

Future of Pharmacy Regulation in Northern Ireland

Consultation Document

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Foreword

As Minister for Health, Social Services and Public Safety, my mission is to improve the health and well-being of all the people of Northern Ireland. An important aspect of my vision is to sustain and enhance the development of high-quality pharmacy practice at a critical time for the profession with its increasingly clinical and patient-facing focus.

The pharmacy profession has a key role to play in the wider transformation of Northern Ireland's Health Service. As a result we are seizing opportunities to develop and best utilise the unique clinical and technological skills residing in our pharmacy teams and integrate these effectively within the Health and Social Care (HSC) sector. This will enable the profession to collaborate with other health and social care professionals to optimise patients' medicines use and improve the health and well being of the public.

The proposals set out in this consultation are designed to deliver modernised and strengthened regulation of the pharmacy profession in Northern Ireland. Protection of the public is the clear first priority of regulation. I also want to enhance patient, public and professional confidence in the regulatory arrangements.

I feel that now is the right time to consider the best way forward for the regulation of the profession in Northern Ireland as there are many new and exciting opportunities ahead for the pharmacy profession. This consultation exercise is important in designing and developing modern, fit for purpose regulatory arrangements which will ensure the effective and efficient delivery of professional regulation both for now and into the future.

I hope that the options and the analysis of those options outlined in the consultation will help to engender an informed debate about the future of pharmacy regulation and professional leadership arrangements in Northern Ireland. I welcome views from a wide range of stakeholders to help inform the design of the future arrangements.

Introduction

1. The Department of Health, Social Services and Public Safety ('the Department'), is consulting with the public, the pharmacy workforce and other stakeholders about future arrangements for the regulation of the pharmacy profession in Northern Ireland.
2. While pharmacy professionals and their teams in Northern Ireland deliver an excellent service to a high professional standard, this consultation is aimed at strengthening and modernising existing arrangements for pharmacy regulation. The purpose of this review is to ensure that the public and professionals can have greater assurance and confidence in the governance and delivery of the regulation of pharmacy in Northern Ireland.

The purpose of the consultation

3. Since 1925 regulation of the pharmacy profession in Northern Ireland has been performed by the Pharmaceutical Society of Northern Ireland ('the Society') based in Belfast. The Society currently performs the functions of both regulation and professional leadership for pharmacists in Northern Ireland. However, this dual role is counter to modern thinking regarding professional regulation which advocates that, to operate effectively in the public interest, a regulator should be totally and demonstrably independent from the profession it regulates.
4. In total there are nine healthcare regulators in the UK which include, for example, those bodies responsible for the regulation of doctors and nurses. In comparison with the other UK healthcare regulators the Society is the only regulator which retains this dual, potentially conflicting, role. Furthermore, pharmacy is the only healthcare profession which is not regulated on a UK wide basis.
5. The Minister for Health, Social Services and Public Safety, Simon Hamilton MLA, has agreed in principle to split the regulatory and professional leadership functions currently undertaken by the Society. Further analysis of

the important reasons is discussed later in the document. However, in broad terms, two key issues are being consulted on:

1. The transparent and complete separation of the Society's dual role;
and
2. Viable options for a future model to deliver modernised and strengthened Statutory Regulation of the pharmacy profession in Northern Ireland. In this respect, three options are under consideration:
 - i. no change to the current arrangements;
 - ii. a future Northern Ireland-based regulatory arrangement;
and
 - iii. a future UK-wide regulatory arrangement.
6. The Department invites the public and stakeholders to use this consultation exercise to provide their views on (1) the separation of functions and (2) whether, if no change to the current arrangements is not a viable option, to establish UK-wide or modernised Northern Ireland-based regulatory arrangements. It is recognised that any change to separate the functions of the Society raises issues regarding how leadership of the profession may be best secured in the future. The Department is taking the opportunity to invite views on this related issue.
7. All consultation responses will be given full consideration by the Department and will inform the advice given to the Minister in advance of making a final decision on the future regulatory arrangements. The Department intends to undertake a further consultation should legislation be required to implement the Minister's decision.

Background

What is regulation of healthcare professionals?

