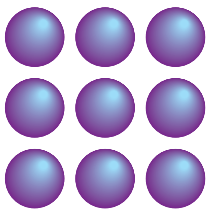
Advice to the Department of Health and the Pharmacy Regulation and Leadership Oversight Group on aspects of the establishment of the General Pharmaceutical Council

November 2008



council for healthcare regulatory excellence

Contents

1 Introduction

1.1 Pharmacy practice will undergo significant change over the next decade. The new regulator of the pharmacy profession will need to meet that challenge. Pharmacists and pharmacy technicians are a mobile workforce, operating in a wide range of settings, often working within commercial imperatives while ensuring that patients receive the best possible service. The future development of pharmacy outlined by recent policy initiatives presents the profession with exciting challenges and changes as it moves increasingly towards the delivery of clinical services.

1.2 The establishment of the General Pharmaceutical Council presents an opportunity to create a truly patient-focused regulatory body, whose activities are directed by assessment of risk to patient safety of rapidly developing pharmacy practice, which anticipates change and reacts quickly to it. The GPhC has the potential to become an exemplar of modern professional regulation: effective in protecting patients, agile in identifying and responding to change, and balanced in its approach to risk and regulation.

2 Executive summary of recommendations

2.1 The Council for Healthcare Regulatory Excellence's key observations are:

- Change in pharmacy will be rapid, in terms of role development of pharmacists and pharmacy technicians, and technological advancement in pharmacy products.
- Pharmacists and pharmacy technicians will be interacting with patients and the public in new and different ways.
- With the changes in their roles, pharmacists and pharmacy technicians will need to develop new ways of working with colleagues.
- Change will introduce new areas of risk to patient safety.
- Pharmacists and pharmacy technicians will need clear advice and guidance on standards in these new areas.
- Pharmacists and pharmacy technicians will need to acquire what may be new skills and knowledge, for example in behaviour change in the public health role.
- Pharmacy will in future be practised in a wider range of settings, for example in patient's homes or GP/veterinary surgeries.
- Individual pharmacists increasingly work across different settings, in different sectors, potentially resulting in a complex risk profile at an individual level.
- Changes in an increasingly globalised society will affect both the practice of pharmacy and present challenges to its regulation and the protection of public safety – for example, the availability of pharmaceutical products on the internet.
- Changes in IT, for example electronic prescribing and online pharmacy, will affect practice, and will need to be reflected in GPhC's standards.
- Pharmacists will continue to play an important role in industry, clinical departments and regulatory matters.

2.2 Our main recommendations are that:

- It is essential to ensure that the closely integrated regulation of pharmacy professionals, premises and products continues. This is a great strength in ensuring patient safety.
- Across all of its functions, GPhC will need to allocate its resources according to assessment of risk to patient safety, taking a light touch where risk to patient safety is low and focusing on areas where risk is highest.
- The GPhC will need to establish a horizon-scanning function capable of anticipating the changes in pharmacy practice which will occur over the next decade.
- GPhC itself will need to be able to adapt quickly to reflect change in its standards, structures and processes.
- The GPhC's standard-setting function will need to be flexible, with new areas of practice being anticipated and standards developed and promulgated quickly.
- In the establishment of the GPhC consideration should be given to the examples of best practice which have arisen from the CHRE 2008 performance review.
- In the transfer of responsibility to GPhC, areas of good and developing practice in the current regulation of the pharmacy professions, identified by CHRE's performance review, should not be lost.

- In the preparation of legislation for the new GPhC appropriate statutory powers should be included to make continuing professional development (CPD) mandatory.
- The governance arrangements of the GPhC should follow the principles set out in the report *Enhancing Confidence in Healthcare Professional Regulators*[1].
- The GPhC is set up in such a way that at a logistical level it is a straightforward matter to register Northern Ireland's pharmacists and pharmacy technicians, should Northern Ireland's Health Minister decide in future that this is his wish.

2.3 These recommendations are based on the Better Regulation Executive's five key principles of better regulation[2]:

- Proportionate: regulators should only intervene when necessary. Remedies should be appropriate to the risk posed, and costs identified and minimised.
- Accountable: regulators must be able to justify decisions, and be subject to public scrutiny.
- Consistent: government rules and standards must be joined up and implemented fairly.
- Transparent: regulators should be open, and keep regulations simple and user-friendly.
- Targeted: regulation should be focused on the problem, and minimise side effects.

In addition CHRE proposes a sixth principle:

- Agile: regulators must be consistently in a state of readiness to respond to changes and developments in healthcare professional practice and circumstances.

2.4 These recommendations are also based on the following good governance principles[3]:

- The council should uphold the purpose of the organisation as established by parliament, determine its values and keep both its purpose and values in mind at all times, with mechanisms in place for annual review.
- The council should be forward- and outward-looking, focussing on the future, assessing the environment, engaging with the outside world, and setting strategy.
- The council should determine the desired outcomes and outputs of the organisation in support of its purpose and values.
- For each of the desired outcomes the council should decide the level of detail to which it wishes to set the organisation's policy – any greater level of detail of policy formulation should then be a matter for the determination of the chief executive and staff.
- The means by which the outcomes and outputs of the organisation are achieved should be a matter for the chief executive and staff; the council should not distract itself with operational matters.
- The chief executive should be accountable to the council for the achievement of the organisation's outcomes and outputs.
- In assessing the extent to which the outcomes have been achieved, the council must have a framework of pre-determined criteria against which performance is reported both internally and externally.

