Consultation on the regulation of healthcare professionals from the Law Commissions of England and Wales, of Northern Ireland and of Scotland

A response from the General Pharmaceutical Council

Introduction

1. The General Pharmaceutical Council is the regulatory body for pharmacists, pharmacy technicians and registered pharmacies in England, Scotland and Wales. We are very pleased to be able to respond to the Law Commissions’ consultation on the regulation of healthcare professionals (and social care professionals in England).

2. Set out in the following pages is our formal response to the consultation; however, we have already had the opportunity to feed back views on the full range of topics through the pre-consultation engagement undertaken by the Law Commission (England and Wales on behalf of the three main UK commissions) which we found very helpful. Our response to this consultation sets out what we see as the key issues of principle at stake, is clear about those issues on which the Council has had a chance to reach a considered view and highlights where we think further work is required by the Law Commission before specific policy proposals can be put to ministers for consideration.

3. We have structured our response in a way which mirrors the consultation document, but with an overview covering key issues of principle as well as information on our role, legislation and approach to regulation.

Overview

Our role

4. We are the newest of the nine statutory health professional regulators in the UK. The Pharmacy Order 2010, endorsed by both the UK and Scottish Parliaments, set out the regulatory powers of the General Pharmaceutical Council in Great Britain and brought regulation of the pharmacy professions in Great Britain into line with other health professions, with a statutory regulatory body quite separate from the professional leadership body. The Pharmaceutical Society of Northern Ireland retains both roles in Northern Ireland.

5. Consistent with the other health professional regulators our legislation makes explicit that our purpose is that of patient protection. Specifically, the Pharmacy Order set out our role as:

“...to protect, promote and maintain the health, safety and well-being of members of the public, and in particular of those members of the public who use or need the services of registrants, or the services provided at a registered pharmacy, by ensuring that registrants, and those persons carrying on a retail pharmacy business at a registered pharmacy, adhere to such standards as the Council considers necessary for the safe and effective practice of pharmacy.”

6. Our principal functions are set out in Article 4 (3) of the Pharmacy Order 2010. These cover:
- Approving qualifications for pharmacists and pharmacy technicians and accrediting education and training providers;
- Maintaining the register of pharmacists, pharmacy technicians and pharmacy premises;
- Setting standards for conduct, ethics, proficiency, education and training, and continuing professional development (CPD);
- Establishing and promoting standards for the safe and effective practice of pharmacy at registered pharmacies;
- Establishing fitness to practise requirements, monitoring pharmacy professionals' fitness to practise and dealing fairly and proportionately with complaints and concerns.

7. We are unique amongst the UK health professional regulators as we also have a statutory role in relation to ‘system’ regulation (i.e. regulating the provision of services by registered pharmacies as well as the individual registrants). The Pharmacy Order sets out a range of powers in relation to the functions above which relate to the registration of pharmacies and setting of standards in relation to registered pharmacies as well as enforcement powers. We note that Part 11 of your consultation describes our powers in relation to registered pharmacies in some detail and we do not intend to replicate that in this response.

Key issues of principle

8. The GPhC strongly supports the aim of this review; namely to create a new legal framework which enables regulation to adapt and provide flexible and responsive systems that protect public safety and promote high standards in professional practice, whilst ensuring consistency between professions on the core common requirements. We agree with the Law Commissions’ assessment that the current legal framework is complex and expensive. However, there are risks in moving away from the current model/s without clarity about the principles which should underpin a major reform process. Although the focus is a change to the legal framework, rather than an imposed change to the principles of regulation, how this change is done will have an impact on some key issues of principle.

9. In considering the Law Commissions’ proposals our response has been informed by the following important points:

- The establishment of a new professional regulator for pharmacy and development of new standards and approach to compliance (see our recent consultation on standards for registered pharmacies) represent a significant change for the pharmacy professions and we would argue against any significant further change which would have the potential to cause confusion as well as disruption and increased costs.
- There has been a significant amount of communications work to explain our role, particularly in relation to registered pharmacies, and further significant change could create uncertainty for patients and the public as well as those we regulate.

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1 Our consultation, Modernising Pharmacy Regulation, set out those registered pharmacies we have powers to register and regulate as well as those pharmacies we do not register (e.g. hospital pharmacies who only supply pharmacy medicines to their own patients)
2 [www.registeredpharmacies.org](http://www.registeredpharmacies.org) or [www.pharmacyregulation.org](http://www.pharmacyregulation.org)
Our Council is only recently established, and we believe it has made a good start in meeting the requirements placed upon us and doing so in a way consistent with accepted good regulatory principles (for example dealing with our legacy cases in a transparent and proportionate manner). As such it is perhaps too early to identify specific governance issues and consider the case for further change. This is in contrast to some regulatory bodies which have been much longer established, perhaps with larger numbers on Council and with different governance mechanisms.

Specific GPhC principles

10. Through our discussions in Council and informed by ongoing engagement with key interest groups, we have identified the following principles against which we have tested the proposals:

i. **Patient and public protection should be the foundation**, through our explicit statutory role, for what we as regulators do.

ii. **The core functions within professional regulation should be maintained**, whereby each of the regulators is responsible for holding registers, setting the standards for entry and remaining on our register, as well as a role in taking action when registrants’ fitness to practise may be impaired.

iii. **Regulators must remain independent**, and be seen to remain independent of government, the regulated professions or any specific interest group.

iv. **Clear accountability is required** and government intervention should not be seen as a proxy for parliamentary accountability, but nor should regulators be ‘protected’ through their independence from urgent intervention when required.

v. **The legislative framework should support consistent outcomes** between regulators. A high level framework supports flexible, agile and proportionate regulation, but patients and the public have a right to expect consistency. One should not come at the expense of the other.

vi. **Legislation should be explicit about the purpose and role** of Government, CHRE (and PSA as it will become), Councils and the executives of Councils; functions should be allocated which enable the defined roles to be fulfilled.

vii. **Legislation should enable regulators to reflect the local and devolved context** and in particular recognise the divergent health delivery, local regulator and patient and professional engagement structures across Great Britain.