8. The main purpose of the regulators is to protect the public and those using the services of registered professionals from harm. Regulators do this by holding registers of individuals who meet their standards of education, training, professional skills, behaviour and health. Regulators are also responsible for investigating concerns and taking action to prevent or restrict practice in cases where professionals fail to meet those standards.
9. There are nine healthcare regulatory bodies in the UK responsible for regulating 32 healthcare professions, consisting of approximately 1.44 million professionals. Information about the nine bodies and the professions which they regulate is listed in the table at [Annex 1](#). The data contained in this table is derived from the Professional Standards Authority Annual Report 2014-15¹ and provides some context about the size of the regulators, in terms of the number of professions and professionals that they regulate and the size of their workloads. The framework for the statutory regulation of healthcare professionals, including the core functions and duties of regulators, is enforced by law. Further detail on the general role and functions of healthcare regulators and key principles which underpin regulation is also contained at [Annex 2](#).
10. This consultation is about the 'regulation of healthcare professionals' which is concerned with individual practitioners, as opposed to regulation of health sector organisations or systems. It is a key element of a much broader system of ensuring patient safety and public protection.

¹ Professional Standards Authority for Health and Social Care - Annual Report and Accounts and Performance Review Report 2014/2015. Available at: <https://www.professionalstandards.org.uk/docs/default-source/scrutiny-quality/performance-review-report-2014-2015.pdf?sfvrsn=0>

Why is regulation of healthcare professionals important for the public?

11. Modern and effective arrangements for regulation of healthcare professionals are extremely important as they provide the public with confidence and assurance that the professionals administering their care continue to meet professional standards set by their regulator. The public can also be confident that, in the rare cases where something goes wrong, there is an independent and impartial regulator to investigate the matter and deal with deficiencies in a skilled, thorough and fair way.
12. To operate effectively in the public interest a modern regulator must be totally and demonstrably independent from the profession it regulates. There has been a public perception at times that regulatory bodies can be overly sympathetic to the professionals they regulate. Regulators must be impartial, and be seen to be impartial, in their decisions and actions. Clear independence provides enhanced assurance to the public that the regulatory arrangements are focused on public protection and not on professional self-interest. It is also essential that the regulator has the authority, competence and capacity to perform its role rigorously and efficiently.

Why are we consulting on pharmacy regulation at this time?

13. The Department is satisfied that the Society has performed its regulatory role over many years with due diligence and with commitment to the protection of the public. In its most recent published performance audit of the Society, the Professional Standards Authority (which oversees the work of healthcare professional regulators in the UK) found that the Society has generally performed well.
14. However, in addition to the important matter of considering separation of the dual role of the Society, there are other important reasons to now review pharmacy regulation in Northern Ireland. The practice of pharmacy is being called upon to support transformation of the health care systems across the UK. This means that the clinical and technical skills which exist within the pharmacy team are being increasingly utilised to help patients live longer,

healthier lives and gain the best outcomes from their medicines. This requires a greater emphasis on patient safety, collaborative working with other health care professionals and delivering care in settings most suitable for patients and the public. The regulatory system must be fit for purpose as health service delivery evolves in this way and should incorporate responsibilities both for 'overseeing' functions in addition to stretching performance and stimulating ongoing quality improvement

Regulation of pharmacy in Northern Ireland

15. The regulation of healthcare professionals is a devolved matter in Northern Ireland. As such it is for the Minister for Health, Social Services and Public Safety in Northern Ireland to decide on the future regulatory arrangements for the pharmacy profession here, with appropriate approval from the Northern Ireland Assembly. Regardless of the outcome of this consultation, the regulation of healthcare professionals will remain a devolved matter in Northern Ireland. The Department does not consider that any of the options discussed later in this consultation impact on Northern Ireland's devolved competence.

Arrangements in Northern Ireland for regulation of pharmacy premises - Inspection and Enforcement

16. In Northern Ireland the Pharmacy Inspectors, employed by the Department, undertake routine compliance visits to all registered pharmacies to ensure that the premises and the pharmacist on duty are complying with the standards of conduct and performance set by the Society and with obligations imposed by statute. Where a person registered with the Society or lawfully conducting a retail pharmacy business fails to comply with those standards and legal obligations, a number of enforcement actions and sanctions may be deployed.

17. The various options for future regulation discussed in this consultation will have implications for the way in which inspections are secured potentially as either:

- i. the responsibility of the Department;

- ii. the responsibility of a stand-alone NI Regulator;
- iii. the responsibility of General Pharmaceutical Council (GPhC); or
- iv. a combination of the above.

18. Regardless of any organisational regulatory changes, arrangements will not impact on the requirement for an inspection and enforcement function within Northern Ireland.

Separating the Regulatory and Professional Leadership functions of the Society

19. There has been a public perception at times that regulatory bodies can be overly sympathetic to the professionals they regulate with a focus on progressing the profession and professional interest which detracts from and conflicts with the regulator's core focus of public protection. An explanation of terminology is contained at [Annex 2](#) which may be helpful to contextualise the matters discussed in this section.

