Pharmacists' Defence Association Response to The Department of Health, Social Services and Public Safety on the Future of Pharmacy Regulation in Northern Ireland

March to June 2016

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pda
the pharmacists' defence association

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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 25,000 members throughout the whole of the UK. 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

Executive Summary

At present, the Pharmaceutical Society of Northern Ireland (PSNI) performs the functions of both regulation and professional leadership for pharmacists in Northern Ireland. Pharmacy technicians are not regulated.
The professional leadership function is currently delivered by Pharmacy Forum Northern Ireland, which operates under the governance structures of the PSNI.

The Minister for Health, Social Services and Public Safety in Northern Ireland has agreed in principle to split the regulatory and professional leadership functions undertaken by the PSNI. The Department of Health, Social Services and Public Safety (DHSSPS) has requested views on the matter.

Our recommendations are:

- Due to the:
  - Idiosyncrasies of pharmacy and healthcare provision in Northern Ireland
  - Likely financial non-viability of the professional leadership body in the event of a split with the regulatory function.
  - **Absence** of any evidence of a lack of public confidence in pharmacy regulation in Northern Ireland under current arrangements.
  - **Absence** of any evidence showing that separation of the regulatory and professional leadership functions would be beneficial to the public.

The professional leadership body and regulator should not be separated and should continue to operate structurally as they do now, under the same umbrella organisation. The inspectorate should remain the responsibility of the DHSSPS.

- To provide assurances with respect to the appropriateness of the interactions between the regulator and the professional leadership body in Northern Ireland, the regulator and professional leadership body should be subject to regular audits from the Professional Standards Authority in that regard.

- As a secondary, though much less suitable option, a stand-alone regulator in Northern Ireland would be preferable to a UK-wide regulatory arrangement.

- We would be against the introduction of a UK-wide regulatory arrangement in Northern Ireland and against pharmacy regulation being subsumed into the GPhC's remit at this time.

- Academic research must be conducted in order to understand whether splitting the regulatory and professional leadership functions in pharmacy is in the short, medium or long term interest of the public in Northern Ireland.

- The DHSSPS must provide supporting evidence to show how it has calculated projected costs in this consultation. The absence of such evidence makes it very difficult to properly engage in this consultation.

- If (and only if) a UK-wide arrangement for pharmacy regulation did go ahead, of the organisations currently in existence, the General Pharmaceutical Council would be best placed to regulate it; however, we are against that option. We take the view that the GPhC will take some considerable time yet to function at full capacity as a regulator and may need a significant overhaul before it can do so. It needs more time to become established in Great Britain before considering expanding its remit to Northern Ireland.

- If the regulatory and leadership functions of the PSNI are split (we are against this at this time), it would be important for the DHSSPS to ensure that the assets that belong to the membership organisation are assigned to the professional leadership body.

- If the outcome of this consultation is that pharmacists and pharmacies in Northern Ireland are to become regulated by the GPhC (we are against this option), regulation of pharmacy technicians must not be an automatic consequence. The DHSSPS must ensure that the regulation of pharmacy technicians is the subject of a separate consultation.

- Before regulation of pharmacy technicians is considered, a robust strategy and vision should be agreed by the profession in Northern Ireland. Only then will it be possible to establish the supporting role that can be played by pharmacy technicians.

The Consultation Document

As a general principle, we recommend that questions in a consultation such as this should be asked in an entirely neutral manner. Commencing questions with leading wording such as 'do you agree' could lead to acquiescence bias.[1,2,3,4] This may mean that the responses obtained will not truly represent respondents' views.

We note and we are concerned about what appears to be a considerable bias in the consultation document and questions towards a view that the right answer would be option three – to separate the regulatory and professional leadership functions and to have a UK-wide regulatory arrangement.

On pages 15 and 24 of the consultation document it states that not splitting the functions is not acceptable to the DHSSPS. The decision to split the regulatory and leadership functions may have already been made. This leaves some serious concerns over why the question about whether to split the functions at all has been asked in the consultation.

The wording of the 'Policy Option 3' section of the impact assessment indicates that in the event of choosing 'Policy Option 3' the GPhC would become the regulator for pharmacists in Northern Ireland. However, Policy option 3 is described as opting for a UK-wide regulatory arrangement, not selecting the GPhC as the regulator. Has there been a predetermination that the GPhC would become the regulator for pharmacists in Northern Ireland? We are concerned that both of the issues described above could have produced an exposure to a judicial review.