Part 2: The structure of reform and accountability

11. The Council agrees with the Law Commissions’ analysis that the current legislative framework for professional regulation creates an inconsistency in the ability of the regulators to deliver their statutory functions. The General Pharmaceutical Council, through the Pharmacy Order 2010, is operating within a relatively new legislative framework. We think this legislative framework is working well. That said, we have already identified a number of changes required if we are to keep up to date with the expectations on us to deliver high quality, efficient regulation in a cost effective manner. These changes can only be delivered through a Section 60 order and as the consultation describes, the process for delivering changes through a Section 60 order takes about two years and although easier to secure than primary legislation, is only marginally quicker.

3 www.bis.gov.uk
12. We also think there will be opportunities for regulators to learn and adapt from best practice more quickly within the proposed new single act framework.

13. The consultation document sets out a number of issues and proposals in relation to changing the way in which Rules are scrutinised. We do not support the proposals for CHRE to take on additional responsibilities for scrutinising Rules. We see this concept as likely to lead to exactly the sorts of difficulties your consultation has identified including: issues of quality, as CHRE does not currently have this expertise; duplication of effort and process – this would simply replicate the work of regulators in making rules; and call into question the clarity of the role of CHRE now and in the future.

14. Accountability and transparency are enhanced by clarity and certainty on the question of who is responsible for what. The more the regulators (which are the bodies with responsibility for regulation) are explicitly, or in effect, subject to direction by CHRE, the less accountable and transparent regulation as a whole will become, with (almost inevitably) more and more control being exercised, less transparently and with less accountability, by a body which is not legally responsible for regulation.

15. The GPhC sees the consultation process as fundamental to delivering good regulation. Our regulatory policies will not work if they do not command the confidence of either those in whose interest we regulate – patients and the public – or those we regulate – our registrants, and the owners of pharmacies. Our Council and our staff have expertise in a wide range of areas, but good regulatory policy can only be developed through meaningful engagement. The consultation sets out a specific proposal that the regulators should be required to consult on anything which is binding or sets a standard or benchmark to be achieved. We agree with this proposal in principle, although we have some concerns about what is meant by ‘anything which is binding’. There are requirements that regulators may in future insist upon which do not necessarily need to be set out in rules. For example, we impose a requirement for international pharmacist applications to demonstrate that they have met IELTS level 7 on language competence. This is not set out in rules but is binding. We would also caution against too much specificity in the proposal about the different groups required to be consulted. Good consultation should be tailored to the issue and the format for each consultation will often vary. We are not convinced of the benefit of listing organisations in the way proposed although we support the principle in proposal (2-7).

Parliamentary accountability

16. As the consultation makes clear, the regulators have always been accountable to the UK Parliament and in the case of the GPhC and a number of other regulators also to the Scottish Parliament. We agree with the Commissions’ assessment that, given the responsibilities that the regulators have for assuring patient and public safety, it is essential that an effective and transparent mechanism for Parliamentary scrutiny is established. The GPhC fully supports the proposition that accountability should be more than symbolic. Currently only the GMC and the NMC have been called before the House of Commons Select Committee as part of a wide-ranging scrutiny session. However, even in these instances, there is a limit to the amount of scrutiny and genuine accountability that can be exercised.

17. We note the Law Commissions’ preliminary view that a Joint Committee of both Houses of Parliament is unlikely to be welcomed by Parliament itself. We are not in a position to agree or disagree with this assessment, although we would welcome formal feedback from the relevant parliamentary authorities as this
does seem likely to be the most appropriate and effective mechanism allowing more detailed scrutiny of the regulators’ work.

18. We also think that, particularly in relation to the proposal to enhance parliamentary accountability and the proposal to remove the formal role of the Privy Council, further consideration is required in relation to how accountability to the devolved legislatures is also made more meaningful. One of the benefits of the current process, including the role of the Privy Council, is the requirement to ensure all rules are consistent with legislation in Scotland and Wales, and take proper account of divergent health service delivery and management arrangements.

The role of government

19. Statutory regulatory bodies should not have the authority to define their own terms of reference and the scope of their own powers. The GPhC is therefore in agreement with the proposition that the Secretary of State should be given formal powers to make decisions on matters where there is sufficient public interest. This is on the presumption that there will be effective liaison and consultation mechanisms within government to ensure appropriate engagement on the part of the devolved administrations.

20. We also note that the proposal is for the government to be given similar order making powers to section 60 orders for regulation-making powers, for example, to establish, merge or abolish certain regulators. Safeguards should be considered including setting out of criteria when this may occur, the need for full public consultation as well as suitable parliamentary scrutiny as described in paragraphs 2.95-2.99.

Default powers of the Privy Council

21. The Commissions’ consultation recommends that the current power to issue directions to certain regulators (excluding those covered by the Dentists Act 1983, The Pharmacy Order 2010 and the Pharmacy (Northern Ireland) Order 1976) should be transferred directly to the Government.

22. This proposal goes to the heart of the debate about accountability of the regulators. On the one hand, it must be right that when a body whose statutory purpose is to protect the public, is failing to carry out its statutory functions, that suitable powers of intervention are available. On the other hand, it is not in the best interests of patients and the public, nor likely to support consistent and proportionate regulation if regulators look ‘up’ to government for ‘direction’ about what is expected, rather than looking ‘out’ to patients and the public. If the criteria relating to when powers of intervention can be used are not clear, or they are used too often, this proposal has the potential to undermine the independence of the health professional regulators.

