less responsibility. The level of assurance that the regulation of such a group of practitioners can provide to the public is therefore severely limited by salary. Indeed, the consultation document states: *"The consequences of having registration removed are serious, usually resulting in the loss of a person's livelihood."* A person does not lose his or her livelihood if he or she can simply secure another job at an equivalent or better salary in a general retail role; regulatory traction cannot be achieved in such cases and the requisite public protection is not afforded.

> ***Recommendation***
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> The 'impact of the controls provided through regulatory sanctions including removal from the register', considering the salaries of the regulated group, should be among the criteria used to assess whether an occupational group or profession needs regulatory oversight.

Pharmacy premises

This consultation is focused on the regulation of healthcare professions and occupational groups. However, the GPhC and the PSNI also have responsibility for regulating pharmacy businesses and by extension, pharmacy owners. The PSNI does not currently have the powers to enforce any sanctions against pharmacy businesses or pharmacy owners. The GPhC does have those powers, but seemingly has little interest in using them.

The GPhC has issued 3,539 sanctions against individual registrants since 2010 (1,512 of these in the last two financial years combined). [5] [6] [7] [8] [9] [10] [11] Following a Freedom of Information request concluding in November 2017, it was found that the GPhC has never issued any sanction for a failure to comply with the standards for registered pharmacies (let alone initiated a fitness to practise hearing). It hasn't laid those standards before parliament in accordance with its legal duty.

Though the GPhC was established in 2010, it has never:

- Fulfilled its legal obligation to set Standards for Registered Pharmacies in rules (which then have to be laid before parliament)
- Issued an improvement notice to a pharmacy owner*

- Brought a fitness to practise case against a registrant for a failure to comply with the Standards for Registered Pharmacies. It confirmed that its focus, as far as individual registrants and standards are concerned, is on the Standards for Pharmacy Professionals

- Established a category in its fitness to practise database for recording allegations which relate to compliance with the Standards for Registered Pharmacies

- Disqualified, removed, or sought to disqualify or remove, a pharmacy premises from the register (article 14 of the Pharmacy Order 2010 – failure to comply with an improvement notice, which could lead to a fine)

- Sought or obtained a conviction against a pharmacy owner under articles 12 or 14 of the Pharmacy Order 2010 (failing to assist or obstructing an inspector, providing false or misleading information to an inspector, failing to produce a document or record to an inspector when requested to do so or failure to comply with an improvement notice)

* The GPhC has the power to issue improvement notices either for:

- a failure to meet its Standards for Registered Pharmacies OR

- a failure to meet the conditions of the pharmacy's registration with the GPhC.

The lack of action from the GPhC in respect of the regulation of pharmacy premises may in part be because the overarching regulator – the Professional Standards Authority (PSA) – focuses on the regulation of healthcare professions and occupations. Its annual performance review of the GPhC for 2016/17 awarded the GPhC the highest possible score – 24 out of 24 – for the standards of good regulation. However, the report makes no mention at all of the GPhC's performance in inspecting and regulating pharmacy premises. [12]

This represents a fundamental lack of oversight and cannot be a satisfactory situation from a public safety perspective. The PSA's expertise and interest does not extend to premises regulation (see our response to question 11). Premises inspection and professional regulation in other healthcare settings rests with different regulators, such as the CQC. In the interests of public safety and care, we make the following recommendation.

Recommendation

Pharmacy premises inspection and regulation should not be conducted by the same regulator as that which regulates pharmacists and/or pharmacy technicians. It requires different expertise and should be conducted by a regulator which does not fall under the remit of the PSA. The PSA's focus solely on the regulation of individuals could then be justified. In principle, consideration should be given to transferring the regulation of pharmacy premises to a dedicated premises regulator. In our view, this would improve public safety and protection.

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

Prohibition orders allow unregulated individuals to be barred from practising a specified profession or from carrying out specific activities and could set the standards required of certain unregulated occupations.

In pharmacy, this could, in some cases (we cannot offer statistics), be a useful measure for dispensing assistants convicted of unspent criminal offences who were seeking to continue to work, for example. Prohibition orders – to prevent them working in pharmacies in certain situations (for example where the crime involved the theft of medicines) – could provide assurance to the public in these cases.