20. Following the Shipman Inquiry and other inquiries of the same period, a key principle emerged in relation to healthcare professional regulation that professional leadership and regulation should not be undertaken by the same body. This was reinforced by the 2007 UK Government White Paper '*Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century*' which set out a number of key principles underpinning modern regulation.

21. Legislative amendments introduced by the Department in 2012 modernised, to some degree, the public protection and regulatory activity of the Society. However, the Northern Ireland Health Minister at the time indicated that, while the changes developed a partial separation of the Society's functions, he wished to follow up how full separation could be achieved in the interest of the public and the profession.

22. The 2014 UK Law Commissions' Review of the Regulation of Healthcare Professionals recommended that the Society should not be incorporated

into the Commissions' proposed legislative scheme unless its representational [leadership] role was removed. The review also noted (page 20) that:

'We remain concerned that by retaining its dual role of regulation and professional leadership, the Pharmaceutical Society of Northern Ireland has adopted a fundamentally different approach to professional regulation from the rest of the UK. This sits uncomfortably with our final recommendations set out in this report which are based on the understanding that the regulators must be – and be seen to be – independent of the professions they regulate'.

23. Subsequent to that review, it was agreed that the Society should also be excluded from the *Safety and Quality Act 2015* which sought to emphasise the public protection objectives across the other UK healthcare regulators². This was again due to the difficulties posed by the Society's dual role and because its current statutory objects are more reflective of a membership organisation rather than focused on public protection.

Regulation of Pharmacy in Great Britain

24. The 2007 White Paper noted that, unusually, the then Royal Pharmaceutical Society of Great Britain (RPSGB) was both the regulator and the professional leadership body for the pharmacy profession in Great Britain. The Paper recommended separation of these functions. In September 2010 the General Pharmaceutical Council (GPhC) was established in Great Britain to focus exclusively on the regulation of the pharmacy profession in England, Scotland and Wales while the RPSGB's focus moved to that of professional leadership.

² An overarching public protection objective was introduced for the General Medical Council through the *General Medical Council (Fitness to Practise and Overarching Objective etc) Order 2015*. The *Safety and Quality Act 2015* introduced the overarching public protection objectives for all UK healthcare regulators with the exception of the Pharmaceutical Society of Northern Ireland.

The Department's proposal

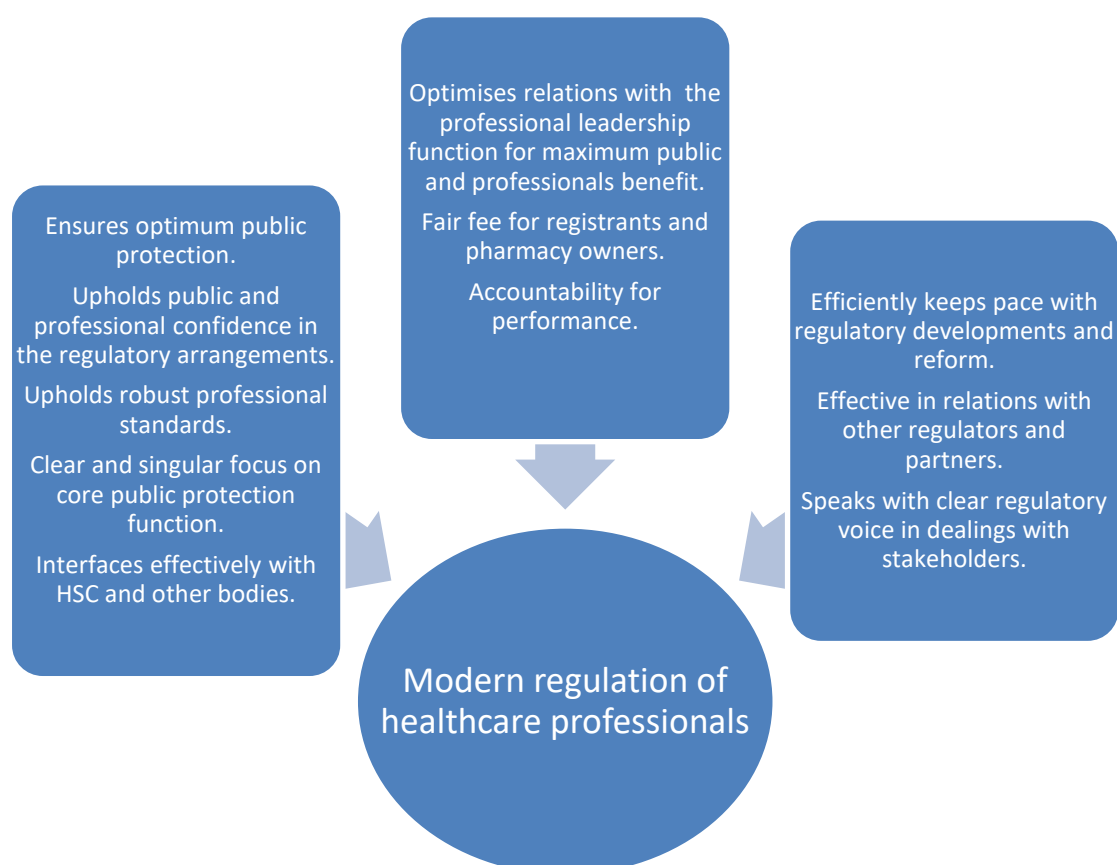
25. The Minister for Health, Social Services and Public Safety has agreed, in principle, to split the regulatory and professional leadership functions currently undertaken by the Society. The Department's proposal is that the two functions should be undertaken by two separate bodies, each with its own distinct remit, role and responsibilities which are clearly defined and easily understood. This will ensure that the body responsible for regulation operates in a manner which is totally and transparently independent from the profession, has no role in representing the interests of the profession, and is free to focus exclusively on public protection.