23. The proposals also suggest that the Secretary of State should be given powers to exercise certain functions of a regulator. Paragraph 2.106 compares these powers to ‘best value authorities’ which are covered by local government legislation and are different in constitution and are taxpayer funded. Professional regulators are independent statutory bodies, funded through fees charged to registrant groups and although we think it right government should be able to intervene, these powers should be limited and we do not support provisional proposal (2-18).

24. The consultation also suggests that CHRE should be given statutory power to make recommendations in relation to the regulation of new professions or the removal of regulation for professions. The intended
future role of CHRE is not clear from the consultation and until that is resolved it is hard to offer a view on this particular proposal. The case for it is not self-evident. We do not feel it appropriate to provide CHRE with new powers until its future role and functions have been clarified.

Implementation issues

25. Paragraphs 2.121-2.124 set out possible legacy issues should the statutory framework change. As described in the consultation document, the GPhC inherited a large number of legacy cases which we have been able to make significant progress with through certain powers set out in the Pharmacy Order. This mechanism has worked well in our view and the quality of decision making has been endorsed by CHRE who have carried out an audit in this area.

GPhC views on specific proposals in Part 2

Proposals 2-1 and 2-2: We support the proposals to bring forward a single Act with consistency across each of the regulators through the same core functions and certain guaranteed minimum procedural requirements.

Proposals 2-3 and 2-4: We support the proposal for the regulators to be given broad powers to make or amend rules, but disagree with the idea that CHRE could be given an active role in scrutinising rules.

Proposal 2-7: We support the requirement for regulators to consult on anything which sets a standard, benchmark or competence.

Proposal 2-8 and 2-9: We support the proposals to remove the role of the Privy Council and consider holding annual accountability hearings for the regulators in each of the Parliaments.

Proposal 2-10 and 2-14-2-15: We support the arguments set out in paragraph 2.68 that the government has a legitimate need to make decisions on areas where there is a sufficient public interest and that this should include certain regulation making powers.

Proposals 2-11 and 2-12: We support the proposal for each regulator to provide information to the public and registrants about its work; for the CHRE to lay key publications before UK Parliament, Scottish Parliament and Northern Ireland and Welsh Assemblies.

Proposal 2-16: The intended future role of CHRE is not clear from the consultation and until that is resolved it is hard to offer a view on this particular proposal. The case for it is not self-evident.

Proposal 2-17: We agree, subject to clear published criteria, that the government should have powers to issue a direction to regulators.

Proposal 2-18: We do not agree with this proposal.
Part 3: Main duty and general functions of the regulators

26. This part of the consultation focuses on the main duties of the regulators and the need to provide greater consistency across each regulator. We support this principle. We note much of this part of the consultation considers whether it is appropriate to have included in the regulators’ main duty reference to ‘preserving confidence’ in the profession. We strongly support the need to embed this in the statutory purpose of regulators.

27. Historically, discussions about perceptions of Councils and apparent or perceived bias have generally focused on governance issues and proportions of lay and registrant members on Councils and the role of Council members in decision making, particularly fitness to practise and registration appeals panels.

28. The concept of upholding confidence in the profession is most noticeable when considering the behaviour of registrants which, if not considered by the regulator, has the potential to reduce trust and confidence in the profession as a whole. Often, but not exclusively, these issues relate to serious criminal convictions. We believe that if this concept were to be removed, it would undermine a fundamental tenet of professional regulation, that the regulator should concern itself with matters beyond professional competence and the importance of the public’s trust in professionals and that profession.

GPhC views on specific proposals in Part 3

Proposal 3-1: We support option (2) that the duty of regulators should be to protect, promote and maintain the health, safety and well-being of the public and maintain confidence in the profession, by ensuring proper standards for safe and effective practice.

Part 4: Governance

29. Our response in this area is heavily influenced by the fact that we are a newly established Council and have only been operating in full for less than two years. The key question which we think needs to be addressed, but which is not covered in the consultation is a clear statement about what the Council or Board is for and what the expectations on those appointed to it are. If that were clearer it would be easier to consider which of the three options were best suited to the role.

30. Of the three options proposed by way of a board structure, Council can see little benefit and many risks by having a statutory executive board. We do not think this would command the confidence of the professions we regulate; we have concerns about difficulties of holding required expertise in such a group; and, there would be reduced level of public accountability and fewer checks and balances in the system. Of the other two options, we support the retention of the current model. We see this as well established, understood well by our stakeholders with a transparent separation between Council Members and the Executive. With appropriate governance policies in place, there is no inherent reason why the non-executive Council and the executive management should not work very well together, whilst maintaining clarity as to their respective roles. We see the current model as working well and would be reluctant to undertake such a significant
structural change so soon after establishment, although we recognise further work would be required to set out whether ‘board-like’ refers to behaviours, composition, or a mixture of these two or other factors.

31. The competence, values and behaviours of those involved (whatever the structure) are likely to have a much greater impact on the effectiveness, efficiency and accountability of the regulators than the seemingly endless quest for some ideal governance structure.

Status of the Councils

32. The GPhC has a Council of 14 with the Chair appointed through an independent appointments process. We believe Council is working effectively and any question about changes to size and composition should be based on further clarification about the roles and function of Council. There would be many challenges in reducing numbers, but two in particular are most obvious to the GPhC, namely how, with a much smaller Council, you can recruit effectively from both registrant groups (pharmacists and pharmacy technicians) as well as from each of the three countries of Great Britain.