However, the regulators are funded by membership fees. Prohibition order systems could not be funded by fee paying members and alternative sources of funding would need to be found; this may involve funding from the taxpayer.

We agree with the PSA's conclusion that an in-depth analysis of the costs, benefits and proportionality of prohibition orders, in relation to particular groups, should be conducted. [13] The practicalities of prohibition orders are challenging. Whilst this consultation asks for views on prohibition orders, it is only one aspect being considered and the responses to this consultation are unlikely to provide sufficient information upon which to conduct the aforementioned in-depth analysis.

Recommendation

Detailed analyses should be conducted and consulted upon separately in respect of each occupational group where consideration is being given to subjecting it to prohibition orders.

5. *Do you agree that there should be fewer regulatory bodies?*

We need an appropriate number of regulators to best meet the needs of patients. Ideally, a single regulator should be able to nimbly and swiftly deal with a patient's concerns in relation to all healthcare professionals in a multidisciplinary team involved in a patient's care. This would avoid a circumstance where the patient needed to talk to multiple regulators in relation to his or her concerns.

6. *What do you think would be the advantages and disadvantages of having fewer professional regulators?*

Potential advantages of fewer regulatory bodies, in addition to those listed on page 15/16 of the consultation document

- It may be less likely to be influenceable by employers than at present (though this would not be true if employers sat on the regulatory council; note our response to question 19).
- It may have additional internal governance mechanisms which mean its actions are fairer, more consistent, more balanced and better thought through.
- It may help avoid situations where patients had to talk to multiple regulators about their concerns, if they related to different healthcare professionals.

A larger regulatory body may need to have internal committees focused on each regulated profession in order to retain expertise about that profession.

7. *Do you have views on how the regulators could be configured if they are reduced in number?*

The suggested reduction put forward in the consultation document is from nine to three or four regulators. However, no rationale has been provided for that number. It appears to be arbitrary.

We are aware that the prospect of a "high street" regulator has been discussed by government bodies, to incorporate the regulation of pharmacists, dentistry and optics. We are opposed to such a proposal; each of these is not merely a "high street" profession. For example, pharmacists work in hospitals, GP surgeries, the pharmaceutical industry and in medicines information.

There are other alternatives that the Department of Health may wish to consider:

- Reducing to two regulators: one for professions (such as doctors, pharmacists, dentists, nurses and midwives) and the other for occupational groups and technical disciplines (such as pharmacy technicians). This carries the advantage that it would allow the professional regulator to focus on regulating the professional groups, without needing to inappropriately simplify standards to make them universally applicable to occupational groups as well (this happens in pharmacy at present; as one example among many, the GPhC has applied the same standards of conduct, ethics and performance to both pharmacists and pharmacy technicians). [1]
- Reducing to two regulators: one for individuals working primarily in primary care and one for those working in secondary care. An advantage of this is that within some settings (e.g. hospitals), it may be easier for the same regulator to speak to all registrants involved in a particular matter. It carries the disadvantage that because people often work in portfolio careers, it may cause confusion over the best regulator with which to register – or may mean that people working in more than one setting had to register with more than one regulator.
- Reducing to one regulator for all professions and ceasing to regulate occupational and technical groups. Such a regulator would require multiple subcommittees related to each regulated profession.
- Retaining the same number of regulators as exist at present, but focusing instead on improving regulatory powers and performance.

We are also of the view that the regulation of pharmacy premises should be transferred to a separate premises regulator; please refer to our response to question 3 for the rationale.

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

YES. At present, we see no reason to restrict regulators' powers in this regard, since that is a key part of their function.

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

The explanation of mediation given in the consultation document was limited. We have copied the following from the Health and Care Professions Council:

"The Health and Social Work Professions Order 2001 provides that, in relation to a fitness to practise allegation, if:

- *an Investigating Committee Panel concludes that there is a case to answer, it may undertake mediation instead of referring the allegation to another Practice Committee;*
- *a Panel of the Conduct and Competence Committee or Health Committee finds that the allegation is well founded, it may undertake mediation if it satisfied that it does not need to impose any further sanction on the registrant*

"Mediation is a voluntary process. The participants choose to attend, making a free and informed choice to enter and if preferred, leave the process. If the process and the outcome is to be fair, all parties must have the willingness and capacity to negotiate and there must be a balance of power between the parties."

