General Pharmaceutical Council

GPhC response to DH consultation: *Promoting professionalism, reforming regulation*

1. Foreword

There is, and will continue to be, a lot of change ahead across the health and care sector. This requires all healthcare professionals, and the environments in which they work, to be flexible and focussed on the patients and public to whom they provide advice, support and treatment. In this context, we believe that a few things will not change. The first of these is that patients and the public will always have the right to expect safe and effective care from healthcare professionals. The second is that the attitudes and behaviours of healthcare professionals in their day-to-day work make a key contribution to patient safety and the quality of care. Finally, that the system and environment in which healthcare is delivered should be optimally designed and governed and act as enablers for professionals to deliver good quality care.

We welcome the consultation 'Promoting professionalism, reforming regulation', and the objectives it is seeking to achieve. At the heart of our strategy are the key objectives we want to achieve for patients and the public: 'assurance' and 'improvement'. We have long said that regulation must be more than enshrining and enforcing minimum standards. Our focus should be on promoting and supporting professionalism because it enhances patient safety and quality of care. The consultation reflects this view and is an opportunity to enhance the tools we have available to achieve these goals.

We also believe that a longer term vision for healthcare regulation is needed. Changes in society, technology and innovation will alter the way that healthcare is delivered, and the way that healthcare professionals provide services. Whilst it is hard to predict the future, we can be sure that people's health and care needs will continue to evolve and change and therefore so must the services to which they have access, and how they then access them. To meet those challenges we as regulators must also evolve.

The purpose of regulation must be clear and consistent, and its design must provide autonomy and flexibility as well as accountability. Our legal framework must serve that purpose so that we are equipped to regulate effectively, and we should be held to account for doing so. It is only then that we can assure the delivery of a pharmacy workforce, pharmacy premises and services that are fit for the future, providing safe and effective care to patients and the public.

2. About the GPhC

We regulate pharmacists, pharmacy technicians and pharmacies in Great Britain. We work to assure and continually improve standards of care for people using pharmacy services, by:

- Setting standards for pharmacy professionals and pharmacies to enter and remain on our register.
- Seeking assurance that pharmacy professionals and pharmacies continue to meet our standards, including by inspecting pharmacies.
- Acting to protect the public and to uphold public confidence in pharmacy if there are concerns about a pharmacy professional or pharmacy on our register.
- Helping to promote professionalism, supporting continuous improvement and assuring the quality and safety of pharmacy.

3. Introduction

3.1 Regulation of pharmacists, pharmacy technicians and registered pharmacies transferred to the GPhC in 2010, and therefore our legislation is relatively new compared to the other regulators. We have seen the benefits of this in that our legislation is not as prescriptive or cumbersome as older versions, and therefore we have benefitted from being able to regulate in a more flexible way. At the same time we have also seen how, in a short period of time, our legislation could be improved as the pharmacy landscape and that of the health and care environment change at a rapid rate.

3.2 Our Council has made clear in its strategy what we want to achieve for patients and the public.

'Firstly, we want to provide assurance to patients and the public about the standards of practice and quality of services they will receive from pharmacy professionals and pharmacies, now and in the future. Secondly, we want to play our part in improving the quality of pharmacy practice – so that patients and the public can receive better care and advice, which will in turn improve their health and wellbeing.'

3.3 Regulation is most effective at ensuring safe and effective care for people who use pharmacy services when it has a wide range of flexible regulatory tools that can be used to provide assurance and help to promote improvement, which reduces the risks of poor care in the future. This means we require a legal framework that provides us with the flexibility to regulate in a changing context, recognising the role of technology and innovation and the changing needs of a population that becomes ever more diverse and informed. This framework could be delivered through one or more section 60 orders, and would not require a Bill.

3.4 Flexibility must be balanced with clear arrangements for accountability. In order to hold the confidence of the public and professions, we must ourselves be open to the same principles of giving assurance and driving improvement through effective oversight of what we do and how we do it. The consultation offers many options for how we may assure and improve both pharmacy and ourselves in new ways. We are open to these options; in fact we have proposed many of them over the course of the years of discussion on reform. Regulatory models should be designed to serve a clear purpose. It follows that:

- The people and places that are regulated must be the right ones to provide safe and effective care
- The regulatory model must suit that system of care.
- The oversight of the regulatory model must be focused on the right things.

3.5 If this is the case, then the entire system of care, regulation and public accountability will be able to drive both assurance and improvement. The wrong choices now will have adverse consequences over many years ahead.

4. Protecting the public

Deciding which professional groups are subject to regulation

4.1 Health and social care has changed considerably in recent years with new services, new technology, and new roles developing to meet the changing needs of the population; and it will continue to change. It is therefore essential that regulation should be flexible or it risks embedding approaches which become redundant or outdated in the future. That may mean that new professions need regulation or that, as new roles emerge, some professions will no longer require regulation. The form of that regulation must also develop over time.