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?

Options for future arrangements for Pharmacy Regulation in Northern Ireland

26. This section considers three potential options for future statutory regulation of the pharmacy profession in Northern Ireland. The Department has set out at **Diagram 1** what it considers to be key components of a modern regulator for healthcare professionals. Each of the three options is considered in the context of this model and a summary of the Department's analysis is set out below.

Diagram 1 - Modern healthcare professional regulation



27. The Department invites respondents to provide views on the options presented and on the analysis of the options and where appropriate to put forward alternative proposals and supporting evidence. Views and comments should be submitted using the consultation questionnaire which is published on www.dhsspsni.gov.uk/consultations.

Initial Regulatory Impact Assessment

28. The Department has presented the findings from its Initial Regulatory Impact Assessment, published on www.dhsspsni.gov.uk/consultations and which contains some further detail on the options. This consultation exercise also provides as an opportunity to gather further evidence on any potential impacts which may arise from the options outlined. The Department will continue to work with relevant stakeholders during and following consultation to identify and assess potential costs arising from the options presented.

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.

Analysis of options

29. The Department has identified three high level options for the future arrangements for the regulation of pharmacy in Northern Ireland and is seeking your views. The options are:

- i. Do nothing. The Society remains responsible for undertaking both the regulatory and professional leadership functions.
- ii. Separate the regulatory and professional leadership functions of the Society and establish a separate Northern Ireland-based arrangement for the regulation of the pharmacy profession.
- iii. Separate the regulatory and professional leadership functions of the Society and establish arrangements for the regulation of the pharmacy profession on a UK-wide basis.

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

Option One - The Society continues to function as both the regulator and professional leadership body

30. As discussed above, the Department believes that this is not an acceptable option as it fails to secure the aim of clear separation of the regulatory and professional leadership functions. Therefore this option does not provide demonstrable and clear independence between the regulator and the profession it regulates. There remains potential for the perception at least that professional self interest is prevalent in the regulatory function and could take precedence over public protection. This could undermine public confidence in the regulatory arrangements. There also remains significant potential for a lack of clarity amongst the public, registrants and other stakeholders with regard to the regulator's core function which is to protect the public.

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?

Option Two - Separate the regulatory and professional leadership functions. Establish modernised Northern Ireland-based arrangements for regulation of the pharmacy profession

31. This option separates the regulatory and professional leadership functions. Separation establishes the regulator's primary focus on public protection and acting in the public interest and therefore enhances public confidence in the impartiality of the regulator. This arrangement allows the regulator to engage with all stakeholders with a clear regulatory mandate and without any confusion based upon links with the professional / representational agenda. It also brings the Society into line with the rest of the UK healthcare regulators.
32. There are some positive aspects to a Northern Ireland standalone regulator (i.e. operating without a professional leadership role). This includes providing for a regulatory arrangement which is focused on the local health care system. The local regulator could also build on existing organisational networks including public interest and advocate groups, commissioners, the HSC sector and the NI Assembly.
33. Based on pre-consultation research the Department has undertaken, the following potential difficulties associated with the standalone Northern Ireland-based option have been identified.