[1] Department of Health (2008). *Implementing the White Paper Trust Assurance and Safety: Enhancing Confidence in Healthcare Professional Regulators*
[2] Better Regulation Executive www.berr.gov.uk/bre/index.html
[3] Department of Health (2008). *Implementing the White Paper Trust Assurance and Safety: Enhancing Confidence in Healthcare Professional Regulators,* Table 1

- The council should engage with its key interest groups including patients, the public, registrants, employers, educators and the devolved administrations, and be confident that it understands their views and priorities.
- The membership of the council should have the capacity and skill to understand the priorities of each of these key constituents.
- Information received and considered by the council should support one of three goals – to allow informed decision making, to fulfil control and monitoring processes or to enable the council to co-operate with CHRE and to be accountable to parliament.
- The council must govern itself effectively, with clear role descriptions for itself, its chair, and its members, with agreed methods of working and self-discipline to ensure that time is used efficiently.
- The council must ensure that issues of equality and diversity are considered as part of all its work.

2.5 The recommendations are also based on CHRE performance standards[4]:

2.5.1 Standards and guidance
- The regulator publishes standards of competence and conduct which are appropriate, comprehensive, prioritise patient interests and reflect up-to-date professional practice.
- The regulator makes its standards available and accessible proactively to registrants and potential registrants in the UK[5], and informs them of their current or future responsibility to meet these standards.
- The regulator informs the public of the standards that professionals should meet and the action that they can take if these standards are not met.
- The regulator requires registrants to maintain standards through a process of CPD or equivalent systems, and is working towards a system of revalidation.

2.5.2 Registration
- The regulator has efficient, fair and transparent processes for entry to the register and periodic renewal of registration.
- Registers are accessible to the public and include appropriate information about registrants.
- The regulator takes appropriate action to prevent non-registrants practising under a protected title.

2.5.3 Fitness to practise
- The regulator has a process through which patients, the public and others can raise concerns about registrants and understand how their concerns will be dealt with.
- The regulator keeps all relevant parties informed of progress on cases at all appropriate stages.
- Fitness to practise cases are dealt with in a timely manner at all stages.
- There are quality processes for the appointment, assessment and training of fitness to practise panel members. Panel members also have clear guidance on how to assess cases.

[4] CHRE (2007). *Standards of Good Regulation*
[5] It is noted that at establishment GPhC will cover England, Scotland and Wales. Pharmacy regulation in Northern Ireland is discussed at paragraphs 3.4 and 9.3.8-9.3.12

- Decisions made at the initial stages of the fitness to practise process (pre-fitness to practise panel stage) are quality assured.
- Fitness to practise panels make appropriate, well reasoned decisions on cases.

2.5.4 Education

- The regulator ensures that its standards for the education and training to be met by students are appropriate, comprehensive, prioritise patient safety and interests and reflect up-to-date professional practice.
- The regulator ensures that its standards for the delivery of education and training are appropriate, comprehensive, prioritise patient interests and reflect up-to-date professional practice.
- The regulator has a transparent and proportionate system of quality assurance for education and training providers.

2.5.5 Governance and external relations

- The regulator is a transparent and accountable organisation and significant policy decisions are demonstrably based on the public interest.
- The regulator establishes and works within efficient and effective organisational processes.
- The regulator fosters a culture of continuous improvement within the organisation.
- The regulator co-operates with stakeholders and other organisations.

3 Background

3.1 On 6 May 2008 CHRE was commissioned by the Department of Health to provide advice on the following aspects of the establishment of the General Pharmaceutical Council:

- Existing good practice in relation to the regulation of the pharmacy professions.
- Likely changes to pharmacy practice over the next five to ten years which could have implications for the way that the pharmacy professions are regulated.
- The core functions of a regulatory body (drawing on the White Paper *Trust Assurance and Safety – the Regulation of Health Professionals in the 21st Century* and the preceding reviews of regulation).
- What constitutes good governance arrangements, in terms of the functions and procedures of a Board and internal governance processes.
- Operational implications arising from the various settings for pharmacy practice (eg community, hospital, industry etc), the need to operate in the context of devolved government in the United Kingdom, European Community law and the general movement of people across international boundaries.

3.2 In preparing to provide advice on these aspects of the establishment of the new body, we have both looked at the key documents setting out the future of pharmacy practice across the UK, and have held face-to-face discussions with a wide range of people and organisations. This has included the Royal Pharmaceutical Society of Great Britain, the Pharmaceutical Society of Northern Ireland, other regulatory bodies, the devolved administrations, and organisations representing pharmacists working in specific sectors. In a few cases, where meeting has not been possible, written submissions have been received.

3.3 We are extremely grateful to those with whom we have discussed aspects of this advice and other contributors for the time that they have taken to share their thoughts with us. We are particularly grateful to the RPSGB and the PSNI for their proactive co-operation with us, and for the lengths to which they have gone to ensure that we have the information that we need and to set up meetings. We have enjoyed wide-ranging discussions on the future of pharmacy, and ask our contributors to recognise that unfortunately it has not been possible to reflect on all of the matters that we have discussed when writing our advice on the specific questions put by our commission, or to reflect all points of detail.

3.4 Throughout this advice in discussing the future of pharmacy we have taken a UK-wide perspective, unless otherwise stated at any point, while appreciating that in the first instance at least GPhC will be a body which covers England, Scotland and Wales. We discuss the regulation of pharmacy in Northern Ireland in more detail at 9.3.8-9.3.12.

4 Existing good practice in relation to the regulation of the pharmacy professions

4.1 In this section we draw on our performance review of the RPSGB and PSNI in 2008, summarising the particular points which were noted as good practice and commenting on wider issues and areas for further work going forward into the establishment of GPhC. As the existing regulatory departments of RPSGB will form the basis of the new GPhC in the first instance, we have considered the performance review of RPSGB in more depth than that of PSNI.

Existing good practice at RPSGB and related issues

4.2 Our 2008 performance review confirmed that the RPSGB carried out its regulatory functions successfully during a period of change and challenge, not least of which being the preparations for the establishment of the GPhC. It will be important to ensure that successful performance of functions and current developmental work across the organisation is not lost in the transfer to GPhC.