4.2 It is for governments to determine which professions should be regulated and how they should be regulated. In making these decisions, we believe there are some important tests that need to be met and the rationale for decisions should be clear and transparent. These are:

- Regulation should serve the public interest and therefore members of the public, and particularly patients, must be involved in the decisions.
- Sound regulation is only effective with the consent of the regulated and so aspirant or regulated groups must be involved in decisions.
- Any model for regulation should support professionalism and improvement beyond minimum standards.
- Regulation should enable safe multidisciplinary working and avoid reinforcing the segregation of professional boundaries.
- Given the way in which the PSA and regulators are funded, there could be a perceived conflict of interest, and the government must be mindful of this when seeking advice about which groups are subject to regulation.
- The competing priority of ensuring a suitable health and care workforce needs to be balanced against appropriate regulation to ensure the quality of a workforce that delivers care safely.
- The process for making decisions, and the decisions themselves, should be robust and transparent.
- For any decisions on de-regulation, consideration should be given not just to current roles but possible future roles to avoid short-sighted decisions.
- The impact of de-regulation on a professional group should be considered. The presence of a regulatory body may mean that other organisations, such as professional bodies, are not

resourced to provide the services of a regulator. This may lead to negative unintended consequences for professional groups subject to de-regulation and the people to whom they provide services.

4.3 The criteria proposed for decision-making require further thought and development in collaboration with regulators and others, for example patient and public representative organisations, professional leadership bodies and the regulated professionals themselves.

4.4 The proposed model for assessing whether professional groups should be regulated does not take account of the diversity of practice within and across professional groups in the evolving health and care system. For example, whilst the majority of pharmacy professionals work in patient facing roles (within community pharmacies or in hospitals providing care to large numbers of patients and the members of the public on a day to day basis), many work within other areas of practice, such as industry, academia and research (where perhaps there is less patient contact, but their attitudes and behaviours will have an impact on the safe and effective care that people receive). There is a risk that a professional group might be regulated because a small number perform a 'high risk' activity or are un-regulated because the majority performs a 'low-risk' activity. The amount of contact a professional has with patients and the public should not equate to a presumed 'level of risk'. We have learnt from previous failures within the NHS that professionals who have relatively little contact with patients, but who have senior roles within hospitals and trusts can have a significant impact on the safe and effective care that people receive.

4.5 Nor do the proposals take account of changes to the way in which professional groups may practise in the future. For example within pharmacy practice, advancements in technology have meant that services are increasingly being provided at a distance, and with this come additional risks that need to be mitigated. Equally, the use of robotics within the dispensing service when properly applied can mitigate some of the risks around human error. These kinds of innovations demonstrate that a 'risk' profile does not remain static or measurable at one particular point in time and underline further the need for any changes to the regulatory regime to be flexible in practice.

4.6 When statutory regulation or accredited voluntary registers are not appropriate for groups, there would be advantages to the use of prohibition orders. We would support prohibition orders because it is right to consider not only traditionally defined professionals but also unregistered staff and their impact on the delivery care. We also believe it is a sound method to have a full range of options available when making decisions on how to protect the public.

4.7 We draw parallels here to our work on establishing disqualification procedures for pharmacy owners We have not been able to use our disqualification powers in relation to registered pharmacies because the relevant legislation is very narrowly and prescriptively drafted. We have seen that this can undermine confidence, through misunderstanding of the powers we hold and

the tests that must be applied. A pharmacy defence organisation has called for a review of our powers, and we believe a legitimate debate should be had.

4.8 If prohibition orders and negative registration were to be taken forward, further consideration will need to be given to ensure that the legal framework is sufficiently flexible, and proportionate to be used effectively to protect the public. In addition the practicalities of such a list, for example who administers the list and how decisions are made would need to be considered. Again, further collaboration with patients and the public and others will be necessary.

Number of regulatory bodies

4.9 Regulation of health professionals has developed alongside the professional groups for the most part. This has meant that professional groups have different regulators and differing models of regulation because they were developed at different times. This has resulted in significant variations in the ways in which regulators can address the same, or similar issues and also complexity for those who are dependent on regulation. However, it does also have advantages, not least of which is that the regulators have an understanding of the context of the professional groups they regulate. This is particularly the case for pharmacy as we regulate registered pharmacies as well as pharmacy professionals.

4.10 The future number and configuration of regulators is a decision for the Governments. However, we believe there are a number of tests that should be used to support any decision to make changes to the current system. These are:

- There should be clear benefits to patients and members of the public to making any change that demonstrably provides greater benefit than the inevitable distraction placed on professionals subject to any change.
- The regulators in whatever number or configuration should be well understood by the public and they should be accessible. The rationale for any change must be driven by the needs of the public and the professional context rather than by an academic algorithm.
- The cost implications of reducing or reconfiguring the number of regulatory bodies needs to be set out clearly and weighed against the benefits for patient safety and accessibility.
- They should have the necessary powers and resources to discharge their functions to assure, improve and support professionalism on behalf of members of the public.
- The contextual understanding of professions, where and how they work must not be lost. The recent decision to create a regulator for social workers in England demonstrates the importance of a regulator that understands a profession and the context in which its members work.

4.11 We reject the notion of “a high street regulator”, which has sometimes been proposed as an option for merger, as it is not reflective of the many ways in which patients, the public and carers access healthcare services. If the definition of ‘high street healthcare’ means services available to the public in retail settings, that is in itself quite restrictive, and does not reflect ways in which access may occur. For example, within the context of pharmacy, services will be increasingly delivered online (both as clinical consultations and the dispensing of medicines), and delivered directly to a patient’s home, as well as a variety of other settings not on the high street , such as care homes.

