

The Council for Healthcare Regulatory Excellence

Performance review report

Changing regulation in changing times
2010/11

Annual report volume II





The Council for Healthcare Regulatory Excellence

Annual report volume II: Performance review report 2010/11: Changing regulation in changing times

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About CHRE

The Council for Healthcare Regulatory Excellence promotes the health and well-being of patients and the public in the regulation of health professionals. We scrutinise and oversee the work of the nine regulatory bodies¹ that set standards for training and conduct of health professionals.

We share good practice and knowledge with the regulatory bodies, conduct research and introduce new ideas about regulation to the sector. We monitor policy in the UK and Europe and advise the four UK government health departments on issues relating to the regulation of health professionals. We are an independent body accountable to the UK Parliament.

Our aims

CHRE aims to promote the health, safety and well-being of patients and other members of the public and to be a strong, independent voice for patients in the regulation of health professionals throughout the UK.

Our values and principles

Our values and principles act as a framework for our decision making. They are at the heart of who we are and how we would like to be seen by our stakeholders.

Our values are:

- Patient and public centred
- Independent
- Fair
- Transparent
- Proportionate
- Outcome focused.

Our principles are:

- Proportionality
- Accountability
- Consistency
- Targeting
- Transparency
- Agility.

Right-touch regulation

Right-touch regulation is based on a careful assessment of risk, which is targeted and proportionate, which provides a framework in which professionalism can flourish and organisational excellence can be achieved. Excellence is the consistent performance of good practice combined with continuous improvement.

¹ General Chiropractic Council (GCC), General Dental Council (GDC), General Medical Council (GMC), General Optical Council (GOC), General Osteopathic Council (GOsC), General Pharmaceutical Council (GPhC), Health Professions Council (HPC), Nursing and Midwifery Council (NMC), Pharmaceutical Society of Northern Ireland (PSNI).



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1. Chief Executive's foreword

Over the last year there has been considerable change in the context in which the health professional regulators operate and there are significant changes still to come. These changes include the UK economic situation and the growing financial pressures on the healthcare system, the consequences of the Department of Health's arm's length body review in England and the development of government policy on professional regulation as set out in the command paper *Enabling Excellence*. It is the government's clear intention to limit statutory regulation and to encourage professional and occupational registers instead.

Government plans also include bringing social workers into the same regulatory framework as health professionals, something which CHRE proposed in its report on the fitness to practise function of the General Social Care Council in 2009. With health and social care system regulation already combined in the Care Quality Commission this makes obvious sense.

In Northern Ireland the Pharmaceutical Society has worked hard to bring about changes to its legislation and, subject to Assembly approval, will be able to operate within a better legal framework in future.

Revalidation for doctors will proceed but the government has made clear that it does not necessarily think revalidation is proportionate to the risks relating to non-medical health professions. The regulators are currently reviewing their plans in the light of this change of emphasis and CHRE will be publishing views on continuing fitness to practise shortly.

There has also been considerable public attention given to those therapies where the evidence for efficacy is contested. Pharmacy regulators have had to consider the place of homeopathic remedies in pharmacy practice in the face of criticism from the Science and Technology Committee. The inclusion of herbal products in the regulatory framework means that herbalists will be regulated in future by the Health Professions Council. Chiropractic has come under scrutiny as a result of the attempt by the British Chiropractic Association to sue a science journalist for libel and the General Chiropractic Council has had to deal with several hundred complaints relating to the claims made about the efficacy of chiropractic for certain conditions.

Questions about risk, about the place of regulation in continuing professional development or the need for revalidation and about the limits of regulation when evidence for clinical practice is a matter for debate, all require us to think clearly about the specific role of regulation and the things it can and can't do. We made our own contribution to this thinking when we published our approach in the paper *Right-touch Regulation*².

The challenge therefore for all of us is to develop a greater capacity to understand and quantify risk and to use regulation effectively and appropriately to reduce it.



Harry Cayton
Chief Executive

² CHRE, 2010. *Right-touch Regulation*. London: CHRE. Available at www.chre.org.uk

2. Executive summary

Introduction

- 2.1 The primary focus of the health professional regulators is patient safety and the protection of the public. Through our review of the nine health professional regulators we are satisfied that most of the regulators are performing well across their regulatory functions. We have however identified some areas of concern in relation to the performance of some of the regulators. We are aware that the regulators in question are already taking action to address these areas.
- 2.2 We have also reviewed key issues and concerns affecting health professional regulation which have the potential to impact on public protection. We have identified a number of issues for CHRE, the Department of Health and (in the case of PSNI) the Department of Health, Social Services and Public Safety Northern Ireland to consider further.

Summary of our findings

The current issues and concerns across health professional regulation

Changes in health and social care regulation

- 2.3 We discuss the changes facing health professional regulation that are proposed in the Health and Social Care Bill and in the command paper *Enabling Excellence: Autonomy and accountability for healthcare workers, social workers and social care workers*³ (*Enabling Excellence*) and the implications of the changes for the health professional regulators and CHRE. We also discuss the changes proposed to pharmacy regulation in Northern Ireland that are set out in the Pharmacy (Northern Ireland) Order 1976 (Amendment) Order (Northern Ireland) 2011.
- 2.4 The Health and Social Care Bill and *Enabling Excellence* set out both the government's rationale for the future regulation of health and social care in England and its plans for how this will be achieved. The government has stated that there will no longer be an assumption that statutory regulation will be the first resort in dealing with risks arising from professional activities or concerns that happen locally (although this may not be the case for practitioners/professionals who work independently and are not employed). There will in future be an increased focus on employers taking local responsibility for supporting, developing and managing staff in order to strengthen and foster professional excellence, and the further development and accreditation of voluntary registers.
- 2.5 Voluntary registers are usually set up where a profession or occupational group wishes to assure the public and employers that its members are appropriately qualified and competent to carry out their roles. In order to support the government's intention to increase the use of voluntary registers, it is proposed within the Health and Social Care Bill that CHRE⁴ will be established as a national

³ Department of Health, 2011. Command Paper: *Enabling Excellence: Autonomy and accountability for healthcare workers, social workers and social care workers*. London: Department of Health.

⁴ CHRE will also be renamed the Professional Standards Authority for Health and Social Care

accrediting body for voluntary registers in the health and social care sector. Accreditation would be a formal recognition that a voluntary register is managed effectively and provides an appropriate level of assurance to the public.

- 2.6 The Health and Social Care Bill and *Enabling Excellence* also set out changes to the roles of the Health Professions Council and CHRE. The HPC will assume responsibility for the regulation of social workers in England and will hold the statutory register for practitioners supplying unlicensed herbal medicines. Its name will also change to the Health and Care Professions Council (HCPC). These changes are subject to parliamentary approval.
- 2.7 CHRE will (subject to parliamentary approval) become the Professional Standards Authority for Health and Social Care (the Authority). The Authority will not be funded by the government. The Authority's remit will be extended to include:
 - Oversight of the regulation of social workers in England, as a result of the transfer of the regulation of social workers in England to the HCPC
 - Provision of advice to the Privy Council on effective and transparent processes for the appointments to the councils of the regulators that we oversee, following the abolition of the Appointments Commission
 - Investigation of certain complaints about the regulatory bodies.
- 2.8 These new powers will enhance our ability to promote the interests and well-being of the public and those using the services provided by health professionals and social workers. As the regulation of social work is devolved, we will work with the regulators of social workers in Northern Ireland, Scotland and Wales to share learning and promote good practice across the UK.
- 2.9 As well as changes to the regulation of health and social care, the Health and Social Care Bill provides for significant changes to the structure of the NHS in England, including the abolition of primary care trusts and strategic health authorities, and the transfer of the responsibility for commissioning secondary care to new commissioning consortia. This will have implications for the regulators. For example, the transfer of commissioning to new commissioning consortia has implications for the GMC's regulation of doctors, in terms of ensuring that doctors have the knowledge and skills to carry out this new aspect of their role and ensuring that the GMC's guidance, *Good Medical Practice*, is sufficiently clear about a doctor's responsibility to be honest in financial and commercial dealings.
- 2.10 Additionally, there have been changes proposed to the regulatory framework in Northern Ireland. In March 2011, the proposed legislation (the Pharmacy (Northern Ireland) Order 1976 (Amendment) Order (Northern Ireland) 2011) was published. We consider that the changes within the proposed legislation will address the concerns that we have previously highlighted about the current limitations on the PSNI's ability to run an effective fitness to practise process. For example, it will empower the PSNI to impose interim orders and impose a full range of sanctions.
- 2.11 The report outlines a number of recent developments impacting on the environment within which the health professional regulators work. The report also comments on developments in health professional regulation that were brought to our attention through the performance review process.

Recent developments impacting on the regulatory environment

- 2.12 Revalidation is the process by which a regulator can regularly and objectively check that their registrants are up to date and remain fit to practise after registration. The government is committed to supporting the GMC in the implementation of its revalidation scheme; however it has asked the non-medical health professional regulators to continue to develop the evidence base that will inform their revalidation proposals. The government will then consider the next steps for implementing revalidation for non-medical health professionals *'where there is evidence to suggest significant added value in terms of increased safety or quality of care for users of health care services'*. The regulators have continued to develop their processes for revalidation during the period covered by the performance review. We note that several of the non-medical health professional regulators are now considering how their continuing professional development (CPD) arrangements may be developed instead of revalidation or may be revised to contribute to revalidation. While this may be a proportionate and cost-effective approach, there are a number of important issues that the regulators will need to bear in mind. Current CPD arrangements are not equivalent to revalidation and do not provide the same level of assurance to the public. We will shortly publish a discussion paper on continuing fitness to practise which we hope will contribute to thinking in this area.
- 2.13 The report highlights two other areas that are under review that should (once changes have been made) enhance and strengthen the regulators' ability to ensure that registrants are able to practise safely and effectively.
- 2.14 The first area is the introduction of a requirement for health professionals to have indemnity insurance in place as a condition of registration. We welcome the outcome of the independent review⁵ which was published in July 2010 and which recommended that the relevant legislation should harmonise practice across the regulators, giving them all the powers to: ensure that a registrant or applicant to the register has appropriate cover; and to refuse registration if a registrant/applicant fails to comply with a request for information, or to demonstrate that they have, or will have, cover. We consider that this should provide a mechanism to enable those who are harmed as a result of negligence by a health professional to obtain financial redress (such redress is normally provided through a professional's indemnity insurance).
- 2.15 The second area is the regulators' inability to systematically language test applicants who obtained their professional qualification within the European Economic Area. We support the regulators' proposal that Article 53 of the Professional Qualifications Directive 2005/36/EC should be clarified to allow them to assess the language competence of applicants at the point of registration, so that the regulators can ensure that their registrants have the necessary language skills to practise safely. We also reiterate that employers have a responsibility to ensure that prospective employees have the communication skills that are necessary to enable them to meet the needs of patients and the public.

⁵ Department of Health, 2010. *The Independent Review of the Requirement to Have Insurance or Indemnity as a Condition of Registration as a Healthcare Professional – Government Response*. London: Department of Health.

- 2.16 We also discuss the ongoing difficulties around the current arrangements for the vetting and barring schemes in the UK being hard to understand and difficult to use. We are particularly concerned about the lack of feedback the regulators receive from the Independent Safeguarding Authority (ISA) following referrals. The ISA currently does not provide regulators with any notification about the reasons for the ISA's decisions to bar or not to bar an individual. This means that the regulators have no opportunity to identify whether they have made referrals inappropriately, or whether further information might have assisted the ISA. In order for the system to work effectively, it is important that there is ongoing dialogue between the regulators and the ISA about referred cases. We note that there are discussions between the regulators, the ISA, the Department of Health, and the Home Office about how the current arrangements could be improved.
- 2.17 We are also concerned about the Scottish Government's advice to the regulators that it does not consider it appropriate for the regulators to make it known (in any public hearing or documentation) that an individual has been barred. We consider that there would be risks to public protection and confidence in regulation if the regulators followed that advice, and we note that the regulators are taking different approaches to it. We consider it important that a consistent approach is taken by all the regulators and we would encourage them to work with the Scottish Government to develop such an approach.
- 2.18 It is a statutory duty of the regulators to investigate whether a registrant's fitness to practise is impaired if they have been convicted of a criminal offence or received a criminal caution. The notifiable occupations scheme provides a direct line of communication between the police and the regulators, so that information about convictions and/or cautions can be shared. The notifiable occupations scheme alerts the regulators to information that they might not otherwise receive (or might not receive promptly) which may demonstrate that a health professional is not fit to practise and therefore that action is required by the regulator to protect the public.
- 2.19 The notifiable occupations scheme is currently under government review and we would be concerned if it were not to be retained. We consider that the scheme is a vital safeguard ensuring that effective regulatory action can be taken when health professionals are convicted or cautioned for criminal offences. We would encourage the government to take account of our thoughts about the importance of the notifiable occupations scheme in protecting the public before taking any decision about its future.

Developments in health professional regulation highlighted through the performance review 2010/11

- 2.20 We highlight below our thoughts on how the regulators' fitness to practise processes could be improved.
- 2.21 Some of the regulators already require a registrant who has been convicted or cautioned for a drink or drug related offence to undergo a routine medical examination, in order to establish whether or not their fitness to practise is impaired as a result of an underlying drink or drug dependency. This enables the regulators to identify health and performance concerns which may not come to light otherwise, and which need addressing in order to protect the public. We recommend that those regulators who currently do not use this process should adopt it.

- 2.22 We also recommend that the regulators should ensure that they have a proportionate system of quality assurance which enables them to review cases that have reached key decision points in the fitness to practise process, to ensure that their procedures are being followed consistently and that appropriate decisions are being made. We believe that such quality assurance can drive continuous improvement, which can only be beneficial to public protection and to public confidence in professional regulation.
- 2.23 There are two further issues that are covered in the overview section of the report: the regulators' process for dealing with complaints about themselves; and the regulators' methods for involving stakeholders in their work.
- 2.24 Over the coming months we will be considering how the Authority might implement its power to investigate certain complaints about the regulators. We will continue to work with the regulators on improving their processes for investigating complaints about themselves, particularly where the concerns are around the quality and timeliness of their responses to complainants. This is for two reasons. The management of an efficient and effective organisational complaints process is important to maintaining public and professional confidence in a regulator. In addition, in line with the principle of right-touch regulation, we consider that direct and local handling of a complaint provides an opportunity for the solution to be identified as close to the problem as possible. It is for this reason that even once we have the power to investigate, we will expect a complaint to be made to the regulator in the first instance, and the way that complaint is dealt with by the regulator will be scrutinised as part of our investigation.
- 2.25 We also report on the outcome of our work on identifying the most effective methods and mechanisms for engaging patients and the public in the work of the regulators. From research we have carried out recently,⁶ we have developed a set of principles for regulators to refer to when planning and carrying out their stakeholder involvement activities. These are:
- Be clear and focused
 - Use existing knowledge, networks and expertise
 - Make it easy for people to participate
 - Listen, act and provide feedback
 - Make patient and public involvement part of everyday business.
- 2.26 These principles build on those outlined in the report of the inquiry into children's heart surgery at the Bristol Royal Infirmary⁷ and the practical examples of good practice outlined in the Joint Health and Social Care Regulators' Patient and Public Involvement Group *PPI Good Practice Handbook*.⁸

⁶ More details can be found on our website, www.chre.org.uk

⁷ Bristol Royal Infirmary Inquiry, 2001. *The Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984-1995: Learning from Bristol (CM 5207(i))*. Presented to Parliament by the Secretary of State for the Department of Health by Command of Her Majesty.

⁸ Joint Health and Social Care Regulators' Patient and Public Involvement Group, 2010. *A PPI Good Practice Handbook for UK Health Care Regulators*. London: Joint Health and Social Care Regulators' Patient and Public Involvement Group.

The performance of the regulators

- 2.27 This performance review has identified that the regulators are generally fulfilling their responsibilities, and have remained focused on public protection despite the challenges faced by several of them in 2010/11 including: the continuing rise in fitness to practise cases (affecting the GDC, GMC and the NMC); changes in leadership (affecting the GDC, GOC, GOsC); and (in the case of GMC, GPhC and HPC) the assumption of new regulatory responsibilities.
- 2.28 In each of the individual regulator's performance review reports we have identified where we consider their performance has improved and where we think that there are areas of concern. We note below some similarities in the performance across the regulators.

Guidance and standards

- 2.29 The regulators have continued to refine their approaches to patient and public involvement in their work (in particular, the development of guidance and standards). There continues to be a move towards greater use of a system whereby the regulators target their involvement activities for each piece of work they undertake at the most appropriate groups. We welcome this change as it should ensure that patient and public involvement is not a 'tick box' exercise but is a valued and meaningful part of the regulators' work. We have also seen new approaches to the gathering of patient and public views. For example, the GMC held oral evidence sessions as part of its work on producing new child protection guidance and the GPhC has used external organisations to run its events so that it received the benefits of those organisations' contacts and experience. We are pleased that the regulators are continually looking for new and innovative ways to involve patients and public in their work.
- 2.30 The regulators have also continued to produce guidance and to revise their standards. A number of the regulators (the GCC, GOsC and GDC) are considering (or have considered) the issue of advertising. This has been prompted by two things: first, concerns by the public that some professionals may promote what are perceived to unnecessary and expensive treatments and second, a requirement imposed by the Advertising Standards Authority⁹ that health promotion claims should be based on sound clinical evidence. Those regulators have either strengthened their existing guidance or developed new guidance on what constitutes appropriate advertising, and have developed processes to help registrants comply with the guidance. We welcome this work and see it as important in helping to promote professional standards and maintain public confidence in the professions.

Education and training

- 2.31 We have seen that the regulators have begun to place greater emphasis on both their standards for education providers and their quality assurance of education providers being outcome-focused. This is in line with our right-touch approach to regulation which prioritises outcomes over process.

⁹ Advertising Standards Authority, 2010. *The UK Code of Non-broadcast Advertising, Sales, Promotion and Direct Marketing (CAP Code)*. London: Advertising Standards Authority.