4.3 We found that standards form the basis of the RPSGB's statutory functions, prioritise patient safety, are comprehensive and the Code of Ethics is well laid out. There is an effective communications strategy with key groups. The registration process is well-managed with applications handled in a timely manner; the register is accessible and reasonably easy to understand and search. There is an effective process to deal with cases of unregistered individuals claiming to be pharmacists. Work is in hand to introduce improved IT-based case management in fitness to practise which we consider is essential for the effective operation of fitness to practise processes. Cases are handled relatively quickly by the RPSGB and further improvements are anticipated.

4.4 The Inspectorate is effective in detecting fitness to practise concerns and investigating them; a future issue to address will be to establish the relationship between the Inspectorate, the fitness to practise department and the National Clinical Assessment Service, as NCAS expands its remit to include pharmacists.

4.5 In the oversight of pharmacy practice the RPSGB collaborates effectively with the Medicines and Healthcare Products Regulatory Agency, the Healthcare Commission and the police. A future issue for resolution will be to manage the relationship and the interface with the Care Quality Commission (once established) to agree protocols on registration of premises, for example, when a pharmacy registered with GPhC expands its activities into areas that are registerable with the CQC[6]. It is essential to ensure that the closely integrated regulation of professionals, premises and products continues. This is a great strength in ensuring patient safety.

[6] In England. We note the comment at paragraph 7.8 of *Pharmacy in England Building on Strengths – Delivering the Future* that it will not be an immediate requirement for pharmacies to be registered with the CQC but that in future as their range of services expand this may be necessary.

4.6 Areas needing further work include raising the profile of the register, in particular with the public, introducing IT-based fitness to practise case management as noted, and setting service standards across fitness to practise. The membership of the Council of the RPSGB does not reflect a sufficiently broad range of interests in view of the wide range of stakeholders in pharmacy regulation, due to existing legislative restraints. This must be addressed by the GPhC in establishing its Council. We discuss board governance in more detail below (paragraphs 7.1-7.3). Finally, the RPSGB does not currently have the statutory power to make CPD mandatory, and it will be essential that the GPhC has the right statutory powers in this area.

Existing good practice at PSNI and related issues

4.7 In our performance review of PSNI we found that it fulfils most of its functions satisfactorily within the constraints of existing outmoded legislation. Noting the good work that is already underway across the range of functions to improve its performance, and the obvious desire and commitment of its leadership to develop its practice, we strongly recommend that a new legal framework for the regulation of pharmacy in Northern Ireland is put in place as soon as possible.

4.8 A particular area of good practice which we commend to GPhC (and other regulatory bodies) is the appointment of pre- and post-registration facilitators by PSNI. These professionals play a useful role in improving communication and promoting standards with students, registrants and employers.

4.9 We discuss pharmacy regulation in Northern Ireland further at paragraphs 9.3.8-9.3.12.

5 Likely changes to pharmacy practice over the next five to ten years which could have implications for the way that the pharmacy professions are regulated

Summary of the likely changes to pharmacy practice

5.1 Pharmacy practice will undergo significant change over the next decade. In the community, there will be an expanded public health role, with emphasis shifting from the dispensing of medicines to the provision of clinical services. Pharmacies will provide a wider range of services supporting healthy living, including helping patients to manage long-term conditions and supporting self-care. In hospital practice, there will be an enhanced clinical role, taking a higher profile in the work of multidisciplinary teams and leading in areas such as medicines reconciliation on admission. Hospital and community pharmacy will work together in health community clinical pharmacy teams. From industry, we heard in particular about innovations in proteomics, and their potential for the development of new more individualised medicines. From veterinary pharmacy we heard about the likely increase in the dispensing of medicines for companion animals by community pharmacies. Increasing automation and technological advancements have freed up pharmacy technicians to be able to make a fuller contribution to services. Pharmacy products and their administration are also changing and developing rapidly, including the increasing range of pharmacy medicines.

5.2 Another area of rapid development will be in the use of IT. Increasingly, prescriptions will be transferred electronically. As pharmacists develop their clinical role, protocols will need to be developed to enable them to access and contribute to the NHS Care Records Service, both the detailed locally-held information and the Summary Care Records held nationally.

5.3 We asked many of those with whom we have discussed this advice if there were significant differences in the development of pharmacy in the different countries of the UK. We heard that there were some differences in emphasis, with specific initiatives occurring in only a single country, or innovations that were more advanced in some locations than others. To some extent this is explained by the different distribution of the workforce in the different countries across the settings in which pharmacy is practised. However, in general it is clear that that the general principles and direction of travel apply across all four countries of the UK.

Key considerations for GPhC arising from change in pharmacy practice

5.4 The key considerations for GPhC are as follows:

- Change will be rapid, in terms of role development of pharmacists and pharmacy technicians, and technological advancement in pharmacy products.
- Pharmacists and pharmacy technicians will be interacting with patients and the public in new and different ways.
- With the changes in their roles pharmacists and pharmacy technicians will need to develop new ways of working with colleagues.

- Change will introduce new areas of risk to patient safety, for example, in the area of the maintenance of proper boundaries in hands-on diagnostic procedures, and in the risks inherent in the prescribing, dispensing and use of more individualised pharmaceutical products which may require highly skilled administration.
- Pharmacists will need clear advice and guidance on standards in these new areas. For example, community pharmacists expanding their role into dispensing veterinary pharmaceutical products will need to understand the boundaries between this area of work and those tasks which must only be carried out by a registered veterinary surgeon, as well as the other considerations specific to dispensing for animals[7].
- Pharmacists and pharmacy technicians will need to acquire what may be new skills and knowledge, for example in behaviour change in the public health role.
- Pharmacy will in future be practised in a wider range of settings, for example in patient's homes or GP/veterinary surgeries.
- Individual pharmacists increasingly work across different settings, in different sectors, potentially resulting in a complex risk profile at an individual level.
- Changes in an increasingly globalised society will affect both the practice of pharmacy and present challenges to its regulation and the protection of public safety – for example, the availability of pharmaceutical products on the internet.
- Changes in IT, for example electronic prescribing and online pharmacy, will affect practice, and will need to be reflected in GPhC's standards.
- Pharmacists will continue to play an important role in industry, clinical departments and regulatory matters.