"Panels need to recognise that certain disputes should never be referred to mediation. As mediation is a closed and confidential process, its use in cases where there are issues of wider public interest – such as serious misconduct, criminal acts, serious or persistent lapses in competence, or abuse or manipulation of service users – where its use would fail to provide necessary public safeguards and seriously undermine confidence in the regulatory process. Mediation will also be inappropriate in situations where there is a power imbalance which cannot be addressed, with the result that one party may dominate the outcome to the extent that the needs and interests of the other are not met." [14]

We can see that there are circumstances in which mediation would be useful; for example, in the event of a patient complaint, where no action was to be taken against the registrant because it was not in the public interest for the case to be heard, it may help each party to understand the others' viewpoint. We would therefore be supportive of this proposal in principle.

We also believe that a plea-bargaining system should be considered where the registrant recognizes he/she has erred; this may often help achieve a swifter resolution which was of satisfaction to the patient. This could also help reduce the time spent dealing with fitness to practice cases and reduce the stress on the registrant.

Recommendation

The Department of Health should consider introducing a plea-bargaining system to allow regulated registrants to enter a plea for a particular finding, where he / she recognises and has learned from his / her error and wishes to avoid a protracted process.

10: Do you agree that the PSA's standards should place less emphasis on the fitness to practise performance and consider the wider performance of the regulators?

YES – there are other aspects to the functioning of the regulators which the PSA should consider. Ultimately, public and patient protection is the most important outcome. The PSA should consider:

- Public perceptions of the regulator and its success in securing patient safety
- The confidence that the regulated profession has in its regulator
- Whether the regulator has made full and proper use of its existing powers

- The proportion of FOI requests to which the regulator has responded and the reasons it has given for not responding to other requests (if any), as a measure of transparency and accountability to the public

- The effective management of conflicts of interest on regulatory councils (beyond declaring such conflicts at meetings)

The Professional Standards Authority should oversee a "fit and proper persons" test for those who wish to serve on regulatory councils. This should aim, amongst other things, to prevent the movement of individuals between the PSA's council and the regulatory councils that it oversees. This would help to ensure that the PSA remained impartial from those regulators.

11: 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?

YES, we do agree with this. We are of the view that the PSA needs more powers than it has at present.

In 2016, the PSA received a letter of complaint about the lack of appropriate action from the GPhC in relation to the standards in the registered pharmacies it regulates (see question 3). The PSA replied, explaining that its role is to scrutinize decisions about whether **people** are fit to practice (emphasis added). Although the nature of the complaint was obvious, the PSA's response was entirely silent on any role it may have in determining whether companies / organisations are meeting appropriate standards – which is part of the GPhC's function. The PSA's reply also points out that the PSA *'has no powers to investigate individual cases of the GPhC nor to compel it to take any specific actions'*.

The limitations of the PSA's function are apparent from its website, which states *"We do not investigate individuals' complaints about regulators or registers and cannot resolve them for you."* [15] Its focus on the regulation of individuals – and not premises / businesses (which the GPhC is supposed to regulate) – is also clear from a statement on its website: *"We help to protect the public by improving the regulation and registration of **people** who work in health and care (emphasis added)."* [16]

The PSA is essentially acting as an ineffective auditor to the GPhC – providing public reports which fail to uncover serious shortcomings in the GPhC's performance. It has no ability to hold the regulator to account in any case. Its function in this respect and in these circumstances can provide little benefit or assurance to the public.

Recommendation

The PSA must be given powers to investigate complaints about regulators, to compel them to take action where shortcomings are identified and to issue sanctions to employees of the regulator.

12: 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?

YES – but this would be achieved through professional bodies setting evolving, higher standards for professionals and the regulator enforcing these, and not through the deregulation of healthcare.