This shift (from stipulating how students should be taught to assessing whether students have achieved the standards required to pass the course) should be beneficial to patient safety, as it requires education providers to focus on preparing students to meet the regulators' standards.

- 2.32 We have also seen that some of the regulators are working to increase the involvement of patients and the public in the process of quality assurance of education providers. For example, the GCC's revised degree recognition criteria now require education providers to produce evidence of the involvement of patients and carers in the review and delivery of education programmes and in the teaching and assessment of students. Some of the regulators have also taken steps to help education providers with this requirement, for example, the GMC has drafted advice, *Patient and Public Involvement*, for education providers, which outlines some key principles which underpin and enable effective patient and public participation. We welcome these developments as we consider it important that patients and the public have the opportunity to contribute effectively to the design and delivery of education programmes.

Registration

- 2.33 There are a number of similar improvements that have been made by the regulators in relation to their registration function. Some of the regulators (the GCC, GOC, GOsC) have introduced online registration systems which have enabled more efficient processing of the applications and a reduction in the number of administrative removals from the register. Some regulators (the HPC, GDC and GOC) have improved or are about to improve the amount of information that is available on their public registers about fitness to practise sanctions imposed on individual registrants. Some regulators (the GCC, GDC, GOsC, GPhC and PSNI) have taken further steps to address the risks presented by unregistered practitioners performing activities which should only be carried out by registered professionals. We welcome all these developments.
- 2.34 However, there is one area in relation to the regulators' registration function which we consider could benefit from a harmonised approach. A number of the regulators (the GDC, GOsC, GCC, PSNI) require each applicant to provide a health declaration that is signed by a registered doctor. In our report on health requirements for registrants¹⁰ we recommended that the regulators should only require applicants to provide a self-declaration in relation to health. This was in order to ensure that fitness to practise is assessed only on the basis of functional capacity, rather than a diagnostic view of health and disability. We do not have any evidence to suggest that those regulators that require a health declaration do not assess fitness to practise appropriately. Nevertheless we regard it as disproportionate to require a health declaration that is signed by a registered doctor in every case, and we are encouraged that those regulators that have this requirement have said that they will reconsider it.

¹⁰ CHRE, 2009. *Health Conditions*. London: CHRE.

Fitness to practise

- 2.35 We acknowledge that some of the regulators (the GDC, GMC and NMC) have faced an increase in fitness to practise complaints and that this has had an impact on the timeliness of their case progression. The regulators are making (or have made) a number of changes to their processes to try to improve throughput of cases including increasing the number of hearing days and improving their case management. Those regulators (the GDC, GOC, GPhC) that do not have effective electronic case management systems are also beginning the process of developing or re-developing such systems. The NMC has also continued to develop its new case management system. We will continue to monitor the timeliness of case progression in next year's performance review.
- 2.36 We also welcome the activities that some of the regulators have undertaken in 2010/11 to develop better support mechanisms for witnesses. For example, the HPC has produced an audio-visual presentation (available from its website) for anyone attending (or simply interested in finding out about) its fitness to practise hearings and the GMC has implemented its vulnerable witnesses scheme. We acknowledge that these initiatives represent significant improvements to the arrangements that have previously been in place to support witnesses. We consider that improving witnesses' and complainants' experience could impact significantly on public protection (because it should improve their willingness to co-operate and the quality of their evidence) and on public confidence in the regulatory system.
- 2.37 We have been able to provide more numerical data about the regulators' activities in the financial year 2010/11 in this report than in our previous reports. This data is recorded in each of the regulators' performance review reports. Whilst we are pleased to be able to include this data, we will be working over the coming months on refining and improving the type and consistency of data that we are able to publish in future performance review reports.

Recommendations

- 2.38 We have identified a number of issues which require further consideration by either CHRE, the Department of Health and, in the case of PSNI, the Department of Health, Social Services and Public Safety Northern Ireland.

For CHRE

- 2.39 *Enabling Excellence* requires CHRE to provide advice to the government on a number of issues which have a bearing on matters highlighted in the performance review. In next year's performance review we will summarise the advice we have provided to the government on the following matters:
- The implementation of our powers to investigate certain complaints about the regulators
 - Modern and efficient fitness to practise adjudication
 - Standards for the appointment of members to the regulators' councils.

- 2.40 We aim continuously to improve the quality of our performance review; as part of this work we will liaise with the regulators to refine and improve the quantitative (numerical) data provided in the regulators' individual reports about their core activities.
- 2.41 We will also continue to develop our relationships with the devolved administrations and governments.

For the Department of Health

- 2.42 We recommend that the Department of Health should:
- Continue to progress the legislative changes required for ensuring that indemnity insurance becomes a condition of registration
 - Take into account our views about the importance of the notifiable occupations scheme in protecting the public when contributing to the Ministry of Justice's review of the scheme.

For the Department of Health, Social Services and Public Safety Northern Ireland

- 2.43 We hope that progress continues to be made on implementing the proposed legislation, (the Pharmacy (Northern Ireland) Order 1976 (Amendment) Order (Northern Ireland) 2011).

For the regulators

- 2.44 We recommend that the regulators should:
- Address the highlighted areas of concern identified in their individual reports
 - Review this document as a whole, taking into account our views, and consider whether they can learn and improve from the practices of the other regulators
 - Adopt the practice of requiring a registrant who has been convicted or cautioned for a drink or drug related offence to undergo a routine medical examination, in order to establish whether or not their fitness to practise is impaired as a result of an underlying drink or drug dependency
 - Ensure that they have a proportionate system of quality assurance which enables them to review cases that have reached key decision points in the fitness to practise process, to ensure that processes are being followed consistently and that appropriate decisions are being made
 - Work with the Scottish Government to develop a consistent approach in publicly reporting on Scottish barring decisions which prioritises public protection and confidence in regulation, and with the Department of Health and Ministry of Justice to improve the management of the vetting and barring scheme in England and Wales
 - Review their processes for handling complaints about themselves to ensure that they have allocated sufficient resources to enable complaints to be managed effectively and efficiently, and, where necessary, to enable them to systematically identify learning which could be used to improve overall performance. The regulators should also review whether they have appropriate governance and oversight arrangements in place in relation to their organisational complaints processes.

3. What does the Council for Healthcare Regulatory Excellence do?

- 3.1 CHRE promotes the health, safety and well-being of patients and other members of the public through our scrutiny and oversight of the nine health professional regulatory bodies. We do this in six main ways:
- 3.2 We annually review the performance of the regulatory bodies to identify areas where regulators are doing well and where they can improve
- 3.3 We audit the initial stages of the regulators' fitness to practise procedures. The audit has two aims; to assess whether the regulators' decision making processes are effective, and whether the decisions they make protect the public
- 3.4 We examine final decisions made by the regulators' fitness to practise panels about whether health professionals are fit to practise. We may refer decisions to court where we believe they are unduly lenient and do not protect the public
- 3.5 We conduct research, share learning with the regulators and hold events to explore ways of understanding and managing new regulatory challenges
- 3.6 We advise the Secretary of State for Health and health ministers in Northern Ireland, Scotland and Wales on matters relating to the regulation of health professionals
- 3.7 We keep up to date with European and international policies to improve our policy decisions on regulation of health professionals in the UK. We inform colleagues in other countries of the outcome of our policy projects that might be relevant to them.

4. Who are the health professional regulatory bodies?

- 4.1 The nine health professional regulatory bodies are:
 - The General Chiropractic Council (GCC)
 - The General Dental Council (GDC)
 - The General Medical Council (GMC)
 - The General Optical Council (GOC)
 - The General Osteopathic Council (GOsC)
 - The General Pharmaceutical Council (GPhC)
 - The Health Professions Council (HPC)
 - The Nursing and Midwifery Council (NMC)
 - The Pharmaceutical Society of Northern Ireland (PSNI).
- 4.2 Details of the professions regulated by each body can be found at Annex A.

- 4.3 The regulatory bodies have four main functions. They:
- Set and promote standards that professionals must meet before and after they are admitted to the register
 - Maintain a register of those professionals who meet the standards. Only those who are registered are allowed to work as health professionals
 - Take appropriate action when a registered professional's fitness to practise has been called into question
 - Ensure high standards of education for those training to be a health professional. In some cases they set standards for those who continue to train and develop as health professionals.

5. What is the performance review?

- 5.1 The performance review is our annual check on how effective the regulators have been in protecting the public and promoting confidence in health professionals and themselves. We are required to report our findings to parliament and to the devolved administrations.
- 5.2 The performance review has two important outcomes:
- It enables improvements in the work of the regulators as we identify strengths and areas of concern in their performance and recommend changes
 - It informs everyone about how well the regulators are protecting the public and promoting confidence in health professionals and the system of regulation in their work.

How do we carry out the performance review?

- 5.3 The regulators are asked to provide evidence of how they meet the *Standards of Good Regulation*. The standards describe what the public expect the regulators to do, but do not set out how they should do it. The *Standards of Good Regulation* can be found at Annex B.
- 5.4 To help us to judge the regulators' performance, we use the standards to:
- Identify the strengths and areas for improvement in each regulator's performance
 - Identify good practice.
- 5.5 The *Standards of Good Regulation* are grouped under the four regulatory functions:
- Guidance and standards
 - Education and training
 - Registration
 - Fitness to practise.

The performance review process

- 5.6 The performance review took place between October 2010 and May 2011. There were seven stages to the performance review:

Stage 1

The regulators provided written evidence of how they met the Standards of Good Regulation.

Stage 2

We examined and tested the regulators' evidence using information we had collated from other sources, including our scrutiny of the regulators' fitness to practise decisions, the complaints that we received from members of the public and others, and the third party feedback we received.

Stage 3

We wrote to the regulators with our requests for additional information or clarification of their evidence.

Stage 4

We held face-to-face meetings with each of the regulators to discuss our outstanding queries, areas of concern and/or areas of good performance.

Stage 5

We considered any additional information provided by the regulators and reached a final view on their performance.

Stage 6

We drafted a report summarising our view on each regulator's performance. We shared the report with the regulators and asked for their comments on the factual accuracy of the report.

Stage 7

We considered the comments made by the regulators and finalised each regulator's performance review report. We also produced an overarching report which included our views on emerging themes and issues in health professional regulation.

We are grateful for the feedback received from third parties. We found this information very helpful in forming our views about the regulators' performance. A full list of third party organisations that provided feedback can be found at Annex C.

6. Our approach to regulation

- 6.1 In 2010 we published *Right-touch Regulation*.¹¹ We developed this approach as a result of our experience in working with the health professional regulators and in advising government on areas of regulatory policy. Right-touch regulation builds on the principles of good regulation identified by the UK Better Regulation Executive. These are: proportionality, consistency, targeted, transparency and accountability.

¹¹ CHRE, 2010. *Right-touch Regulation*. London: CHRE.

To these principles we have added a sixth principle of agility. Agility in regulation means looking forward to anticipate change, rather than looking back to prevent the last crisis from happening again.

6.2 Right-touch regulation is the minimum regulatory force required to achieve the desired result. Too little regulation is ineffective, too much is a waste of effort and resources. We have identified the following eight elements to help us, and others who work in regulation, to focus on right-touch regulation in practice:

- Identify the problem before the solution
- Quantify the risks
- Get as close to the problem as possible
- Focus on the outcome
- Use regulation only when necessary
- Keep it simple
- Check for unintended consequences
- Review and respond to change.

6.3 We consider that there are a number of benefits to using right-touch regulation in our work. These include:

- Considering whether the costs of regulation are really worth the benefits
- Describing outcomes in terms of the beneficiaries of regulation
- Enabling organisations to react appropriately to issues as they arise
- Enabling collaboration and co-operation across the regulatory and healthcare system
- Enabling regulation to remain relevant to the needs of today's society.

6.4 We have used right-touch regulation as a framework to guide our consideration of each regulator's performance, and when discussing the current issues and concerns we have identified in health professional regulation.

6.5 We expect and want to be to be challenged if our own approach is not right-touch; that is risk-based, proportionate, outcome focused and agile.

7. What are the current issues and concerns across health professional regulation?

Overview

7.1 This year we have begun to see change in approaches to regulation generally. It is clear that there is a growing view that statutory regulation is not always the best way to deal with risks arising from professional activities. Consideration is now being given to different methods of assuring quality in professional activities for occupations that are not already statutorily regulated, including the development of voluntary registers and employer-led initiatives.

7.2 We discuss below the changes facing health and social care professional regulation proposed in the Health and Social Care Bill and in *Enabling Excellence: Autonomy and accountability for healthcare workers, social workers and social care*

workers¹² (*Enabling Excellence*). We also discuss the changes proposed to health professional regulation in Northern Ireland set out in the Pharmacy (Northern Ireland) Order 1976 (Amendment) Order (Northern Ireland) 2011. We note that elections have recently been held in Northern Ireland, Scotland and Wales. We wait to see whether this will have any implications for health professional regulation in those countries.

- 7.3 We also discuss below the emerging issues we have identified as a result of the performance review, and report on progress on a number of developments in health professional regulation which have the potential to impact on public protection.
- 7.4 We have collated these issues under the following headings: changes to health and social care regulation; recent developments impacting on the regulatory environment; and developments in health professional regulation highlighted through the performance review 2010/11.

Changes to health and social care regulation

- 7.5 In 2011 the government published the Health and Social Care Bill and *Enabling Excellence*. These two documents set out the government's rationale for the future regulation of health and social care in England and its plans for how this will be achieved. In *Enabling Excellence* the government also endorses our right-touch regulation approach.
- 7.6 Importantly, these documents set out a clear change in approach to the regulation of health and social care. The government recognises that the current system of statutory regulation provides an important safeguard for public protection and patient safety and that it works reasonably well. However, it also recognises that statutory regulation is costly, and can constrain employers and professionals from responding flexibly to the changing needs of service users in their local areas. The government has therefore stated that there will no longer be an assumption that national statutory action will be the first resort in dealing with risks arising from professional activities or concerns that happen locally (although the government has acknowledged that national regulation has a clear role where practitioners are self-employed or independent practitioners). The government has acknowledged that right-touch regulation means that there is usually more than one way to solve a problem, and that regulation is not always the best answer. The government considers that what is required is an approach to risk that is more responsive to local and individual needs. Therefore, there will in future be an increased focus on employers taking local responsibility for supporting, developing and managing staff in order to strengthen and foster professional excellence, and the further development and accreditation of voluntary registers.
- 7.7 A number of changes to the individual roles of the regulators and to CHRE will arise as a result of this change in approach, which we detail below.

¹² Department of Health, 2011. Command Paper: *Enabling Excellence: Autonomy and accountability for healthcare workers, social workers and social care workers*. London: Department of Health.

Voluntary registers

- 7.8 Voluntary registers are usually set up where a profession or occupational group wishes to assure the public and employers that its members are appropriately qualified and competent to carry out their roles.
- 7.9 There are a number of voluntary registers that have already been set up across the health and social care sector but there is no national system which allows the public, employers or professionals to tell whether they operate effectively and to high or common standards. In order to support the government's intention to increase the use of voluntary registers, it is proposed in the Health and Social Care Bill that CHRE¹³ will be established as a national accrediting body for voluntary registers in the health and social care sector. Accreditation would be a formal recognition that a voluntary register is managed effectively and provides an appropriate level of assurance to the public. We are currently considering how this scheme should operate and what standards should be set.
- 7.10 The Health and Social Care Bill will also empower the statutory health professional regulators to establish and maintain voluntary registers of unregulated healthcare workers in the UK (or unregulated social care workers in England). All of the regulators except the HPC will have to show that any voluntary register would support or relate to the work of the profession(s) that the regulator already regulates. The HPC will not be limited in this way. Should the regulators that we oversee wish to pursue this opportunity to set up voluntary registers, we would recommend that they ensure that there is clear separation between their statutory regulatory functions and their voluntary register functions, and that the differences between them are made clear to the public in order to avoid confusion. We will review the regulators' work in this field as part of our annual performance review process in due course and we anticipate that should regulators set up voluntary registers for unregulated occupational groups they will seek to be part of our assured registers scheme.

Changes to the Health Professions Council (HPC)

- 7.11 The Health and Social Care Bill and *Enabling Excellence* propose specific changes to the remit of the HPC. The government intends to transfer the regulation of social workers in England¹⁴ from the General Social Care Council to the Health Professions Council in 2012. This expansion of the HPC's role will further increase the number of different professions that it regulates. It is proposed that the HPC's name will be changed to the Health and Care Professions Council (HCPC). The transfer is intended to support two aspects of government policy. It will make social work regulation in England independent of government (because it will no longer be funded by the Department of Health). It will also put social work regulation in England on an equal footing with the regulation of the healthcare professions (because the regulation of social workers will fall under the remit of CHRE).
- 7.12 This expansion of the HPC's role will also impact on CHRE. Our role in auditing the HPC's initial stages fitness to practise decisions and in reviewing the final decisions taken by its fitness to practise panels will in future include decisions taken in relation to cases involving social workers in England.

¹³ CHRE will also be renamed the Professional Standards Authority for Health and Social Care.

¹⁴ Social work regulation in the UK is devolved. The HPC will only have statutory responsibility for social workers in England.

As the regulation of social work is devolved, CHRE will work with the regulators of social workers in Northern Ireland, Scotland and Wales to share learning and promote good practice.

- 7.13 The government also intends that the HPC will hold the statutory register for practitioners supplying unlicensed herbal medicines. The government believes that this will minimise the risk to the public (through improved assurance of the competence of practitioners) whilst allowing consumers continued access to these unlicensed products.