Implications for the new regulatory body – risk-based regulation

5.5 Having identified the characteristics and changes listed in 5.4, we considered the implications for the new regulatory body. In order to regulate in the diverse, complex and fast-moving area of pharmacy practice it will be necessary for the GPhC to allocate its resources and order its priorities on the basis of risk-assessment in accordance with the Hampton principles[8] and the principles set out by the Better Regulation Executive, as referenced by the Foster review[9], namely that statutory regulation should be:

- Proportionate: regulators should only intervene when necessary. Remedies should be appropriate to the risk posed, and costs identified and minimised.
- Accountable: regulators must be able to justify decisions, and be subject to public scrutiny.
- Consistent: government rules and standards must be joined up and implemented fairly.
- Transparent: regulators should be open, and keep regulations simple and user-friendly.
- Targeted: regulation should be focused on the problem, and minimise side effects.

5.6 In addition, we propose a sixth principle – agile. The regulatory body must be able to anticipate change, including in the environment in which its registrants work, and react quickly. This should be reflected in its structure, standards, policies and processes.

---

[7] We note that this is not a new area in legal terms, however is likely to become more prevalent in future. The boundary with the veterinary surgeon is only one example of the various areas that would need to be covered, including matters relating to dispensing, storage, the 'cascade', breaking of packs, labelling and recording as specific to veterinary products.

[8] Hampton, P (2005). *Reducing Administrative Burdens: Effective Inspection and Enforcement,* Box E2, p7

[9] Department of Health (2006). *The Regulation of the Non-medical Healthcare Professions: A Review by the Department of Health,* chapter 1 paragraph 12

5.7 The RPSGB is thorough and detailed in the application of its processes. Given the rapid pace of change that is anticipated in the development of pharmacy practice, the GPhC will need to develop its approach to risk management and proportionality so that it can focus most closely on those areas where risk to patient safety is assessed to be highest. This approach will give GPhC the flexibility to adapt quickly as pharmacy practice develops in future. The organisation will wish to refer to the outcome of the work currently being commissioned by the Department of Health on risk assessment in the context of the implementation of *Trust, Assurance and Safety*, specifically for the working groups on non-medical revalidation and extending professional regulation.

5.8 We heard about the work currently being undertaken to develop and define advanced practice, both within RPSGB and other initiatives such as that being led by the Joint Programmes Board (London, East and South East England)[10]. This is an area of rapid development, where pharmacists are working in the areas of greatest uncertainty and have the highest levels of responsibility for managing that uncertainty, for example in combining drugs in unprecedented ways for critically ill patients. As such, it is a good example of an area where GPhC should focus its attention, where there are demonstrable issues of public protection. GPhC should support those working in high risk areas by defining standards and advising on the circumstances and parameters within which risks can reasonably be taken. Following the report *A High Quality Workforce: NHS Next Stage Review*[11], CHRE will be undertaking work on advanced practice in close liaison with the regulatory bodies, and drawing on existing work from across the UK.

Implications for the new regulatory body – horizon scanning and stakeholder network management

5.9 The next question that we considered was how the new regulatory body would stay abreast of, and ahead of, the rapid advance in practice that is anticipated over the next five to ten years.

5.10 Our advice is that from the outset GPhC will need to establish the capacity for continuous horizon scanning. This will ensure that it stays ahead of practice and anticipates changes and developments before they occur, enabling it to reflect these back into its standard-setting and other functions of the organisation. In doing so, it will need to manage proactively a network of stakeholders, including the professional body, patients and the public, consumer groups, employers in all sectors, organisations representing pharmacists and pharmacy technicians working in particular sectors, higher education institutions, trades unions, the Medicines and Healthcare Products Regulatory Agency, and the devolved administrations (see section 9).

5.11 Several times during our interviews the issue arose of whether it would be cost effective for the regulatory body to perform its own horizon scanning given that the professional body would also be performing a similar function, and whether the professional body might in some way be commissioned to perform horizon scanning on behalf of the regulatory body. Although there could be some sharing of intelligence in this area, and the professional body will be an

[10] www.postgraduatepharmacy.org
[11] Department of Health (2008) *A High Quality Workforce: NHS Next Stage Review*

important source of advice and input, the organisations must perform their own horizon scanning, reflecting their distinct roles – the professional body will be creating and shaping the future of pharmacy practice, while the regulatory body will be anticipating change and reflecting it in the standards that it upholds for its registrants.

Implications for the new regulatory body – standard setting

5.12 We are aware that the standards documentation of the RPSGB was revised last year and published in August[12], and that a wide range of stakeholders was involved in the redrafting. We are also aware that, in order to remain up to date for as long as possible without the need for review, the standards were worded in such a way as to be statements of principle and therefore to some extent future-proof. The standards are comprehensive, prioritise patient safety, and are well laid out.

5.13 However, given the likely pace of change over the next 10 years, a standards-setting function based on a document reviewed at intervals and published in paper form will not be the best way to ensure that standards stay up-to-date with practice and cover all eventualities.

5.14 We advise that the GPhC moves towards a more flexible and dynamic standards-setting process, in which standards can be reviewed and changed quickly. The organisation will need to establish protocols for deciding when changes to practice as they occur require changes to standards, and how stakeholders will be consulted on proposed changes. It will also need to find ways to communicate changes to registrants, building on the RPSGB's current effective communications strategy, for example through supplementary and issue-specific guidance. As changes to the standards may occur more frequently in future, an archiving and version control process will be required to ensure that it will always be possible to know what version applied at any given time, not least to inform fitness to practise processes.

5.15 In the remaining paragraphs in this section we reflect in general terms on the implications of a more flexible, rapidly developing standards-setting function for the other functions of the new regulatory body.

