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EMAIL ONLY

Dear Sir/Madam

Ref: Review of pharmacy regulation in Northern Ireland

Please consider this letter as part of our consultation response. The Pharmaceutical Society NI is grateful for the opportunity to contribute to this consultation. At the outset it would wish to place on record that it supports the policy direction set out around the modernisation of pharmacy regulation in Northern Ireland. For many years it has sought to further modernise its legislative base and strengthen its primary objectives around the protection of the public.

Before providing detailed answers to the consultation questions it would, however, wish to place on record a number of concerns around errors and omissions in the consultation document. The Council is of the view that the nature of these errors and omissions is such that the analysis of responses may be difficult to uphold.

Background

In May 2008, after an Assembly motion was passed supporting the current arrangements for leadership and regulation in Northern Ireland, the then Minister introduced, in 2012, legislative reform. The Pharmaceutical Society NI had sought more wide reaching reform, including the introduction of the registration of pharmacy technicians but this was not advanced by the Department of Health Social Services and Public Safety (the Department).

More recently the Law Commission's proposed legislative reform for the nine UK regulators of healthcare professions, which had the broad support of the regulators concerned, was not progressed by the recently elected UK Government. The UK Government is, however, currently considering alternative reforms for the regulatory framework for health and social care professionals, across the UK.

In the lead up to the launch of this consultation the Department invited submission from stakeholders including the Pharmaceutical Society NI including financial and other information. We have attached a copy of the final letter to the Department, which highlighted key issues that we contend ought to have been addressed or highlighted in the consultation.

Concerns and issues

Firstly we are concerned that at Paragraph 21 of the consultation reference is made to the then Minister's speech, in which it was suggested that further separation may be required, but no mention is given of the unanimous support for the current arrangement and improved legislation.

At paragraph 25 the consultation fails to describe the arrangements which are in place to manage any perception of bias, including the scheme of delegation to an arm's length body with totally separate governance structures. Given that one of the options is the status quo, the Pharmaceutical Society NI is concerned that this has not been set out at all in order that those less familiar with the arrangements, in particular patients and patient groups, can make objective and properly informed submissions to the consultation.

This point is not made to support or undermine the status quo, but to ensure that similar detail is given for each option to ensure valid responses.

Paragraph 28 and question two seeks views on costs and impacts associated with the options. Earlier in this paper we advised that we had been asked to provide financial information to support the consultation and confirmed that we had done so. As part of that process we raised the issue of both organisational assets and

transition costs, in particular the question of who would fund such costs, and provided further information on the latter, whilst inviting the Department to address the former in the consultation document.

We are extremely disappointed that the Department has not published the transition costs as we have identified costs of up to £344k associated with the establishment of a UK wide arrangement and £34k associated with the establishment of NI arrangements, information which we would suggest is a critical consideration for respondents.

We would have anticipated that the wider effects on the local economy of any transfer or retention of function should have been highlighted for consideration.

At paragraph 30 we would have welcomed any evidence that the Department has around its assertions of perceptions of professional self-interest. For example, the Department will be aware that the Professional Standards Authority (PSA) has the power to appeal any unduly lenient sanction handed down by the Statutory Committee – no such appeal has been lodged since the legislative reform of 2012– we work closely with a range of patient groups and the dual function has never been a barrier to securing their support and assistance.

At paragraph 32 we note that the Department identifies “some” positive aspects to a Northern Ireland based regulatory arrangement. There is no mention of the consistency with the devolution settlement, social care, system regulation etc. all having been established as standalone, as they were established post the 1998 settlement.

By contrast the consultation then devotes a section to the “potential difficulties” associated with such an establishment.

Paragraph 34 refers to capacity and resilience of a local arrangement. At the request of the Department information was provided in detail showing how, at a significantly reduced retention fee, such an arrangement could be delivered in Northern Ireland. We are disappointed that this concern has been raised when the Department has received detailed financial projections, scrutinised before submission by an independent accountant, which does not support this assertion.

Paragraph 35 refers to viability issues, we are required to annually lay our accounts before the Northern Ireland Assembly and these accounts consistently confirm the organisation as a going concern – the Department adduces no evidence to suggest this is incorrect but appears to question viability.

Similarly, Paragraph 36 raises the issue of registration of technicians – the Department has been provided with fully funded proposals, designed to be cost

neutral to introduce such registration and longer term self-funding proposal to maintain such a register. We are disappointed that this evidence did not form part of the consultation document.