The environment in which professionals work is a fundamental enabler to supporting professionalism. Our recommendation to split the regulation of premises from the regulation of professionals would go a long way to addressing this issue in pharmacy (see our response to question 3). It would also help to ensure that regulators properly investigate complaints received by professionals – for example in to working conditions which presented a risk to patient safety.

We are also concerned about the degree of focus on patient outcomes that seems to be emerging in pharmacy regulation. Whilst we do agree with a regulatory approach involving in part the inspection and monitoring of patient outcomes, it is not appropriate to monitor outcomes alone, particularly in the context of the substantial corporatisation of community pharmacy. Would it be appropriate for the Civil Aviation Authority to simply ask "Did the majority of passengers get to their destination on time"? Without checking that the underpinning prescriptive standards of aircraft, airspace, air traffic control and airport safety are being upheld, the outcome would not give an indication of the risk – and potential harm – to passengers. There are various issues with monitoring outcomes alone, without monitoring more prescriptive requirements:

- By definition, a focus on outcomes is not a focus on preventative measures which reduce risk.
- The outcomes could be delivered by any means necessary, which may result in inappropriate approaches from some employers.
- If the outcomes are not written in a prescriptive manner, they may be subject to wide interpretation. Fundamental requirements which underpin patient safety may not be adhered to. Some pharmacy owners may choose to focus on specific operational elements in an effort to demonstrate that an outcome has been achieved, whilst avoiding drawing the inspector's attention to those which have not been achieved. Further, an inspector may conclude that overall, an outcome has been achieved, even where fundamental underlying problems have been identified.

Outcomes-focused regulation may be more appropriate for the regulation of healthcare professionals than for premises. Working conditions and environments within premises provide a safety platform in which professionals operate; they should support professionals to deliver those outcomes. The requirements around premises may need to be inherently more prescriptive ("black and white") and focused on prevention to deal with the practicalities and ensure this is the case.

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

There are some benefits to closer working e.g. between regulators – for example in data sharing as outlined in question 15. With fewer regulators, data could potentially be used more effectively.

14: 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?

For reference, the suggested areas were:

- A shared online register, search engine or online portal of all registered healthcare professionals.
- A single set of generic standards for all healthcare professionals (underpinned by profession-specific standards owned by the individual regulators).
- A single adjudicator responsible for all fitness to practise decisions.
- A single organization conducting back office functions such as HR, finance and IT.

Unfortunately, the wording of this question appears biased. It has been written such that it might elucidate only how the areas suggested will contribute to improved patient protection. It does not seek views on the reverse – how they could worsen patient protection or ask for views on any risks it may introduce.

At present, the panel in a GPhC fitness to practise committee comprises the chair, a lay member and a registrant. The registrant is able to provide expertise about pharmacy practice and the environment in which the registrant operates. If a single adjudicator responsible for all fitness to practise decisions were to be introduced, it would be necessary to ensure that such expertise was retained on fitness to practise panels, in the same area of practice as the registrant facing a hearing.

The PDA receives a download of the existing GPhC register on a daily basis, for which it pays a subscription fee. This allows the organisation to confirm whether its members are registered pharmacists or not, and provides the ability to send them reminders to renew their registration. This has consequent benefits for the public in helping to ensure that access to pharmacists is retained. We would ask that if a shared register is introduced, such a service be retained – either through a fully downloadable register of pharmacists or by means of querying it easily to check the validity of a person's registration.

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

YES. Data sharing would need to be done with regard to the rights and freedoms of registrants.

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

NO, we do not agree with the deregulation of the regulators as proposed here; changes to their operating practices should require changes to primary or secondary legislation as at present.

Self-regulation of professions has been restricted in order to avoid the interests of registrants taking precedence over those of the public. However, little consideration has been given to what the interests of the regulators as entities may be. At a macro level, these interests might include increasing membership fees, deregulating their operations and practices to reduce their own workload in order to expand their powers, position and control or increasing the salaries of their staff. We are concerned that if not satisfactorily controlled, the proposed change may result in deregulation and reduced controls over fitness to practise, ultimately to the detriment of both the professions and the public.