Changes to CHRE

- 7.14 The Health and Social Care Bill provides for CHRE's name to change to the Professional Standards Authority for Health and Social Care (the Authority). Subject to parliamentary approval, the Authority will be self-funded – principally from a statutory levy upon the regulators that we oversee, but also from fees payable by voluntary registers accredited by the Authority, as well as payments from government and other bodies that commission work from the Authority. The move away from being government funded and to reporting to Parliament through the Privy Council will provide the Authority with a greater degree of independence.
- 7.15 The Authority will continue to have the current powers, duties and functions of CHRE but the Health and Social Care Bill also proposes extensions to the Authority's remit to include:
- Oversight of the regulation of social workers in England, as a result of transfer of social workers in England to the HCPC
 - Encouraging higher standards of care provided by those workers in the health and social care sector who are not statutorily regulated, through powers to accredit voluntary registers
 - Provision of advice to the Privy Council on effective and transparent appointments to the councils of the regulators that we oversee, following the abolition of the Appointments Commission.

Enabling Excellence also sets out that CHRE's powers to investigate complaints against the regulators that we oversee would be implemented once we become the Authority.

- 7.16 These new powers will enhance our ability to promote the interests and well-being of the public and those using the services provided by health and social workers in the regulation of the health and social work. Although the majority of our costs will be met by the regulators through the statutory levy, we will not be answerable to them and we will continue to set our own priorities within our statutory powers.

Impact of restructuring NHS in England on health professional regulation

- 7.17 As well as changes to the regulation of health and social care, the Health and Social Care Bill provides for significant changes to the structure of the NHS in England. These include the abolition of primary care trusts (PCTs) and strategic health authorities, and the transfer of the responsibility for commissioning secondary care to new commissioning consortia. These changes remain subject to parliamentary approval. Some of these changes have implications for the regulators that we oversee – in particular the GMC due to changes to doctor's

roles; doctors will become responsible for both providing care and treatment and commissioning care, which will bring with it obvious conflicts of interests. The abolition of PCTs and strategic health authorities also has implications for certain mechanisms that are currently in place to support patient safety and quality of care.

- 7.18 It is currently unclear what impact the abolition of PCTs will have on the functions of responsible officers for primary care medical professionals. Currently, each primary care doctor is linked to a responsible officer (usually the PCT's medical director). The GMC's scheme for medical revalidation requires the responsible officer to make a recommendation to the GMC about whether or not the primary care doctor should be revalidated. The responsible officer role is clearly important for public protection, and clarity about who will perform this function in the future will be required before the GMC is able to implement its revalidation scheme from late 2012.
- 7.19 The transfer of commissioning to new commissioning consortia also has implications for the GMC's regulation of doctors, in terms of ensuring that doctors have the knowledge and skills to carry out this new aspect of their role. We are aware that the GMC plans to consider this issue and we expect to report further on the GMC's work in this area in next year's performance review.
- 7.20 The GMC's guidance, *Good Medical Practice*,¹⁵ makes it clear that doctors must be honest in financial and commercial dealings. However its current statement that doctors before 'taking part in discussions must declare any relevant financial or commercial interest' is in our view inadequate to provide assurance to the public that the decisions of doctors involved consortia will be free of conflicts of interests. Declaring an interest does not remove the interest, and doctors should not take part in any discussion involving the granting of a contract to any organisation or individual with whom they have a financial, commercial or personal interest. We anticipate that the GMC will consider this matter once the governance membership and powers of the new commissioning consortia become clearer.
- 7.21 There are also implications for midwifery if strategic health authorities are abolished, as planned,. Currently, the local supervising authorities (LSAs) sit within strategic health authorities in England. The LSAs hold statutory roles and responsibilities for supporting and monitoring the quality of midwifery practice and the supervision of midwives at a local level. The LSAs are important for the protection of women and babies, and clarity about where these organisations will sit in the future will be required. We support the NMC's efforts to get clarity about the maintenance of LSAs.
- 7.22 The impact of the probable abolition of PCTs on the arrangements for the performers' lists is also unclear at present. The performers' lists are the lists of primary care professionals (such as GPs, dentists and pharmacists) who are able to provide NHS services. The role of the current PCTs in holding the performers' lists provides an important safeguard for public protection - as it enables the NHS to better regulate professionals providing NHS services. However, at the moment it is unclear whether the National Commissioning Board will hold performers' lists in future, or whether performers' lists will be held by individual new commissioning consortia. We are confident that when considering this issue, the government will take notice of the outcome of the recent investigation by the Care Quality

¹⁵ General Medical Council, 2006. *Good Medical Practice* (para 73(a), page 32). London: General Medical Council.

Commission,¹⁶ which found that national regulations in place for performers' lists were being inconsistently applied across the PCTs¹⁷ and that this had had adverse implications for patient safety. Clearly, once the PCTs' functions have been transferred to new commissioning consortia (of which there are likely to be a greater number) there will be scope for equal or greater inconsistency, unless appropriate guidance and/or safeguards are put in place to ensure consistency.

- 7.23 Another concern regarding the uncertainty of the local arrangements for health professionals is the line of accountability for performance management, and management of complaints. We note that if this is not made clear, there will be a risk of an increase in inappropriate referrals being made to the regulators, at a time where they are already seeing an increase in their caseloads. This could have implications for the regulators in terms of dealing with cases in a timely manner and also ensuring that they are focused on complaints which are relevant to a registrant's fitness to practise.
- 7.24 The Department of Health (England) has consulted on its proposals to establish a new framework for developing the healthcare workforce.¹⁸ It is currently unclear how the proposed new bodies (which will take the place of strategic health authorities and postgraduate deaneries) will relate to the system of health professional regulation. It is important to public and registrants' confidence that there continue to be clear lines of accountability to the regulator for ensuring the quality of education.

Changes to the Pharmaceutical Society Northern Ireland (PSNI)

- 7.25 We have reported in previous performance reviews the limitations the PSNI currently has to work within in respect of managing pharmacists' fitness to practise, due to its legislation. We have also previously recommended that the Department of Health, Social Services and Public Safety Northern Ireland should act to modernise the framework for regulation of pharmacists in Northern Ireland. In March 2011, the proposed legislation (the Pharmacy (Northern Ireland) Order 1976 (Amendment) Order (Northern Ireland) 2011) was published. We consider that this will address our concerns about the limitations on the PSNI once it is enacted. Amongst other things, the PSNI will be empowered to:

- Impose interim orders
- Impose a full range of sanctions ranging from advice through to removal from the register
- Consider cases where a registrant's fitness to practise is impaired as a result of ill health
- Use specialist advisers such as legal assessors and clinical assessors
- Disclose information about the fitness to practise of an individual (including placing fitness to practise concerns on its register) where it is in the public interest to do so

¹⁶ Care Quality Commission, 2010. *Investigation Into the Out-of-hours Services Provided by Take Care Now*. London: Care Quality Commission.

¹⁷ We note that an investigation by the Regulation and Quality Improvement Authority in Northern Ireland found similar inconsistencies. (Regulation and Quality Improvement Authority, September 2010. *Review of GP Out-of-hours Services*. Northern Ireland: Regulation and Quality Improvement Authority.)

¹⁸ Department of Health: 2010. *Liberating the NHS: Developing the healthcare workforce*. London: Department of Health.

- Set standards for CPD; to require completion of an annual declaration that CPD requirements have been maintained; to require submission of records for review; and to deal with registrants who have not met the standards or who have made a false declaration.

7.26 We will report in next year's performance review on the progress of the enactment of the legislation. We note that this may be affected by the recently held Assembly elections in Northern Ireland.

Recent developments impacting on the regulatory environment

7.27 There are a number of ongoing government policy issues which affect health professional regulation. We discussed our views and concerns about these issues in our last performance review report. We outline below the developments that have taken place since that report was published.

Indemnity insurance

7.28 When harm has been caused as a result of negligence by a healthcare professional, the patient who has been harmed should be able to obtain financial redress. Such redress is usually provided through the professional's insurance arrangements.

7.29 Following an independent review,¹⁹ the government has accepted the conclusions that the most cost effective and proportionate mechanism to ensure that all health professionals have indemnity insurance in place is to make it a requirement of registration with the regulator.

7.30 Currently, the health professional regulators' legal frameworks differ in relation to requiring proof of indemnity insurance as a condition of registration. This means that the regulators do not have a consistent approach to requiring indemnity insurance. The independent review recommended that the relevant legislation should harmonise practice across the regulators, giving them all the powers to ensure that a registrant (or applicant to the register) has appropriate cover, and to refuse registration if a registrant/applicant fails to comply with a request for information, or to demonstrate that they have, or will have, cover.

7.31 The government has said that it will work in partnership with the devolved administrations to implement greater consistency across the professions as and when the legislative opportunity arises. We look forward to these changes being introduced, as we believe they will ensure that patients can secure financial redress if a health professional's negligence has caused them harm.

7.32 The independent review did not conclude that the regulators should require each registrant to hold personal cover. It concluded that those registrants who are NHS or independent sector employees will be able to satisfy the condition of registration through their employer's corporate cover. Personal insurance cover will only be required in relation to self-employed practice. We agree with this proportionate approach. However, we note that there are particular difficulties in relation to securing insurance cover for independent midwives (regulated by the NMC). The

¹⁹ Department of Health, December 2010. *Government Response to The Independent Review of the Requirement to Have Insurance or Indemnity as a Condition of Registration as a Healthcare Professional*. London: Department of Health.

cost of personal cover for independent midwives is prohibitive due to the significant risks involved with childbirth and the cost of compensation that becomes payable when there are incidents of negligence. The NMC has funded a joint project with the Royal College of Midwives to consider whether there are any indemnity insurance arrangements that could be implemented in relation to independent midwives.

- 7.33 We note that as the government is committed to providing choice to women during their pregnancies, it too will have a key contribution to make in ensuring that independent midwives can comply with the requirement for indemnity insurance, if it becomes mandatory for registration with the NMC.

Language testing

- 7.34 As reported last year, the implementation of Article 53 of the Professional Qualifications Directive 2005/36/EC (the directive) prevents the health professional regulators from systematically checking the language competence of health professionals who qualified within the European Economic Area (EEA) before they are registered. In other words, the health professional regulators are not able to assess this crucial aspect of the standards for registration before allowing EEA-qualified applicants entry onto their registers.
- 7.35 The European Commission is currently consulting on proposed changes to the directive. It is seeking further to remove barriers to free movement across Europe as a means to promote economic recovery. The regulators have jointly and individually responded to this consultation to state that whilst they recognise the importance of freedom of movement, this should not take priority over protection of the public. The regulators consider that it is essential that the competent authorities in each country can assure themselves of the language competence of individuals who will practise in their jurisdiction, because effective communication with patients, fellow professionals and within the wider healthcare system is key to patient safety. The regulators have asked for Article 53 to be clarified to allow them to assess the language competence of applicants at the point of registration to ensure that they have the necessary language skills to practise safely. We support the regulators' proposals and reiterate that employers also have a responsibility to ensure that prospective employees have the communication skills that are necessary to enable them to meet the needs of patients and the public.
- 7.36 The Coalition Agreement committed the government to ensuring that all overseas workers who come to work in the UK have the language and professional skills needed to practise safely and effectively. We welcome the government's approach (set out at paragraph 5.5 of *Enabling Excellence*) of working with the NHS Commissioning Board and the regulators to develop proposals for more effective assurance systems that are consistent with the need to provide for the free movement of professionals across the European Union.

Ensuring that registrants remain up to date and fit to practise

- 7.37 Revalidation is intended to be a mechanism to ensure that healthcare professionals maintain the necessary skills, knowledge, practice and professionalism throughout their careers; in other words that professionals are up to date and remain fit to practise. The health professional regulators have been developing their proposals for delivery of revalidation for several years.

- 7.38 The regulators have reviewed their work on revalidation during 2010/11 in light of the change in emphasis by the government. The government is committed to supporting the GMC in the implementation of its revalidation scheme; however it has asked the non-medical health professional regulators to continue to develop the evidence base that will inform their revalidation proposals. The government will then consider the next steps for implementing revalidation for the non-medical health professionals *'where there is evidence to suggest significant added value in terms of increased safety or quality of care for users of health care services'*.
- 7.39 Several of the non-medical health professional regulators are now considering how their continuing professional development (CPD) arrangements may be developed instead of revalidation or may be revised to contribute to revalidation. While this may be a proportionate and cost-effective approach, there are a number of important issues that the regulators will need to bear in mind. Current CPD arrangements are not equivalent to revalidation and do not provide the same level of assurance to the public. We will shortly publish a discussion paper on continuing fitness to practise which we hope will contribute to thinking in this area.
- 7.40 We will want to see evidence in next year's performance review of how the regulators have taken our views about continuing fitness to practise into account in their proposals for delivering the objectives of revalidation. We will be particularly interested to see how any of the regulators that intend to adopt an enhanced version of their current CPD arrangements in place of a revalidation scheme have assured themselves and the public that their proposals will deliver the objectives of revalidation (ie that registrants remain up to date and fit to practise).

The vetting and barring scheme, England/ Protecting Vulnerable Groups, Scotland

- 7.41 The government has reported on a review of the vetting and barring scheme managed by the Independent Safeguarding Authority (ISA). The purpose of the review was to ensure that the scheme provided a proportionate method of barring unsuitable professionals from working with vulnerable patients/service users. The review recommended that the vetting and barring scheme should be scaled back, and identified that improvements could be made if only one organisation was responsible for conducting pre-employment criminal records checks as well as barring activities. This recommendation is to be implemented by the enactment of the Protection of Freedoms Bill, which will merge the functions of the ISA with those of the Criminal Records Bureau (CRB). We support the proposed merger, as we consider that it will reduce both the costs and the burden on employers and other registered groups (including the health professional regulators) who will no longer have to liaise with two separate organisations. This approach is in line with right-touch regulation, although we do not consider that all aspects of the proposed scheme are proportionate, risk-based or sufficiently targeted.
- 7.42 We note that the safeguarding regulations that were introduced in October 2009 remain in place, which means that the health professional regulators have an ongoing legal duty to notify the ISA of relevant information about individual registrants to enable the ISA to take appropriate barring action. We are pleased that the regulators and the ISA have reached agreement about the types of case that should be referred and when referral should take place. However we understand that this agreement is based on an agreed interpretation of the legislation, rather than because the underlying concerns with the legislation have

been addressed. We are concerned about the lack of feedback the regulators receive from the ISA once referrals have been made. The ISA currently does not provide a regulator with any notification about the reasons for a decision to bar/not to bar an individual professional that the regulator has referred. This means that the regulators have no opportunity to identify whether they have made referrals inappropriately, or whether further information might have assisted the ISA. In order for the system to work effectively it is important that there is ongoing dialogue between the regulators and the ISA about referred cases. We note that discussions are taking place between the regulators, the ISA, the Department of Health and the Home Office about how the current arrangements for the vetting and barring scheme could be improved.

- 7.43 We have also become aware of advice issued by the Scottish Government to the health professional regulators regarding the Scottish Protecting Vulnerable Groups scheme (the equivalent to the vetting and barring scheme in England). The Scottish Government has advised the health professional regulators that it does not consider that it would be appropriate for regulators to make known the fact that an individual has been barred in any public hearing or documentation. We are concerned that there are public protection and confidence risks to the regulators in following that advice. For example, following that advice might conflict with the regulator's duty to take action against a registrant, or if a hearing is held in private, that might give rise to a perception that the professional's interests are being prioritised over the public interest. We note that the regulators are currently taking different approaches to the advice, including seeking their own legal advice, following the advice, or ignoring the advice. Such inconsistency in itself carries risks to public confidence in regulation. We consider it important that a consistent approach which is in the interests of patients and the public is taken by all the regulators. We would encourage them to work with the Scottish Government to develop a consistent approach in this area which prioritises public protection and confidence in regulation.

Notifiable occupations scheme

- 7.44 It is a statutory duty of the regulators to investigate whether a registrant's fitness to practise is impaired if they have been convicted of a criminal offence or received a criminal caution. The notifiable occupations scheme provides a direct line of communication between the police and the regulators, so that information about convictions and/or cautions can be shared. The notifiable occupations scheme alerts the regulators to information that they might not otherwise receive (or might not receive promptly) which may demonstrate that a healthcare professional is not fit to practise and therefore that action is required by the regulator to protect the public.
- 7.45 The scheme is under government review and we would be concerned if it were not to be retained, even if dismantling it had the effect of saving police resources. We acknowledge that there are weaknesses with the current scheme (the most significant of which is the inconsistent approach taken by different police forces about the kinds of information that they disclose). However, even taking those weaknesses into account, we consider that the scheme is a vital safeguard, ensuring that effective regulatory action can be taken when health professionals are convicted or cautioned for criminal offences.

- 7.46 We know that the health professional regulators have participated in various activities aimed at addressing the weaknesses in the current scheme in recent years, and we are confident that they would be willing to liaise with the Home Office/Association of Chief Police Officers to identify any further improvements and/or to help streamline the process, if that would be helpful. We would encourage the government to take account of our thoughts about the importance of the notifiable occupations scheme in protecting the public before taking any decision about its future.

Developments in health professional regulation highlighted through the performance review 2010/11

- 7.47 We discuss below a number of areas of good practice that we have identified as a result of this year's performance review. We have also highlighted those areas where we consider the regulators' practice could be improved. We will expect all the regulators to consider these areas carefully to see whether their own performance could be improved through the adoption of the good practice discussed below.

Outcome-focused standards for education

- 7.48 As part of their registration criteria, the regulators stipulate the initial qualifications that an applicant must possess in order for their registration application to be considered. The regulators also assure the quality of educational qualifications by setting the standards that education providers have to meet, and by checking the education providers' performance to ensure compliance.
- 7.49 The regulators have recently begun to place greater emphasis on their standards for education and their processes for quality assurance of education providers being outcome-focused. This is in line with the right-touch regulation approach, which prioritises outcome over process. This means that the regulators are now less concerned about stipulating how students should be taught (eg specification of student/teacher ratios) and assuring how each education provider is governed (eg reviewing their funding arrangements). The regulators now aim to focus on assessing whether students have achieved the standards required to pass the course which makes them eligible for registration with the regulators. We consider that this shift of focus to learning outcomes is more proportionate and should be beneficial to patient safety because it requires education providers to focus on preparing students to meet the regulators' standards. We also consider that it provides greater assurance to the regulators that those passing the education providers' courses are competent to practise safely and effectively. Regulating outcomes rather than processes is difficult, and we look forward to further progress in this area.