Response

The wording and the approach used in the consultation document and the nature and order of the questions asked has presented difficulties in structuring a response. We have therefore set out our response here and will refer to parts of it in response to the questions asked.

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Overall Position

Primary Recommendation

Recommendation

Due to the:

- *Idiosyncrasies of pharmacy and healthcare provision in Northern Ireland*
- *Likely financial non-viability of the professional leadership body in the event of a split with the regulatory function.*
- ***Absence** of any evidence of a lack of public confidence in pharmacy regulation in Northern Ireland under current arrangements.*
- ***Absence** of any evidence showing that separation of the regulatory and professional leadership functions would be beneficial to the public.*

The professional leadership body and regulator should not be separated and should continue to operate structurally as they do now, under the same umbrella organisation. The inspectorate should remain the responsibility of the DHSSPS.

Recommendation

To provide assurances with respect to the appropriateness of the interactions between the regulator and the professional leadership body in Northern Ireland, the regulator and professional leadership body should be subject to regular audits from the Professional Standards Authority in that regard.

Secondary (Non-preferred) Option

Recommendation

As a secondary, though much less suitable option, a stand-alone regulator in Northern Ireland would be preferable to a UK-wide regulatory arrangement.

Recommendation

We would be against the introduction of a UK-wide regulatory arrangement in Northern Ireland and against pharmacy regulation being subsumed into the GPhC's remit at this time.

Why we Advocate the Retention of Existing Arrangements with the Regulator / Professional Leadership Body in Northern Ireland

As a theoretical concept, having separate regulatory and professional leadership bodies would promote independence of their respective functions, but we do not believe that this is the optimum solution for the public in Northern Ireland due to a range of other factors.

We take this view for the following reasons:

- To sustain the professional leadership body would likely involve expensive membership fees for pharmacists, which may be unaffordable for some. The relatively small number of registered pharmacists in Northern Ireland may therefore result in financial non-viability of the professional leadership body in the event of a split with the regulatory function. Having a professional leadership body for pharmacists in Northern Ireland is very much in the interests of the public as it enables the development of pharmacy as a profession and it allows any regulator to face a proper challenge in Northern Ireland if required. The loss of a Northern Ireland professional leadership body would be contrary to the public interest.
- The idiosyncrasies of healthcare provision and of pharmacy in Northern Ireland are best understood by experienced pharmacists who live and work in Northern Ireland. It is important that such individuals contribute to both the regulatory and professional leadership functions. Such an arrangement would produce a manifestly superior form of both regulation and professional leadership than a UK-wide arrangement. This would be more beneficial to the interests of the Northern Ireland public.
- There is no evidence (that has been presented by the DHSSPS or of which we are aware) of a lack of public confidence in pharmacy regulation in Northern Ireland in its present form.
- There is no evidence (that has been presented by the DHSSPS or of which we are aware) showing that separation of the regulatory and professional leadership functions in pharmacy would be beneficial to the public in the short, medium or long term.
- Control will be retained over the number of pharmacist staff members working at the regulator.
- The alternative options in the event of a split are problematic (see other parts of our response).

Theory and Academic Research Relating to Regulatory / Professional Leadership Separation

We would like to see academic research and a broader debate undertaken to establish whether splitting the regulatory and professional leadership functions in the pharmacy sector in Northern Ireland would improve patient safety and public protection, and ultimately whether it would be in the medium and long term public interest. If the government does decide to split the functions in Northern Ireland, we suggest it should commission such research. The decision, ultimately, should be about the optimum benefit to the public – and this should be based on evidence and balanced, open debate rather than on theory or ideology.

> ***Recommendation***
>
> *Academic research must be conducted in order to understand whether splitting the regulatory and professional leadership functions in pharmacy is in the short, medium or long term interest of the public in Northern Ireland.*

Pharmacists working for the Regulator

We are of the view that a greater proportion of senior staff working within pharmacy regulation 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; a lack of pharmacists working within pharmacy regulation 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 and is demonstrated in Great Britain by the proposal from the GPhC to allow P medicines to be made available to the public for self-selection. Retaining the current arrangements in Northern Ireland means that control can be retained over the proportion of pharmacist staff with experience in Northern Ireland; we accept that the same would be true of a standalone regulator but this would not be the case in the event of a move to UK-wide regulation.

A Secondary (non-preferred) Option – A Standalone Regulator in Northern Ireland

Our view is that the professional leadership body and regulator should continue to operate under the same umbrella organisation as at present, with certain provisions. We have provided a rationale for that position.