The role of the PSA

4.12 We have no strong opinions on the future role of the PSA. We urge the Governments to focus on the purpose of professional regulation, and the framework that that implies. The level of oversight and accountabilities of the regulators should follow once there is this clarity.

4.13 The future role of the PSA should demonstrably provide additional benefits and protection for patients and the public beyond that provided individually and collaboratively by regulators.

5. Responsive regulation

5.1 We welcome the recognition that regulators require more flexibility to adapt to new ways of working. In pharmacy regulation, we have moved away from setting minimum standards, and from a prescriptive approach to those standards. We recognise that pharmacy professionals are exactly that; professionals who must exercise judgement and ensure that person-centred care is delivered wherever they practise. Our standards for both pharmacy professionals and registered pharmacies focus on the outcomes that patients and the public have a right to expect and we seek assurance that those outcomes are being met using the regulatory levers that we have, for example educational outcomes, revalidation, registration, fitness to practise procedures and inspection. We ask governments to be clear about the purpose of regulation and the outcomes that they expect regulators to achieve, and then provide us, and others, with a legal framework that enables and empowers us to regulate in a proportionate, flexible way to achieve those outcomes.

5.2 We agree that all regulators should have the same tools at their disposal for managing and responding to concerns. Regulators should also be able to use other approaches for managing concerns as they consider appropriate for ensuring safe and effective care. For example, the regulators should be given the flexibility to develop alternative mechanisms for managing concerns that fall outside the current tools we use, whether that is mediation or something else. Otherwise there is a risk that we are unable respond in a flexible manner as the types of

concerns we receive change over time. A legal framework that provides us with the flexibility to design additional tools through rules and regulations would be welcome.

5.3 Fitness to practise currently can feel like an adversarial process, invariably causing anxiety and fear for those involved. Instead of focusing on the needs of patients, professionals are concerned about 'what the regulator will say or do'. Fitness to practise processes should be focused on the most serious types of concerns, and we believe that there should be further opportunity to look at the purpose of fitness to practise, not just the mechanisms for dealing with concerns. We can then use our other regulatory levers, such as revalidation, inspection and registration to support and promote professionalism with the aim of improving the quality and safety of the care that people receive.

5.4 We believe that much that can be done without new legislation; for example our revalidation model has been designed, piloted and consulted on without the need for additional rules and regulations. It will be implemented in 2018, and has been widely welcomed by the pharmacy sector. We are also developing guidance for pharmacy owners about supporting and empowering the whole pharmacy team. Our role as the regulator of registered pharmacies provides us with the opportunity to ensure that the environment in which pharmacy services are delivered supports and enables the delivery of safe and effective care.

Supporting professionalism

5.5 The consultation raises important questions about the role of regulation in supporting and promoting professionalism. We believe the professional knowledge, attitudes and behaviours of the people working in pharmacy offer the best assurance to people using pharmacy services. Our most effective role is in helping to promote an environment in which professionalism can flourish. We strongly agree that regulators have a role in supporting professionalism.

5.6 Our standards for pharmacy professionals are outcome focused. They support and promote professionalism, making clear the expectations of patients and members of the public. The standards are not prescriptive but explain the attitudes and behaviours that pharmacy professionals must demonstrate. We have been aware that we must reflect what we say about our expectations of professionalism through all our work, for example when we manage concerns.

5.7 We have already made changes to the way we regulate pharmacy professionals and registered pharmacies to play a more effective role in supporting professionalism and we are working now to do more:

- Our standards for pharmacy professionals, developed collaboratively with patients and pharmacy professionals came into effect in May 2017. These standards set the common expectations for person-centred professionalism as nine outcomes applicable to the full range of roles and settings of pharmacy practice. This approach was welcomed by patients and the public, as well as those we regulate, during the consultation. We also heard from some that the standards we had developed could equally apply to other healthcare professionals. We also recognise that the development of standards is not the end of our regulatory role. We have a clear responsibility to communicate these to pharmacy professionals, patients, employers and others on an ongoing basis, so that the standards are understood and applied in practice.
- Our approach to revalidation, again co-created with pharmacy professionals and taking into account the expectations and views of members of the public and patient representatives, is designed to encourage reflection upon those professional standards and on the benefits to the people using a pharmacy professional's services. Our revalidation model demonstrates what we have achieved without legislative changes in the context of the evolving profession.
- Through inspection of registered pharmacies, we seek assurance that our standards are being met and require the development of improvement action plans in those circumstances that standards are not met. We provide pharmacy owners with inspection reports which can be used by owners to improve the quality of services they provide. We will also begin to publish inspection reports once the necessary legal power is commenced.
- We are now turning our attention to the initial education and training of pharmacy professionals to ensure that our standards are woven into training, alongside the skills to reflect upon learning and practice to drive improvement and foster ongoing assurance.

5.8 As well as focusing on professionalism, we have also acted in our role as the regulator for registered pharmacies to ensure that the ways that people employ and deploy pharmacy professionals are supportive of professionalism. There is undoubtedly interplay between the setting of practice and the people in it which can have a significant impact on both professional behaviours and the experience and outcomes for patients.