Drink/drug related offences

- 7.50 In our first audit of the initial stages of the regulators' fitness to practise processes,²⁰ we commended some regulators for treating convictions and/or cautions arising from drink or drug related offences as evidence that the registrant might have an underlying health problem which could impair their fitness to

²⁰ CHRE, 2009. *Fitness to Practise Audit Report 2009/10*. London: CHRE.

practise. In particular, we commended the approach taken by the GMC and GCC. When these regulators are notified of convictions/cautions for drink-drive/drug related offences, they require registrants to undergo health assessments. They consider that such assessments have identified health and performance concerns which might not otherwise have come to their attention and which needed addressing in order to protect the public. Since the publication of our first audit report the NMC has adopted a similar process. The NMC has reported that this change in process has proved valuable and enabled it to better protect the public. Like the GMC, the NMC has found that single drink or drug related convictions are regularly indicative of an underlying problem. Given the evidence from the GMC, GCC and NMC about the value of this approach, we consider that all regulators should now adopt the practice of requiring a registrant who has been convicted or cautioned for a drink or drug related offence to undergo a routine medical examination, in order to establish whether or not their fitness to practise is impaired as a result of an underlying drink or drug dependency. We will continue to press all regulators to adopt best practice and will report on progress in next year's performance review.

Internal quality assurance

- 7.51 In our previous performance review reports we have commended the GMC's approach to the quality assurance of its processes, including its fitness to practise processes. This is exemplified in its internal audit and review process, which enables the GMC to systematically check samples of fitness to practise cases for compliance with its policies and procedures. We therefore welcome the recent move by some other regulators to introduce similar quality assurance processes.
- 7.52 We consider that the regulators should ensure that they have a proportionate system of quality assurance in place that enables the review of cases that have reached key decision points (such as decisions about whether to impose an interim order, decisions taken at the end of the investigation stage, decisions taken about the formulation of allegations prior to a hearing and decisions taken by panels at hearings) to ensure that procedures are being followed consistently and that appropriate decisions are being made. We believe that such quality assurance can drive continuous improvement, which can only be beneficial to public protection and to public confidence in professional regulation. We would also suggest that the regulators incorporate within their quality assurance systems the review, consideration and dissemination of the learning points we identify from our review of final fitness to practise decisions.

Communications with witnesses (including complainants)

- 7.53 Witnesses (including complainants) play a critical role in enabling the regulators to protect the public. They are an essential source of information which the regulators use when taking action against registrants whose fitness to practise may be impaired. It therefore follows that complainants should be supported to make complaints and that both complainants and witnesses should be supported as cases that they are involved in progress through the fitness to practise process.
- 7.54 We welcome the activities that some of the regulators have undertaken in 2010/11 to develop better support mechanisms for witnesses. Improving witnesses' and complainants' experience could impact significantly both on their willingness to co-

operate (and therefore on the amount of resources required to persuade otherwise reluctant witnesses to attend hearings) and the quality of their evidence, but it could also serve to maintain public confidence in the regulatory system. For example, the HPC has produced an audio-visual presentation, available on its website, for anyone attending (or simply interested in finding out about) its fitness to practise hearings. The GMC has implemented its vulnerable witnesses scheme, following the positive outcome of a pilot study. The pilot demonstrated an improvement in vulnerable witnesses' confidence about giving evidence, their awareness of how to access support and their willingness to co-operate with the fitness to practise process. We acknowledge that these initiatives represent significant improvements to the arrangements that have previously been in place to support vulnerable witnesses.

- 7.55 We were asked by the Secretary of State for Health to advise on what a modern and efficient fitness to practise adjudication system would look like. As part of this commission we have undertaken research to understand what it is like for people to appear as a witness in a fitness to practise case. We will publish the outcomes of this work shortly and will take account of it in next year's performance review.

Stakeholder involvement

- 7.56 We have seen that the regulators have continued to refine their mechanisms for involving stakeholders in their work. This year CHRE has carried out some work on identifying the most effective methods and mechanisms for engaging patients and the public in the work of the regulators. As a result, we found that the regulators were carrying out a wide range of activities to encourage the public and patients to participate in their work. Much of this engagement activity was undertaken by the regulators directly, but some had begun to liaise with existing patients/stakeholders to carry out these activities for them, using their established knowledge and contacts. Generally these activities were carried out as part of specific projects.
- 7.57 It was clear from our discussions that the regulators find it easier to involve patients and the public in certain areas of their work (eg standards and guidance development) than others (eg fitness to practise and registration). This is because fitness to practise and registration are process-oriented and technical areas, which may be seen to be of less direct relevance to patients and the public than the standards of care and treatment they should receive. However, there are obvious patient safety and public confidence implications in the regulators' work in fitness to practise and registration, which means efforts should be made to encourage patient/public participation in the development/revision of these areas, where relevant.
- 7.58 From our discussions with those patients and members of the public who have participated in such activities, it is clear that they see benefits in allowing them to participate in the work of the regulators, stating that it fostered greater confidence in the regulator, it made things simpler for everyone (by clarifying processes and procedures) and in some cases it initiated productive and ongoing relationships. However, at times the stakeholders found it frustrating that they had neither been asked for feedback on their experiences, nor been told of the outcomes of the work to which they had contributed.

7.59 From our research,²¹ we have developed a set of principles for regulators to refer to when planning and carrying out their patient and public activities. These are:

- Be clear and focused
- Use existing knowledge, networks and expertise
- Make it easy for people to participate
- Listen, act and provide feedback
- Make patient and public involvement part of everyday business.

7.60 These principles build on those outlined in the report of the inquiry into children's heart surgery at the Bristol Royal Infirmary²² and the practical examples of good practice outlined in the Joint Health and Social Care Regulators' Patient and Public Involvement Group PPI *Good Practice Handbook*.²³

Complaints about the regulators

7.61 Throughout this performance review period, we have continued to work with some of the regulators on improving their processes for dealing with complaints about themselves, particularly around the quality and timeliness of their responses to complainants. The management of an efficient and effective organisational complaints process is important to maintain public and professional confidence in a regulator. Furthermore, when an organisation is struggling with its performance, complaints are often a useful indicator of areas where improvements need to be made, and can assist in identifying a benchmark against which improvements can be measured. We consider that it is essential that organisational complaints processes are allocated sufficient resources to enable complaints to be managed effectively and efficiently and, where necessary, for learning to be systematically identified and used to improve overall performance. We also consider it essential that there is appropriate governance and oversight of the outcomes of organisational complaints processes, so that the senior management and governing bodies of the regulators can ensure that appropriate learning from complaints is identified and disseminated.

7.62 As mentioned above, it is proposed that the Authority will be empowered to investigate certain complaints about the regulators. We will be considering over the coming months how we might implement such a power. However we are clear that any complaints investigation system we introduce will require the initial complaint to be investigated by the relevant regulator – the regulator is in the best position to appreciate what may have gone wrong and to take appropriate and timely action to put it right (and to adopt any relevant learning to ensure that similar issues do not occur again). In line with the principle of right-touch regulation, we consider that direct and local handling of a complaint provides an opportunity for the solution to be identified as close to the problem as possible.

²¹ More information can be found on our website, www.chre.org.uk

²² Bristol Royal Infirmary Inquiry, 2001. *The Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984-1995: Learning from Bristol (CM 5207(i))*. Presented to Parliament by the Secretary of State for the Department of Health by Command of Her Majesty.

²³ Joint Health and Social Care Regulators' Patient and Public Involvement Group, 2010. *A PPI Good Practice Handbook for UK Health Care Regulators*. London: Joint Health and Social Care Regulators' Patient and Public Involvement Group.

We will scrutinise the way that a complaint is dealt with by the regulator as part of our investigation. This is another reason why it is important for the regulators to ensure that both their organisational complaints processes and their internal quality assurance processes are working effectively.

8. The individual regulators' performance review reports

- 8.1 Our individual performance review reports for the regulators provide our overall assessment of their performance against the four regulatory functions: guidance and standards, education and training, registration, and fitness to practise. The reports focus on where the regulators practices have improved since 2009/10, where the regulators have performed well, and any new or continuing areas of weakness.

9. The General Chiropractic Council (GCC)

Overall assessment

- 9.1 Before discussing our views of the performance of the GCC, we outline below some key information in paragraph 9.2 about the GCC's activities for the financial year 2010/11. When reading this data for each of the regulators, care should be taken to ensure that misleading comparisons are not made. There are differences in the size of the regulators both in terms of staff numbers and registrants, they all work to differing legislation, rules and processes, they have a varying caseload in terms of registration applications and fitness to practise referrals and are dependent to a greater or lesser extent on information from third parties which can impact on the timeliness of their work.
- 9.2 The General Chiropractic Council (GCC) regulates one profession: chiropractors. The GCC is responsible for the quality assurance of three chiropractic educational programmes. It has 2,650 registrants and received 177 new registration applications since the last review. The median times taken to process initial registration applications for UK graduates, international non-EU applicants and EU applicants was 7, 80 and 35 days respectively.²⁴ There were no appeals against registration decisions. The GCC has an annual retention fee of £1,000. The GCC's investigating committee considered 29 non-website cases and 689 website cases and its final fitness to practise committees determined 16 non-website cases and 375 website cases. The median time taken from receipt of initial complaint to the final investigating committee decision was 228 days for non-website complaints and 366 days for website cases. The median time taken from final investigating committee decision to final fitness to practise hearing decision was 199 days for non-website cases and 279 days for website cases.

²⁴ This includes the time taken for the necessary documentation to be received and collated by the GCC and for the payment to be received and processed.

There were no complaints/information indicating the need for an interim order referral. There were no registrant or CHRE appeals against final fitness to practise decisions.

- 9.3 We are satisfied the GCC has continued to perform as an effective regulator despite the testing year it has faced. It has had to continue to manage the challenges associated with the unprecedented and unanticipated number of complaints that it received in summer 2009 concerning the content of some chiropractors' websites. For example, its investigating committee has considered and reached decisions in 718 complaints compared with an average of 30-40 in previous years. As such a high number (689) of those complaints related to very similar issues there was a greater risk to confidence in the process should there have been any significant inconsistency in the decisions reached by the investigating committee. To address this risk, staff providing specialist support to the investigating committee developed and maintained a running record of categories of complaints and associated decisions. We recognise that the significant increase in workload has placed heavy demands on GCC staff, investigating and professional conduct committee members. We consider that the GCC has responded to and dealt with the challenges associated with these complaints well.
- 9.4 The GCC has also had to respond to an expression of no confidence from some members of its profession. The four chiropractic professional associations jointly wrote to the GCC in October 2010 to outline concerns about a wide range of issues including: the approach taken by the GCC in investigating the complaints about the content of some chiropractors' websites; registration fees; the level of involvement of the professional associations in the regulator's work; and the GCC's revalidation proposals. The GCC commissioned an investigation into the joint professional associations' concerns, which concluded that there was no basis to the majority of the concerns that had been raised. However, it was accepted that it would be timely to consider the GCC's approach to internal quality assurance of decisions; the role of the council in the GCC's work; and to improve communications with the professional associations. We expressed concern at the time about the GCC's response to the letter from the chiropractic associations and noted that there was a risk it would be deflected from its task of protecting the public by the interests of the profession. The GCC assured us that this was not the case, and we have concluded that the GCC investigated the concerns raised by the professional associations satisfactorily without being diverted from its core duties as a regulator. The GCC should now return to continuing to focus on protecting the public and maintaining confidence in the profession through its regulatory functions.
- 9.5 We note that whilst managing these challenges the GCC has maintained its focus on improving its performance. During 2010/11 it has:
- Implemented an online service for registrants to use when renewing their registration and when submitting their continuing professional development summaries
 - Published guidance for people with disabilities who are interested in becoming chiropractors
 - Amended its degree recognition criteria so that it now requires education providers to involve patients and the public in programme design and student assessments.

- 9.6 The GCC has also made progress in the areas we identified in last year's review for follow up:
- As outlined above, the GCC has identified and mitigated against the risks associated with handling the large number of complaints it received in 2009 concerning the content of some chiropractors' websites. Further details of this can be seen at paragraphs 9.26 to 9.30
 - The GCC has put in place a written agreement with employers of chiropractors about the range of information that should be exchanged between them.
- 9.7 Another area we wished to follow up was the piloting of practice placements. The GCC has not received any specific proposals from any of the current education providers for piloting the use of practice placements. Therefore no action has been taken in this area.
- 9.8 We are content that during 2010/11 the GCC has managed to maintain its performance in its regulatory functions, improved its performance in a number of areas and managed and responded well to a number of challenges.
- 9.9 As a result of this year's review, we have identified that we would like to review the following areas in next year's performance review:
- The review of the GCC's practitioner-led continuing professional development scheme
 - Any progress made by the GCC in considering only requiring a self-declaration in relation to an individual's health, rather than a certified health declaration
 - Any progress in developing and implementing changes to the rules governing the GCC's investigating and professional conduct committees.

Guidance and standards

- 9.10 The GCC has undertaken a range of activities this year to ensure that its registrants have access to up-to-date standards and additional guidance to help them apply the standards to specific issues. By helping registrants to understand the standards that they should meet when providing care and treatment, the GCC is carrying out an important part of its role in protecting the public.
- 9.11 The GCC's updated and revised code of practice and standard of proficiency came into force in June 2010. To encourage each registrant to read and understand the code, the GCC distributed a copy to each registrant, and asked them to sign a statement that they had read the code and understood that their actions may be judged against it during fitness to practise proceedings. The GCC has had a good response rate (60 per cent of the profession) so far, and will be following up with those registrants who have not yet responded.

9.12 As a consequence of the number of complaints received about the content of some chiropractors' websites, the GCC identified a need for specific guidance to help registrants address requirement C4 of its code of practice and standard of proficiency.²⁵ Requirement C4 relates to the advertising of chiropractic services. The GCC's advertising guidance sets out that any claims about the effectiveness of chiropractic care should be based on the 'best research of the highest standard', and strongly encourages all registrants to use the GCC's commissioned report about the effectiveness of manual therapies to review the content of their advertisements. This is to ensure that they are not making any misleading claims about chiropractic care. A copy of the commissioned report and the guidance on advertising was sent to all registrants.

9.13 The GCC has carried out an evaluation of the impact of its advertising guidance. It has reviewed the websites of all chiropractors, to ascertain whether any claims about the effectiveness of chiropractic care which are not based on the 'best research of the highest standard' are still being made.

This work identified a number of websites that do not comply with the advertising guidance, and therefore may be misleading the public about what they can expect from chiropractic care. The GCC is engaging with the chiropractors involved to resolve this informally.

9.14 Aside from the work on advertising, the GCC has also established a working group to develop specific guidance for chiropractors regarding the Ionizing Radiation (Medical Exposure) Regulations 2000. This is to ensure that concerns identified by the enforcement agencies in the course of visits to chiropractic practices are resolved. Work has begun in a number of areas including producing documentation for dose recording and diagnostic reference levels and drafting written procedures for employers.

Education and training

9.15 In 2010 the GCC completed its revision of its degree recognition criteria – the criteria it uses to approve education providers' courses for student chiropractors. The criteria set out the educational outcomes that have to be achieved by students which directly relate to the code of practice and standards of proficiency. We consider that the linking of the standards applicable to students with those applicable to registrants embeds the importance of meeting the requirements of the GCC's code of practice and standards of proficiency and of being competent and safe to practice chiropractic at a very early stage in the student chiropractor's career.

²⁵ C4 Publicising your work or practice. You or anyone acting on your behalf must use only factual and verifiable information when publicising your work or practice. The information must not: a) mislead b) be inaccurate c) abuse the trust of members of the public d) exploit their lack of experience or knowledge about either health or chiropractic matters e) instil fear of future ill-health f) put pressure on people to use chiropractic g) bring the profession into disrepute. Extract from General Chiropractic Council, 2010. *Code of Practice and Standard of Proficiency*. London: General Chiropractic Council.

- 9.16 It is also positive that the degree recognition criteria now require education providers to provide evidence of the involvement of patients and carers in the review of the structure, content and delivery of education programmes, the teaching and learning of students and the assessment of students. This will provide patients and carers with an opportunity to ensure that their needs influence the education and training of student chiropractors.
- 9.17 In addition to the work that the GCC has undertaken to assure the quality of education and training of student chiropractors, it has also produced detailed guidance for people with disabilities who are interested in becoming chiropractors. The guidance also contains advice for admissions staff to consider when they receive an application from an individual with a disability. The purpose of the guidance is to ensure that entry to the profession is available to the widest group of the public.
- 9.18 The GCC has also undertaken a range of activities to review the quality of education and training undertaken by registrants after graduation. Registrants undertake this education and training (continuing professional development or CPD) to ensure that they remain fit to practise throughout their career.
- 9.19 In 2010 the GCC audited 20 per cent of its registrants' CPD records. As a result of the review, it identified the need for additional advice about acceptable CPD activities. The GCC published a detailed advice note in May 2010 and sent it to all its registrants. The advice note outlined the importance of ensuring that CPD is focused on improving patient care and/or the development of the profession, and that it must be undertaken outside a chiropractor's day-to-day activities.
- 9.20 In common with the other regulators the GCC has been developing a revalidation scheme – which will allow the regular review of registrants' knowledge, skills and attitudes by the regulator in order to ensure that they remain fit to practise. In August 2010 the GCC agreed proposals for a potential revalidation scheme which was then widely consulted on. Workshops were held across the four countries and a consultation paper was published on the GCC's website.
- 9.21 The results of the consultation were discussed by the GCC's council in March 2011, including a recommendation that the GCC should take forward the objectives of revalidation through an enhanced CPD process.
- 9.22 During its discussion, the GCC was conscious of the government's view (as set out in Enabling Excellence) that for revalidation to be worthwhile 'there must be evidence of significant added value in terms of increased safety or quality of care for users of health care services from additional central regulatory effort on revalidation.' Based on the evidence derived from the consultation, the GCC decided that its proposed revalidation scheme would not deliver significant added value to the safety of patients or to the quality of care. In reaching this decision, the GCC took into consideration evidence that the practice of chiropractic is low risk in terms of potential harm, and the majority of the fitness to practise concerns considered by the GCC concern misconduct by chiropractors rather their lack of competence in chiropractic. It therefore decided to cease working on a revalidation scheme. The GCC plans to carry out a full review of its CPD scheme to assess how it can be strengthened. We will want to see evidence in next year's review of how the GCC has assured itself and the public that its registrants will remain up to date and fit to practise in the absence of a scheme of revalidation.