However, there are considerations if the final option chosen is to have a stand-alone regulator, which we would prefer rather than regulation in Northern Ireland becoming subsumed into the remit of the GPhC (we are against this option).

A Standalone Regulator working Alongside the GPhC

A standalone regulator could work closely with the GPhC, whilst not being part of it. This may be a productive way of working as the two separate bodies could challenge and learn from one another. The learning may be greater for the individuals concerned than if they were based in the same organisation working under the same doctrine.

The Importance of the Regulator being based in Northern Ireland

A regulator in Northern Ireland should have its own principal offices based there (though a stand-alone regulator is not our preferred option). We would see this as a necessity for the pharmacy regulator in Northern Ireland as it enables it to effectively recruit those who live and work in Northern Ireland and in turn to more readily understand and appreciate the structure of government, the framework of health, social care and pharmacy service provision and the politics in the country.

A Standalone Northern Ireland-based Regulator – Cost Calculations

We assume that the figures in Table 1 on page 19 of the consultation document (the projected registration fees associated with a standalone regulator) have been calculated with a view to ensuring that a Northern Ireland-based regulator would have sufficient resources to regulate effectively. We understand that the costs would be subject to fluctuation dependent on the number of registrants, the number of registered pharmacy premises, regulatory workload etc. It is not possible to say to what extent such fluctuations will be of concern, since the method of calculating those costs has not been provided.

> ***Recommendation***
>
> *The DHSSPS must provide supporting evidence to show how it has calculated projected costs in this consultation. The absence of such evidence makes it very difficult to properly engage in this consultation.*

A Standalone Regulator's Use of Public Funds

We do not believe that a standalone regulator will have any impact on the use of public funds. We form this view because paragraph 43 on page 19 of the consultation document states *'like the other UK healthcare regulators, a pharmacy regulator in Northern Ireland is required to be independently self-financing, principally through income from fees applied to those registered and fees applied to pharmacy premises.'* A standalone regulator will therefore **not** be dependent on public funds. With that context, we are unsure why a question has been asked about it in the consultation document.

Why we would be against a UK-wide Regulatory Approach in Northern Ireland

Our view is that the professional leadership body and regulator should continue to operate under the same umbrella organisation as at present, with certain provisions. We have provided a rationale for that position.

We must also explain why we do not believe that a UK-wide regulatory approach would be appropriate at present in Northern Ireland.

GPhC History and Legislative Functions

The GPhC was established in 2010. In contrast to other regulators such as the General Medical Council (established in 1858) and the General Dental Council (established in 1956) it is relatively new and as such has no extensive organisational memory. As an organisation it is making progress but it has, at present, insufficient experience of pharmacy and is still in its formative phase as a regulator.

It does not have the power to regulate pharmacy owners or non-registrant pharmacy staff (though both have a significant impact on public safety and are often at the root cause of regulatory episodes). It is currently seeking powers to publish the results of its inspections in the public domain. Its inspection model is still in its pilot phase.

Corporate Influence on the GPhC's Standards of Conduct, Ethics and Performance for Individual Pharmacists

The pharmacy sector, pharmacists and members of the public in Northern Ireland may well be concerned about the GPhC's approach to the corporate multiples.

We have already mentioned that the GPhC currently does not have the powers to regulate owners of pharmacy businesses. However, we are concerned that neither does it understand the special risks posed – particularly by the large corporate multiples.

In response to the Law Commission's consultation on the Regulation of Healthcare Professionals, the GPhC said *"We think there is potential to over-estimate the impact that [the fact that pharmacies are businesses] has for us as a regulator when compared to other regulators who solely or predominantly regulate professions or provision of services within an NHS managed environment"* and *"one specific example cited is the commercial context or financial pressures within pharmacy. This is undoubtedly a relevant factor, but the key factor in development of our regulatory policy is the provision of patient care, not that we are regulating in a commercial context. Although different, NHS organisations also have many pressures not directly related to patient care; GP practices are in effect private businesses; NHS providers in England are increasingly required to compete for income and financial pressures have in a number of high profile failures in the NHS played a significant part."*[5]

We do not agree with the GPhC's comparison of NHS organisations and GP practices to commercial businesses, especially to those which are large corporate multiples. In addition, many pharmacy businesses are operated by non-pharmacists. The GPhC's position overlooks that fact and is at odds with the position taken by learned judges in the European Court of Justice. In its determination C-531/06 - and in joined cases C171/07 and C172/07, May 2009, the ECJ effectively concluded that non-pharmacists do not provide the same safeguards as pharmacists in the operation of a pharmacy and that member states may therefore take the view that 'the operation of a pharmacy by a non-pharmacist may represent a risk to public health'. Furthermore, it said that 'there is a risk that legislative rules designed to ensure the professional independence of pharmacists would not be observed in practice, given that the interest of a non-pharmacist in making a profit would not be tempered in a manner equivalent to that of self-employed pharmacists and that the fact that pharmacists, when employees, work under an operator [, which] could make it difficult for them to oppose instructions given by him'.[6]