33. A key concern of the GPhC in this part relates to the appointment of Council members. The current process of appointment, managed by the Appointments Commission and approved by the Privy Council, provides effective scrutiny, independence, transparency as well as quality of process. Whatever mechanism is used to replace the Appointments Commission should meet these three key principles as well as an equally high quality process. We have serious reservations about responsibility for appointing its own Chair and members being given to Councils and we would not support this proposal. Even if ways of ensuring proper scrutiny and transparency can be found, we see no way of making this process truly independent – and seen to be independent. We do not believe that giving responsibility for approval of appointments to the CHRE would be appropriate or independent. This is an area we believe needs further consideration including specific thought to possible alternative options including whether the Commissioner for Public Appointments or the Civil Service Commissioner could be used, or whether an independent body could be set up by the professional regulators themselves. We think there remains an argument for retaining a role for the Privy Council in affirming appointments.

GPhC views on specific proposals in Part 4

Proposal 4-1: We support option (1) to reform the existing structure to encourage Councils to become more board-like.

Proposal 4-3 to 4-5: We believe this area needs further consideration. Although we see the potential for an increased role for Councils in determining how their members are appointed, we believe the process needs to be at arms-length.

Proposal 4-6: We support the current model of composition with equal lay and registrant members. It is important that there is consistency across each of the regulators.

Proposal 4-7: We support the definitions of lay and registrant members as described.
Part 5: Registers

34. The management of registers is fundamental to the system of professional regulation. Registration status provides each registrant with a licence to practise and allows the public to check the register to identify registered professionals. Decisions taken about whether to allow entry onto or removal from the registers are central.

35. The operation of this system, as the consultation makes clear, has traditionally been done by appointing a Registrar who has a number of specific powers and duties set out in statute and further delegated responsibilities from Council. We see this as providing clarity in relation to responsibility and accountability as well as providing clear internal mechanism for decision making.

36. Given the view we have expressed about the nature of the governing body, and the need for a transparent and legally accountable focus of decision-making in relation to the register, we do not see any case for removing the standard requirement for Councils to appoint a registrar.

Specialist lists

37. The General Pharmaceutical Council does not hold ‘specialist lists’ or registers. We do, however, provide an annotation on the register to show where registrants hold a qualification to enable them to act as a Supplementary or Independent Prescriber. Although there have been no specific requests to establish separate lists, we recognise that this could change in future. In this case we support the view that this would be a legitimate matter for government to decide rather than the regulator, taking into account the requirements of the health services in the devolved administrations. This is consistent with our view that the regulators themselves should not have the final say on the scope of their own regulatory task, which is given to them to carry out on behalf of the public.

Student registers

38. We would see any proposal to introduce student registers as costly, bureaucratic and likely to add significant regulatory burden to students and universities as well as the regulators without providing significant enhancement to patient safety which other measures at a local level could not do in a more effective and proportionate way. We have continued the policy in pharmacy of looking to education and training providers both to play their full part in inculcating professionalism and to uphold this through ‘student fitness to practise’ policies and procedures: an effective way of achieving the desired objective without the additional cost and administrative burden of registration.

Non-practising registers

39. We do not support maintaining non-practising registers. We recognise that some might view it as a mechanism for retaining details of former practising registrants to call upon in the event of a national emergency, such as a flu pandemic, but we are not convinced that this is either proportionate or would necessarily be effective.
Registration appeals and proceeding from provisional to full registration

40. We support the need for regulators to establish an appeals process and the proposal to move away from appeals to be made to the county courts or sheriff in Scotland. We agree that the High Court is likely to be better placed to make such decisions.

41. We also support the proposal outlined in paragraph 5.66 for conditional registration to be established at the application stage and for additional requirements to be made. Although we would not foresee this power being used frequently there are circumstances when patients would be better protected if applicants who, for example were previously on the register or who make fitness to practise declarations (for example about a previous conviction or where we may wish to monitor health cases) were required to practise under certain conditions.

Restoration to the register

42. Table 5 on page 89 is incorrect in stating that the time limit for application for restoration is 12 months for former GPhC registrants. This is set out in The Pharmacy Order Article 57(2)(b). There is a twelve month restriction on the time between a failed application for restoration and a subsequent application.

43. We would suggest that patients and the public would expect there to be a consistent time period before which applications for restoration can be made when the applicant has been erased as a result of fitness to practise proceedings.

Content of the registers and restricted titles

44. Page 94 sets out the views around the publication of information about qualifications through annotations as well as fitness to practise determinations. We support proposals (5-25) to (5-30) which are in line with the principle of consistency set out in the introduction to this consultation response.

45. The consultation proposes that restricted titles should be set out in statute and the power to do so should be that of Government. The Law Commission should note that in addition to those protected titles set out in the Pharmacy Order 2010, the General Pharmaceutical Council is required to consider applications related to protected titles which are in some cases set out in the Medicines Act 1968 (as amended).

46. The Law Commission makes a specific recommendation that Councils would need to develop and publish a policy on prosecutions. We agree with this proposal and in part to enable good decision making, the GPhC has an established and published prosecutions policy.
Part 6: Education, conduct and practice

47. Patients and the public can have confidence in the integrity of our register in part because we set the standards for the outcomes of education and training and quality assure the process. We can have confidence that those coming onto the register are fit to practise. The consultation document sets out some of the reasons why education and training differs across the professions. Because of these differences it is right that the regulators should have flexibility about how we set and assure our education standards. We do not have responsibility for the funding of education and in pharmacy there is the potential for major changes in the way in which undergraduate pharmacy education is delivered, at least in England with a major review by Modernising Pharmacy Careers which is part of Medical Education England. Significant consideration is also being given to future requirements in Scotland and Wales.