Capacity and resilience of a future Northern Ireland arrangement

34. There is a considerable programme of modernisation which all UK regulators of healthcare professionals, including those responsible for regulation of pharmacy, will be required to consider and address. Much of this agenda is derived from the UK Law Commissions' work examining regulation of healthcare professionals across the UK.
35. A Northern Ireland stand-alone regulatory body will need to provide assurance that it has sufficient capacity to be responsive to rapidly emerging changes in the way pharmacy practice is becoming increasingly integrated within healthcare systems. The pharmacy

profession in Northern Ireland is experiencing significant ongoing transformation with further changes likely in the near future.

36. Regulatory matters specific to pharmacy which must be considered in Northern Ireland include, for example, statutory regulation of pharmacy technicians. Technicians are important members of the broader pharmacy team and are increasingly undertaking patient facing services. Unlike the position in Great Britain, pharmacy technicians are not regulated in Northern Ireland.

37. A recent UK-wide development has been the delivery of clinical pharmacy services within the GP practice setting in order to optimise patients' treatments with medicines. These roles are currently being established at pace in Northern Ireland.

38. The pharmacy regulator must have sufficient capacity to assess effectively, and manage the impact on, pharmacy of the changing healthcare environment. At the same time it needs to be agile and responsive to emerging issues, and able to anticipate and manage further change, opportunities and challenges. The considerable pace of policy and legislative change must be managed in a timely manner and in a way which ensures optimum protection for the public, maintains professional standards and ensures public and professional confidence in the regulatory arrangements.

39. Anticipated pressures on the operating costs associated with, for example, responding to regulatory updates, delivery of fitness to practise functions, developing and maintaining consistent standards with the other UK countries must be managed in an efficient manner without excessive increases to registration fees.

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?

UK-wide consistency

40. Within Option Two pharmacy would remain the only healthcare profession not regulated on a UK-wide basis. This presents a number of challenges, for example, the public expectation that pharmacists are regulated to consistent standards wherever they are practising across the UK.

Legislative considerations

41. The Department estimates that to draft, consult and bring into operation new primary legislation to support a modernised regulator in Northern Ireland and to repeal the Pharmacy (Northern Ireland) Order 1976, which governs the Society's powers as the local regulator of pharmacy, could take up to four years, subject to other Departmental and Assembly considerations. This would require a significant and resource intensive legislative programme to be delivered by the Department and its legal advisors. The Department would also be responsible on a continuing basis thereafter for updating the legislation and for approving, where appropriate, statutory instruments emanating from the legislation.
42. Government resource required to maintain effective working relations with regulators, including timely maintenance of policy and legislation, is likely to be most efficiently managed through a UK-wide regulatory arrangement.

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?

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

Other issues to note - Registrant and Premises Fees

43. 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. The level of fees is an important factor to: those applying to be registered; registrants; and to pharmacy premises owners.

44. To assist with this consultation the Society undertook an exercise to project likely fees that might be charged to registrants in order to recover the costs of regulatory activity of a standalone regulator. The Society's projected fees are set out at **Table 1** below. The Department has not yet validated these figures and continues to work with the Society to assess its projected fees and supporting financial data. Fees are subject to periodic review by the regulator. The registrant fees set out below do not include an element for professional leadership services. Professionals would need to decide whether to pay for professional leadership services from another body.

Table 1 – The Society's Projected Fees

Description	Projected fee
Registrant Fees	
Ongoing annual registration fee charged to pharmacists	£299
Ongoing annual registration fee charged to pharmacy technicians (provided technicians are subject to regulation)	£118
Premises Fees	
Retention of premises fee	£241
Registration fee	£590

**Option Three - Separate the regulatory and professional leadership functions.
Establish arrangements for the regulation of the pharmacy profession on a
UK-wide basis**

45. Option Three also delivers the required transparent and complete separation of the regulatory and professional leadership functions. This allows each distinct function to focus solely on its core role for the benefit of the public and the profession.
46. Regulation of the pharmacy profession in England, Scotland and Wales is already delivered by a single body, which is the General Pharmaceutical Council (GPhC). There are some positive aspects of establishing UK-wide arrangements for regulation of pharmacy.

Consistent UK-wide standards

47. Professional regulators set standards which cover education, registration, training, continuing professional development and fitness to practise. The regulator must be flexible to support the new pharmacy roles which are being developed in the Health and Social Care system in order to optimise patient outcomes. Modernised regulation must ensure clarity of standards, maintain public confidence, provide transparency in tackling fitness to practise, be responsive to change and protect patients and the public.
48. A UK-wide arrangement would deliver consistency of regulatory standards across the UK. This is important for a number of reasons. For example, should a registered professional's practice be called in to question, both the public and the profession can have confidence and be assured that consistent disciplinary and, where appropriate, fitness to practise processes are applied to the same standard of rigor and fairness as across the rest of the UK. Consistent standards also help facilitate the increasing movement of professionals across the UK. The Society currently works with GPhC to maintain parity in standards setting; however consistency is more likely to be completely and efficiently achieved through a UK-wide arrangement.