Implications for the new regulatory body – quality assurance of education

5.16 The standards-setting function will need to inform the quality assurance of the education function to ensure that pharmacists and pharmacy technicians with the right skills, knowledge and professional attitudes to meet contemporary standards are emerging from pharmacy courses. We note as a result of the recently published *A High Quality Workforce: NHS Next Stage Review* CHRE is to be commissioned to conduct research to identify and promote best practice in the quality assurance of education[13].

Implications for the new regulatory body – fitness to practise

5.17 A mechanism will be required to ensure that the standards setting function and the fitness to practise function inform each other. As standards change, this will inform the way

[12] RPSGB (2007). *Code of Ethics for Pharmacists and Pharmacy Technicians and Professional Standards and Guidance Documents*
[13] Department of Health (2008). *A High Quality Workforce: NHS Next Stage Review,* paragraph 138 p41

that referrals are handled at an early stage, the indicative sanctions guidance available to panels when a case proceeds to a hearing and the training of panellists. Likewise, learning from fitness to practise cases will need to feed back into the standards setting function. If in future standards are to evolve more quickly than has previously been the case, version control will be required so that throughout the consideration of a case it is judged against the standards applicable at the relevant time.

5.18 It will be essential to ensure that GPhC has a full range of sanctions available to it in fitness to practise cases. CHRE is currently working on harmonisation of the sanctions available across the healthcare professions. Another issue for the GPhC to consider in establishing its fitness to practise function concerns the chairing of panels in fitness to practise hearings. From its consideration of over 4000 decisions by fitness to practise panels CHRE concludes that panels with legally qualified chairs do not produce higher quality decisions or better-written adjudications than panels with chairs who are not legally qualified.

Implications for the new regulatory body – continuing professional development

5.19 High-quality continuing professional development will be essential for a profession going through rapid change and development, to ensure that the existing workforce in pharmacy is able to keep pace with the new skills and knowledge they will need to acquire. This adds further weight to the urgency for CPD to be made mandatory under the GPhC, which we discuss elsewhere in this advice (paragraphs 4.6 and 8.5).

Implications for the new regulatory body – revalidation

5.20 Revalidation decisions will be based on whether a registrant meets the contemporary standards, based on submitted evidence. It will need to be clear to registrants which is the contemporary set of standards against which this decision will be made in order to ensure that they provide relevant evidence and information.

5.21 The GPhC will need to develop sophisticated methods of risk profiling its registrants as the basis for revalidation, given the increasing appearance of combined roles across sectors in pharmacy, the increasing differentiation of roles within sectors and the mobility of the pharmacy workforce. The organisation will need to determine the amount and nature of information that it will be reasonable to demand of registrants towards the revalidation decision, given the range of roles that they may have at any one time. To do so will require dedicated efforts to map trends in the pharmacy workforce, building on the work that RPSGB already undertakes in this area.

Implications for the new regulatory body – patient and public involvement

5.22 The rapid pace of change will present GPhC with a considerable challenge in patient and public involvement, both in finding ways to communicate to the public the standards that they can expect from pharmacists and pharmacy technicians, and in involving patients and the public in its work. There are various successful models of patient and public involvement, such as the approach by the General Medical Council, which we would encourage GPhC to consider, building on the strong programme of work already being developed by RPSGB and

on its existing links with public and patient representative organisations. Key characteristics of successful models are that they engage with a wide range of people, use a variety of methods and that those involved are able to see that their involvement makes a difference.

6 The core functions of a regulatory body

6.1 CHRE reviews the performance of the health professional regulators against five key standards and a set of minimum requirements under each standard. The standards were developed during 2007 in collaboration with nine health regulators, and focus on the outcomes for regulation and the protection of patients and the public[14]. They were piloted in the 2008 performance reviews. It should be noted that the standards will be reviewed in the light of this pilot process and in advance of the 2009 performance review round. For reference they are quoted below in paragraphs 6.2-6.6. At 6.7 we quote the functions as defined by the White Paper *Trust Assurance and Safety*.

6.2 Standards and guidance

- The regulator publishes standards of competence and conduct which are appropriate, comprehensive, prioritise patient interests and reflect up-to-date professional practice.
- The regulator makes its standards available and accessible proactively to registrants and potential registrants in the UK, and informs them of their current or future responsibility to meet these standards.
- The regulator informs the public of the standards that professionals should meet and the action that they can take if these standards are not met.
- The regulator requires registrants to maintain standards through a process of CPD or equivalent systems, and is working towards a system of revalidation

6.3 Registration

- The regulator has efficient, fair and transparent processes for entry to the register and periodic renewal of registration.
- Registers are accessible to the public and include appropriate information about registrants.
- The regulator takes appropriate action to prevent non-registrants practising under a protected title.

6.4 Fitness to practise

- The regulator has a process through which patients, the public and others can raise concerns about registrants and understand how their concerns will be dealt with.
- The regulator keeps all relevant parties informed of progress on cases at all appropriate stages.
- Fitness to practise cases are dealt with in a timely manner at all stages.
- There are quality processes for the appointment, assessment and training of fitness to practise panel members. Panel members also have clear guidance on how to assess cases.
- Decisions made at the initial stages of the fitness to practise process (pre-fitness to practise panel stage) are quality assured.
- Fitness to practise panels make appropriate, well-reasoned decisions on cases.

[14] CHRE (2007). *Standards of Good Regulation*

6.5 Education

- The regulator ensures that its standards for the education and training to be met by students are appropriate, comprehensive, prioritise patient safety and interests and reflect up-to-date professional practice.
- The regulator ensures that its standards for the delivery of education and training are appropriate, comprehensive, prioritise patient interests and reflect up-to-date professional practice.
- The regulator has a transparent and proportionate system of quality assurance for education and training providers.

6.6 Governance and external relations

- The regulator is a transparent and accountable organisation and significant policy decisions are demonstrably based on the public interest.
- The regulator establishes and works within efficient and effective organisational processes.
- The regulator fosters a culture of continuous improvement within the organisation.
- The regulator co-operates with stakeholders and other organisations.