5.9 We believe that professionalism can be further supported by regulators through:

- Engaging further with patients, the public and their representatives to understand their current and changing expectations of care, in particular the common standards and approaches they expect from all health professionals.
- Communicating the expectations placed on professionals through supportive methods designed to assist adaptation in the context of change, such as sharing learning we gather from the concerns we hear from members of the public digitally
- Working more regularly and collaboratively alongside the organisations that employ, fund and support professionals.

6. Efficient regulation

6.1 Working more closely together is undoubtedly a way in which the regulators can drive both greater efficiencies and effectiveness and has not required legislative change. Healthcare professionals already work alongside one another and increasingly do so as health and social care become further integrated, for example through the work of the sustainability and transformation plans in England. Similarly, so too must the regulators, especially as distributed multi-disciplinary team working becomes more common and patients and the public will less easily recognise the boundaries between professions simply based on where people work and what people do. It is also notable that members of the public often will not recognise or indeed be interested in the differences between regulators. Many may see the role of professional and systems regulators as essentially being the same thing.

6.2 The purpose of regulators' collaboration needs to be clearly articulated so that it can be used as an appropriate test for evaluating efficiency and effectiveness. We believe the purpose of collaboration is to make the experience of engaging with regulatory bodies trusted, consistent, simple, and valued by members of the public, health professionals, their employers and any other party with a stake in regulation. Therefore, the focus on possible financial savings, which is likely to be a by-product with no guarantee that the benefit flows to patients, should not be a primary motivation or driver for that collaboration. Indeed it is at present unclear to us whether any projected savings would in fact materialise, or whether they would be significant enough to outweigh any disadvantages.

6.3 There are already many examples of effective co-operation between the health regulators but we agree and are keen to develop this further. We have, for example:

- Carried out joint inspections with other systems regulators, the Care Quality Commission and MHRA, when looking at services that cut across the GPhC and others; and
- Worked collaboratively with other professional regulators on areas such as conflicts of interest, the duty of candour and pandemic flu statements.

6.4 Mandating and requiring collaboration to be reported on through clear accountability processes could provide a useful opportunity for regulators to show how they are continuing to work together in the interests of patients and the public.

6.5 Often the barrier to effective collaboration is felt to be moving decisions through differing governing structures, and the scheduling of such collaboration when each regulator works to a different timetable. Whilst one solution could be to look at new legislation that mandates such collaboration, or changes to the governance structures of the organisations we believe that there are other more efficient, less costly mechanisms that can be adopted much more rapidly. For example, through effective agreements on how certain types of joint-working are governed and led.

6.6 We strongly believe that the principle of joint working should not be limited to the professional regulators. The environments in which health professionals work are critical to delivering the context for professional, safe and effective care. If the environments are not supportive of the professionals who work in them, then the individuals in that place (both professionals and patients) suffer. As the regulator of both pharmacy professionals and registered pharmacies we believe the interplay between the regulation of people and places is fundamental to assuring and improving health and social care.

6.7 It is a decision for government on whether structural change is needed to foster more effective collaboration between regulators but we think the tests of any decision should be:

- That the views of the public and of the professions are taken into account.
- That the understanding of the context of health professionals' practice should not be lost in any future arrangements.
- That the outcomes achieved are enhanced trust, consistency, simplicity and value for the people who are regulated or rely upon regulation.

Data driven regulation

6.8 Regulation has evolved from a system based on assumptions about the role and functions of regulatory bodies and the impact they have on regulated communities and the people they are designed to protect. This evolution has taken place as data and the insight it gives have grown from the work of all the regulators.

6.9 The power of data to inform regulation is great, but it is also necessary to be realistic about what can be achieved. It is unlikely, based on the evidence that we have, that regulators will be able to use data in such a way to intervene before harm occurs in a particular instance. However, we can use our data, especially when shared, to support professionalism, empowering the people and places we regulate to increasingly avoid the rare instances of harm and more widely improve the experience and outcomes of patients. There is also an opportunity for data driven regulation to provide us with a greater understanding of equality, diversity and inclusion issues and the effect of regulation on these.

6.10 We are committed to looking at how best we can share the data we hold and related insights across our functions, for example:

- Within fitness to practise, not only the learning from cases but also the information we hold about concerns that do not progress through the fitness to practise process.
- Through CPD returns and in the future revalidation.

- Uniquely through our work in regulating registered pharmacies and inspection - information and data we hold about meeting our standards, and the publication of inspection reports.

6.11 Data sharing might also assist with targeting our resources more effectively. For example, we may be able to see patterns about certain geographies, programmes of professional education or types of service which suggest that we should scrutinise areas using our tools for assuring standards more frequently or more intensely. This is something we are currently exploring in our role as the regulator for registered pharmacies and as a result of the introduction of revalidation for pharmacy professionals.

Autonomy and accountability

6.12 Regulation is most effective when it is independent from governments, flexible in the face of change, but accountable through a variety of transparent mechanisms. As we have said, we believe we need greater flexibility than we currently have because our legislation can sometimes be a barrier to our taking appropriate and timely action and seeking change can be a long process. Further, we suggest that we could provide such assurances to the parties to whom we are accountable, granted that additional flexibility. This would ensure there are checks and balances over our decisions and actions.