Paragraphs 37 and 38 refer to differing contexts for pharmacy practice and question the capacity of a Northern Ireland based regulator to respond. In our view this underlines a fundamental misunderstanding of the role of a modern regulator. The same code of conduct applies to pharmacists in a range of settings, hospital, community, industry and administration and there is a tendency for regulators to focus on the proper exercising of professional judgement with less emphasis on prescriptive practice guidance.

We have worked effectively with the GB regulator and others over many years to respond to changes and would question the consultation document's listing of this issue of a potential difficulty in the absence of any evidence in support of that claim.

Paragraph 39 raises the potential of increased costs – we would question the evidence base to raise this concern under this option and would further question the evidence base to not then raise it under any other option.

Question five then invites responders that have not been provided with the information set out earlier in this section, to make an objective assessment and response.

Paragraph 40 raises concerns that regulation not exercised on a UK wide basis including a challenge to the public expectation that regulation is carried out on a consistent basis. The PSA, which oversees and annually reports on the performance of both the GB and Northern Ireland regulator for pharmacy, has not reported any lack of consistency across any of the four functions. The Northern Ireland Social Care Council, which is an Non Departmental Public Body of the Department, carries out the regulation of Social Care with counterparts in each of the three GB countries operating on a devolved basis. We are aware of no evidence that any perception exists around consistency, and note that each of the regulators have taken differing approaches to social care workers with the support of their relative administrations. This highlights the benefits of flexible arrangements that can be tailored to each administration's needs and we are confused that bit is listed as a potential difficulty, rather than a benefit

We would have expected the consultation to highlight the positive nature of this devolved approach alongside any legitimate, evidence based, concerns.

Paragraphs 41 and 42 raise concerns about DHSSPS resources required to support a local regulatory arrangement. This issue appears to us to be political consideration around whether regulation should be a devolved matter. Presumably if so then there

would be an expectation that the necessary resources would be available to support it. Our issue with this is the assertion earlier in the document at Paragraph 15 that there would be no change to the devolved nature of pharmacy regulation and we would question the lack of consistency in these two sections.

Question six, which asks whether the establishment of a standalone regulator gives rise to the value for money use of public funds, again appears to be a challenge to the devolved exercise of public functions and could be asked of any devolved function. The Pharmaceutical Society NI directly receives no public funding and the consultation provides no information on the extent of public funding that is or would be expended.

Paragraph 44 suggests that the Department has not validated the fees provided – this is a surprise as the Department asked for full supporting information by a specified date and we complied. The section appears to suggest a lack of reliability on the data, which may mislead some respondents.

On a matter of accuracy, the data supplied included, in the premises fee, at the request of the Department, the costs of inspection and enforcement. We note that the final consultation paper offers options for inspection and enforcement which presumably would attract differing funding models – it may be misleading for respondents that this is not clear.

We would again refer to the issue of transition costs which should have been included for each option.

Option three, commencing at Paragraph 45 again refers to “some positive” aspects of UK wide regulation but is not consistent with the separate section which identifies “potential difficulties”.

Paragraphs 49 and 50 appear to make sweeping assertions around size of regulator and “efficiency” – if an economic argument is introduced it would be beneficial to provide all the information available in order to allow objective responses – for example the location of the regulator directly impacts upon cost base, there is evidence that some larger regulators struggle to meet the PSA performance review standards and the issue of transition costs and effect on the local economy is not referred to.

We note that the Department is not seeking to validate the UK wide costs in the same manner as Northern Ireland.

Paragraphs 55 to 59 are in our view extremely leading and call up many of the issues that we have raised concerns about earlier in this response.

We regard as contradictory the suggestion at Paragraph 15 that none of the options impacts on the devolved competence of the Northern Ireland Assembly when contrasted with the concerns raised around the use of Northern Ireland resources to introduce and maintain a Northern Ireland based regulator – clearly in the case of the local resource, consultation and approval would be the exclusive remit of the Northern Ireland Assembly, interfacing only with local stakeholders, whilst in a UK wide arrangement the Northern Ireland Assembly would have no influence on the primary amending instrument, a Section 60 Order and the views of stakeholders across the entire UK would determine the outcome at consultation.

Turning to the Regulatory Impact Assessment, we note that the question is specifically asked of the status quo around the approach in other EU countries, in particular the Republic of Ireland. We note that this section has not been completed and question why the model for pharmacy regulation is not provided along with details of number of registrants and costs of registration.

In providing comparative fees we note only the lower two fees (personal and premises retention) are reported for the General Pharmaceutical Council, whilst a further fee (premises registration) is reported for the Pharmaceutical Society NI. Only in the case of the latter are the current fees paid by the respective registrants quoted, making objective comparison difficult.