Consistency with *Trust Assurance and Safety*

6.7 The definition of the functions of a regulatory body as set out above in our view is consistent with that set out in the White Paper *Trust, Assurance and Safety*, namely: setting and promoting standards for admission to the register and for remaining on the register; keeping a register of those who meet the standards and checking that registrants continue to meet the standards; administering procedures for dealing with cases where a registrant's right to remain on the register has been called into question; and ensuring high standards of education for the health professionals that they regulate[15].

Examples of best practice arising from CHRE's 2008 performance review

6.8 We have recently published our reports on the performance reviews of the healthcare professional regulatory bodies, including a general report on the state of healthcare professional regulation[16]. We commend the examples of best practice that are identified.

[15] Department of Health (2007).*Trust, Assurance and Safety – the Regulation of Healthcare Professionals in the 21st Century,* chapter 1, paragraph 1.2
[16] CHRE (August 2008) *Performance review of health professions regulators 2007/08 - Helping regulation to improve*

7 What constitutes good governance arrangements in terms of the functions and procedures of a Board and internal governance arrangements

General observations – policy governance model

7.1 CHRE supports the findings of the report of the working group (chaired by Niall Dickson) *Implementing the White Paper Trust Assurance and Safety: Enhancing Confidence in Healthcare Professional Regulators*. As a contribution to the discussions of the working group CHRE compiled a list of principles that should underpin the work of a board, which the working group refined into principles specifically applicable to the council of a healthcare professional regulator. The principles are quoted in 7.3 below.

7.2 We advise that the governance arrangements of the GPhC reflect the findings of that report, and the 'policy governance' model developed by John Carver[17].

7.3 Principles that should underpin the work of a council of a healthcare professional regulator[18]:

- The council should uphold the purpose of the organisation as established by parliament, determine its values and keep both its purpose and values in mind at all times, with mechanisms in place for annual review.
- The council should be forward- and outward-looking, focusing on the future, assessing the environment, engaging with the outside world, and setting strategy.
- The council should determine the desired outcomes and outputs of the organisation in support of its purpose and values.
- For each of the desired outcomes the council should decide the level of detail to which it wishes to set the organisation's policy – any greater level of detail of policy formulation should then be a matter for the determination of the chief executive and staff.
- The means by which the outcomes and outputs of the organisation are achieved should be a matter for the chief executive and staff; the council should not distract itself with operational matters.
- The chief executive should be accountable to the council for the achievement of the organisation's outcomes and outputs.
- In assessing the extent to which the outcomes have been achieved, the council must have a framework of pre-determined criteria against which performance is reported both internally and externally.
- The council should engage with its key interest groups including patients, the public, registrants, employers, educators and the devolved administrations, and be confident that it understands their views and priorities.

[17] In preparing the principles, we drew in particular on the work of John Carver, and his 'policy governance' model as described in *Boards that Make a Difference,* Third Edition, 2006. We commend this model to the GPhC. It draws a clear distinction between the strategic, monitoring, and oversight role of a board, and the delivery of an organisation's executive functions.

[18] Department of Health (2008). *Implementing the White Paper Trust Assurance and Safety: Enhancing Confidence in Healthcare Professional Regulators,* Table 1

- The membership of the council should have the capacity and skill to understand the priorities of each of these key constituents.
- Information received and considered by the council should support one of three goals; to allow informed decision making, to fulfil control and monitoring processes or to enable the council to co-operate with CHRE and to be accountable to parliament.
- The council must govern itself effectively, with clear role descriptions for itself, its chair and its members, with agreed methods of working and self-discipline to ensure that time is used efficiently.
- The council must ensure that issues of equality ands diversity are considered as part of all its work.

Implications of CHRE's special report to the Minister of State for Health Services on the Nursing and Midwifery Council

7.4 CHRE's special report to the Minister of State for Health Services on the Nursing and Midwifery Council[19] highlighted the importance of good governance arrangements to a healthcare professional regulator. Our recommendations to the NMC reflect this.

7.5 We commend the recommendations to the NMC in some respects as general pointers for good governance, and in particular, that 'there should be no representative members on the new council and no reserved places for interest groups. All members, whether registrant or public should be appointed against defined competencies and be subject to appraisal. The President should be appointed not elected'[20]. We also highlight to GPhC the recommendations for an effective statement of organisational values and a code of conduct for council members.

Office of the Health Professions Adjudicator

7.6 A strategic decision will need to be made at an early stage about the point at which the Office of the Health Professions Adjudicator will hear cases against pharmacists and pharmacy technicians. GPhC should anticipate the likely transfer of the adjudication to OHPA at whatever stage by ensuring best practice in the separation of adjudication from other fitness to practise functions. The capacity of OHPA may be affected by our recent recommendation that the Department of Health and the Nursing and Midwifery Council consider early transfer to OHPA.

[19] CHRE (2008). *Special Report to the Minister of State for Health Services on the Nursing and Midwifery Council*
[20] As footnote 19, paragraph 5.2.1

8 Operational implications arising from the various setting for pharmacy practice

8.1 Our commission asked us to consider the operational implications arising from the various settings for pharmacy practice. We have focused our advice in four particular areas.

Revalidation

8.2 A key component of revalidation will be evidence and information about performance which arises from the registrant's workplace. This places two specific responsibilities on a regulatory body. First, it will need to understand the workplaces in which any given registrant practises pharmacy, in order to be able to determine what is a reasonable evidence base to require from the registrant in support of their revalidation application. In pharmacy this will be a significant challenge, given the high percentage of locums in the workforce and the increasing trend towards pharmacists moving between sectors not just as a sequence of jobs but as part of a portfolio of different posts held at any one time. Within this mobile workforce, the GPhC will need to find ways to manage the particular risk around failing professionals who move jobs quickly.