6.13 Firstly we would gladly offer consistent accountability to all legislatures on the breadth of our work. We welcome direct accountability to Parliament, the Scottish Parliament and the Welsh Assembly across the discharge of all of our functions to regulate pharmacists, pharmacy technicians and registered pharmacies.

6.14 Secondly we would suggest that there may be different mechanisms for us to be held to account, perhaps some collectively with other regulators, which we would want to explore so that our work is more visible and can be tested consistently by governments, the public and the professions.

6.15 Finally, the culture of autonomy and accountability should run like a strong thread through the entire system. Health professionals and regulators should all have the flexibility to innovate, change and respond to the needs of the people, but do that within a clear framework of accountability. This culture is the one that will empower the whole system to adapt and improve safely, in the face of change.

Governance

6.16 Our Council is constituted of seven pharmacy professionals and seven lay members, with a lay chair. The council directs the strategy of the organisation and holds the executive to account for its performance. This method of governance has proved very effective because there is:

- Separation between the council and the executive providing clear lines of accountability. Without that separation it is much more difficult for the executive to be held to account for their actions.
- Balanced representation of the views of professionals and informed lay people.

6.17 Given the clear effectiveness of our current arrangements we will continue to value clear lines of accountability and a balance of professional and lay perspectives. The professional members are important and necessary members of the Council, who ensure that the context in which regulated professionals practice is understood, and whose presence on Council also enhances the confidence of the regulated professions in the deliberations and decisions made. It is for these reasons that a professional and lay Council is most valuable. When considering the number of Council members, it is important that the size is not so small that it precludes effective decision making and continues to ensure that the context of the regulated is considered. Decisions in the past have resulted in a reduction in the size of the Councils of regulatory bodies, and there is no doubt that this has improved governance overall; but the case for a further reduction is not made, in our view.

6.18 The breadth of the structure of our Council enables us to draw upon a wealth of experience of different models of governance, and we remain unconvinced of the potential benefits of a unitary board where the executive do not have any clear lines of accountability within the organisation. Such an arrangement compromises the accountability of the Chief Executive – who is then playing two roles of blurred identity, which have the potential to conflict.

6.19 The views of employers are critical to the way in which we regulate. Much of the regulatory model is dependent on employers understanding how we regulate and their responsibilities in relation to that. This is especially true in the context of pharmacy as we regulate registered pharmacies as well as the pharmacy professionals who work in them and in other settings. Employers within the pharmacy context include not only NHS organisations but also commercial organisations of varying size and purpose. We consider the important views of employers through a number of different methods, such as:

- Strategic relationship managers for very large employers.
- Employer representatives on working groups such as that for revalidation.
- Consultation and engagement activities.

6.20 We feel however that the interests of employers and those of the regulator and the regulated can sometimes not be aligned fully. The regulator has an important role in balancing the interests of the patients, of professionals and the economic realities of a commercial operation. Therefore, we do not agree that governing councils or boards should be mandated to be constituted to include employers. The existing legal duties to consult, including with employers, and the other methods of engagement seem more appropriate to include the views of employers in our decision-making but where necessary to take action in the interest of the public that may not be consistent with the interests of employers.

6.21 All regulators should have a clearly stated strategy and model for the assurance they provide that the people and places they regulate are safe and effective. We have been developing our approach in this area and see the range of levers we have available to us as working collectively to provide that assurance. From initial education and training, registration and renewal of registration, revalidation for pharmacy professionals, quality assurance of registered pharmacies, and to investigating and acting upon concerns, the whole model drives assurance and improvement.

Fees

6.22 The cost of regulation sits with the people and places that we regulate. This means that we are accountable not only to the Governments and the general public for the services we provide but also to pharmacy professionals and registered pharmacies to make sure we are performing those services as efficiently as possible.

6.23 We have already been working to make sure that we are both efficient and effective and that we evidence it. We were able, through a commitment to efficiency, to decrease fees for pharmacy professionals in 2011 and even after an increase in 2015, the cost remains lower than it was in 2010.

6.24 We agree therefore that if savings are realised, which do not need to be committed to further effective public protection or to support professionalism, then fee reductions would be appropriate. However, it is difficult based on the proposals in this consultation to determine the impact on registration fees and more information will be required to be able to determine that impact. It should be noted that savings through joint-working or merger may take some time to be realised and that there is also an opportunity cost to be factored into the balance.

7 Closing remarks

We are pleased that there is an opportunity for reform that places supporting professionalism so high in its ambitions. We have long stated that supporting professionalism is the most effective way that we can act to empower pharmacy professionals to provide safe and effective services and improve them. We remain committed to ensuring that the way in which we regulate pharmacy must improve the safe and effective care that people receive. We will continue to engage with people to ensure that regulation does this.

We have already made considerable progress since we were formed in 2010 to embody a regulatory approach that provides both assurance and drives improvement in the interests of patients. We have done much of that without the need for legislative reform. We will continue to act now, before any legislative reform comes so that our approach is more collaborative, more supportive of professionalism, informed further by data, well governed, efficient and effective so that we can continue to demonstrate to the public that the trust they have in pharmacy professionals and pharmacy is well placed.