The above point can be illustrated through two examples:

- In 2017, the GPhC made changes to deregulate CPD sampling, reducing the sampling rate from 20% to "at least 2.5%" of registrants' records each year. An estimated saving of £200,000 per year for the Council was identified. [17]

- In 2017, the GPhC proposed to cease setting training requirements and assessing and approving training courses for dispensing and medicines counter assistants. [18] [19]

Since it has not accounted for the apparent savings in either of the examples cited above, it could appear that the GPhC merely seeks to absorb any cost savings, rather than reinvesting to protect the interests of the public; this might not be the case, but given the lack of any accountability or scrutiny of its funding in such respects, the suggested increases in "flexibility" could lead to further examples of deregulation and reduced public protection.

Recommendation

Changes to the operating practices of the regulators should continue to require changes to primary and secondary legislation as at present.

17: 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?

YES; we think that this would be of benefit to the public.

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

NO

We do not necessarily agree.

We are of the view that a greater proportion of staff working within pharmacy regulation (within an overarching regulator) should be pharmacists than seems to the case at the GPhC. We can understand the viewpoint that if pharmacists regulate pharmacists, they may be overly sympathetic to the professional situation. However, an appropriate balance must be struck; too few pharmacists working within pharmacy regulation in a decision-making capacity could lead to the regulator having a lack of insight as to the effect of any of its regulatory policies and proposals, caused by a lack of experience and comprehension of the pharmacy environment. This in turn could lead to poor decision making. It was demonstrated in Great Britain by a proposal from the GPhC to allow pharmacy-only medicines to be made available to the public for self-selection. [20] [21]

It is also unclear how, in a regulator regulating more than one profession, how the composition of the council would be established to reflect that responsibility.

19: 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?

NO, we do not agree. We are fundamentally opposed to this proposal.

The statement in the consultation document that the government expects "professional regulators to work in partnership with employers…" is cause for concern. It would have serious implications for the maintenance of patient care and safety through pharmacy regulation, since the corporate objectives of profit-making organisations being reflected on the council could lead to a diminution of standards of education and training – since they may regard profit as being in competition with certain aspects of quality. Many – and an increasing – number of employers in the NHS are profit-making. In addition

- If large employers – many of whose directors may be non-pharmacists – had representation on the council, they would be in a position to influence the regulation of many pharmacies – and that would likely be the perception.

- Employers sometimes refer pharmacists to the regulator where they have fitness to practice concerns. For the same employers to be represented on the council of the regulator would be entirely inappropriate, since they could influence – or at least, be perceived to influence – the outcome of any action taken. This would be entirely unfair for the registrant.

The GPhC's guidance on conflicts of interest for council member appointments states *"Certain categories of candidate would usually be considered to have an irreconcilable conflict of interest, and so would be ineligible. This would include, for example, members or employees of:*

- *organisations representing registrants' interests…"* [22]

The same standard must therefore apply to employers; since the GPhC is meant to regulate employers and the standards they create in registered pharmacies, the conflict of interest for them holding positions on the governing council would be irreconcilable.

There is already some concern that the GPhC and the PSNI are reticent to challenge pharmacy employers for their practices (please refer to our response to question 3). Employers have a fundamental role is setting the environments in which professionals work, and in fitness to practise cases, those environments may be cited as mitigation by registrants. This could not be achieved effectively if employers were on regulatory councils or "working in partnership" with the regulator. This situation would be entirely unfair to registrants. Additionally, employers often refer registrants to the regulator where they have concerns over fitness to practise. It would be wholly improper for such an employer to have a presence on the governing council due to the influence they could exert – or be perceived to exert – on the proceedings. It is important that the public perception – and of course the reality – is that there can be no interference from employers in the regulatory process.