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?

Improved efficiency of the regulatory function

49. The broad functions which a regulatory body must deliver are the same regardless of the number of registrants it regulates. It is likely that significant opportunities for enhanced efficiencies exist within a larger regulatory body, both in terms of the cost of delivering regulation and also in relation to shared knowledge, resource, expertise and experience. These are important advantages in delivering more rigorous, cost effective and efficient regulation in the public interest. This may be particularly beneficial for example in areas important to public protection such as: fitness to practise cases (see [Annex 1](#)); setting and revising professional standards; and Inspection.

50. The position that larger regulators are more cost efficient was supported by the Professional Standards Authority in its 2012 paper '*Review of the cost effectiveness and efficiency of the health professional regulators*'. This paper found that scale (the size of the register) has an impact on efficiency. In addition to this, government resource required to maintain effective working relations with regulators, including timely maintenance of policy and legislation, is likely to be most efficiently managed through a UK-wide regulatory arrangement.

Q9.

- a) To what extent do you agree that enhanced efficiencies exist within larger regulatory bodies?*
- b) How might these impact on the delivery of more cost efficient and effective regulation which better protects the public? Please provide your views.*

Other issues to consider - Local influence on policy

51. Any move to a UK-wide arrangement may give rise to concerns that Northern Ireland may lose some influence on shaping regulatory policy. However, this could be mitigated in a number of ways, as is the case for pharmacy regulation in Scotland and Wales. For example, GPhC has agreed that, if this option was to be implemented, it would appoint a Northern Ireland Director to lead any operation here. Provision would also be made in statute, subject to appropriate approvals, that a member of the GPhC Council would live or work wholly or mainly in Northern Ireland. It should be noted that GPhC already operates effectively in both Scotland and Wales.

52. The Department is content with the current UK-wide arrangements for regulation of the other healthcare professions and is also content that it has sufficient input and scope to influence policy to reflect the local context. This is facilitated by effective communication with registrants and the public and, where necessary, through early and ongoing discussion with government and other local bodies to understand respective roles and responsibilities and to consider local need.

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?

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

Legislative considerations

53. At the time of creating the GPhC in Great Britain, provision was made to enable the transfer of the regulatory functions of the Society to GPhC should a Northern Ireland Health Minister decide to do so. The Department estimates that to draft, consult and bring into operation the required legislation to achieve the transfer, and to repeal the existing Pharmacy (Northern Ireland) Order 1976, and any other associated

legislative implications, could take two to three years, subject to other Departmental and Assembly priorities.

Registrant and Premises Fees

54. To assist with this consultation exercise GPhC has confirmed that, based on the assumption that the operating model would be as it is currently for England, Scotland and Wales, the fees GPhC would charge for Northern Ireland would be the same as fees it charges to its current registrant population. These are set out at **Table 2** below. Fees are subject to periodic review by the regulator. The Department continues to work with the GPhC to assess the costs associated with the option to move to a UK-wide arrangement. The registrant fees set out below do not include a fee for professional leadership services. As in Option Two above, professionals would need to decide whether to pay for professional leadership services from another body.

Table 2 – GPhC Projected Fees

Description	Projected fee
Registrant Fees	
Ongoing annual registration fee charged to pharmacists	£250
Ongoing annual registration fee charged to pharmacy technicians (currently regulated by GPhC)	£118
Premises Fees	
Retention of premises fee	£241
Registration fee	£590