The International Pharmacy Federation Executive Committee and Community Pharmacy Section officially concluded in its summary of its symposium on Professional Autonomy in 2009 that 'Because of prevailing social, economic, and political forces, there will continue to be immense tension between corporate and professional imperatives in pharmacy.'[7] We believe that the GPhC's position is at odds with this conclusion.

It is our view that the position taken by the GPhC has created an inadequate approach to pharmacy regulation in Great Britain.

A standalone regulator could help to avoid such concerns and will also be a superior proposition from a public protection point of view than becoming part of a regulator whose principal offices are based in London.

It is unclear what is meant by the comments on page 24 of the consultation document - that UK-wide regulation would have benefits for large employers who operate UK-wide. The overriding interest taken into account must be that of the Northern Ireland public.

GPhC Inspection Model

In mid-April 2016, The Guardian published an article about a large UK-based multiple pharmacy chain. It described how pharmacists were constantly exposed to poor staffing levels and were put under pressure to perform unnecessary pharmacy services – specifically Medicines Use Reviews. The Guardian prompted a 'flood of letters' from pharmacists blowing the whistle about working conditions at the multiple. The letters editor said it was the 'largest haul of mail he has ever received about a single article.'[8] The multiple pharmacy responded by saying that it did not recognise the concerns[9] and that the GPhC had conducted 1,135 inspections of its pharmacies and had only identified one pharmacy requiring improvement on measures related to incentives and targets.[10] The disparity between the findings of the GPhC inspection regime and the views of the health professionals it regulates is self-evident.

In a PDA survey carried out in 2015/2016, members were asked 'When you are working for your main employer, how often are there enough suitably qualified and skilled staff, for the safe and effective provision of the pharmacy services provided?' 53.3% of the 2,849 respondents said this was the case half the time or less. When asked 'When you are working for your main employer, how often have you found yourself in a position whereby commercial incentives or targets have compromised the health, safety or wellbeing of patients and the public, or the professional judgement of staff?', 46.3% of the 2,849 respondent said this was the case half the time or more. These figures represent the averages for the community pharmacy sector, across all employers. The wording of the questions is closely aligned to the GPhC's Standards for Registered Pharmacies.

The Professional Standards Authority oversees the work of the GPhC and scrutinizes its decisions; in its performance report in 2014/15, the GPhC met all but one of the PSA's *Standards of Good* Regulation.[11] This is a troubling paradox in light of the patient safety survey results.

European Influence on Regulation in Northern Ireland

The UK is part of the EU (although a referendum is scheduled for the 23rd of June 2016). At present, regulation in the UK is influenced to a significant extent by European legislation. To that extent, whatever it may be, adopting a UK-wide system of regulation as opposed to maintaining a standalone system of regulation should have a limited impact on public confidence in the regulation of pharmacy and the assurances that provides (if any). Any NI standalone regulation will have to conform to the European standard in any event.

A UK-wide Regulatory Approach – Efficiency Considerations

We note from the consultation document that even if pharmacists, pharmacy technicians and pharmacy premises in Northern Ireland become regulated by the GPhC, the GPhC's fees will remain the same as they are now in Great Britain. It is therefore difficult to see that there is any efficiency as a result of having a larger regulatory body in this instance; if that were the case, we would have expected a UK-wide reduction in fees.

The Professionals Standards Authority in its 2012 paper 'Review of the cost effectiveness and efficiency of the health professional regulators'[12] said *'The PSNI works closely with its equivalent regulator on the mainland – the GPhC. This raises the possibility that, by sharing certain activities and/or information with the GPhC, it benefits (to an unknown degree) from some of the larger organisation's scale economies.'* The PSNI then, as a stand-alone regulator, perhaps already benefits from the scale economies of the GPhC. If it does, the efficiencies associated with becoming part of the GPhC would be reduced in relative terms.

The Importance of Local Knowledge, Experience and Working in Northern Ireland

We note from the consultation document that if the regulatory function becomes part of the GPhC, provision has been that one GPhC Council member will 'live or work wholly or mainly in Northern Ireland'. To reiterate, the council member might simply ***work mainly*** in Northern Ireland. We do not think that this would be a satisfactory way to operate the regulator in the country.