The omission of transition costs, in the possession of the Department is difficult to justify in such an assessment.

In option two, Northern Ireland based regulation, the section under “Description and scale of key monetised benefits by ‘main affected groups’” fails to highlight the reduction in retention fees for registrants of approximately £100 that would arise out of the creation of a standalone Northern Ireland regulator.

Please find enclosed direct answers to the consultation questions.

Yours faithfully

Dr Jim Livingstone

President

Q1: Do you agree that the regulation and professional leadership functions should be completely separated and undertaken in future by two distinct and separate bodies?

The Council of Pharmaceutical Society NI agrees with the Department's option, as set out in the consultation, that the regulation and professional leadership functions should be completely separated and undertaken in future by two distinct and separate bodies. It is clear that the body of evidence and the position of the UK Government is that Healthcare Professional Regulators should be completely and demonstrably separated from the professions they regulate.

Q2: 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.

The Council is concerned at the lack of evidence presented to substantiate the assertion made in the assessment that "*the relatively small size of a standalone regulator may give rise to concerns regarding sufficient capacity, resilience and sustainability*". The Council contends that the current evidence suggests the contrary to this assertion is the case at present; the PSA regularly rates the Pharmaceutical Society NI as one of the better performing healthcare regulators in the UK. In addition, the organisation has been in existence for a considerable period of time and is financially viable as evidenced by the going concern rating provided by external auditors and regularly reported to the Northern Ireland Assembly.

The Council is particularly concerned that the potential transition costs associated with options 2 and 3 have not been provided to consultees in the Initial RIA or any cost savings, despite the Council having provided this information to the Department. The Council also requested, prior to the launch of the consultation that the Department give an indication as to who would bear these costs. This has not been done and could affect consultees' assessments.

Finally, the Department has not provided information on any savings or costs arising from pharmacy inspection and enforcement passing from the Department to either a reformed Pharmaceutical Society NI or a UK wide regulator

Finally, in relation to option 2 and 3 the Council considers that a number of potential impacts have not been included in the assessment and the consultation in general as follows:

- **Benefits of accountability and the impact on devolution**
    - The Council contends there are benefits to accountability for the Northern Ireland Assembly associated with a Northern Ireland based regulator – in particular benefits around the primacy of the NI Assembly and influence available to Northern Ireland stakeholders
- **Responsiveness of a NI Regulator**
    - The Council contends that a Northern Ireland based and accountable regulator will be more responsive to Northern Ireland Assembly policy and priorities, and will have greater agility given its regional focus whilst continuing to provide confidence **and** assurance to Northern Ireland public and patients**.**
- **The benefits of a NI Regulator for registrants**
    - The relative size of the registrant base facilitates better communication and engagement within a Northern Ireland based context.
- **Regulatory benefits for patients, the public and registrants of a NI Regulator**
    - Council has identified issues around better accessibility, visibility, including of Fitness to Practise (FtP) activity, influence in relation to Northern Ireland consultations on standards and policy compliance with trust assurance and safety associated with a Northern Ireland based regulator.
    - Pre-registration training programme is run directly by the Northern Ireland regulator, with published information on results and satisfaction providing high levels of assurance to registrants, and patients.
    - The system for Continuing Professional Development was developed and introduced based upon the outcome of a consultation with those most closely affected, registrants and the public in Northern Ireland – whilst it differs from the GB system it was endorsed by local stakeholders.
    - Stakeholder engagement is drawn from Northern Ireland and resultant policies, standards and guidance are influenced only by this group.

- **The Council would highlight the work of the successful Pharmacy Network Group operated with the Northern Ireland regulator and question whether the current regime would continue to be viable in a UK wide context from a cost and resources perspective**

- **Financial Implications**
- The costs of transition for each of the options should have been clearly articulated in the RIA.
- The potential costs to stakeholders, including FtP parties (complainants, registrants and witnesses), stakeholders who would seek to attend regulatory Council or other meetings and registrants or others that may need for any reason to visit the regulators premises, associated with and arising from, the movement of any function to London, should be fully considered
- **Economic Implications**
  - The effect on the local economy of any transfer of function should be identified in the consultation to aid responders.
  - Council remains willing to further discuss these matters with the Department.

Q3. In your view are there any other viable options which have not been considered? Please provide supporting rationale for your proposal.