Overview of the options

55. The Department's view is that Option One is not acceptable as it fails to secure the aim of complete separation of the regulatory and professional leadership functions. Option Two (Northern Ireland standalone regulator) and Option Three (UK-wide regulatory arrangement) both achieve this important aim which allows the regulator to focus clearly and solely on public protection.
56. From its pre-consultation research, the Department has identified a number of important factors for consideration. A Northern Ireland based regulator allows for a stronger local presence and provides an opportunity to build upon existing networks and relations. However, potential issues are ongoing capacity and financial resilience.
57. It is likely that there are opportunities for enhanced efficiencies within a larger organisation operating a UK-wide arrangement, both in terms of the cost of delivering regulation and also in relation to shared knowledge, resource, expertise and experience. This option also provides greater consistency across the UK in the full range of regulatory standards and processes. This has important benefits for the public and registrants alike, and indeed for large employers who operate UK-wide.
58. The UK government is currently considering a wide-ranging agenda aimed at modernising the regulation of healthcare professionals. One important aspect of this work is greater cost effectiveness of regulation and a focus on seeking to identify areas where efficiencies can be realised so that operational costs are minimised. The importance of cost effective regulation has been highlighted by stakeholders including the Professional Standards Authority in its August 2015 paper *Rethinking Regulation*.
59. Maintaining a Northern Ireland based regulator for a relatively small number of registrants gives rise to value-for-money considerations. In the Department's view, UK-wide regulatory arrangements for the other healthcare professions operate effectively and the Department believes

this can be replicated for pharmacy. The view that larger organisations are likely to be more efficient, given their relative size, is supported by the Professional Standards Authority which reviewed the efficiency of UK healthcare regulators. In addition to this, government resource required to manage relations with regulators is likely to be most efficiently managed through a UK-wide regulatory arrangement.

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?*

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

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

Professional Leadership

60. It is for the Minister to decide on arrangements for the statutory regulation of the pharmacy profession in Northern Ireland. Therefore, regulation is the primary focus of this consultation. However, the Department acknowledges that a decision to split the dual function of the Society has inevitable consequences for professional leadership. The professional leadership function of the Society is currently delivered by its Pharmacy Forum, which operates under the governance structures of the Society.

61. The establishment of professional leadership arrangements is principally a matter for the profession itself rather than a Ministerial decision. However, in pursuance of its strategic and policy aims, the Department's view is that it is extremely important that pharmacy professionals are adequately supported in their professional practice by the strongest possible professional leadership arrangements. The Department's view is that, overall, a credible and confident leadership body working independently from but alongside and complementing the role of a strong independent regulator is the ideal outcome.

62. In the event of a split in the Society's current functions, the Department is committed to working closely with professionals and other key stakeholders to help ensure a focus on collective leadership for the pharmacy profession and to offer appropriate assistance in establishing robust and sustainable arrangements for professional leadership. This consultation affords stakeholders an opportunity to consider and help develop such arrangements.

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

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

Impact Assessments

63. The Department has conducted an initial equality screening of the proposals contained within this consultation and does not consider any of the Section 75 groups to be adversely impacted by these proposals. A copy of the screening template is available as a separate document on the website and the key equality questions are contained in the consultation questionnaire.

64. The Department has also developed an initial regulatory impact assessment. Your views are also sought on this document via the relevant section in the consultation questionnaire which is published on the consultation webpage alongside a copy of the initial regulatory impact assessment document.

How to respond

You can respond to the consultation document by e-mail, letter or fax using the accompanying questionnaire on the Department's website (www.dhsspsni.gov.uk/consultations).

If this document is not in a format that suits your needs, please contact us and we can discuss alternative arrangements.

Before you submit your response, please read Annex A of the consultation questionnaire about the effect of the Freedom of Information Act 2000 on the confidentiality of responses to public consultation exercises.

Responses should be sent to:

E-mail: pharmacyregulation@dhsspsni.gov.uk

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The closing date for responses is 5pm on the 14 June 2016

Annex 1

Nine UK healthcare professional regulators:

General Chiropractic Council (GCC) regulates the chiropractic profession.

General Dental Council (GDC) regulates dentists and dental care professionals. This includes dental nurses, dental technicians, clinical dental technicians, dental hygienists, dental therapists and orthodontic therapists.

General Medical Council (GMC) regulates doctors.

General Optical Council (GOC) regulates the optical professions.

General Osteopathic Council (GOsC) regulates osteopaths.

General Pharmaceutical Council (GPhC) regulates pharmacists, pharmacy technicians and pharmacy premises in Great Britain.

Health and Care Professions Council (HCPC) regulates 16 health and care professions: arts therapists, biomedical scientists, chiropodists/podiatrists, clinical scientists, dietitians, hearing aid dispensers, occupational therapists, operating department practitioners, orthoptists, paramedics, physiotherapists, practitioner psychologists, prosthetists/orthotists, radiographers, social workers in England and speech and language therapists.

Nursing and Midwifery Council (NMC) regulates nurses and midwives.

Pharmaceutical Society of Northern Ireland (PSNI) is the regulatory and professional leadership body for pharmacists in Northern Ireland.

The Professional Standards Authority oversees the professional regulators, working with them to improve the way that professionals are regulated.