Knowledge of pharmacy practice in Northern Ireland is, generally speaking, poor in Great Britain. Given that the GPhC's offices are in London, the number of GPhC staff with current experience of pharmacy practice in Northern Ireland is likely to be limited. We envisage that Northern Ireland would have significant difficulty influencing the GPhC's policy in order to address its local needs, unless substantial provisions were accommodated in the arrangements set up at this early stage (however as already stated we are against regulation in Northern Ireland becoming subsumed into the remit of the GPhC).

Recommendation

If (and only if) a UK-wide arrangement for pharmacy regulation did go ahead, of the organisations currently in existence, the General Pharmaceutical Council would be best placed to regulate it; however, we are against that option. We take the view that the GPhC will take some considerable time yet to function at full capacity as a regulator and may need a significant overhaul before it can do so. It needs more time to become established in Great Britain before considering expanding its remit to Northern Ireland.

Considerations in the Event of any Split of the Regulator / Professional Leadership Body, Regardless of how this was Achieved

Our view is that the professional leadership body and regulator should continue to operate under the same umbrella organisation as at present, with certain provisions.

We must also explain, however, the factors which would need to be taken into consideration in the event that the regulator was split from the professional leadership body.

Split of the Pharmacy Regulator / Professional Body Functions – Historical Example in Great Britain – Consequences for the Professional Body

In Great Britain, the Royal Pharmaceutical Society of Great Britain (RPSGB) split in 2010 to form the General Pharmaceutical Council (GPhC, the regulator) and the Royal Pharmaceutical Society (RPS, the professional leadership body). Membership of the RPS is non-compulsory and as a result, the RPS has become reliant to some extent on support from major corporate businesses in paying membership fees of its pharmacist employees. This creates a problematic conflict for the RPS in setting policy and ostensibly allows major businesses to exert a significant influence on it in Great Britain. Given that the interests of business-owners are business-related as opposed to healthcare-related, this is arguably not in the public interest and may hamper the RPS from holding the government and others to account on matters of public safety. If the same conflict of interest arose in Northern Ireland, it may be detrimental to the public.

A Professional Leadership Body in Northern Ireland – Financial Considerations

It is important for pharmacists and also for the public of Northern Ireland to retain a pharmacy professional leadership body. As described in the consultation document, the number of pharmacists in Northern Ireland is relatively small compared to the number in Great Britain. We are concerned as to how the professional leadership body would survive financially if membership were to become optional (which it would in the event of a split). It is our view that, if an independent professional leadership body was to be created in Northern Ireland, legal measures should be put in place to secure its financial viability and to avoid that body becoming hamstrung by the influence of large employers.

However, if membership of the professional leadership body was made mandatory in Northern Ireland, this may result in unaffordable costs for some pharmacists (again due to the relatively small number of pharmacists who would be paying fees to support its function). If membership was funded by the government, this would be contrary to the government's rationale for the split – independence. It is for this reason among others that we are against splitting the regulatory and professional leadership body functions in Northern Ireland.

A Professional Leadership Body in Northern Ireland – Governance and Development

A professional leadership body has a role in advancing the profession and developing the service it provides to the public, and in challenging the government when it believes it has 'got it wrong'. It is part of the system of governance or 'checks and balances' which serves to protect the public.

A professional leadership body represents members' interests. Those members are pharmacists – healthcare professionals who have chosen a career protecting and serving the public. The professional leadership body supports training, provides guidance and encourages Continuing Professional Development, each of which ultimately serves the interests of patients to some extent. Its role in protecting the public (although delivered in a different way) is, in our view, as important as the role of the regulator.

Assets Belonging to the Membership of the Professional Leadership Body

In Great Britain, prior to the split of the RPSGB into the RPS and the GPhC in 2010, during the negotiations it became apparent that key assets (such as the RPSGB's building and its contents) which belonged to the RPSGB as a membership organisation were possibly going to be transferred to the regulatory function and therefore defacto was to be used solely for regulatory purposes. The Save our Society Campaign challenged this by taking the RPSGB to court and launching an election campaign to deselect the incumbent RPSGB Council members, effectively blocking the Privy Council from implementing a draft charter which would have seen the RPSGB's assets[13] being applied solely to the purpose of regulation. Had the challenge been unsuccessful, the membership representation function of the RPSGB would have lost control of millions of pounds' worth of assets and may well have become unsustainable, meaning that the RPS may not exist today in its current form.