8.3 Secondly, the regulatory body will also need to keep up to date with different employers' processes for producing the kinds of evidence and information which will be germane to revalidation decisions. The regulatory body will also need to set out evidence requirements for those who work outside a corporate structure which is routinely producing information – for example, owners of individual high-street pharmacies.

Receiving fitness to practise referrals

8.4 Concerns about registrants working within corporate structures with developed human resources capacity, for example in the commercial sector or where NHS clinical governance arrangements apply, will often be dealt with by their employers, and will frequently not be brought to the attention of the GPhC. This is desirable; ensuring that concerns are identified and dealt with quickly at a local level where appropriate should be an objective of the new regulator. However, where there is no corporate structure, referrals will often be made directly to the regulatory body. The GPhC will need to be able to manage referrals at all levels, with appropriate training and protocols for staff on how to handle reported concerns at all levels of seriousness.

Continuing professional development

8.5 Pharmacists are increasingly moving between jobs at any one time as part of a portfolio of posts in different sectors. This raises significant challenges for the GPhC in developing a system of continuing professional development which will be able to address development needs arising from those different sectors. It will also be a significant challenge to ensure that CPD is effective in supporting the upskilling of the existing pharmacy workforce. The system developed will need to feed into GPhC's processes for making decisions on whether or not to revalidate registrants. We are aware of, and commend, the work currently being undertaken by

RPSGB on developing CPD systems, and advise that in the preparation of legislation for the new GPhC appropriate statutory powers are included to make CPD mandatory.

Standards-setting function

8.6 As has previously been discussed, the GPhC will need to stay abreast, and indeed ahead, of practice development across all of the different settings for pharmacy practice as part of its standards-setting function, and will need to understand the characteristics of the different environments in which pharmacists and pharmacy technicians work through its network and stakeholder management.

9 The need to operate in the context of devolved government in the UK

General observations

9.1 It will be important for the new regulatory body to maintain close contact with the devolved administrations, to participate in discussions about the future direction of pharmacy in the different countries and to reflect this back into GPhC's standard-setting and other functions. For example, as part of its horizon scanning the GPhC will want to understand the effects on practice of the different contractual arrangements for pharmacy services. This process could be led by country-based offices, subject to the decisions taken about the functions to be conducted at country level as described in the section below.

Delegation of functions to country level

9.2 A major focus of discussion in the preparation of this advice has been the question of what country presence the GPhC should have, distinct from its headquarters functions.

9.3 A number of suggestions were made for country-level functions, the most frequently occurring of which were:

Receiving fitness to practise referrals

9.3.1 It was suggested by many interviewees that a country-level facility for receiving fitness to practise referrals would be desirable, not least on the grounds that members of the public might be likely to be most comfortable reporting concerns to an office based in their own country. We are not however aware of any evidence to support this proposition. GPhC might wish to commission market research to establish the views of the public and other complainants on this point.

Providing advice to registrants

9.3.2 No interviewees were of the opinion that separate standards of conduct and performance were needed for the different countries. However, many felt that it would be useful if GPhC could offer a service to registrants to assist them in understanding how the GPhC's standards applied to the particular circumstances in their own country. This could well arise in 'learning points' to be fed back to GPhC's central standards-setting function.

Holding fitness to practise hearings

9.3.3 Several interviewees suggested that fitness to practise hearings should be held in the country in which the concerns arose, rather than requiring registrants who were the subject of hearings to travel to distant venues. It was also noted by some, however, that from a registrant's perspective it might be preferable to have a hearing held at a distance from home. If GPhC wished to pursue this policy, it would need to commission further research and advice on the Scottish law implications.

Country-level relationship management and stakeholder engagement

9.3.4 Many interviewees commented that there was a country-level role for working with the devolved administrations and other country-based stakeholders.

Patient and public involvement work

9.3.5 Several interviewees felt that public and patient involvement work conducted at country level, feeding into the central standards-setting and other functions, would result in patients and the public having greater confidence in the regulatory body, its standards and their application. It was noted that many patient groups are locally based and it would be sensible for there to be a country-based presence to which they could relate.

9.3.6 Less frequently occurring suggestions included assessing CPD portfolios and making revalidation decisions, pre-registration examination and assessment and support for health problems.

9.3.7 We advise that the costs and benefits to the organisation of conducting these functions at a country level are assessed and used as the basis for deciding what GPhC's country presence will be. There is the possibility of different regulators sharing premises, functions and costs to achieve economy at country level.

Northern Ireland

9.4 We have heard the arguments surrounding the issue of whether or not Northern Ireland's pharmacists and pharmacy technicians should be registered by a UK-wide GPhC.

9.5 At the time of writing the position of Northern Ireland's Health Minister is that a final decision will be deferred until the GPhC has been established and its protocols for working with the devolved administrations have been agreed.

9.6 It could be some considerable time before a final decision is taken, and therefore we advise that In the context of the provision made in the Health Act, the GPhC is set up in such a way that at a logistical level it is a straightforward matter to register Northern Ireland's pharmacists and pharmacy technicians should the Minister decide in future that this is his wish.

9.7 We have also drawn attention in our 2008 performance review of PSNI to the need for early legislative change in Northern Ireland to enable PSNI to fulfil its aspirations to be a better regulator and to perform its functions better on behalf of the people of Northern Ireland.

9.8 We have no doubt whatever of the commitment of PSNI's leadership to protect the public in Northern Ireland. However, we believe that it would be in the interests of public protection in the longer term for a closer working relationship between GPhC and PSNI to be developed, perhaps through working towards shared standards and CPD, as an interim measure until the way ahead for Northern Ireland is made clear. This could assist in maintaining cost-effectiveness.