8 Questions

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

It is for governments to determine which professions should be regulated and how they should be regulated. And we agree that the UK governments should seek advice on which groups of healthcare professionals should be regulated. In making decisions about which groups should be regulated, we believe there are some important tests that need to be met and the rationale for decisions should be clear and transparent. The tests are set out in para 4.2.

One of tests we outline is the need to be mindful of the perceived conflict of interest of the PSA, particularly given they are funded by the regulators (and therefore by those who are regulated) and also oversee voluntary accredited registers.

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

Our experience in regulating pharmacy professionals and registered pharmacies means that we are able to see how some elements of the criteria, and the criteria as a whole, may not work in practice – given the way in which care and the context in which it is delivered continues to evolve. We are of the view that the criteria proposed for decision making require further thought and development in collaboration with others, for example patient and public representative organisations, professional leadership bodies and the regulated professionals themselves.

The proposed model for assessing whether professional groups should be regulated does not take account of the diversity of practice within and across professional groups in the evolving health and care system. Nor do the proposals take account of changes to the way in which professional groups may practise in the future. There is a risk that a professional group might be regulated because a small number perform a 'high risk' activity or are un-regulated because the majority perform a 'low-risk' activity. The amount of contact a professional has with patients and the public should not equate to a presumed 'level of risk'. We have learnt from previous failures within the NHS that professionals who have relatively little contact with patients, but who have senior roles within hospitals and trusts can have a significant impact on the safe and effective care that people receive.

Within pharmacy practice, advancements in technology have meant that services are increasingly being provided at a distance, and with this come additional risks that need to be mitigated. Equally, the use of robotics within the dispensing service when properly applied can mitigate some of the risks around human error. These kinds of innovations demonstrate that a 'risk' profile does not remain static or

measurable at one particular point in time and underline further the need for any changes to the regulatory regime to be flexible in practice.

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

In making decisions about which groups should be regulated, we set out in para 4.2 some important tests that need to be met and the rationale for decisions should be clear and transparent. These included:

- For any decisions on de-regulation, consideration should be given not just to current roles but possible future roles to avoid short-sighted decisions.
- The impact of de-regulation on a professional group should be considered. The presence of a regulatory body may mean that other organisations, such as professional bodies, are not resourced to provide the services of a regulator. This may lead to negative unintended consequences for professional groups subject to de-regulation and the people to whom they provide services.

Decisions to de-regulate should be treated cautiously, and must involve collaboration with patients and the public, the professionals who are at risk of de-regulation and organisations that support those professionals.

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

When statutory regulation or accredited voluntary registers are not appropriate for groups, there would be advantages to the use of prohibition orders. We would support prohibition orders because it is right to consider not only traditionally defined professionals but also unregistered staff and their impact on the delivery care. We also believe it is a sound method to have a full range of options available when making decisions on how to protect the public.

We draw parallels here to our work on establishing disqualification procedures for pharmacy owners We have not been able to use our disqualification powers in relation to registered pharmacies because the relevant legislation is very narrowly and prescriptively drafted. We have seen that this can undermine confidence, through misunderstanding of the powers we hold and the tests that must be applied. A pharmacy defence organisation has called for a review of our powers, and we believe a legitimate debate should be had.

If prohibition orders and negative registration were to be taken forward, further consideration will need to be given to ensuring that the legal framework is sufficiently flexible, and proportionate to be used

effectively to protect the public. In addition the practicalities of such a list, for example who administers the list and how decisions are made would need to be considered. Again, further collaboration with patients and the public and others will be necessary.

Q5: Do you agree that there should be fewer regulatory bodies?
Q6: What do you think would be the advantages and disadvantages of having fewer professional regulators?

It is a decision for the Governments on the future number and configuration of regulators. However we believe there are a number of tests that should be used to support any decision to make changes to the current system. Please see para 4.10 for further detail.

We also reject the notion of "a high street regulator", which has sometimes been proposed as an option for merger, as it is not reflective of the many ways in which patients, the public and carers access healthcare services. If the definition of 'high street healthcare' means services available to the public in retail settings, that is in itself quite restrictive, and does not reflect ways in which access may occur. For example, within the context of pharmacy, services will be increasingly delivered online (both as clinical consultations and the dispensing of medicines), and delivered directly to a patient's home, as well as a variety of other settings not on the high street , such as care homes.

We understand that one of the reasons for considering consolidation of regulators is the financial efficiencies of mergers. However we remain unconvinced about the evidence for this. We believe that many of the financial efficiencies could be gained through more effective collaboration and co-operation between regulators, using some of the examples set out in the consultation. And this can be done without the need for legislation.

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

No. There are many ways in which the regulatory bodies could be configured. The focus of any reconfiguration should be whether a new configuration can evidence and demonstrate better outcomes for patients and the public than currently.

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

Yes. We agree that all regulators should have the same tools at their disposal for managing and responding to concerns. Regulators should also be able to use other approaches for managing concerns as they consider appropriate for ensuring safe and effective care. For example, the regulators should be given the flexibility to develop alternative mechanisms for managing concerns that fall outside the current tools we use, whether that is mediation or something else. Otherwise there is a risk that we are

unable respond in a flexible manner as the types of concerns we receive change over time. A legal framework that provides us with the flexibility to design additional tools through rules and regulations would be welcome.