48. The GPhC currently holds a registration assessment, akin to a national registration examination for trainee pharmacists. We believe that this is a helpful tool that contributes to ensuring only those students who are

GPhC views on specific proposals in Part 5

Proposal 5-3: We agree that the Government should be given regulation-making power to add, remove or alter the parts of the register and specialist lists.

Proposal 5-4: We do not support the introduction of student registers.

Proposal 5-8: We do not support the reintroduction of non-practising register in pharmacy.

Proposal 5-11: We support the proposal that in order to be registered applicants must be appropriately qualified, be fit to practise, have adequate insurance and have paid a fee.

Proposal 5-12: We support the proposal for regulators to have the power to establish registration and renewal criteria.

Proposal 5-13: We do not support the proposal to introduce a new test of a ‘fit and proper person’. We see very significant difficulties in this proposal, particularly when we have an established test of fitness to practise.

Proposal 5-17 and 5-18: We support this proposal for statute to require an appeals process and that in England and Wales this would be to the High Court and in Scotland for it to be to the Court of Session.

Proposal 5-23: We think that there should be consistency on the time limit for applications for restoration between each of the regulators.

Proposals 5-25 to 5-30: We support the proposal for regulators to set out in rules the content of the register. We support also the proposal to allow annotations to the register. We believe that it is important that there is transparency in relation to sanctions and that where erasure is the sanction this should be indicated when a search of the register is made for at least five years. Previous sanctions should, as a minimum, remain a matter of public record and be available on request.

Proposals 5-31 to 5-34: We support the proposals to set out in statute existing protected titles and for there to be powers of prosecution for the regulatory bodies.
competent to practise are entered onto the register. However, we recognise that this registration assessment, introduced in 1993, reflects the unique circumstances of the pharmacy education model including the way in which pre-registration is managed and quality assured across Great Britain.

Guidance

49. The consultation sets out the wide variation in style, content and format of the various codes, standards and guidance issued by the regulators. In part we see this as a legitimate manifestation of the numbers and activities of the differing professions we regulate. It is also recognition that what constitutes ‘best practice’ has changed.

50. The GPhC has adopted an approach whereby a ‘standard’ is something which must be met, whereas ‘guidance’ is a description or advice about how to meet the standard. It is also consistent with the normal use of the term ‘guidance’ which implies advice which is not mandatory. This we see as consistent with the approaches of other regulators, such as the General Medical Council. What we also recognise is that good regulation requires providing support and advice about how to meet the standards, but that in many cases, particularly when it comes to professional practice, professional representative or leadership bodies are likely to be better placed to provide this.

51. We are not convinced that the description of ‘tier one’ and ‘tier two’ guidance is appropriate and it could lead to greater, not less, confusion.

52. We support the desire for greater consistency across the regulators, but would argue that the statute has, in many cases, provided an unhelpful degree of specificity about the requirement to publish standards for differing settings (e.g. professional conduct; proficiency; training etc). One issue that should also be recognised is that clarity of definitions between standards and guidance will not necessarily be created through the mechanism proposed. Professional bodies (in our case for example the Royal Pharmaceutical Society or the Association of Pharmacy Technicians UK) publish a range of guidance and use a range of descriptors such as ‘standards’ or ‘guidance’ or advice ‘bulletins’. For other regulated professions, for example, medicine, the medical royal colleges set standards for post-graduate training which are approved and quality assured by the GMC.

53. On a number of issues there is a need for enhanced joint planning and working, for example on issues consistent across many of the regulators – this may include issues relating to consent of patients, or requirements for confidentiality.

54. The point of prime importance here is that there should be clarity and consistency in the statute as to the unique status and nature of standards defined by the regulator which must be met, and against which continuing fitness for registration will ultimately be assessed; as distinguished from every other kind of document, the names and ownership of which will vary between professions, partly as a function of the diverse nature and history of the leadership bodies.
Revalidation

55. The GPhC currently requires all registrants to undertake CPD. This requirement is set out in rules and we currently review and provide feedback on CPD records from all registrants on a cyclical basis. Council has also agreed a number of core principles which will support our work to assure continuing fitness to practise of registrants. We note that on page 119 of the consultation it states that regulators will ensure ongoing standards of conduct and practice through CPD. While we consider that CPD is an important requirement for all registrants, given the nature of the CPD requirement it may be over-claiming to suggest that CPD ensures conduct and practice, as opposed to contributing to it. One of the principles for revalidation endorsed by Council was that evidence would be required from more than one source and not solely CPD records.

GPhC views on specific proposals in Part 6

Proposal 6-5: Currently we hold a national assessment for pre-registration pharmacy students and the statute should enable (but not require) this to continue and develop.

Proposal 6-9: We think that it is important that core standards are issued for each profession which are available for both registrants and members of the public.

Proposal 6-10: We do not think this proposal would provide the clarity desired. We think further research would be helpful.

Proposal 6-12: We already require all registrants to complete CPD records and need the ability to make rules in connection with continuing fitness to practise (revalidation).

Part 7 Fitness to Practise – impairment

56. There has been considerable case law built up over recent years which has provided enhanced clarification about the purpose of the regulators’ fitness to practise proceedings and the requirements in relation to the various steps involved in how fitness to practise is determined (fact finding; fitness to practise decisions; and, sanctions).

57. Council has discussed and considered the various options presented in part 7 of the Commissions’ consultation and there was a clear consensus that if fully implemented the proposal set out in the Shipman Inquiry would not be a step forward. We consider that this option has a number of limitations including additional complication for both registrants and complainants; it appears very legalistic; it requires different tests at different stages; and in our view is likely to lead to delays and additional costs.