To illustrate this with an example, in 1998, a young baby died as a result of a dispensing error in a Boots pharmacy. The case is well known in pharmacy and is still taught to students; it is known as the "Peppermint Water case". The company was not held to account by the regulator at the time (the Royal Pharmaceutical Society of Great Britain (RPSGB)), though it could potentially have been held to account in three areas:

- A pre-registration graduate was expected to work under the supervision of a tutor pharmacist. To become a tutor pharmacist, it was necessary under applicable by-laws to have three years' post-qualification experience working as a pharmacist. The pharmacist had been permitted to act as the tutor with just 21 months' experience at the time of the error. [23] [24] [25]

- The pharmacy had not been registered by the company to provide pre-registration training. [23] [24] [25]

- The pre-registration graduate would only have been allowed to work in the pharmacy for seven days in the year under RPSGB regulations, but had in fact been allowed to work there one day per week for several months. [23] [25]

A notable commentary on the case was made by Alan Nathan, who was long-standing member of the RPSGB Council from 1986 until May 2002, a member of the Infringements Committee for twelve of those years and chairman of the Infringements Committee for five years. He explained that normally in such cases, even those where a patient has suffered harm, if a criminal charge was brought, it would be for a Medicines Act offence; it was also normally only the supervising pharmacist and, if a limited company, the company and its superintendent pharmacist who were considered for prosecution, as non-qualified staff are considered to be working under the pharmacist's supervision. [23]

Alan Nathan said *"[an] unusual aspect of the case was that the company and its superintendent pharmacist were not prosecuted or formally involved in the case in any way… I considered that the company had a case to answer as it had been responsible for the trainee being in the branch on the day that the incident occurred, and that the Society's regulations on pre-registration training (Byelaw XX) had not been complied with."* [23]

The superintendent is the most senior pharmacist in a pharmacy business, as recognized by the regulator. The existing Boots superintendent at the time of the incident, and his predecessor who had left the position three weeks before it occurred, had been in senior positions on the regulatory council at the time of the investigations of the incident. [23] [26] [27] [28] [29] [30] [31] [32] [33] There was no finding from the regulator against the company; however, it is important that the perception of equal treatment of employers and employees is not tarnished by the presence of employers on regulatory councils. History need not repeat itself in this case; that could not be an acceptable position for the new regulator in which to find itself.

The proposal, if enacted, would increase the risk of regulatory capture – a phenomenon wherein, through the continuous close proximity of working, the regulator becomes dominated or heavily influenced by those with whom it works. Much can be read about this phenomenon online.

Recommendation

Employers must not be represented on the councils of regulatory bodies or be "working in partnership" with the regulators. Regulators may rely on them for input in to consultations, for example, but they must not be established as partners in deed or in practice.

20: 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?

NO, we do not agree. A statement about how they will do this in the future would not provide the requisite assurance that the public needs.

Our view is that regulatory bodies ought to be directed as to how they will produce and sustain fit-to-practise professionals. The standard should be set "top down" rather than "bottom up". The regulators might then demonstrate – alongside specific measures being examined by the PSA – how they **have already** ensured that they produced and sustained fit-to-practise professionals.

21 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?

Any savings generated through the reforms should be quantified and set out clearly. At least some of this money ought to be invested appropriately as necessary to improve the functioning of regulators, but must be fully accounted for. Beyond that, any savings should lead to fee reductions for pharmacists. If professional leadership bodies were to develop standards as per our recommendation, this would further reduce costs since that is done by regulators at the moment. However, as already stated, we would like to see improvements in the regulation of pharmacy premises, which may mean that there would not necessarily be a fee reduction for the registration of a pharmacy.

22: 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.

The PDA represents pharmacists as its members. The costs to its members of regulatory registration fees may change (see our response to question 21). However, whilst the financial saving would be in the interests of our members, more important than this is the maintenance and furtherance of professional standards. We would not want to see diminution of professionalism arise as a consequence of any of the proposed changes and we would ask that the Department of Health have public protection, care and safety and the furtherance of professionalism as its linked objectives when considering if and how to enact these proposals.

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

Unfortunately, the wording of this question appears biased. It has been written such that it might elucidate the public and patient safety benefits and not the adverse consequences. It does not seek views on the reverse. We are concerned that this may suggest that the Department of Health is looking to justify the implementation of changes to regulation without considering balanced evidence; this in turn might suggest that it was already keen on achieving this objective before this consultation.

If the proposals are implemented, the effect on public safety and protection could be monitored through academic scrutiny; it would certainly be of interest to universities to conduct a research study on the effects. This may be supported, for example, by multiple-choice surveys of patients and registrants before and after implementation, if the changes are enacted.

24: 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?

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?

We don't foresee the proposals having any significant effect on the above.

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