10 European Community law and freedom of movement across international boundaries

10.1 The RPSGB collaborates with other regulatory bodies is discussing and managing the issues arising from the free movement of professionals and patients across borders. This work should continue within GPhC, such that the new body stays up to date with European Union developments and contributes to best practice. The GPhC must comply with EU legislation particularly in respect of mutual recognition of professional qualifications. They must be consistently aware of changes and developments in EU legislation which affect patients, professionals and the pharmaceutical industry. RPSGB has played an active and valuable role both in the development of EU directives and also with the cross member state voluntary project Healthcare Professionals Crossing Borders[21]. It is recommended that GPhC continues with this valuable work.

10.2 GPhC will need to keep abreast of pharmacy practice internationally, in order to understand any risks to patient safety that might result from pharmacy practice in other countries differing from that in the UK.

[21] http://www.hpcb.eu/

Annex 1

Documents consulted

A High Quality Workforce: NHS Next Stage Review, Department of Health (June 2007)
Boards that Make a Difference, John Carver (Jossey-Bass 2006)
Code of Ethics for Pharmacists and Pharmacy Technicians, Royal Pharmaceutical Society of Great Britain (August 2007)
Future of Pharmacy Registration, Regulation and Representation in Northern Ireland, Pharmaceutical Society of Northern Ireland (February 2008)
Implementing the White Paper Trust Assurance and Safety: *Enhancing Confidence in Healthcare Professional Regulators,* Department of Health (June 2008)
Healthcare Professionals Crossing Borders Agreement, Alliance of Health Regulators on Europe, Scottish Executive, Department of Health (October 2005)
Healthcare Professionals Crossing Borders Portugal Agreement (October 2007)
Making it Better – A Strategy for Pharmacy in the Community, DHSSPSNI (February 2004)
Pharmacist Work Patterns – Pharmacy Workforce Census 2005: Main Findings, Royal Pharmaceutical Society of Great Britain, University of Manchester (August 2006)
Pharmacy in England, Building on Strengths, Delivering the Future HM Government, Department of Health (April 2008)
Professional Leadership in Pharmacy – Exploring the Case for a Royal College for the Pharmacy Profession, King's Fund (April 2007)
Professional Standards and Guidance Documents, Royal Pharmaceutical Society of Great Britain, August 2007
Reducing Administrative Burdens: Effective Inspection and Enforcement, HM Treasury (March 2005)
Remedies for Success – A Strategy for Pharmacy in Wales, Welsh Assembly Government (September 2002)
Report of the Independent Inquiry into a Professional Body for Pharmacy, The Clarke Inquiry (April 2008)
Report of the Working Party on Professional Regulation and Leadership in Pharmacy, Department of Health (May 2007)
Special report to the Minister of State for Health Services on the Nursing and Midwifery Council, Council for Healthcare Regulatory Excellence (June 2008)
Standards of Good Regulation, Council for Healthcare Regulatory Excellence (2007)
Statutory Code of Practice for Regulators, Department for Business, Enterprise and Regulatory Reform (December 2007)
The Regulation of the Non-medical Healthcare Professions – a Review by the Department of Health, Department of Health (July 2006)
The Right Medicine – A Strategy for Pharmaceutical Care in Scotland, Scottish Executive (2002)
Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century, Secretary of State for Health (February 2007)

Annex 2

We are grateful to the following people who gave their time to discuss this piece of work with us, or made a written contribution.

RPSGB
Steve Churton, President
Andrew Cairns, Chair, Veterinary Pharmacists Group Committee
Jane Nicholson, member, Industry Pharmacists Group Committee
Jeremy Holmes, Chief Executive and Registrar
Wendy Harris, Deputy Registrar
Sue Ambler, Head of Research and Development
Richard Anderson, Acting Head of Registration
Sarah Billington, Chief Inspector
Lyndon Braddick, Director, Scotland
Howard Duff, Director, England
Janet Flint, Head of Support Staff Regulation
Christine Gray, Head of Corporate Governance
Ros Hayles, Head of Investigations and Hearings
Elaine Mulingani, Governance Co-Ordinator
Martha Pawluczyk, Head of Overseas Registration
David Pruce, Director of Policy and Communications
Cath Savage, Director, Wales
Vanda Thomas, Patient and Public Involvement Manager
Peter Wilson, Head of Post-registration

PSNI
Raymond Anderson, President
Trevor Patterson, Director
Mark Neale, Head of Public Affairs

Other Regulatory Bodies
Peter Coe, former Chief Executive and Registrar, General Optical Council
Jane Hern, Registrar, Royal College of Veterinary Surgeons

Scotland
Bill Scott, Chief Pharmaceutical Officer, Scottish Government Health Directorates
Audrey Cowie, Professional Adviser, Scottish Government Health Directorates
Catherine Clark, Head of Regulatory Unit, Scottish Government Health Directorates

Wales
Jeremy Savage, Deputy Pharmaceutical Adviser, Welsh Assembly Government
Barbara Bale, Head of Workforce Policy, Development and Commissioning, Welsh Assembly Government
Mary Gilbert, Regulation and Education Project Lead, Welsh Assembly Government

Northern Ireland
Norman Morrow, Chief Pharmaceutical Officer, DHSSPSNI
Joyce Cairns, Deputy Director HR, DHSSPSNI

Other
Nigel Clarke, Chair, Clarke Inquiry, member CHRE
David Colin-Thome, National Director of Primary Care, Department of Health
Felicity Cox, Pharmacy Negotiating Lead, NHS Employers
Jean Curtis, Professional Secretary, Guild of Healthcare Pharmacists
Rob Darracott, CEO, Company Chemists Association
Catherine Duggan, Senior Clinical Lecturer, School of Pharmacy, University of London/UK Clinical Pharmacy Association
Margaret Goose, Chair, Royal College of Physicians Patient and Carer Involvement Steering Group
Taryn Harding, Project Manager, NHS Employers
Peter Noyce, member, PROLOG

Council for Healthcare Regulatory Excellence
11 Strand
London
WC2N 5HR

Telephone: **020 7389 8030**
Fax: **020 7389 8040**
Email: **info@chre.org.uk**
Web: **www.chre.org.uk**

council for healthcare regulatory excellence