Recommendation

If the regulatory and leadership functions of the PSNI are split (we are against this at this time), it would be important for the DHSSPS to ensure that the assets that belong to the membership organisation are assigned to the professional leadership body.

Other Relevant Considerations

Pharmacy Technicians – Regulation and Impact on Costs

In the 'Policy Option 3' section of the impact assessment for this consultation, under the heading *'Description and scale of key monetised benefits by 'main affected groups''*, the Department has asserted that registration fees are 'projected to be cost neutral for pharmacy technicians'. We assume from this that selecting option 3 – separating the regulatory and professional leadership functions - will mean that the GPhC becomes the regulator and that pharmacy technicians will become regulated, though this is not explained in the consultation document. If this is the case, given that pharmacy technicians are not currently regulated in Northern Ireland, the move to option 3 will not be cost neutral for them – they will need to pay a registration fee of £118 per year where currently they pay none. In addition, the DHSSPS must consult explicitly as to whether it wants pharmacy technicians to become regulated in Northern Ireland, if that is its intention.

The decision as to whether pharmacy technicians become regulated is hugely problematic and is an entirely separate consideration to the decision to split the regulatory and professional leadership functions in Northern Ireland.

In 2010 in Great Britain, as a result of an initiative driven by civil servants, an administrative register of pharmacy technicians was created. This registration process was not led by pharmacy technicians and did not emerge through a robust and traditional process of professional consciousness being gradually built up layer by layer over a period of time and in response to changes in the ambitions of the pharmacy profession. It was not developed by a group with highly specialist skills, expert knowledge and rigorous high-level training that led to the emergence of a professional group represented by a strong leadership body who could represent and articulate its ambitions (such as with doctors, nurses and pharmacists).

What resulted was one profession formed by pharmacists over many generations and in the traditional way and a distinctly separate register of pharmacy technicians that was created by government edict. Consequently, many of those on this register are separated by great differences in training, experience, capability and, most importantly of all, widely differing ambitions. Pharmacy technicians have not joined a profession in the common sense of the word; rather, they came to work as usual and on one particular day, it became a requirement for their name to be entered onto a register. As such, the register 'joined them'.

Generally speaking, there is also a distinct difference between pharmacy technicians in the hospital setting - where standards have been developed over many years with the support of senior hospital pharmacists - and those in the community setting, where pharmacy technician development has been held back by a lack of investment by community pharmacy employers.

For this reason, pharmacy technicians in Great Britain should not be considered, in terms of public safety assurance, as a group whose registration confers anything like the same protection to the public as does a professional group that emerged through the more traditional route over a period of centuries alongside the development of pharmacy. Yet the failure to make appropriate distinctions between the two groups continues to plague pharmacy and is not helped by the GPhC and other's continued misuse of the word 'professional' to refer to both pharmacists and pharmacy technicians.

Pharmacy Technicians – the Opportunity to get it Right in Northern Ireland

Ultimately the debate should be about how best to develop professionalism and high standards amongst such a large and disparate group in a way that benefits patients.

The pharmacy sector in Northern Ireland has the opportunity and time to develop and adopt the right approach for its pharmacy technicians. It should establish a robust pharmacy strategy and vision for pharmacy accompanied by an understanding as to how pharmacy technicians could support that vision. This would then need to be followed by the appropriate training and qualification requirements, career development pathways and support for pharmacy technicians. By enhancing and clarifying the role of pharmacy technicians, particularly in community pharmacy, it could ultimately help to free up pharmacists to spend time building meaningful clinical relationships with patients. It could create in pharmacy technicians a much more valuable resource to the NHS which conforms to higher standards. It should be at that point that it decides whether and how it wants pharmacy technicians to become regulated.

Northern Ireland must not make the same mistakes that have been made in Great Britain with pharmacy technician regulation merely as the unintended consequence of a consultation about the split of the regulatory and professional leadership functions in pharmacy (if it chooses to opt for UK-wide regulation of pharmacists and pharmacy premises and the regulator becomes the GPhC).

Recommendation

If the outcome of this consultation is that pharmacists and pharmacies in Northern Ireland are to become regulated by the GPhC (we are against this option), regulation of pharmacy technicians must not be an automatic consequence. The DHSSPS must ensure that the regulation of pharmacy technicians is the subject of a separate consultation.

Recommendation

Before regulation of pharmacy technicians is considered, a robust strategy and vision should be agreed by the profession in Northern Ireland. Only then will it be possible to establish the supporting role that can be played by pharmacy technicians.