April 2014 to March 2015	PSNI	GPhC		GCC	GDC	GMC	GOC	GOsC	HCPC	NMC
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Registration Activity

Number of registrants	2,237 (individuals) 171 (bodies corporate) 551 (premises)	72,985 (50,292 pharmacists 22,693 pharmacy technicians 14,369 premises)		3,034	66,314 dental care professional (DCP); 39,385 dentists	266,959	20,762 (individuals) 2475 (bodies corporate)	4,970	330,887	686,782
Annual retention fee	£372	Pharmacist £240 Pharmacy Technicians £108 Premises £221		£800 practising £100 non-practising	£890 ³ dentist £116 DCP	£390 licensed £140 unlicensed	£290 ⁴ qualified registrant £25 student registrant	£320 (1 st year) £430 (2 nd year) £570 (3 rd year onwards)	£80	£120 ⁵

³ The GDC's annual retention fee rose from £576 to £890 for dentists on 30 October 2014. At the same time, the annual retention fee for DCPs reduced from £120 to £116.

⁴ The GOC's annual retention fee rose from £290 to £310 for registrants on 1 April 2015

⁵ The NMC's annual retention fee rose from £100 to £120 on 1 February 2015

April 2014 to March 2015	PSNI	GPhC		GCC	GDC	GMC	GOC	GOsC	HCPC	NMC
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Education Activity

Number of educational institutions the regulator is responsible for quality assuring	2	87		3	49	52	16	11 ⁶	142	77
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Number of Employees

Average number of employees	13	202		14	326	1,020	49	23	215	545
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⁶ The GOsC notes that its governing legislation requires it to quality assure qualifications rather than institutions. It quality assures 23 qualifications offered by 11 institutions

April 2014 to March 2015	PSNI	GPhC		GCC	GDC	GMC	GOC	GOsC	HCPC	NMC
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Fitness to Practise Activity

Number of cases <u>concluded</u> by investigating committee	12	131		67	1,229	2,528	176 (including case examiners)	49	810	2,208 (including case examiners)
Number of cases <u>concluded</u> by final fitness to practise committee	3	80		28	192	232	27	22	351	1,592

Annex 2

Terminology

65. It might be helpful to outline a brief description of the distinct functions generally undertaken by the 'Regulators of healthcare professionals' and by 'Professional Leadership' bodies. Although these are not legal or business definitions they help contextualise some of the issues raised in the consultation document.

Statutory Healthcare Professional Regulator

66. In broad terms, the primary purpose of a modern healthcare professional regulator is to ensure the protection of the public. This is achieved not only through the regulator taking action in circumstances where individuals fall short of professional standards but also by ensuring high standards of practice and behaviour in the first instance and, as a consequence, reducing the need for disciplinary intervention.

67. Overarching functions of a regulatory body include: setting the standards of behaviour; competence and education that professionals must meet; dealing with concerns from patients, the public and others about professionals who are unfit to practise because of poor health, misconduct or poor performance; and keeping registers of professionals who are fit to practise and setting the requirements for periodic re-registration for each profession.

68. Healthcare professionals in the UK must be named on the register maintained by the relevant regulator in order to practise.

Key principles of statutory regulation

69. In the 2007 Government White Paper '*Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century*', the UK Government set out a number of key principles that should underpin statutory professional regulation:

- Its overriding interest should be the safety and quality of the care that patients receive from health professionals.
- Professional regulation needs to sustain the confidence of both the public and the professions through demonstrable impartiality. Regulators need to be independent of government, the professionals themselves, employers, educators and all the other interest groups involved in healthcare.
- Professional regulation should be as much about sustaining, improving and assuring the professional standards of the overwhelming majority of health professionals as it is about identifying and addressing poor practise or bad behaviour.
- Professional regulation should not create unnecessary burdens, but be proportionate to the risk it addresses and the benefit it brings.
- The regulatory system should ensure the strength and integrity of health professionals within the United Kingdom, but be sufficiently flexible to work effectively for the different health needs and healthcare approaches within and outwith the NHS in England, Scotland, Wales and Northern Ireland and to adapt to future changes.

Professional Leadership Body

70. In broad terms, a professional leadership body will work to support, develop, promote, lead and advance the profession. An effective professional leadership body can be an advocate for the profession and its members and can speak with an authoritative voice on behalf the profession. At times this may involve lobbying with government and other bodies to represent and further the interests of members.

71. While a regulator sets standards and requirements to protect the public, the leadership body will: produce guidance on how these standards can be met in practice; promote excellence; and be a source of expert clinical information and advice to professionals. Senior figures in

professional representation bodies are often elected directly by the members.