Registration

- 9.23 The GCC has continued to process registration applications effectively. It has also improved its process by implementing online services for the retention of registration and for the completion of mandatory CPD summaries. We note that the online services have received positive feedback from registrants.
- 9.24 As part of its initial registration processes the GCC requires each applicant to provide a health declaration that is signed by a registered doctor. In our report on health requirements for registrants,²⁶ we recommended that the regulators should only require applicants to provide a self-declaration in relation to health. This was in order to ensure that fitness to practise is assessed on the basis of functional capacity, rather than on a diagnostic view of health and disability. We note that the GCC does currently assess whether or not any condition declared impairs the person's ability to practise safely and effectively when considering initial registration applications. Nevertheless we regard it as disproportionate to require a health declaration signed by a registered doctor in every case, and we are encouraged that the GCC has said that it will reconsider this.
- 9.25 The GCC manages the risk of harm to the public and of damage to public confidence in the profession related to non-registrants using a protected title in a proportionate and risk-based manner. It issues 'cease and desist' letters to those chiropractors who practise when they are not registered with the GCC and it follows these up with random telephone calls. These methods have proved effective.

The GCC has also made changes its registration certificates to raise public and patient awareness of the regulation of chiropractors. The certificates now state that chiropractors must be registered with the GCC, and must comply with the code of practice and standards of proficiency. The contact details for the GCC are also provided.

Fitness to practise

- 9.26 In 2009 the GCC received over 600 complaints about the content of chiropractors' websites. The complaints appeared to be a consequence of a libel action brought against a science journalist by the British Chiropractic Association. We reported in last year's report the actions that the GCC had taken to plan how it would manage the progress of these complaints through its fitness to practise process.
- 9.27 The GCC has managed the investigation and conclusion of the complaints effectively. It has provided relevant training for its staff, committee members and legal assessor that deal with the complaints. The committee members, with the support of staff, have addressed the risk of inconsistency across the decisions in these complaints by developing tools to use when writing complaint summaries and when communicating decisions.
- 9.28 We note that the GCC has dealt with an exceptional volume of complaints during this performance review period. We do not consider that the time taken to consider these cases is reflective of the timeframes that would apply in normal circumstances. However, we would encourage the GCC to continue to make every effort to progress cases as quickly as possible.

²⁶ CHRE, 2009. *Health Conditions*. London:CHRE.

- 9.29 From our 2010 audit of a sample of the cases closed by the investigating committee, we found that the GCC had dealt with the cases thoroughly and carefully. We commended the investigating committee for undertaking a detailed investigation of each website that formed the subject of a complaint, in order to ensure that all potential concerns (not just those specifically highlighted by the complainant) were considered.²⁷ From our ongoing review of every case closed by the professional conduct committee we consider that these cases have also been dealt with appropriately.
- 9.30 We acknowledge that these complaints have placed heavy demands on GCC staff and committee members. In addition they have generated considerable anxiety and uncertainty amongst respondent chiropractors. We note that the GCC has sought to help respondent registrants, as it was aware that registrants' professional indemnity insurance did not cover these complaints. It offered all respondent registrants the opportunity to meet or speak with one of the legal assessors who advises the professional conduct committee. This was to give respondent chiropractors an opportunity to ask questions about the different stages of the process.
- 9.31 Dealing with these cases has reinforced the GCC's view about the lack of proportionality in its primary legislation with regard to the powers of its investigating committee. Currently, when the investigating committee comes to a decision that there is 'a case to answer', it has no choice but to refer matters on to the professional conduct committee. We support the changes to its legislation that the GCC has previously asked the Department of Health to progress, namely that the investigating committee be empowered, in appropriate cases, to close cases by asking the chiropractor to give a relevant undertaking or to accept a warning. We agree with the GCC that if the investigating committee were so empowered, it would help the GCC to manage cases in a more cost-effective and proportionate manner.
- 9.32 We note that the GCC has also attempted to address concerns about the transparency, timeliness and cost-effectiveness of the procedures of the professional conduct committee through proposals for significant amendments to its procedural rules. The proposals were subject to consultation and were submitted to the Department of Health. The GCC is in discussion with the Department of Health and the Privy Council on the proposals.
- 9.33 As well as considering changes to its processes, the GCC has also in 2010 considered the quality of the outcomes of its work. The GCC commissioned an external audit of all the investigating committee and professional conduct committees' decisions in 2009. The audit report was positive and did not highlight any cause for concern. This echoes our view that the GCC has effectively managed and reached appropriate decisions in its fitness to practise cases during this period.

²⁷ CHRE, 2011. *Fitness to Practise Audit Report*. London: CHRE

10. The General Dental Council (GDC)

Overall assessment

- 10.1 Before discussing our views of the performance of the GDC, we outline below some key information in paragraph 10.2 about the GDC's activities for the financial year 2010/11. When reading this data for each of the regulators, care should be taken to ensure that misleading comparisons are not made. There are differences in the size of the regulators both in terms of staff numbers and registrants, they all work to differing legislation, rules and processes, they have a varying caseload in terms of registration applications and fitness to practise referrals and are dependent to a greater or lesser extent on information from third parties which can impact on the timeliness of their work.
- 10.2 The General Dental Council (GDC) regulates seven professions: dentists, clinical dental technicians, dental hygienists, dental nurses, dental technicians, dental therapists and orthodontic therapists. The GDC is responsible for the quality assurance of 79 dental professions' educational programmes.²⁸ It has 96,348 current registrants and received 10,385 new registration applications since the last review. The median times taken to process initial registration applications for UK graduates, international non-EU applicants and EU applicants was 3 days, 2 days and 3 days respectively. The number of upheld registration appeals was 5 out of a total of 15 appeals (eight were dismissed and two were adjourned). The GDC has an annual retention fee (outside of any initial discount period) of £96 for dental care professionals and an annual retention fee for dentists which has risen from £438 in 2010 to £576 at the start of 2011. The GDC's investigating committee considered 845 cases and its final fitness to practise committees 106. The median time taken from receipt of initial complaint to the final investigating committee decision was 5.9 months. The median time taken from final investigating committee decision to final fitness to practise hearing decision was 10.7 months. The median time taken from receipt of a complaint/information indicating the need for an interim order referral to an interim order decision was 4.4 months. The number of successful registrant appeals was one and there were no CHRE appeals against final fitness to practise decisions.
- 10.3 The GDC is going through a period of transition. There have been major changes to key personnel during 2010 – a new chief executive (who came into post in October) and a completely new executive management team (three of whom came into post in early 2011). It is undergoing a modernisation programme which began at the end of 2010 to enable it to meet the demands of regulating seven professional groups and a higher annual fitness to practise caseload than pre-2009. We note that this programme will address each of the GDC's regulatory functions. We are particularly concerned with the scale of improvements that are required around the GDC's fitness to practise work.
- 10.4 The GDC says that it is fully aware of the improvements that it needs to make. We agree with the GDC that the next 12 months is critical to the improvement of its overall performance. We understand that it can take time for the impact of wide-reaching and significant changes to become evident in an organisation's day-to-day

²⁸ This number includes current and new programmes being offered or that have been inspected. Graduate entry programmes for dentistry are counted as separate entries.

activities. This is particularly true in an area of work as complex as fitness to practise. However, as the difficulties that the GDC is experiencing have implications for its ability to maintain the confidence of the professions and the public in its role as an effective regulator, we will want to see that progress is being made as quickly as possible. We will continue to work with the GDC to assist it in making the required improvements prior to the next performance review.

- 10.5 The management of an efficient and effective organisational complaints process is important to maintaining public confidence in a regulator. Furthermore, when an organisation is struggling with its performance, complaints are often a useful indicator of areas where improvements need to be made and can assist in identifying a benchmark against which improvements can be measured. We have raised our concerns with the GDC about its organisational complaints process, particularly in relation to the timeliness and quality of responses to complaints. We are satisfied that the GDC is aware that it needs to improve its management of organisational complaints, particularly those involving concerns about the fitness to practise process.
- 10.6 In last year's review we highlighted a number of areas in which we wanted to see evidence of progress. We discuss these in more detail later in this report but highlight the key points below:
- The GDC's review of its standards – the GDC is in the process of reviewing its standards document, *Standards for Dental Professionals*, to ensure that it is fit for purpose. It is also revisiting other key guidance documents. Importantly, it has changed its approach to public and patient involvement. It is moving to a system in which it will target its engagement activities for each piece of work it undertakes at the most appropriate groups
 - The GDC's review of the education standards and quality assurance process for undergraduate education – the review of the education standards has continued. A draft of the proposed learning outcomes has been formally consulted on. The GDC aims to agree and publish learning outcomes by autumn 2011, and the review of the quality assurance process will take place shortly afterwards
 - The planned changes to the register – there have already been some changes to the GDC's register such as the introduction of a 'sounds like' functionality. Further changes to the register should be implemented by July 2011
 - Reduction in delays in fitness to practise case progression – the GDC has made a slight improvement in the delays in its fitness to practise case progression. However, we consider that there is still room for significant improvement. The GDC has a good understanding of the reasons for the delays in the progression of fitness to practise cases, and has already introduced a number of mechanisms to improve case progression
 - The review of the GDC's case management system – as a result of the review the GDC decided that it required a new case management system. It expects that this new system should be implemented by November 2011.

10.7 In next year's review we would like to see evidence of progress in relation to:

- The review of *Standards for Dental Professionals*
- The effectiveness of the co-regulatory working relationship with the Care Quality Commission in England
- The publication of the GDC's standards for education
- The revision of its education quality assurance processes
- The review of its continuing professional development (CPD) arrangements and the development of a revalidation scheme
- Planned changes to the register
- The consideration given to making the registration process more robust, fairer and more efficient
- The outcome of the fitness to practise policy and process review
- The impact of the changes on the GDC's performance in fitness to practise.

Guidance and standards

10.8 There have been two key strands to the GDC's work in guidance and standards during 2010/11. First it has made some progress on its strategic review of its standards document, *Standards for Dental Professionals*. Second, it has addressed specific areas of concern in dental practice/regulation, through the development of guidance and advice. We consider that this is a sensible approach which ensures that public protection and registrants' needs continue to be met.

10.9 Since the GDC first published *Standards for Dental Professionals* in 2005, six additional dental care professions have become statutorily regulated.

The relevant professionals have to abide by the GDC's standards, although the needs of these groups and their effect on patient care were not considered in the development of those standards. We agree with the GDC, therefore, that it is timely to review its standards.

10.10 We note that since our last performance review the GDC has developed a consultation and engagement strategy for this work. A variety of activities are planned or have been undertaken. These include registrant events across the four countries, internal workshops with staff from across the organisation, and the commissioning of research to ascertain patients' and the public's expectations of dental care professionals and what guidance they consider should be available to registrants. The GDC also intends to call for views on its existing standards document on its website, and will use website surveys to obtain more structured feedback on the proposals and ideas that it is contemplating. We consider that the GDC is taking positive steps to ensure that its standards reflect patients' needs and are up to date and evidence based.

10.11 In addition to the review of the standards, and in line with its corporate strategy, we note that the GDC is currently revisiting its scope of practice guidance. This guidance describes the areas in which registrants should have the knowledge, skills and experience to practise safely and effectively in the best interests of the patients. We agree with the GDC's proposal that the principal focus of this guidance should be on patient safety and the public interest, rather than on professional concerns such as career development and the operational priorities of service providers.

- 10.12 Alongside its longer-term work, we note that the GDC has also addressed some specific areas of concern in its standards work during 2010/11. In particular, it has published a new advice sheet, *Escalating and Raising Concerns*, which offers practical advice to registrants who have concerns about their colleagues. The GDC's aim is to encourage registrants to speak out about their concerns appropriately and to dispel any perception that registrants will not be supported in doing so.
- 10.13 The GDC is also continuing to develop guidance to help registrants apply the *Standards for Dental Professionals* in relation to advertising their services. As we stated last year, the GDC had identified that misleading advertising was a common subject matter of fitness to practise complaints. In autumn 2010 the GDC released a draft version of its *Principles for Ethical Advertising* document for consultation and although it received over 1,000 responses, we note it was disappointed that few of the responses it received were from members of the public. To ensure that the public's views were taken into account, the GDC carried out further research into public and patient attitudes. This research showed that the promotion of what were perceived to be expensive and unnecessary treatments (particularly those which are cosmetic) feeds into patients' and the public's concerns about dental professionals being more concerned about running a successful business than providing healthcare that it is in the patients' interests. We note there has been a short delay in publishing the *Principles of Ethical Advertising* guidance; this is due to the GDC making efforts to ensure that the views of patients and the public influence the development of guidance in an area which is of particular concern to them.
- 10.14 The GDC has also responded to changes in legislation which have impacted upon the dental professions. An example of this is the requirement for dental practices in England to be regulated by the Care Quality Commission from April 2012. The GDC is establishing a working relationship with the Care Quality Commission, to ensure that the organisations' standards are aligned, and that information which is relevant to both organisations' aims is shared at appropriate times. As this is a new area of regulatory overlap, we would like to see how effectively this working relationship develops, and we will revisit this matter in next year's performance review.
- 10.15 Alongside the work around the development and revision of standards and guidance, the GDC has published a patient information leaflet, *Our Standards and How They Affect Your Care*. This leaflet details the standards to which registered members of the dental professions must adhere, what delivery of these standards look like in everyday practice, and how these standards protect patient and public safety. It also contains a reminder that patients check that their dental professional is registered with the GDC. We consider that this document should help patients understand the standards of care and treatment they are entitled to receive when they visit a dental professional, and therefore will empower patients to take action should these standards not be met.

Education and training

- 10.16 The GDC's revision of its standards for education and training has continued in 2010/11. We note that this has been an extended process, but this is the result of the GDC carrying out extensive discussion and engagement with stakeholders, including the consultation undertaken late in 2010, which the GDC believes will

result in a better product. The GDC also considers that its consultation process has led to support from education providers for its change in focus to one based on learning outcomes. We note that the GDC aims to publish the learning outcomes by autumn 2011, and that these will be incorporated into training courses and assessments from September 2012.

- 10.17 Whilst the revision of the standards for education and training continues, the GDC is unable to make much progress on the substantive review of its quality assurance processes for education providers. However, in anticipation of the changes, it is refining its current approach. Its approach now has a greater focus on educational outcomes – inspecting student portfolios and the signing-off of students to ensure that they have achieved the learning outcomes – rather than reviewing the provider’s facilities, its funding, and whether the learning outcomes have been covered in the curriculum. We consider that focusing on learning outcomes is beneficial to patient safety, as it enables providers to prepare students to meet the GDC’s standards for registration
- 10.18 We note that the GDC considers that it has become more accessible to education providers, which has encouraged providers to speak to the GDC when difficulties have occurred concerning their courses. Raising its profile has also meant that students and others have felt more able to approach the GDC with their concerns. This has resulted in the GDC changing the focus and/or timing of quality assurance visits, to ensure that it is considering the most pertinent issues during the visits. The GDC is developing a policy on how it will deal with concerns that are raised about education providers, to ensure that it is managing each concern in an open, effective and consistent manner. We consider that ensuring it is accessible to students, teachers and education providers who want to raise concerns can only improve the standard of education received by students, and consequently improve patient safety and public protection.
- 10.19 Following registration with the GDC, its registrants have to undertake continuing professional development (CPD) to ensure that they keep their skills and knowledge up to date throughout their careers. As part of the most recent CPD audit cycle, the GDC has surveyed its registrants asking them whether they consider that CPD is of value and whether it enables them to meet their development needs. We consider that this goes to the heart of whether CPD is achieving its aim of ensuring that registrants remain fit to practise, or whether it is merely a ‘tick box’ exercise with no real benefit. This matter is also pertinent to the development of the GDC’s revalidation scheme as revalidation will enable the GDC to check that dental professionals continue to meet its standards after initial registration. We note that the results of this survey will feed into the comprehensive review of CPD that will begin this year. The GDC aims to dovetail the review of CPD with its emerging revalidation scheme.
- 10.20 The GDC has built on its revalidation proposals in 2010/11 by publishing a consultation document which detailed how the GDC would carry out the checks of dental professionals’ evidence at each of the three stages – compliance, remediation and in-depth assessment. The GDC is currently analysing the consultation responses, and will modify the draft scheme accordingly. This will then be subject to a cost/benefit analysis.

We will be interested to see the outcome of this analysis and any further consideration by the GDC of the costs and benefits, particularly in light of the government's view recorded in *Enabling Excellence* that *'there must be evidence of significant added value in terms of increased safety or quality of care for users of health care services from additional central regulatory effort on revalidation'*.

- 10.21 We will follow up in next year's performance review on the GDC's progress on publishing its standards for education, revising its quality assurance processes, its review of its CPD arrangements, and the development of a revalidation scheme.