Consultation Questions

1. *Do you agree that the regulation and professional leadership functions should be completely separated and undertaken in future by two distinct and separate bodies?*

NO

Please take our full response our answer to this question.

The section 'Why we Advocate the Retention of Existing Arrangements with the Regulator / Professional Leadership Body in Northern Ireland' is particularly relevant.

2. *Please review the Initial Regulatory Impact Assessment and detail any further costs and benefits (both monetary and non-monetary) which you think the Department should consider. Please provide supporting evidence where appropriate.*

Please read the following section(s) of our response as our answer to this question:

- A Secondary (non-preferred) Option – A Standalone Regulator in Northern Ireland: A Standalone Northern Ireland-based Regulator – Cost Calculations
- A Secondary (non-preferred) Option – A Standalone Regulator in Northern Ireland: A Standalone Northern Ireland-based Regulator – A Standalone Regulator's Use of Public Funds
- Why we would be against a UK-wide Regulatory Approach in Northern Ireland: A UK-wide Regulatory Approach - Efficiency Considerations
- Considerations in the Event of any Split of the Regulator / Professional Leadership Body, Regardless of how this was Achieved: A Professional Leadership Body in Northern Ireland – Financial Considerations
- Other Relevant Considerations: 'Pharmacy Technicians – Regulation and Impact on Costs'

3. *In your view are there any other viable options which have not been considered? Please provide supporting rationale for your proposal.*

YES

Please take our full response our answer to this question.

The section 'Why we Advocate the Retention of Existing Arrangements with the Regulator / Professional Leadership Body in Northern Ireland' is particularly relevant.

4. *To what extent do you agree with the Department's view that retention of regulation and professional leadership functions in the same body is not an acceptable option?*

We do not agree. Please take our full response our answer to this question.

The section 'Why we Advocate the Retention of Existing Arrangements with the Regulator / Professional Leadership Body in Northern Ireland' is particularly relevant.

5. *To what extent do you believe that a lack of sufficient capacity and financial resilience will be a concern for a stand-alone Northern Ireland-based regulator of a relatively small number of registrants?*

Please read the following section(s) of our response as our answer to this question:

- A Secondary (non-preferred) Option – A Standalone Regulator in Northern Ireland: A Standalone Northern Ireland-based Regulator – Cost Calculations

6. To what extent do you believe that a stand–alone Northern Ireland-based regulator for a relatively small number of professionals gives rise to value for money considerations in the use of public funds?

Please read the following section(s) of our response as our answer to this question:

- A Secondary (non-preferred) Option – A Standalone Regulator in Northern Ireland: A Standalone Regulator's Use of Public Funds

7. Please detail any other factors in relation to a Northern Ireland-based regulatory arrangement which you think the Department should consider?

Please read the following section(s) of our response as our answer to this question:

- A Secondary (non-preferred) Option – A Standalone Regulator in Northern Ireland (all sections)

8. To what extent do you believe that public confidence and assurance in the regulation of pharmacy would be enhanced through consistent UK-wide standards?

Please read the following section(s) of our response as our answer to this question:

- Why we would be against a UK-wide Regulatory Approach in Northern Ireland (all sections)

9.

a) To what extent do you agree that enhanced efficiencies exist within larger regulatory bodies?

Please read the following section(s) of our response as our answer to this question:

- Why we would be against a UK-wide Regulatory Approach in Northern Ireland: A UK-Wide Regulatory Approach – Efficiency Considerations

b) How might these impact on the delivery of more cost efficient and effective regulation which better protects the public? Please provide your views.

Please read the following section(s) of our response as our answer to this question:

- Why we would be against a UK-wide Regulatory Approach in Northern Ireland (all sections)

10. To what extent do you believe that Northern Ireland could maintain sufficient influence on a UK-wide pharmacy regulator's policy in order to adequately address local need?

Please read the following section(s) of our response as our answer to this question:

- A Secondary (non-preferred) Option – A Standalone Regulator in Northern Ireland: The Importance of the Regulator being based in Northern Ireland
- Why we would be against a UK-wide Regulatory Approach in Northern Ireland: The Importance of Local Knowledge, Experience and Working in Northern Ireland

Both of the above sections encapsulate our views in this regard.

11. Please detail any other factors in relation to a UK-wide regulatory arrangement which you think the Department should consider?

Please read the following section(s) of our response as our answer to this question:

- Why we would be against a UK-wide Regulatory Approach in Northern Ireland (all sections)
- Other Relevant Considerations (all sections)

12. In your view which is the best future model to deliver modernised and strengthened statutory regulation of the pharmacy profession in Northern Ireland:

– A Northern Ireland based arrangement?