58. Each of the other two options (retaining the widely used two-stage approach and introducing a new consistent test based on a risk to the public) has merits. If the recommendation from the Commission is to move to a simplified test it should include the test that confidence in the profession has been, or will be, undermined. On balance, the GPhC’s view is to support a two-stage approach for determining impaired fitness to practise (as set out in Para 7.49) but enabling Councils to set the basis for determining whether a registrants’ fitness to practise is impaired.
Part 8: Fitness to Practise – investigation

59. The Commissions’ consultation sets out a number of options in relation to whether or not to remove the concept of an allegation. The consultation refers to the GPhC’s ‘Just disposal’ policy whereby the Pharmacy Order 2010 conferred powers on us to dispose of legacy cases in a manner we consider just. This policy has been a significant success with the disposal of legacy cases made in a timely manner with no reduction in quality of decision making. It has been managed through a quality assured process, reported to Council and externally audited.

60. The successful operation of this policy has raised a number of fundamental questions about whether the legislative framework enables regulators, with appropriate external scrutiny, to innovate and bring forward further reforms. Once the lessons of our own ‘Just Disposal’ policy are reviewed and considered by others, for example, further extension of this approach, both during and outside of transition arrangements, might aid quality and efficiency of decision making in new ways.

Initial consideration and investigation

61. As a Council we have already had lengthy discussions about reform of fitness to practise including how allegations are considered and the role of the Investigating Committee. Having only been in operation for a relatively short period, it is already clear that improvements can be made to assist the quality of decision making and the timeliness of decisions. We are supportive of any proposals which enable the regulators to be more agile in reforming procedures where opportunities to enhance quality and timeliness are identified and where there is good evidence to support this. Examples of this are where consistent decisions from Committees may enable review and updating of threshold criteria.

62. We note the development of models in other regulators to investigate and consider cases either in advance of, or instead of, an Investigating Committee. Council is mindful that there are significant advantages to retaining the existing committee structure, particularly in relation to the benefit of separation of decision making. The GPhC has not come to a view as to whether this is a model we would like to pursue, however the way in which decisions have been made in relation to legacy cases supports the arguments made in the
consultation that an Investigating Committee is not always the most efficient or effective way of organising investigations (paragraph 8.42). That said the Commissions’ suggestion is that future decisions about how to organise investigations would be left to the regulator and we think that this would be a sensible way of enabling innovation and for sharing of learning between regulators.

Disposal of cases

63. Decisions in this area need to balance the advantages of flexibility against the important principle of consistency between the regulators. The suggestion is that all regulators should have powers to issue or agree a range of sanctions at investigation stage. Although further discussion could be had about the range of sanctions, we think it important that the powers should be the same across each of the regulators. We note the suggestion that the current section 29 powers of appeal held by CHRE could be extended to sanctions at investigation stage. This would seem an appropriate mechanism for ensuring that decisions taken at all stages are subject to appropriate review.

GPhC views on specific proposals in Part 8

Proposal 8-1: This proposal would represent a significant departure from the traditional process for consideration of allegations and decisions on referrals. Council has not had the opportunity to consider this issue in detail, however we can say that our Just Disposal policy has worked effectively and we would be happy to share learning from this process with the Law Commissions or other regulatory bodies.

Proposal 8-2 and 8-3: We agree that it must be in the best interests of patient safety for the regulators to be able to consider any information, not just formal complaints, which come to their attention as an allegation. We believe it would be consistent with the principles of openness, transparency as well as supporting equality and diversity for statute to make clear that there is no set format for allegations. We already have and use this power.

Proposal 8-5: We support the proposal that regulators should have the power to establish a formal process for the initial consideration of allegations.

Proposal 8-7: We support the proposal that regulators should have the powers to establish referral criteria for an investigation and specify cases which must be referred directly to a Fitness to Practise Panel.

Proposal 8-9 and 8-10: We support this proposal that regulators would be enabled, but not required, to establish an Investigating Committee.

Proposal 8-11: We note that the power to require disclosure already exists but support the suggestion that this is made explicit in legislation.

Proposal 8-15: We agree that the test for all referrals to a Fitness to Practise panel across the regulators should be a ‘real prospect’ test.

Proposal 8-16 and 8-17: We see merits in this concept and recognise the need for appropriate safeguards if the public and registrants are to have confidence in the regulators’ decision making process.
Part 9: Fitness to Practise – adjudication

64. Separation between investigation and adjudication functions is a well established benchmark of good practice both within and beyond professional regulation. The debates about the pros and cons of the current model within health professional regulation are also well worn with significant debate about the strengths and weaknesses of a new system agreed previously by Parliament with the establishment of the Office for Health Professions Adjudicator.

65. The way in which statutory committees are established ensures clear independent decision making. However, this independence does limit the capability of Councils (or the executive operating on their behalf), who are ultimately accountable for the decisions made, to take any action where they have significant reservations about the quality of decision making. This causes confusion in the eyes of patients and the public and isolated decisions by panels, which Councils may wish to challenge in the interests of patients and the public, continue to undermine the confidence in the regulator more generally.

66. Our main concern relating to the proposals is that if it is accepted that the current system is either not separate enough, or not perceived to be separate enough, each of the regulators may rightly feel obliged to pursue further separation, but in different ways at different speeds. In the absence of some overarching model, this will lead inevitably to yet further inconsistency of process, something the consultation is striving to avoid, with different regulators reforming at different stages in a piece-meal way. The GPhC is supportive of further structural separation between investigation and adjudication functions, and that one of the key lessons of previous reform proposals is that this should be applied consistently to all regulatory bodies at the same time.