Registration

- 10.22 The GDC has maintained its performance in its registration function and shown improvement through the decline in the number of registration appeals from 23 in 2009 to six in 2010. However, the GDC's registration function continues to be developed. Following the restructure reported in last year's review, the GDC is now considering a number of changes/improvements to the registration processes and criteria used by staff.
- 10.23 The GDC commissioned an external audit of its registration function. In December 2010, the audit found that the function was adequate in most respects, but it did identify some areas for improvement. In early 2011 the GDC developed an action plan to address these areas. Alongside this, the GDC is reviewing a number of aspects of its registration criteria and processes to see whether they can be improved in terms of robustness, fairness and efficiency. The GDC is considering whether it can make its process more robust by requiring a signed photograph alongside a certified copy of an identification document as part of the application process. This would be kept on the registrations database and used to check identity, where necessary. The GDC is reviewing how it considers the health and good character of applicants to the register – it is considering moving to a health self-declaration rather than a doctor certified declaration. It is considering whether to develop functionality to enable online retention of registration, and is mapping its business processes to identify where efficiencies can be made. It is also considering how to put into practice a requirement for indemnity insurance to be a condition of registration. We will follow up in next year's review the changes that have been made to the registration function in 2011.
- 10.24 This year the GDC managed a data breach which resulted in personal email addresses being shared with others. This occurred when candidates who had undertaken the overseas registration examination were informed of their results. We recognise that the GDC took appropriate action to manage this data breach. It reported the breach to the Information Commissioner's Office, it notified the individuals affected by the breach, and it identified the cause of the breach – a staff member had failed to follow set policies and procedures. We note that the GDC has taken action to mitigate against a risk of recurrence. Additional training has been given to the examinations team and a reminder was issued to the registration department reminding staff of the importance of following procedures.
- 10.25 The GDC continues to improve the information that is available on its register and the accessibility of that information. It has introduced a 'sounds like' function to help individuals search for dental professionals. It has also placed the 'search the register' signpost prominently on its new website. Further changes will be implemented by the end of 2011, and will include making information about

individuals who are temporarily registered or who have been struck off the register visible (other sanctions are already visible on the register) and providing a clearer link to the fitness to practise determination associated with the recorded sanction. We acknowledge that these developments are in line with our recommendations²⁹ and that they should help to maximise the contribution of registers to public protection.

- 10.26 The GDC has undertaken a significant amount of work to protect the public from treatment provided by people who either do not have the training and qualifications necessary for registration as a dental professional, or who are not registered with the GDC. There have been 13 successful prosecutions for illegal practice (including providing tooth whitening services) and, as a result of improved liaison with local police forces and the NHS Counter Fraud Services, the GDC has also issued 20 'cease and desist' letters to those who are practising illegally. The GDC has worked to inform the public and the professions about its action by issuing local and trade press releases. The GDC considers that this is having a notable impact, as it has resulted in representative bodies encouraging their members to ensure that their registration is up to date.
- 10.27 The GDC is looking at another issue associated with unregistered practice. Dental care professionals who are unregistered legitimately undertake some activities usually restricted to a registered professional whilst they are undergoing training. Anecdotal feedback received by the GDC indicates that this allowance may be abused in practice, which may have implications for patient safety. The GDC is looking into the risks around this, including practitioners undertaking work that they should not do whilst they are training and practitioners continuing to carry out such activities on a long term basis on the grounds that they are 'in training', when they have no intention of registering with the GDC. We would like to see the outcomes of this work, as we agree that misuse of the 'in training' provision may impact on patient safety and also confidence in the regulator to maintain the integrity of its processes.

Fitness to practise

- 10.28 We consider that there are currently significant weaknesses in the performance of the GDC's fitness to practise function. These have been developing since mid 2009. The GDC has attempted to address these weaknesses through restructuring its fitness to practise directorate on several occasions; this has not resulted in any significant improvement thus far. We would recommend that the GDC going forward focuses on the functions that its department performs, rather than its organisational structure.
- 10.29 We consider that the GDC is now aware of the extent of these weaknesses and plans to address them through:
- Reviewing its processes, procedures and rules
 - Developing and improving working practices
 - Developing a fit-for-purpose case management system.

²⁹ CHRE, 2010. *Health Professional Regulators' Registers: Maximising their contribution to public protection and patient safety*. London: CHRE.

We hope that the newly appointed director of regulation will help to drive forward the improvements required in this area.

- 10.30 The GDC is undertaking a review of its processes, procedures and rules to ascertain if they are appropriate, if they are focused on protecting the public, and if they enable the GDC to work in the most effective and efficient manner. It is likely that some of the improvements that may be identified will require legislative change, but it is also hoped that some can be achieved quickly through changes to working practices. One improvement would be to change the GDC's policy on dealing with registrants who have convictions and cautions arising from drink-driving and drug abuse. The GDC currently does not seek further information about a registrant's health when it is notified of a conviction/caution for drink-driving or drug related offences. This creates a risk that registrants whose fitness to practise may be impaired as a result of ill-health (suffering from addiction or substance misuse problems) may not be identified promptly, which could affect patient safety. The GDC should discuss the benefits of seeking health information when considering such cases with the GMC and the NMC.
- 10.31 An external audit report that the GDC commissioned in late 2010 on its fitness to practise function identified that standard operating procedures were being interpreted and applied inconsistently across and within the different teams within the fitness to practise department. The GDC said that it is addressing this concern in two different ways. It is reviewing its standard operating procedures and guidance, including those used by the investigating committee. It plans to remove ambiguities and to ensure that the procedures are robust and transparent. It is also providing practical training to staff, investigating committee members and panelists on the basics of the fitness to practise process. This training includes guidance on the practical application of the legal tests at the assessment, investigating committee and final hearing stage. We consider that it is essential to public protection, to registrants, and to public confidence in regulation that there is consistent application of processes, procedures and rules.
- 10.32 We note that the inconsistencies in the application of the GDC's processes, procedures and rules may also be due to the inexperience of many of the GDC's caseworkers. The GDC has recruited a significant number of new caseworkers. The external audit report found that the induction and development process for caseworkers was inadequate, with the effect that staff were often unable to form appropriate judgments. We note that the GDC plans to address this issue by producing a training log outlining the training that has to be completed within each individual caseworker's six month probation period. The topics included are how to undertake assessments, preparation and the contents of bundles for investigating committees, how to manage interim order cases, indemnity insurance, and illegal practice. We consider that the GDC's intention to address both staff training and the quality of its processes, procedures and rules will improve the quality of the GDC's work. It may also negate the need for such reliance on lawyers throughout the process, which brings with it higher costs.
- 10.33 We noted in last year's report that the GDC was reviewing its case management system to ascertain whether it was fit for purpose. The GDC has concluded that it is not. The system does not allow case managers to easily track the workflow of their staff which impedes active case monitoring. Nor does the system allow the production of reliable performance management information. The GDC decided that the implementation of a new system is critical to achieving improvements in its

performance. We note that work is underway for the development of such a system, which the GDC hopes will be implemented by November 2011. We continue to consider that this work should be a priority for the GDC, and will want to see evidence of the progress that has been made in the next review.

10.34 The number of fitness to practise complaints made to the GDC in 2010 has matched the level of 2009. Receiving a similar level of complaints has impeded the GDC's ability to significantly reduce its case backlog, and to decrease the time taken for cases to proceed through the fitness to practise process. This is reflected in the GDC's poor performance against all its service standards relating to fitness to practise. We are concerned about this. We note that the GDC is taking a variety of steps to improve the time taken for cases to progress through its fitness to practise process. It has:

- Made more efficient use of its hearings capacity, by improving its process for organising hearings. This has meant that there has been a gradual decline in the number of days suitable for hearings being lost; 45 per cent more cases were finalised in the first 11 months of 2010 compared with 2009
- Recruited 50 additional fitness to practise panelists and 50 legal advisers, and identified an additional hearings venue. It is hoped that this will lead to 25 per cent more cases being heard in 2011
- Introduced greater oversight of the progression of cases referred to its external solicitors for investigation
- Improved liaison with external solicitors regarding their investigations
- Liaised with defence organisations to ensure that, if there is evidence of remediation, this is brought to the GDC's attention at an early stage. It may be that this evidence will save investigation time.

10.35 Whilst we are satisfied that the GDC is taking action to address delays, we have concerns that its focus is solely on improving the time taken for cases to progress from investigating committee to a final hearing. We note that in both our audit of initial decisions and in the GDC's external audit, delays were identified at the investigation stage of the process. We also note that (from the information detailed in paragraph 10.2) the median time taken from receipt of a complaint/information indicating the need for an interim order referral to an interim order decision is 4.4 months, which we consider to be too slow. We would remind the GDC that it needs to consider improving case progression throughout the fitness to practise process. In particular, improvements to the timeliness of the holding of interim order hearings are required, as the imposition of interim orders, where they are necessary, is an important safeguard for public protection. The oversight of the performance of the fitness to practise department by the GDC's council and fitness to practise policy committee should help the GDC to ensure that these improvements are undertaken effectively.

10.36 We would also suggest that the GDC undertakes an evaluation of the measures it has introduced to improve case progression, to ensure that these will clear the backlog, rather than just maintain current performance.

- 10.37 The GDC currently does not have any formal quality assurance processes in place concerning fitness to practise. It is now considering how it could best apply such processes to all aspects of its fitness to practise work, from the initial assessment of a complaint to the final fitness to practise hearing decision. We would recommend that quality assurance processes are introduced urgently, as they are an important tool for continuous improvement. We consider that the GDC would particularly benefit from introducing effective quality assurance, which might help it to identify and remedy concerns about the quality of its investigating committee, its assessment decision letters and its final fitness to practise committees' determinations.
- 10.38 The GDC has made changes to its written communications with complainants, registrants and witnesses. It has reviewed its standard letters and its information sheets to improve their accuracy and clarity. It has provided more comprehensive advice to registrants about how they should respond to a complaint at the investigating stage and what information should be included. It has also improved its witness care leaflet and made this available on its website. We are encouraged that the GDC has reviewed its communications in this way.
- 10.39 While the focus of the fitness to practise function has understandably been on improving its performance, we note that the GDC has also engaged with its stakeholders and other regulatory agencies. The GDC has engaged with other regulatory agencies to improve awareness of each organisation's roles and responsibilities and to facilitate greater information sharing about concerns which may have implications for public protection.
- It has also tried to improve registrants' understanding of the fitness to practise process by providing more information in its *Gazette* on the learning from fitness to practise cases that concluded at the investigating and final stages of the fitness to practise process. We welcome this engagement, as we consider that it can only improve public protection.

11. The General Medical Council (GMC)

Overall assessment

- 11.1 Before discussing our views of the performance of the GMC, we outline below some key information in paragraph 11.2 about the GMC's activities for the financial year 2010/11. When reading this data for each of the regulators, care should be taken to ensure that misleading comparisons are not made. There are differences in the size of the regulators both in terms of staff numbers and registrants, they all work to differing legislation, rules and processes, they have a varying caseload in terms of registration applications and fitness to practise referrals and are dependent to a greater or lesser extent on information from third parties which can impact on the timeliness of their work.
- 11.2 The General Medical Council (GMC) regulates one profession: doctors. The GMC is responsible for the quality assurance of 32 medical schools, and around 1,310 postgraduate programmes across the Foundation Programme and 60 specialties. It has 239,102 registrants and received 13,200 new registration applications since the

last review. The median times taken to process initial registration applications for UK graduates, international non-EU applicants and EU applicants are 2, 19 and 19 working days respectively. There were nine successful appeals against registration decisions out of 17 appeals (which include eight which were quashed and one which was remitted back to a registrations panel to consider). In addition, there were three successful certification decision appeals out of nine cases referred to a panel for determination. The GMC has an annual retention fee (outside of any initial discount period) of £420. The GMC's case examiners considered 1,653 cases,³⁰ its investigation committee considered 31 cases, and its final fitness to practise committee 322. The median time taken from receipt of initial complaint to the final investigation committee decision was 312 days. The median time taken from receipt of initial complaint to the final case examiner decision was 195 days. The median time taken from final case examiner decision to final fitness to practise hearing decision was 379 days. The median time taken from receipt of a complaint/information indicating the need for an interim order referral to an interim order decision was 66 days (from the initial enquiry) and 19 days (from the case examiners' decision to refer). The number of successful registrant appeals against final fitness to practise committee decisions was two and there have been no successful CHRE appeals.

- 11.3 The GMC has maintained and in many ways improved its levels of good performance across all of its regulatory functions this year. In particular, we continue to be impressed with the extent and nature of stakeholder engagement in the development and revision of its standards. The GMC has used innovative techniques to ensure that its guidance meets the needs of patients, carers, registrants and others. We also note that it has continued to improve its good performance in its registration and education functions, which is particularly noteworthy given that it assumed responsibility for the certification process and postgraduate education of doctors in 2010.
- 11.4 In last year's review we noted that there were seven areas of the GMC's performance which we wanted to follow up this year. We welcome the progress that has been made. We outline brief details of the progress made below, and provide further detail in the main report:
- Two stage programme of work on continuing professional development (CPD) - the GMC advised that CPD was included as part of its revalidation consultation in 2010, which included a series of principles underpinning doctors' approach to CPD. The outcome of the consultation showed that 80 per cent of respondents agreed that the principles are important criteria to guide doctors' CPD activities for revalidation. The GMC is conducting a review of the regulator's role in CPD, and will report on this later in 2011
 - The outcome of the GMC's affiliates pilot – a more cost-effective model was approved in October 2010, and there has been a change of title. Rather than using a medical and lay GMC affiliate at a local level, the GMC is now piloting use of a single employer liaison adviser (ELA) role that will operate at a regional level. The revalidation pilots using ELAs are continuing

³⁰ This does not equate to the same number of doctors as one doctor may, for example, have more than one case against them.

- The impact of an increased volume of complaints on the timeliness of the fitness to practise process – the volume of complaints received by the GMC continues to increase. The GMC has taken a number of measures to maintain its performance despite this increase
- Outcome of the vulnerable witnesses pilot – the GMC has reported that the pilot was well received by vulnerable witnesses and achieved benefits for the overall fitness to practise process. The scheme is now being implemented on a permanent basis
- The merger of the Postgraduate Medical Education and Training Board (PMETB) with the GMC – there was a generally effective transition, which allowed delivery of the PMETB’s former functions and operations from the first day of the merger. The GMC is able to report on some high-level benefits and costs. We discuss these at paragraph 11.10
- Patient involvement in the quality assurance of education providers - the GMC has drafted advice, *Patient and Public Involvement*, which outlines some key principles which underpin and enable effective patient and public participation. It has also held stakeholder events
- The impact of the research, which took account of the GMC’s ethnicity and diversity data on policy and operational matters – the GMC has used the research to increase its support for international medical graduates, so that they can improve their understanding of the ethical obligations of working in the United Kingdom.

11.5 In next year’s review we will expect to see progress in the following areas:

- The outcome of the GMC’s work on developing guidance on child protection and for people with learning disabilities
- The GMC’s ongoing work to evaluate the usefulness of its guidance documents
- Patient involvement in the quality assurance of education providers
- The development of the GMC’s CPD and revalidation proposals.

Guidance and standards

11.6 The GMC has advised that its core standards document, *Good Medical Practice* (GMP), and related supplementary guidance in areas such as patient confidentiality, consent, and raising concerns about patient safety, will be reviewed in early 2011 as part of a five-year rolling review programme. This will involve information-gathering, taking into account an analysis of enquiries to the standards team, fitness to practise cases, and comments, suggestions and criticisms of the existing standards. It will also take account of wider changes in the provision of healthcare. The GMC will seek the views of key interest groups through meetings and questionnaires to help establish the nature and most appropriate format and length of any guidance required. We believe that this approach will ensure that GMC guidance remains patient centred and prioritises patient safety and care.

- 11.7 We note that the GMC has undertaken extensive work this year aimed at adding to and improving the already impressive catalogue of guidance it makes widely available to the public, patients, employers and registrants. Following recent tragic and highly publicised events that highlighted issues around child protection, the GMC set up a working group to produce new guidance that will help doctors interpret and apply the standards expected by the GMC in this complex and challenging area. The working group issued a formal call for written evidence and conducted oral evidence sessions during a series of meetings with key organisations. A wide range of groups representing parents' and family interests (including Roma and other black and ethnic minority communities, disabled children and parents, and 'looked-after' children) have given evidence, and the GMC plans to conduct further meetings to expand the range of engagement with parents, and with children and parents, during the formal consultation. It completed the evidence-gathering stage in April 2011 and the guidance will be completed by the end of 2011.
- 11.8 Following the success of *Good Medical Practice In Action*, an e-learning package which helps doctors interpret GMC guidance in real-life situations, the GMC has initiated a major project designed to develop materials to support and assist doctors who are caring for patients with learning disabilities. The GMC has worked closely with organisations such as Mencap to gain an understanding of the needs of this patient group. It has employed some innovative techniques in its efforts to reach them. For example it commissioned a short play highlighting the experiences of a young woman with learning difficulties trying to access care, to provoke discussion amongst the audience about how her experiences could have been improved. We welcome the GMC's considered and inclusive approach to identifying and protecting the interests and safety of particularly vulnerable patient groups. We believe the work it has undertaken in relation to child protection and patients with learning disabilities is extremely valuable. It has important and obvious benefits for public protection, and we will be very interested to follow up the outcomes of these projects in next year's review.
- 11.9 While the GMC has devoted a great deal of effort and resources towards the improvement and development of its standards and guidance, it has also taken steps to determine that what is produced accurately and usefully represents patient experience and front line practice, and is used by those it is intended for. For example, in 2010 the GMC developed an evaluation framework to define and measure what 'good' guidance should achieve. A survey of 1,000 doctors was commissioned to establish levels of awareness and the usefulness and relevance of GMC guidance, and to explore ways to communicate guidance to the profession. The results indicate that there is a good awareness of the guidance, and a consensus that it is useful and relevant. The GMC is undertaking further work in 2011 to understand in more depth how the guidance is used by doctors and what more the GMC needs to do to ensure its guidance is used as a working and a reference tool. We consider that this ongoing evaluation, along with the GMC's widespread engagement with stakeholders, should help ensure that its guidance remains current, relevant and centred on patient care. We will be interested to learn of further developments in this area in next year's review.