– Part of a UK-wide regulatory arrangement?

A Northern Ireland based arrangement.

Please read the following section(s) of our response as our answer to this question:

- Overall Position (all sections)
- 'Why we Advocate the Retention of Existing Arrangements with the Regulator / Professional Leadership Body in Northern Ireland'

13. To what extent do you agree that a UK-wide arrangement for pharmacy regulation would be best delivered by General Pharmaceutical Council?

Please read the following section(s) of our response as our answer to this question:

- Why we would be against a UK-wide Regulatory Approach in Northern Ireland (all sections)

14. Do you have any other comments you wish to make in relation to the options?

YES

Please take our full response our answer to this question.

15. To what extent do you agree that a separate leadership body, working independently from the regulator, strengthens the professional leadership arrangements for pharmacy?

We do not agree that this is the right approach in Northern Ireland.

Please take our full response our answer to this question.

16. Do you have any views on how best the pharmacy profession might establish strong, sustainable professional leadership in Northern Ireland?

Please read the following section(s) of our response as our answer to this question:

- Considerations in the Event of any Split of the Regulator / Professional Leadership Body, Regardless of how this was Achieved (all sections)

Personal details

I am responding: ☐ as an individual ☑ on behalf of an organisation *(please tick a box)*

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References

1. Avoiding the Yes Bias by Dave Vannette
   https://www.qualtrics.com/blog/avoiding-the-yes-bias/

2. Lean Analytics: Use Data to Build a Better Startup Faster by Alistair Croll, Benjamin Yoskovitz page 166

3. Preventing Chronic Disease: Public Health Research, Practice and Policy, Volume 2 No 1, January 2005:
   A Catalog of Biases in Questionnaires by Bernard
   C.K. Choi, PhD and Anita W.P. Pak, PhD
   http://www.cdc.gov/PCD/issues/2005/jan/pdf/04_0050.pdf

4. Questionnaire Design: Asking Questions with a Purpose by Ellen Taylor Powell, University of Wisonsin – Extension
   http://cstpr.colorado.edu/students/envs_5120/taylorpowell_QD1998.pdf

5. Consultation on the regulation of healthcare professionals from the Law Commissions of England and Wales, of Northern Ireland and of Scotland A response from the General Pharmaceutical Council
   https://www.pharmacyregulation.org/sites/default/files/Law%20Commission%20GPhC%20response%20FINAL%20v2%203.pdf

6. European Court of Justice C531-06 and Joined Cases C-171/07 and C-172/07
   Apothekerkammer des Saarlandes and Others v Saarland and Ministerium für Justiz, Gesundheit und Soziales
   Commission of the European Communities v Italian Republic
   http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:62007CJ0171
   http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:62006CJ0531

7. Pharmacist Ethics and Professional Autonomy: Imperatives for Keeping Pharmacy Aligned with the Public Interest - International Pharmaceutical Federation
   https://www.fip.org/www/uploads/database_file.php?id=358&table_id=

8. Your, a Stressed Pharmacist: Boots Article Prompts Flood of Letters, The Guardian, 17 April 2016
   https://www.theguardian.com/business/2016/apr/17/yours-a-stressed-pharmacist-boots-article-prompts-flood-of-letters

9. Regulator to look into Boots MUR evidence,
   Chemist and Druggist, 14 April 2016
   http://www.chemistanddruggist.co.uk/news/breaking-guardian-claims-boots-staff-forced-abuse-murs

10. Did Boots cuts affect patient safety? Company faces possible investigation, The Nottingham Post, 18 April 2016
    http://www.nottinghampost.com/Did-Boots-cuts-affect-patient-safety-Company/story-29131439-detail/story.html

11. Professional Standards Authority for Health and Social Care Annual Report and Accounts and Performance Review Report 2014/2015 Volume II Performance Review Report 2014/2015
    http://www.professionalstandards.org.uk/docs/default-source/publications/performance-reviews/performance-review-report-2014-2015.pdf?sfvrsn=10

12. Professional Standards Authority in its 2012 paper 'Review of the cost effectiveness and efficiency of the health professional regulators'.
    http://www.hpc-uk.org/assets/documents/10003EA8enc05-costeffectiveness.pdf

13. Why the new RPSGB draft Charter is unacceptable – Save our Society Campaign Document
    http://www.the-pda.org/pdf/documents/SOS.pdf

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