In relation specifically to pharmacy regulation, the Council's view is that there are no other viable options. The Council, however, is concerned that the options offered have not been contextualised within the current wider discussion across the UK about the future of healthcare professional regulation and[1] take no account of how the outcome of these discussions might affect any of the proffered options – this gives rise to questions around the timing of the consultation in relation to the other analysis

[1] https://www.parliament.uk/business/publications/written-questions-answers-statements/written-statement/Lords/2015-12-17/HLWS421/

Q4. 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?

The Council refers you to its answer to Question 1 above.

Q5. 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?

There is no evidence to suggest that a lack of sufficient capacity and financial resilience will be a concern for a stand-alone Northern Ireland-based regulator.

By asking 'to what **extent** do you believe', the Council is concerned that this question is premised on the unfounded assumption that a lack of sufficient capacity and financial resilience is already a current concern in relation to the PSNI.

The Council is disturbed that without the presentation of any evidence to substantiate this assertion, the question may lead respondents to make a response based on an erroneous supposition rather than actual evidence.

It should be noted that on the basis of successive PSA reports and Annual Reports on Accounts, laid before the Northern Ireland Assembly, there is no evidence to suggest that a lack of sufficient capacity and financial resilience will be a concern for a stand-alone Northern Ireland-based regulator.

For example, fee increases in the last 6 years have been limited to one and by comparison to inflation there has been a significant cost reduction which will be further built upon by legislative reform to remove barriers to efficiency already identified.

The current regulator has delivered against its objectives for many years, has stable accounts and sound reserves, all confirmed by an independent auditor and oversight body.

Q6. 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?

The Pharmaceutical Society NI does not directly receive any public funding.

The Council is deeply disturbed that without the presentation of any evidence to substantiate this statement, the question, as posed, may lead respondents to make a response based on supposition rather than actual evidence.

The Consultation document does not provide any details on the extent or nature of public funds deployed to support Northern Ireland based regulation; therefore it is difficult to see how any respondent can answer this question regarding value for money.

Q7. Please detail any other factors in relation to a Northern Ireland-based regulatory arrangement which you think the Department should consider?

Please see answer to Question 2

Q8. To what extent do you believe that public confidence and assurance in the regulation of pharmacy would be enhanced through consistent UK-wide standards?

The Council is concerned that the question implies that consistent standards can only be achieved by a UK body and that there is evidence to suggest that there is less public confidence arising out of delivery by the current Northern Ireland based regulator.

The PSA regularly rates the Pharmaceutical Society NI as one of the better performing regulators in the UK.

Public confidence in nine UK health professional regulators is assured by the PSA. The Pharmaceutical Society NI has consistently performed as an above average regulator in the PSA's annual performance reviews and there is no reason to believe that this situation is likely to change under the current arrangements and when updated legislation is provided, there is a likelihood that performance will be further enhanced.

Within that review process the PSA scrutinises the Fitness to Practise processes of all nine professional healthcare regulators to ensure consistency and robustness of decision making. The PSA has the power to refer decisions by Fitness to Practise Committees, it deems to be too lenient, to the High Court for a review. The PSA has to date not referred any cases of the Pharmaceutical Society NI to the High Court for review since the legislative improvement in 2012.

Q9.

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

The Council does not agree enhanced efficiency automatically flows from larger regulatory bodies. Other factors such as location, complexity of task and context have a bearing on efficiency

The Council further notes that based on the findings of a PSA report, the Pharmaceutical Society NI out-performed the GMC, the GOsC and the GCC in relation to its unit operating cost. It is further noted that the unit operating costs of the NMC and HCPC were considerably lower than the remaining seven regulators and if these regulators are not considered, the Pharmaceutical Society NI's unit operating costs were 14.2% lower than the average operating cost for the remaining seven regulators.

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

As indicated above in relation to question 9 a) the Council does not agree with the premise of the question and argues that no evidence has been provided to support the notion that larger bodies automatically better protect the public. The Council refers the Department to successive PSA Performance Review reports which do not support this premise.

The Council reiterates the benefits it considers a Northern Ireland based regulator brings, to the public, registrants and the Northern Ireland Assembly, as laid out in answer to Question 2. Council does not accept there is any evidence to support the contention at b).

Q10. 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?

The Council considers that the ability of Northern Ireland stakeholders to maintain sufficient influence on a UK-wide pharmacy regulator and the wider field of professional healthcare regulation to adequately address local needs would be considerably diminished.