Education and training

11.10 In last year's review we indicated our interest in following up on any outcomes or impacts of the merger of the Postgraduate Medical Education and Training Board (PMETB) with the GMC. The GMC has reported some high level quality and cost benefits arising from the merger so far, including:

- A generally effective transition, which allowed delivery of the PMETB's former functions and operations from the first day of the merger (1 April 2010)
- The meeting, and in some cases exceeding, of key performance indicators based on PMETB's past performance
- The creation of a single point of contact for key stakeholders, with a single team handling concerns about undergraduate and postgraduate medical education.
- An integrated approach to education and training, allowing the opportunity to develop a single set of standards for use by those responsible for postgraduate education and training
- Access to a wider range of resources at the GMC
- Financial savings that allowed the GMC not to claim £1.36 million in 'gap' funding from the Department of Health (England), and enabled the GMC to reduce the registration fees to trainees for its GP and specialist registers.

We note that the GMC expects further benefits to become apparent in future as it realises more efficiency/effectiveness gains arising from having responsibility for the overall regulation of medical education.

More generally, since the merger the GMC has sought to integrate the work undertaken by PMETB and has taken on the Quality Framework (QF) that PMETB previously delivered. The GMC completed the current Quality Assurance of Basic Medical Education Quality Assurance of the Foundation Programme and QF cycles by the end of 2010, which provided the opportunity to co-ordinate quality assurance across all stages. In March 2011 the GMC published a new Quality Improvement Framework, encompassing both undergraduate and postgraduate medical education and training in the UK. Anticipated benefits of this integrated approach are the ability to undertake combined visits to deaneries and medical schools based on geographical regions, greater consistency in the processes and outcomes, and the quality assurance visit process becoming more proportionate. We welcome these developments. We acknowledge that the merger provides the GMC with the opportunity to ensure that each stage of education prepares students or doctors for the next, and that training is seen by every doctor as a career-long experience.

11.11 We indicated in last year's report that we would follow up on any progress regarding public and patient involvement in the quality assurance of medical education provision. The GMC publishes *Tomorrow's Doctors*, which sets out the standards for knowledge, skills and behaviours that medical students should learn at UK medical schools. The GMC has reported that it is currently consulting on draft advice to supplement *Tomorrow's Doctors*, relating to public and patient involvement in medical education. The draft advice (*Patient and Public Involvement*) will outline some key principles which underpin and enable effective patient and public participation. We agree with the GMC that in order to be most effective at a local level, action needs to be undertaken by the medical schools in

their own communities. We note that the GMC intends to hold a joint event with National Voices (a patient representative group) on how to encourage local patient and public involvement in medical education and training. We consider the GMC's activities in this area should encourage public involvement in the design and delivery of education programmes, and help to ensure that patient perspectives are taken into account.

11.12 We were interested to learn that, following a report and recommendations made last year by the Basic Medical Education Fitness to Practise group, the GMC will continue to provide training to the Medical Schools Council's (MSC) external fitness to practise panelists and to work with the MSC to develop further guidance on indicative sanctions for student fitness to practise cases. We believe that this will help to ensure greater consistency, fairness and transparency in student fitness to practise matters. The GMC will also assist the MSC to develop processes to transfer information about students who have been the subject of fitness to practise procedures.

11.13 Revalidation is the process by which licensed doctors will demonstrate to the GMC that they remain up to date and fit to practise. It is scheduled to start towards the end of 2012. The GMC consulted on its original revalidation proposals last year, including holding 11 events throughout the UK that concentrated on patient and public perspectives. Revalidation recommendations, based on a portfolio of appraisal information gathered over a five-year period, will be submitted to the GMC by the doctor's local responsible officer. To revalidate a doctor, the GMC will require assurance that he or she is meeting the required standards, based on the GMP framework and agreed core supporting information (including CPD, patient and colleague feedback, complaints and clinical audit) and that there are no known concerns about the doctor's practice. We note that in response to the consultation exercise, action taken by the GMC includes:

- Streamlining revalidation into a single process by replacing the twin processes of relicensing and recertification. The GMC appraisal framework (based on GMP) has been revised, so that all doctors need to supply only one set of supporting information, tailored to their specialty or area of practice
- Developing proposals for how revalidation will work for non-clinical and non-mainstream registrants
- Adding more details to the process, for example clarifying how the GMC's register will show the field of medical practice that provides the basis for a doctor's revalidation, while continuing to recognise that some registrants practise across more than one discipline
- Considering options around quality assurance, including considering a possible GMC programme of sampling and auditing of the information on which responsible officers will base their recommendations
- Piloting and testing elements of revalidation
- Undertaking a literature review of relevant areas, including clinical governance and appraisal, clinical audit, and patient and public involvement in healthcare delivery and evaluation of health professionals' practice.

- 11.14 The significant amount of resources which the GMC has devoted to developing a proportionate, flexible and relevant revalidation scheme should help to assure patients and the public, employers and other healthcare professionals that licensed doctors are up to date and fit to practise. We will follow up on this area of work in our next performance review.
- 11.15 We note that although the GMC does not currently operate a CPD scheme, CPD will form part of the portfolio of evidence that doctors will submit as part of revalidation. The GMC has advised that CPD was included as part of its revalidation consultation in 2010, which included a series of principles underpinning doctors' approach to CPD. The outcome of the consultation showed that 80 per cent of respondents agreed that the principles are important criteria to guide doctors' CPD activities for revalidation. We understand that the GMC is currently undertaking a fundamental review of the role of the regulator in CPD. The review will result in revised guidance for doctors, and the outcome of the review will be subject to public consultation. We would like to follow up on any progress in this area in our next performance review.

Registration

- 11.16 The GMC manages an effective, efficient, secure, transparent and continuously improving registration function. It has continued to make improvements to its registration processes, using tools such as those described in last year's performance review – audits of decisions, staff workshops, and analysis of registration application errors. One outcome of this has been the continued decrease in the number of registration application form errors, down from an average of 1.63 errors per application in 2009 to 1.35 errors per application in 2010. Another is the publication of step-by-step guidance for prospective applicants for some European Union member states to help them identify which route of registration is right for them. The GMC is also considering how it will implement a requirement for indemnity insurance to be a condition of registration.
- 11.17 Linked to the general improvements being made to the GMC's registration process, the GMC has also learnt from appeals against its registration decisions. Following three cases where the registrations appeal panel used a different interpretation of the acceptable overseas qualification to that used by the GMC's registrar, the GMC has revised and strengthened the relevant policy. This should ensure that risks around medical tourism (medical schools offering short courses or allowing students who have failed courses elsewhere to transfer onto their course with recognition of the previous failed medical study) should be better managed. We welcome this revision. As part of its wider work around validating international medical graduates, the GMC is also reviewing how it assesses language competence, and has contributed to the continuation of the overseas medical schools directory, which is used to validate applicants' qualifications.
- 11.18 Doctors must be entered in the specialist register in order to be appointed as honorary, fixed term or substantive consultants in the NHS. Doctors must be entered in the GP register in order to work as GPs (other than trainees) in the NHS. Following the merger of PMETB with the GMC, certification is now part of the wider registration function at the GMC. The majority of applicants for specialist or GP registration are doctors who have undertaken approved training in the UK. The doctors who follow GMC approved specialist and GP training are issued with a

certificate of completion of training (CCT). The remainder of applications are from doctors who seek to demonstrate that: their qualifications, training and experience are equivalent to that provided by an approved UK programme (if the specialty is one in which the UK awards a CCT); or (in the case of non CCT specialties) that their knowledge and skills are consistent with practice as a consultant in the NHS. The GMC has processed a large number of applications efficiently. It has provided guidance to those applying under both certification routes, describing both the certification process and the type of evidence they should provide. It has taken part in a number of roadshows and given presentations to potential applicants. It has also continually sought feedback from applicants and used this to develop and enhance the information it provides. A recent example of this is the inclusion on its website of information on the common reasons for an unsuccessful application. We consider it noteworthy that the GMC has managed the impact of the merger with PMETB on its workload very well.

- 11.19 We note that the GMC inherited formal structured quality assurance processes for the equivalence routes which are designed to ensure that the doctors who gain the certificates have the required knowledge and experience to enter the specialist or GP registers. It also inherited a system of informal quality assurance of the colleges' and faculties' roles within certification. The GMC is developing this further, with the aim of having a formal process in place by mid 2011. We consider that this is a sensible approach, and should contribute to driving up standards of education.
- 11.20 The GMC is continuing to make improvements to its already comprehensive register. During 2011 its registrants will be asked to provide information (for the register) on where they practise, any role they have as a trainer/trainee, their practice within or outside the NHS, and their specialties. In response to feedback from workforce planners, the GMC has also extended the data that is included on the daily download of its register to the NHS across the UK to include primary medical qualifications and warnings. We consider that this information can only be helpful.
- 11.21 Alongside this, the GMC is looking at ways to improve its automated registration checking service. Analysis of the users of the service indicated that it was used predominantly by locum agencies and pharmacists. The GMC wants to ensure that the information is easier for those groups to obtain. We consider that this is sensible and should ensure that those groups continue to check doctors' registration status.

Fitness to practise

- 11.22 We consider that the GMC has maintained effective, efficient, transparent, proportionate and secure fitness to practise processes which are focused on public protection. We have also seen that the GMC has enhanced its communications with all parties involved in the fitness to practise process, and has undertaken a number of activities to address the growing volume of fitness to practise complaints that it receives.
- 11.23 In an effort to enhance its communications with registrants, the GMC has carried out a review of all its standard letters to doctors to ensure that they are accurate, clear and that the tone is appropriate. It has prepared a simple guidance document for doctors whose cases have been referred to a hearing. This is sent to all doctors following referral to a hearing, and is also available online.

- 11.24 The GMC has also acted on the outcomes of its recent research into the over-representation of international medical graduates in the fitness to practise process. The research showed that qualifying outside of the UK and being male means that there is a greater likelihood of fitness to practise concerns being raised. Ethnicity was not found to be a risk factor. The GMC has worked to increase the support for international medical graduates, to improve their understanding of the ethical obligations of working in the UK. For example, it has contributed to the work of the British Medical Association's ethics team to develop induction training on the matter. We consider that this work should help registrants understand what is required of them when working in the UK.
- 11.25 The GMC has also looked to enhance its engagement with employers. It has developed guidance on the thresholds for referral of fitness to practise matters for each of the four countries of the UK. The guidance provides examples of the types of issues which would raise fitness to practise concerns and should be referred to the GMC for consideration. We hope that this guidance will help employers to refer appropriate cases to the GMC.
- 11.26 Employers will shortly also have access to employer liaison advisers (ELAs) to help them identify appropriate cases for referral. The ELAs were previously known as GMC affiliates. The model, which has been agreed for implementation across England, is of one ELA for each region, working alongside a regional liaison team. The ELA will provide expert advice on fitness to practise matters to employers in the region, and the regional liaison team will focus on the management of stakeholder engagement (the intelligence network) within that region. This was considered to be a cost-effective alternative to the GMC affiliates scheme. It has also been agreed that the GMC will implement the model of closer liaison with medical directors in Scotland. We consider that these are positive developments, which should ensure improved links between local and national regulation, improved resolution of complaints, and better outcomes for patients and doctors.
- 11.27 The GMC's vulnerable witnesses support pilot concluded in 2010 and has now been evaluated. The pilot showed a high level of satisfaction with the service amongst GMC staff and vulnerable witnesses. The benefits identified were that witnesses had greater confidence about giving evidence and better awareness of how to access support. Staff also felt that witnesses were more willing to co-operate with the fitness to practise procedures. The pilot also identified learning points – a need to ensure a high number of female volunteers, a need to ensure that there were a sufficient number of volunteers across the four countries, and a need to ensure the impartiality of the witness support. The GMC has identified an external provider to manage the scheme, which is now being implemented on a permanent basis. We consider that the availability of the scheme, alongside the witness help leaflet and the interactive virtual tour of the hearing rooms, demonstrates the GMC's commitment to supporting participants in the fitness to practise process.
- 11.28 The GMC has also looked to enhance its communications with complainants. It has learnt from a review of its 'Rule 12'³¹ cases that it needs to improve the clarity of its decision letters to complainants when it closes cases. Through that review, the GMC identified that it was evident that in a number of the cases, the complainants'

³¹ Rule 12 allows the GMC to review a decision if it is materially flawed or new information has been received which would lead it to a different decision.

belief was that the totality of their complaints had not been considered. The GMC felt that the review showed that all aspects of the complaints had been considered, but identified that the decision letters sent to the complainants had not reflected this fact well enough. The GMC has also initiated an organisation-wide 'tone of voice' review to look at how it communicates with different stakeholders, and this is likely to impact on the content of its future correspondence with complainants. We consider that this work should improve the GMC's relationships with complainants.

- 11.29 The GMC has had to manage a significant change to its planned activities during 2010. The government decided to abolish the Office of the Health Professions Adjudicator (OHPA) which meant that the GMC would maintain its responsibilities for the adjudication stage of the fitness to practise process. The GMC is currently consulting on changes to how it will deal with cases at the adjudication stage of its process. The changes are aimed at improving public confidence in adjudication outcomes (which was the reason that OHPA was established). The GMC has asserted that it has a clear commitment to delivering independent decision making within its adjudication function, and to modernising this function. To demonstrate this, it intends to establish a Medical Practitioners' Tribunal Service, which will be responsible for the running of and the decision making by panels at the adjudication stage. This service would be separate from both the GMC's investigation function and its presentation of cases to panels at hearings. We will monitor the progress of this work in our next performance review. We will do all we can to ensure that the work of the Medical Practitioners' Tribunal on behalf of the GMC remains within the remit of our oversight on behalf of the public, and that it is subject to appeal under Section 29 of our legislation (the NHS Reform and Health Care Professions Act 2002).
- 11.30 We reported in last year's performance review that the GMC had seen an increase in the number of fitness to practise referrals it was considering. The GMC has reported that this increase (and an increase in the average length of hearings) has been sustained in 2010. The GMC said that this has consequently made meeting its service standards difficult. It has managed to maintain its performance by increasing the number of concurrent hearings it holds, by improving its case management, and by adopting a more robust approach to encourage constructive engagement with the process. It has also completed a restructure of its fitness to practise directorate. Cases which are likely to be suitable for warnings or undertakings are handled by teams on a regional basis, while another team manages those cases which are likely to result in a hearing. The aim of this division is to streamline the handling of hearings cases, and to anticipate the arrival of ELA's at regional level. The GMC is also undertaking analysis of the reasons for the increase in referrals from persons acting in public capacity, in order to identify any local issues that may be resulting in an increased referral rate and what action, if any, it can take to address these. We consider that these activities seem sensible. We will continue to monitor the time taken for cases to progress through the fitness to practise process and the actions taken by the GMC to manage the increases in referrals and the average length of hearings.
- 11.31 Whilst we acknowledge that timeliness remains a concern for the GMC, we are pleased that its continued good performance has meant that it could revise its service standard for the referral of interim orders to make it more ambitious. The standard now requires 100 per cent of cases referred for an interim order to be heard within three weeks (instead of four weeks) and, whilst this has been missed

on two occasions recently, that was as a result of only two of 67 cases not being heard within the three week timeframe. The GMC has reviewed the reasons for this and has implemented measures to avoid repetition in the future.

- 11.32 As part of its longer-term plans to address timeliness in its fitness to practise processes, the GMC is also consulting on changes to the way it deals with cases at the end of the investigation stage. The following four main changes are currently subject to consultation: encouragement of doctors to accept proposed sanctions in all cases without referral to a public hearing, introduction of greater discussions with doctors including in some cases meeting with them before the end of the investigation stage, introduction of a presumption of erasure for some criminal convictions which are incompatible with being a doctor, and introduction of automatic suspensions for doctors who refuse to engage with the fitness to practise process. The GMC considers that these changes should enable it to perform its fitness to practise function more effectively, whilst also maintaining public protection. We have provided a response to the consultation. We welcome the GMC's general direction but are concerned at the possible loss of transparency of and accountability for fitness to practise decision making. We will seek to ensure that any decisions that are made under any new process will be subject to oversight and appeal by CHRE on behalf of the public. We will monitor the outcomes of this work in our next performance review.

12. The General Optical Council (GOC)

Overall assessment

- 12.1 Before setting out our view of the performance of the GOC, we outline below some key information in paragraph 12.2 about the GOC's activities for the financial year 2010/11. When reading this data for each of the regulators, care should be taken to ensure that misleading comparisons are not made. There are differences in the size of the regulators both in terms of staff numbers and registrants, they all work to differing legislation, rules and processes, they have a varying caseload in terms of registration applications and fitness to practise referrals and are dependent to a greater or lesser extent on information from third parties which can impact on the timeliness of their work.
- 12.2 The General Optical Council (GOC) regulates two professions: optometrists and dispensing opticians (including student optometrists, student opticians and optical businesses). The GOC is responsible for the quality assurance of 38 educational programmes for the training of optical professionals. It has 24,645 current registrants and received 2,187 new registration applications since the last review. The median times taken to process initial registration applications for UK graduates, international non-EU applicants and EU applicants are 2 days, 3 days and 2 days respectively. There have been 3 appeals against registration decisions and 100 per cent were upheld. The GOC has an annual retention fee (outside of any initial discount period) of £325 for optometrists and bodies corporate, £280 for dispensing opticians, and £20 for student registrants. The GOC's investigation committee considered 64 cases and its final fitness to practise committee 20. The median time taken from receipt of initial complaint to the final investigation committee decision was five months. The median time taken from final investigation

committee decision to final fitness to practise hearing decision was 39 weeks. The median time taken from receipt of a complaint/information indicating the need for an interim order referral to an interim order decision was 14 weeks. The number of successful registrant or CHRE appeals against final fitness to practise decision was one registrant appeal and no CHRE appeals.

12.3 The General Optical Council (GOC) has experienced significant changes this year. Changes to key personnel have included the appointment of a new chair and a new smaller management team. A new chief executive and registrar took up post in March 2011. In addition, the GOC has rationalised its organisational structure by aligning all four of its regulatory functions under the remit of the director for regulatory services. All corporate functions are now managed by the director of corporate resources and the policy, governance and research functions are managed by the chief executive and registrar. There are plans to introduce a performance management system which the GOC believes will improve business effectiveness and increase accountability to stakeholders. Despite significant internal changes, patient and public protection continues to be the GOC's primary focus and we acknowledge that it has performed as an effective regulator across the four regulatory functions: standards and guidance, registration, education and training and fitness to practise.