Fitness to practise currently can feel like an adversarial process, invariably causing anxiety and fear for those involved. Instead of focusing on the needs of patients, professionals are concerned about 'what the regulator will say or do'. Fitness to practise processes should be focused on the most serious types of concerns, and we believe that there should be further opportunity to look at the purpose of fitness to practise, not just the mechanisms for dealing with concerns. We can then use our other regulatory levers, such as revalidation, inspection and registration to support and promote professionalism with the aim of improving the quality and safety of the care that people receive.
Q9: What are your views on the role of mediation in the fitness to practise process?

We urge the UK governments to give regulators a legal framework that provides us with the flexibility to design additional tools through rules and regulations. Otherwise there is a risk that we are unable respond in a flexible manner as the types of concerns we receive change over time.

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

Yes. PSA standards should reflect the importance of all the regulators tools that contribute to safety and quality of care. While fitness to practise is an important part of the regulatory framework, it is of course not the only or most important of the regulators functions.

In addition, we would welcome additional oversight of our work to regulate registered pharmacies by the PSA.

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

Yes, given our current statutory powers. However, if we were to be given a regulatory framework similar the GMC, with separation of investigation and adjudication and a right of appeal held by the GPhC, then this power may not be necessary.

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

Yes. We have long said that regulators have a role to play in supporting professionalism. We believe the professional knowledge, attitudes and behaviours of the people working in pharmacy offer the best

assurance to people using pharmacy services. Our most effective role is in helping to promote an environment in which professionalism can flourish.

Our standards for pharmacy professionals are outcome focused. They support and promote professionalism, making clear the expectations of patients and members of the public. The standards are not prescriptive but explain the attitudes and behaviours that pharmacy professionals must demonstrate. We have been aware that we must reflect what we say about our expectations of professionalism through all our work, for example when we manage concerns.

We have given examples of our work in this area in para 5.7.

Q13: Do you agree that the regulators should work more closely together? Why?
Q14: Do you think the areas suggested above are the right ones to encourage joint working? How would those contribute to improve patient protection? Are there any other areas where joint working would be beneficial?

We have responded to Q13 and 14 together. Working more closely together is undoubtedly a way in which the regulators can drive both greater efficiencies and effectiveness and has not required legislative change.

Healthcare professionals already work alongside one another and increasingly do so as health and social care become further integrated, for example through the work of the sustainability and transformation plans in England. Similarly, so too must the regulators, especially as distributed multi-disciplinary team working becomes more common and patients and the public will less easily recognise the boundaries between professions simply based on where people work and what people do. It is also notable that members of the public often will not recognise or indeed be interested in the differences between regulators. Many may see the role of professional and systems regulators as essentially being the same thing.

The purpose of regulators' collaboration needs to be clearly articulated so that it can be used as an appropriate test for evaluating efficiency and effectiveness. We believe the purpose of collaboration is to make the experience of engaging with regulatory bodies trusted, consistent, simple, and valued by members of the public, health professionals, their employers and any other party with a stake in regulation. Therefore, the focus on possible financial savings, which is likely to be a by-product with no guarantee that the benefit flows to patients, should not be a primary motivation or driver for that collaboration. Indeed it is at present unclear to us whether any projected savings would in fact materialise, or whether they would be significant enough to outweigh any disadvantages.

There are already many examples of effective co-operation between the health regulators but we agree and are keen to develop this further. We have, for example:

- Carried out joint inspections with other systems regulators, the Care Quality Commission and MHRA, when looking at services that cut across the GPhC and others; and
- Worked collaboratively with other professional regulators on areas such as conflicts of interest, the duty of candour and pandemic flu statements.

Mandating and requiring collaboration to be reported on through clear accountability processes could provide a useful opportunity for regulators to show how they are continuing to work together in the interests of patients and the public. Often the barrier to effective collaboration is felt to be moving decisions through differing governing structures, and the scheduling of such collaboration when each regulator works to a different timetable. Whilst one solution could be to look at new legislation that mandates such collaboration, or changes to the governance structures of the organisations we believe that there are other more efficient, less costly mechanisms that can be adopted much more rapidly. For example, through effective agreements on how certain types of joint-working are governed and led.

We strongly believe that the principle of joint working should not be limited to the professional regulators. The environments in which health professionals work are critical to delivering the context for professional, safe and effective care. If the environments are not supportive of the professionals who work in them, then the individuals in that place (both professionals and patients) suffer. As the regulator of both pharmacy professionals and registered pharmacies we believe the interplay between the regulation of people and places is fundamental to assuring and improving health and social care.

It is a decision for government on whether structural change is needed to foster more effective collaboration between regulators but we think the tests of any decision should be:

- That the views of the public and of the professions are taken into account.
- That the understanding of the context of health professionals' practice should not be lost in any future arrangements.
- That the outcomes achieved are enhanced trust, consistency, simplicity and value for the people who are regulated or rely upon regulation.