Composition of panels

67. The recommendations set out on page 168 are consistent with the current position within the GPhC. We require at least one member of a panel to be a lay member and we have an independent Appointments Committee which oversees the appointments and performance appraisal of our panellists.

Final sanctions and other disposals

68. We agree with the Commissions’ assessment that there should be harmonisation of sanctions across the regulators. We would also support common terminology across the regulators to aid patient and public understanding. Although not formalised, the GPhC uses the term ‘erasure’ in relation to determinations by the fitness to practise committee and ‘removal’ in relation to issues such as removal for non-renewal of registration or failing to comply with CPD requirements. We see this distinction as relatively minor but a helpful way of communicating the nature of the decision. We avoid using the term ‘striking off’ or ‘struck off’ which we see, although favoured by the media and widely understood by registrants and the public, as emotive, unhelpful and old-fashioned.
Ability to reconsider decisions

69. We are unsure about the extent to which the scenarios described in this section (page 188) are likely to occur. However, it is unclear what mechanisms exist for regulators to take action in cases where they believe their own fitness to practise panel may have either not followed required procedures or followed due process. In these cases, there is a theoretical option of attempting to apply for a judicial review of the regulator’s own fitness to practise panel. The highly unusual possibility of a regulator feeling obliged to attempt to judicially review a decision made by a committee for which it holds legal accountability graphically illustrates why consistent further steps to achieve true separation of ‘prosecution’ and adjudication functions should be taken.

GPhC views on specific proposals in Part 9

Proposal 9-2: There is a compelling case for further structural separation between investigation and adjudication, but it needs to be done in a consistent way and jointly across each of the regulators.

Proposal 9-3: The option of joining the Unified Tribunals System is something we would be willing to consider and explore further, but again the key test is ensuring that there is no further fragmentation of approach across the regulators.

Proposal 9-6 to 9-8: We support these proposals.

Proposals 9-24 to 9.31: We broadly agree with the overarching aims contained in these proposals as likely to bring greater consistency across the regulatory bodies.

Proposal 9-34: We think there is merit in further consideration of this proposal.

Part 10: The Council for Healthcare Regulatory Excellence

70. The current and future role of CHRE and subsequently the Professional Standards Authority (PSA) is both a contentious and complex issue. The CHRE has had a multi-faceted role: carrying out performance reviews of the regulators; undertaking fitness to practise audits of the regulators; providing frequent and detailed policy advice to the Department of Health in England; reviewing all the cases from regulators for instances of unduly lenient decision making; carrying out research and identifying good practice. As the consultation makes clear, this range of functions is confusing and is reflected by the lack of clarity about whether CHRE is a meta-regulator (for example section 29 appeals and the proposal to bring into force its powers to investigate complaints about the regulators under section 28) or whether it is carrying out what the consultation refers to as a ‘systemic model’ of oversight rather than regulation. We have concerns about how any organisation which has such a wide array of functions and responsibilities, particularly as they grow with an enhanced role in quality assuring voluntary registers, can develop a truly strategic role.

71. We also have concerns about the accountability structure which, as we argue in our response to the proposals in Part 2 of the consultation, we see as unclear and has the potential to create further confusion.
about what government, CHRE/PSA and the regulators are each responsible and accountable for. We think further clarity is required.

72. We note that the challenges in relation to governance are similar, if not greater for CHRE than the regulatory bodies. As stated earlier in our response, we cannot see how an appointments process whereby Councils can manage the process of appointing their own members can be credible. We think that this is also true for CHRE. It is important that we build on recent innovations in appointments and associated credibility through enhanced independence which have resulted from the current system. In addition, we would argue that appointment of members by government would also raise further questions about independence of CHRE. As CHRE is to be accountable to Parliament, it would seem more appropriate that its Council Members’ appointments should be scrutinised by Parliament itself as well as the Scottish Parliament and Welsh Assembly and NI Assembly for UK regulators.

Part 11: Business regulation

73. The first observation we would make in our response is that although this section is titled ‘business regulation’ we are not and do not see ourselves as regulating businesses but the services provided by registered pharmacies many, although not all, of whom operate in a commercial setting.

74. Our consultation, Modernising Pharmacy Regulation^4 sets out our overall approach as well as the proposed standards for registered pharmacies. This approach sets out what we see as good regulation. We understand that many pharmacies are businesses and how they operate may differ as a result, but we think there is potential to over-estimate the impact that has for us as a regulator when compared to other regulators who solely or predominantly regulate professions or provision of services within an NHS managed environment.

75. One specific example cited is the commercial context or financial pressures within pharmacy. This is undoubtedly a relevant factor, but the key factor in development of our regulatory policy is the provision of patient care, not that we are regulating in a commercial context. Although different, NHS organisations also have many pressures not directly related to patient care; GP practices are in effect private businesses; NHS providers in England are increasingly required to compete for income and financial pressures have in a number of high profile failures in the NHS played a significant part. We see a key requirement as regulating in a way which reflects a ‘pharmacy context’ rather than specifically a ‘commercial context’.

76. We think it is premature to set out whether we require any further powers or reforms. The consultation asks specifically whether regulators should be given powers to disclose any sanction or fine against business to the shareholders. It is our intention, set out in our consultation to publish decisions about whether the required standards have been met in relation to our inspection of pharmacies and relevant inspection reports.\(^5\)

77. We note that the consultation refers to the option of extending powers currently held by the GPhC to other regulators. However, we note that in many cases for other professions this power is already available through, for example, the Care Quality Commission, Health Improvement Scotland, Health Inspectorate Wales or the Regulation and Quality Improvement Authority in Northern Ireland.