- Issues around influence over the primary UK instrument for amending regulatory legislation for UK wide regulators, Section 60 Orders, are not laid

or debated in the Northern Ireland Assembly – contrasted with amendments to the NI based regulator which require full approval by the Northern Ireland Assembly following Northern Ireland consultations

- Given the fact the Northern Ireland represents around 2.8 % of the UK population, future UK wide consultations would see NI based responders with very limited influence in this scenario
- Influence on general healthcare regulatory policy – currently of the nine regulatory bodies that meet and discuss regulatory policy, eight are based in England. The presence of a NI based body presently ensures Northern Ireland context and information is available to this group, ensuring Northern Ireland interests are properly considered. This contrast with a model, as proposed of all nine bodies being based in England.

Q11. Please detail any other factors in relation to a UK-wide regulatory arrangement which you think the Department should consider?

The Council reiterates the point that Professional Healthcare Regulation is fully devolved to the Northern Ireland Assembly.

The Council reiterates the fact that the Northern Ireland Assembly has more limited powers of oversight in relation to the UK-wide regulatory arrangement than the Scottish Parliament which has only partial devolution, as the Health Act 1999 makes no provision for Section 60 orders to be approved by the Northern Ireland Assembly. The Northern Ireland Assembly relies on the Sewell Convention which results in a Legislative Consent Motion for legislative change. This in reality is a lesser check as it only allows the Northern Ireland Assembly to provide approval for legislative change to be made at the start of the legislative process and not at the end, when all of the detail is available– meaning that changes are not subject to appropriate scrutiny. Moving the regulation of pharmacy onto a UK wide setting would move from the current full control and accountability model to the partial early oversight model above.

The Council further notes the wider debate ongoing about the future of professional healthcare regulation in general and the uncertainty this frames the current consultation within[2].

The Council reiterates the points it made in answer to Question 2 in relation to the benefits of a Northern Ireland based regulator.

[2] https://www.parliament.uk/business/publications/written-questions-answers-statements/written-statement/Lords/2015-12-17/HLWS421/

Q12. 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?*

As the points outlined in the Council's answer to question 2, it is the firmly held position that based on the current evidence base, a Northern Ireland based arrangement is the better future model to deliver modernised and strengthened statutory regulation in a devolved context of the pharmacy profession in Northern Ireland, delivered by the existing regulator.

- **Benefits of accountability and the impact on devolution**
    - The Council contends there are benefits to accountability for the Northern Ireland Assembly associated with a Northern Ireland based regulator – in particular benefits around the primacy of the Northern Ireland Assembly and influence available to Northern Ireland stakeholders
- **Responsiveness of a NI Regulator**
    - The Council contends that a Northern Ireland based and accountable regulator will be more responsive to Northern Ireland Assembly policy and priorities and will have greater agility given its regional focus whilst continuing to provide confidence and assurance to Northern Ireland public and patients
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    - Pre-registration training programme is run directly by the Northern Ireland regulator with published information on results and satisfaction providing high levels of assurance to registrants, and patients.

- The system for Continuing Professional Development was developed and introduced based upon the outcome of a consultation with those most closely affected, registrants and the public in Northern Ireland – whilst it differs from the GB system it was endorsed by local stakeholders.
- Stakeholder engagement is drawn from Northern Ireland and resultant policies, standards and guidance are influenced only by this group.
- The Council would highlight the work of the successful Pharmacy Network Group operated with the Northern Ireland Regulator and question whether the current regime would continue to be viable in a UK wide context from a cost and resources perspective.

- **Financial Implications**
- The costs of transition for each of the options should have been clearly articulated in the RIA.
- The potential costs to stakeholders including FtP parties (complainants, registrants and witnesses), stakeholders who would seek to attend regulatory Council or other meetings and registrants or others that may need for any reason to visit the regulators premises, associated with and arising from the movement of any function to London should be fully considered.

- **Economic Implications**
  - The effect on the local economy of any transfer of function should be identified in the consultation to aid responders
  - Council remains willing to further discuss these matters with the department.

Q13. To what extent do you agree that a UK-wide arrangement for pharmacy regulation would be best delivered by General Pharmaceutical Council?

The Council considers this to be a matter for the Departments of Health in GB and Northern Ireland.

Q14. Do you have any other comments you wish to make in relation to the option

No

Q15. To what extent do you agree that a separate leadership body, working independently from the regulator, strengthens the professional leadership arrangements for pharmacy?

The Council's primary concern is regulation. It considers arrangements for professional leadership to be a matter for the profession in Northern Ireland

Q16. Do you have any views on how best the pharmacy profession might establish strong, sustainable professional leadership in Northern Ireland?

See the answer to question 15