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

The power of data to inform regulation is great, but it is also necessary to be realistic about what can be achieved. It is unlikely, based on the evidence that we have, that regulators will be able to use data in such a way to intervene before harm occurs in a particular instance. However, we can use our data, especially when shared, to support professionalism, empowering the people and places we regulate to

increasingly avoid the rare instances of harm and more widely improve the experience and outcomes of patients. There is also an opportunity for data driven regulation to provide us with a greater understanding of equality, diversity and inclusion issues and the effect of regulation on these.

We are committed to looking at how best we can share the data we hold and related insights across our functions, for example:

- Within fitness to practise, not only the learning from cases but also the information we hold about concerns that do not progress through the fitness to practise process;
- Through CPD returns and in the future revalidation; and
- Uniquely through our work in regulating registered pharmacies and inspection - information and data we hold about meeting our standards, and the publication of inspection reports.

Data sharing might also assist with targeting our resources more effectively. For example, we may be able to see patterns about certain geographies, programmes of professional education or types of service which suggest that we should scrutinise areas using our tools for assuring standards more frequently or more intensely. This is something we are currently exploring in our role as the regulator for registered pharmacies and as a result of the introduction of revalidation for pharmacy professionals.

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

Yes. Regulation is most effective at ensuring safe and effective care for people who use pharmacy services when it has a wide range of flexible regulatory tools that can be used to provide assurance and help to promote improvement, which reduces the risks of poor care in the future. This means we require a legal framework that provides us with the flexibility to regulate in a changing context, recognising the role of technology and innovation and the changing needs of a population that becomes ever more diverse and informed. This framework could be delivered through one or more section 60 Orders, and would not require a Bill. We also agree that flexibility must be balanced with clear arrangements for accountability. This would ensure there are checks and balances over our decisions and actions.

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

Yes. Firstly we gladly offer consistent accountability to all legislatures on the breadth of our work. We welcome direct accountability to Parliament, the Scottish Parliament and the Welsh Assembly across the discharge of all of our functions to regulate pharmacists, pharmacy technicians and registered pharmacies.

Secondly we suggest that there may be different mechanisms for us to be held to account, perhaps some collectively with other regulators, which we would want to explore so that our work is more visible and can be tested consistently by governments, the public and the professions.

Finally, the culture of autonomy and accountability should run like a strong thread through the entire system. Health professionals and regulators should all have the flexibility to innovate, change and respond to the needs of the people, but do that within a clear framework of accountability. This culture is the one that will empower the whole system to adapt and improve safely, in the face of change.

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

Our Council is constituted of seven pharmacy professionals and seven lay members, with a lay chair. The Council directs the strategy of the organisation and holds the executive to account for its performance. This method of governance has proved very effective because there is:

- Separation between the council and the executive providing clear lines of accountability. Without that separation it is much more difficult for the executive to be held to account for their actions.
- Balanced representation of the views of professionals and informed lay people.

Given the clear effectiveness of our current arrangements we will continue to value clear lines of accountability and a balance of professional and lay perspectives. The professional members are important and necessary members of the Council, who ensure that the context in which regulated professionals practice is understood, and whose presence on Council also enhances the confidence of the regulated professions in the deliberations and decisions made. It is for these reasons that a professional and lay Council is most valuable. When considering the number of Council members, it is important that the size is not so small that it precludes effective decision making and continues to ensure that the context of the regulated is considered. Decisions in the past have resulted in a reduction in the size of the Councils of regulatory bodies, and there is no doubt that this has improved governance overall; but the case for a further reduction is not made, in our view.

The breadth of the structure of our Council enables us to draw upon a wealth of experience of different models of governance, and we remain unconvinced of the potential benefits of a unitary board where the executive do not have any clear lines of accountability within the organisation. Such an arrangement compromises the accountability of the Chief Executive – who is then playing two roles of blurred identity, which have the potential to conflict.

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

We have explained why employers views should not be better formally represented in the membership of the councils of the regulatory bodies in para 6.19 and 6.20, but agree that it is essential that mechanisms exist to ensure that they are consulted on a regular basis, and that in particular cases of policy review, they play an active part in the formulation of new thinking.

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

All regulators should have a clearly stated strategy and model for the assurance they provide that the people and places they regulate are safe and effective. We have been developing our approach in this area and see the range of levers we have available to us as working collectively to provide that assurance. From initial education and training, registration and renewal of registration, revalidation for pharmacy professionals, quality assurance of registered pharmacies, and to investigating and acting upon concerns, the whole model drives assurance and improvement.

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

It is not prudent to try to determine the answer to these questions absent the context in which any fee decision is made. Different circumstances will apply at different times; no Council could sensibly say in advance what the best approach would be. Certainly both these options may apply; as the question implies, there may be other demands on resource use which require particular investment decisions to be made. No advance formula can realistically help guide that.

Q22: How will the proposed changes affect the costs or benefits for your organisation or those you represent?
- an increase
- a decrease
- stay the same
Please explain your answer and provide an estimate of impact if possible.
The consultation does not set out a comprehensive model for the future of healthcare regulation. Therefore we are unable to answer this question.

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

The consultation does not set out a comprehensive model for the future of healthcare regulation. Therefore we are unable to answer this question.

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

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

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

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

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

The consultation does not set out a comprehensive model for the future of healthcare regulation. Therefore we are unable to answer this question.