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^4 Modernising Pharmacy Regulation, [www.pharmacyregulation.org](http://www.pharmacyregulation.org)

^5 Modernising Pharmacy Regulation: a consultation on standards for registered pharmacies, [www.pharmacyregulation.org](http://www.pharmacyregulation.org)
Part 12 – Overlap issues

78. Although this part is described as ‘overlap issues’ the wider context is really one of three issues:

- Avoiding unnecessary regulatory duplication
- Identifying regulatory gaps
- Enhancing the quality of regulatory outcomes through joint working

79. We would suggest that these issues will not necessarily be resolved through amendments to statute. It may be that the findings from the Mid Staffordshire NHS Foundation Trust Public Inquiry will provide further insight into these issues which can be utilised. We also see this topic as very wide ranging and would welcome the opportunity to discuss further with the Law Commissions and other stakeholders as this was not an issue discussed extensively in the pre-consultation phase.

80. Through our work to develop standards for registered pharmacies we have been asked by registrants and the public about how we currently work, and intend to develop further our work, with other regulators, particularly the Care Quality Commission and the Medicines and Healthcare products Regulatory Agency. We already carry out joint work (including joint inspection visits) but this will need to develop further. We are aware that there are always barriers to joint working between organisations. Different regulatory bodies may be operating with different access to resources, external pressures and priorities which legitimately differ from organisation to organisation and boards may wish to set different priorities. However, these can often be overcome with good, transparent communications and effective working at senior levels which is then communicated to staff in respective organisations who may be working together on a regular basis.

81. In terms of specific joint work between health professional regulators, we see some significant opportunities in policy development and engagement. Joint consultation activities on, for example, ethical guidance would seem worth exploring further. However, for some activities, it may be that the cost saving from sharing of services is limited, while the efforts required (including for example legal fees) is substantial.

82. There are opportunities and risks to setting out a general duty to cooperate. On the one hand it provides a clear requirement to work with others. On the other hand it could become mechanistic and artificial. On balance we think this suggestion is worthwhile.
83. The consultation asks about practical difficulties which arise as a result of parallel criminal and fitness to practise proceedings. We think a distinction should be drawn between investigations and proceedings. Where possible, regulators including the GPhC have sought to avoid running parallel investigations which would duplicate effort, resources and be counter-productive. This has at times led to delays in taking work forward. This is different to running parallel proceedings which is often appropriate as we are trying to establish whether fitness to practise is impaired, not whether a criminal act has been perpetrated. At an operational level we have already moved away from an assumption that all fitness to practise cases should wait until relevant court cases have concluded, to considering on a case by case basis whether proceedings could be taken forward in an appropriate manner without undue risk to other proceedings.

GPhC views on specific proposals in Part 12

Proposal 12-6: We do see potential benefits in having a general duty to promote cooperation. However, we would not want this to lead to an industry of Memoranda of Understanding which are merely a peg around which to do joint working, rather than an end in itself.

Proposal 12-7 and 12-8: We have some concerns that the provisional framework described here could cause significant and unnecessary bureaucracy although we are supportive of the general principle of cooperation.

Part 13 – Cross border issues

84. The consultation proposes that, for transposition of EU law, a different approach is taken; namely a greater degree of specificity about what must go in rules as well as a power for government to intervene.

85. We have some reservations about this approach. The Localism Act 2011 enshrines in law that the regulators would be liable financially as the result of infraction proceedings thus limiting any financial risk to government. We have also seen, in relation for example to the issue of language testing, differing legal interpretations between the regulators and the government. The process for initiating infraction proceedings is lengthy with significant opportunity to take remedial action should disagreement with the Commission and the European Courts emerge.

Accrediting courses abroad

86. There is an error on page 230. The accreditation of courses abroad carried out by us is currently only in relation to the MPharm (we accredit UK qualifications only) degree not the Overseas Pharmacists’ Assessment Programme. For the OSPAP we utilise the comparator statements provided by UKNARIC. There are a number of challenges with accreditation of courses overseas, but these mainly fall into two categories: the access of trainees to training equivalent to that undertaken by the UK based students on the course; and the resource requirements needed to travel overseas and undertake accreditation events. Although costs of overseas accreditation are met by the institutions seeking accreditation there are significant other costs, such as staff costs, associated with this activity.
Distance service provision

87. This is a complex area, but one which is likely to continue to develop as models of healthcare delivery continue to change. Our preliminary view is that if the individual providing the service is based in the UK they should be registered with the appropriate healthcare regulator.

88. If the individual providing the service is not based in the UK they still must be appropriately qualified and regulated in the country in which they are based for the specific service they are providing across borders. It should be the responsibility of the organisation that contracts with the service provider to ensure that this is the case and inform service users of the checks they have undertaken.

GPhC views on specific proposals in Part 13

Proposal 13-1: This may be possible for the automatic route professions where qualifications are listed in the Directive but even for this route not only qualifications but in specified cases work experience also needs to be considered. It will also only work if the amended RPQ Directive clearly states that it relates to the ‘recognition’ of professional qualifications not the registration process which follows recognition. We see significant challenges in implementing this proposal for those professionals exercising free movement rights under the general system as these applications are required to be assessed on a case by case basis, taking into consideration not only an applicant’s qualifications, but also their work experience and continuing professional development/continuing education.

Proposal 13-2: We do not think this is necessary given changes to the Localism Act and existing procedures for requiring remedial action under infraction proceedings.

Proposal 13-3: We agree with this proposal as this is something we already undertake.

Proposal 13-8: As set out above if the provider is contracting with someone overseas, they should ensure that this is transparent to the patient and that they have ensuring the person is qualified and registered with the relevant competent authority.

31 May 2012