12.4 We consider that the GOC has performed well during the review period by:

- Consulting on the nature and extent of historical fitness to practise information to be made publicly available on the GOC website, and aiming to improve public accessibility of fitness to practise information on its register by the end of 2011
- Changing how it deals with declarations made by registrants about their fitness to practise so that any concerns are dealt with more swiftly, and therefore ensuring greater levels of public protection
- Continuing to move forward with plans to use case examiners (in the light of the experience of the GMC) rather than refer every case to the investigation committee in the initial stages of the fitness to practise process. We believe this is a good example of cross-regulatory learning and should lead to speedier decision making.

12.5 We would like to follow up on the three areas below in next year's performance review:

- The introduction of an electronic case management system, and how this has contributed to the GOC's aim to reduce the time taken to complete fitness to practise investigations from a current average of 16 months to three, six, or nine months, dependent on case complexity
- Developments or progress regarding the GOC's plan to use case examiners rather than referring every case to the investigation committee
- Progress made on the pursuit of appropriate cases under the Opticians Act, in the light of the European Court concluding that any such proceedings would not be illegal.

Guidance and standards

- 12.6 We note that the GOC introduced revised codes of conduct for individual and business registrants on 1 April 2010. As part of that review, the GOC's standards committee considered the best practice guidance of other regulators, information from the GOC's fitness to practise committee, and recent legislative changes. Case studies focusing on patient safety were used as part of the consultation and launch process. We agree that drawing from these sources on a regular basis should ensure that the GOC's codes of conduct remain up to date and reflect current best practice and legislation. Also, providing practical examples of how the codes of conduct apply in day-to-day activities through case studies enables registrants to improve their understanding of the codes and how they should be applied in their practice.
- 12.7 The outcome of the review was that aspects of the codes of conduct were strengthened and made more explicit in several important areas. For example, some of the amendments to the code for individual registrants were introduced to ensure that the code:
- Explicitly includes reference to persons undertaking training as optometrists and dispensing opticians (students and trainees) to give greater clarity about who is subject to the code
 - States that registrants must have adequate and appropriate indemnity insurance
 - Highlights the fact that registrants must report information to the GOC and other relevant organisations about themselves or other health professionals or organisations, where this information may mean that they are not able to practise safely or effectively or be trusted to act legally.
- 12.8 We consider that these changes are in the interests of both patients and registrants and give further emphasis to the GOC's public protection role. Another outcome of the review was a new patient information leaflet, *What to Expect From Your Optician*. This provides patients with details of how to contact the GOC if opticians do not meet the necessary standards, and details of other complaint resolution bodies – the Optical Consumer Complaints Service and the Advertising Standards Authority. We consider that this leaflet is beneficial to public protection, as it empowers patients and the public to take action where standards of care and treatment may not have been met.
- 12.9 We note that the GOC has also re-evaluated its competency frameworks for registrants during the performance review period. It did this to ensure that patients' interests are prioritised and that consistency in common areas such as communication and professional conduct is maintained across all the professional groups that the GOC regulates. Separate consultation exercises were undertaken for this two-stage review. The first stage reviewed the framework within which the competencies were set in order to ensure consistency of structure and terminology. The second stage reviewed the content of the competencies, which involved consideration of detailed proposals from the Association of British Dispensing Opticians and the College of Optometrists.
- 12.10 To provide illustrative examples of these changes; all of the frameworks use the term 'an understanding of' to describe knowledge competencies, while 'ability to do' is universally applied to descriptions of practical skills. All elements, performance

criteria and indicators for the communications and professional competency units are now identical for each of the GOC's professional categories. We also note that a new and discrete competency unit for paediatric dispensing has been created from elements previously contained in other competency units, as the GOC felt this potentially higher risk area of practice should be prioritised by having its own profile in the framework. The review also reflected current best practice by drawing on models used by both the World Council of Optometry and the Optometrists Association Australia. The revised competencies were approved by the GOC in June 2010.

- 12.11 The GOC intends to conduct annual surveys with stakeholder reference groups and members of its investigation, companies, and fitness to practise committees to measure the effectiveness of its revised codes of conduct and competency frameworks in order to ensure that these prioritise patient safety and patient centred care. A satisfaction rate of less than 90 per cent for any of the categories will trigger proposals for amendments to be considered by the GOC's standards committee, with a targeted score of 90 per cent to be achieved the following year. These surveys will begin during 2011/12. We believe this activity builds on the GOC's positive engagement with the public as mentioned in our last report and sits well with its strategic aim of promoting a wider understanding of its role and engaging stakeholders (including the public, patients, registrants, educators and their representatives) in all areas of its work.

Education and training

- 12.12 The GOC recognises that previously its approval specification for educational programmes may not have been sufficiently outcomes focused; placing too much emphasis on areas such as staffing levels and facilities, for which it has no real regulatory responsibility. During 2010 the GOC therefore reworked the educational handbooks used by its education programme visitors. The review included input from key stakeholder groups and the Quality Assurance Agency for Higher Education as well as learning from the GOC's own quality assurance processes. The revised handbooks, along with the GOC's implementation of an annual monitoring scheme, allows the focus of its work with education providers to remain firmly on areas of risk such as clinical activities, core competency assessment and patient experience.
- 12.13 The GOC has plans to assist education providers to adopt a learning outcomes based approach by holding a providers' workshop at the end of April 2011. We welcome the increased emphasis on learning outcomes, which should ensure that students are fit to practise on completion of their studies and to maintain levels of patient safety.
- 12.14 There are separate handbooks for undergraduate training in optometry and dispensing optics, for pre-registration schemes and for specialist postgraduate qualifications. Each handbook will contain revised standards of competency and conduct for students and trainees, and will be launched at the training providers' workshop at the end of April 2011. The standards have already been circulated to visitors and education providers. The handbooks detail the outcomes that educational programmes must show. For example, the current optometry handbook states that upon graduation, students must be able to take a structured, efficient and accurate history and symptoms from patients with a range of ophthalmic problems and needs. The handbooks also emphasise the public safety role of the

GOC, as seen in the optometry handbook introduction which states: 'In the interests of the public and for their protection, optometrists and dispensing opticians are regulated by the GOC to promote and enforce high standards of education, training and conduct, so as to ensure an adequate and safe standard of eye care.' These changes should ensure that visits are more focused on outcomes and patient safety.

- 12.15 We note that the GOC now publishes its visit reports on its website in line with its publication policy (as agreed in August 2010 by the education and training committee). We note that this improvement occurred despite strong initial resistance from the education providers themselves, who felt that this information was commercially sensitive and therefore should not be published. We acknowledge that the persuasive approach employed by the GOC – explaining to providers the implications of the Freedom of Information Act and the practices used by other regulators – was key to reaching a satisfactory agreement about the publication of these reports.
- 12.16 The GOC's statutory Continuing Education and Training scheme (CET) sets out that every registrant's CET records can be audited once in every three-year cycle. CET is linked to the GOC's registration/retention process in that registrants must accrue the necessary CET training points by completing the requisite number of training hours. The GOC's process is different to that of other regulators, as it approves CET activities and events. In order for an activity or event to be approved for CET points, it must go through the GOC approval process, which tests the learning outcomes of the activity against the relevant GOC standards and competency framework. Failure to accrue the required CET points can ultimately result in removal from the register, with no restoration allowed until the deficit has been corrected.
- 12.17 Following UK-wide consultations throughout 2010, the GOC is currently developing the CET scheme to include a requirement that registrants undertake peer review activities involving patient record keeping and challenging decision making. We note the GOC's view that these changes to its CET scheme will provide a suitable tool to deliver a system of revalidation that offers public protection and which is proportionate to risk.
- 12.18 We agree that the GOC's approach as outlined above gives registrants an added incentive to undertake recognised training to maintain the knowledge and skills they need to remain fit to practise.

Registration

- 12.19 The GOC maintains five separate registers, which are those for optometrists, dispensing opticians, student optometrists, student dispensing opticians, and optical businesses. A major development impacting on the GOC's registration function during the review period has been the launch of its online retention system in January 2011. Around 70 per cent of registrants had completed retention by the beginning of March 2011, with 63 per cent of those completed online. This completion rate represents a 15 per cent increase when compared to the same date the previous year, before the facility became available. We acknowledge that an online system helps to prevent unnecessary administrative removals and improves the efficiency of applications processing.

- 12.20 All applicants for registration, restoration or retention on the GOC register must make a self-declaration detailing any health or character issues that might impair their fitness to practise. Apart from restoration applications where the applicant had previously been erased by a fitness to practise committee, we note that since November 2010 any matters of concern are no longer referred to the GOC's fitness to practise team. Registration staff now provide case management and advice to the chief executive and registrar who decides whether the application should be approved. We consider that this is a positive change that should allow any concerns to be dealt with more swiftly, and therefore ensure greater levels of public protection. We would be interested to know whether this policy change has had an impact in terms of fitness to practise matters over the next reporting period.
- 12.21 Following consultation in 2010, the GOC has taken steps towards improving public access to fitness to practise information on its registers, to include details of suspended registrants. The GOC also intends to link historical fitness to practise information with register entries, and to make fitness to practise committee decision notices accessible from the GOC website during the currency of any sanction imposed. While we acknowledge that including the records of struck off registrants on the public registers would be likely to require a change to the GOC's *Registration Rules*, we believe that such details should be included in online registers for at least five years.³² The registers are a valuable tool for public protection, and we note that the measures taken by the GOC should play a useful role in providing additional information to help the public make an informed choice when identifying professionals who are qualified and fit to practise.
- 12.22 The GOC suspended prosecutions under Section 27 of the Opticians Act 1989 (involving the unlawful sale of contact lenses on the internet) due to the possibility of an adverse European Court ruling. However the GOC has been advised that the European Court case concluded without deciding that any such proceedings would be illegal. We therefore welcome the GOC's recent decision (in January 2011) to revise its current protocol. It will now aim to pursue appropriate cases involving the unlawful sale of contact lenses and other unregistered practice. We take the view that this has clear benefits for public protection and patient safety, and will be interested to see the results of any action taken in the next performance review.

Fitness to practise

- 12.23 The GOC continues to undertake activities to improve patients', registrants' and employers' understanding of the fitness to practise process. Updated information on the GOC's investigation process is available on the website, including links to an investigations process flowchart, and to its investigation committee guidance. During this review period the GOC has also publicised its fitness to practise function by attending country-wide events such as Citizens Advice Bureau conferences to improve public awareness of the help that the GOC can offer people who have concerns about GOC registrants. The GOC has built on registrants' understanding of the fitness to practise process through articles in newsletters and by providing clearer information on the process in its initial letters to registrants whose fitness to practise is being investigated. We also note that the GOC published its first stand-alone fitness to practise annual report in 2010, articulating

³² As outlined in: CHRE, 2010. *Health professional regulators' Registers: Maximising their contribution to public protection and patient safety*. London: CHRE.

its three-year programme for modernising the GOC's fitness to practise function and highlighting progress made and changes to procedures in this area made during 2009/10. We welcome this increased transparency and accessibility, which we believe should improve public confidence in the regulatory process.

- 12.24 The GOC has maintained its liaison with employers and during 2010 its fitness to practise team has continued to develop relationships with the larger optical employers throughout the country. Main points of contact have been established with most of the major commercial providers of optical services. We welcome this continued involvement and believe that any increase in employer awareness of fitness to practise issues and how to deal with them will have benefits for patients, the public and registrants. We also note activities undertaken by the GOC this year to facilitate the exchange of information in relation to fitness to practise cases with other bodies, such as the police and the NHS Business Services Authority Counter Fraud and Security Management Service. In relation to the GOC's liaison with the police, a guidance document was produced to assist police forces when dealing with requests from the GOC for information about opticians under the notifiable occupations scheme.
- 12.25 Following work done last year to develop draft guidance to encourage consistent decision making by its new investigation committee, we note that this guidance has now been published and is available on the GOC website. An internal audit that was undertaken to examine the effectiveness of decisions taken by the investigation and fitness to practise committees has indicated a marked improvement in the quality of investigation committee decisions in the past year. We acknowledge that these improvements took place at the same time as a new investigation committee was being recruited and trained, and that this was achieved without any major disruption to the GOC's fitness to practise function. The GOC has also advised that its investigations protocol and guidance will be regularly appraised to ensure that it remains relevant, and takes account of any changes in the law and best practice.
- 12.26 We note that in January 2011 the GOC adopted plans to help reduce the overall time taken to deal with fitness to practise cases - to three months for simple cases, six months for standard cases and nine months for complex cases. A fast track system will be introduced for simple cases, and additional staff resources will be reallocated to investigations. We take the view that these steps, in conjunction with the introduction of a new electronic case management system and the changes to the rules that are currently under consultation (including plans to use case examiners rather than referring every case to its investigation committee) should provide important benefits for public protection and public confidence. We note that the GOC met key performance indicators for its fitness to practise function in 2009/10 and that it is now considering whether these indicators should be amended in the light of its recent good performance. We acknowledge that there are many benefits to an efficient fitness to practise process. These include the ability to take remedial action more quickly so that patients and public safety is ensured where necessary, and to reduce the onerousness of the fitness to practise process for all those involved.
- 12.27 Following up from last year's report, we note that the GOC has published its general guidance for witnesses on its website, and it has also distributed this guidance to its panel legal firms. The GOC says that the witness support it provides is based on individual witnesses' needs and that it carefully considers whether

witnesses fall within the 'vulnerable' category. It offers support by maintaining regular contact via the GOC's legal team, and arranging familiarisation visits to the GOC. This provides witnesses with an opportunity to understand what a public hearing involves and the role of witnesses in the proceedings and it also gives them an opportunity to familiarise themselves with the surroundings of the office and the location of the GOC.

13. The General Osteopathic Council (GOsC)

Overall assessment

- 13.1 Before setting out our view of the performance of the GOsC, we outline below some key information in paragraph 13.2 about the GOsC's activities for the financial year 2010/11. When reading this data for each of the regulators, care should be taken to ensure that misleading comparisons are not made. There are differences in the size of the regulators both in terms of staff numbers and registrants, they all work to differing legislation, rules and processes, they have a varying caseload in terms of registration applications and fitness to practise referrals and are dependent to a greater or lesser extent on information from third parties which can impact on the timeliness of their work.
- 13.2 The General Osteopathic Council (GOsC) regulates one profession: osteopaths. The GOsC is responsible for the quality assurance of 19 osteopathy educational programmes. It has 4,440 current registrants and received 300 new registration applications since the last review (272 new graduates, 25 restorations and three applicants under the new powers described in paragraph 13.25 below). The median time taken to process initial registration applications for UK graduates is two days (for international non-EU applicants and EU applicants a median time is not recorded as the number of applicants is so low; however the GOsC aims to complete all such applications within four months). There have been no registration appeals. The GOsC has an annual retention fee (outside of any initial discount period) of £750. In the period April 2010 to March 2011 the GOsC's investigating committee considered 30 cases and its final fitness to practise committees 14. The median time taken from receipt of initial complaint to the final investigating committee decision was four months. The median time taken from final investigating committee decision to final fitness to practise hearing decision was 10 months. The median time taken from receipt of a complaint/information indicating the need for an interim order referral to an interim order decision was four weeks. The number of successful registrant or CHRE appeals against final fitness to practise decisions was nil.
- 13.3 The GOsC has experienced a change in leadership this year, with the new chief executive and registrar beginning his role on 1 November 2010. It has had a productive year, during which it has maintained effective regulation across all of its regulatory functions, with patient safety and public interest at the core of its activities.

- 13.4 Since our last review the GOsC has undertaken significant work to improve communication with patients, students and registrants, including the development of new patient and public involvement and communications strategies. Feedback from newly qualified registrants suggests some have experienced problems associated with professional isolation and lack of support in the transition from student to independent practitioner, often in sole practice. In order to inform its thinking, clarify the issues, and identify possible ways to resolve these problems, the GOsC has commissioned research into newly qualified registrants' preparedness for practice.
- 13.5 The GOsC is also undertaking follow-up work with osteopaths, emerging from its review of online advertising published on osteopathic websites.
- 13.6 The GOsC's patients' expectations research, reflecting the views of around 1,700 osteopathy patients throughout the UK, is now complete. The GOsC's adverse events research project is aimed at assessing the safety of osteopathic care for patients through an evaluation of risk in osteopathic practice, and it is hoped the outcomes will contribute to the improvement of patient safety and experience when receiving osteopathic care. The research comprises four related pieces of research, two of which are now complete (namely a literature review and a study identifying the reasons why patients complain to the GOsC or make claims against registrants' indemnity insurance). The continuing related research is detailed at paragraph 13.8.
- 13.7 We acknowledge the GOsC's positive response to the issues highlighted in our previous report, and consider it has performed well this year by:
- Using the findings of its patients' expectations research where appropriate and necessary, including sharing the findings with other stakeholders to identify areas for development and improvement in the GOsC's own procedures and practices
 - Implementing successful measures to improve the timeliness of fitness to practise cases, including reducing panel size, scheduling more hearings, and ensuring any preparatory hearing work is completed in a timely manner
 - Successfully (and for the first time) using the civil courts in Scotland to obtain an order preventing unlawful use of the title 'osteopath'.
- 13.8 We would like to follow up on the following areas in next year's review:
- Any progress regarding the GOsC's work to improve knowledge, understanding and application of clinical audit amongst osteopaths
 - Any further work undertaken to raise public, patient and registrant awareness of osteopathic regulation and standards of practice, particularly any work to ensure that patients are aware of the existence of a formal complaints process, should they need it
 - The impact of this work on the GOsC's continuing professional development (CPD) and revalidation schemes, along with any evidence of outcomes suggesting benefits to patients

- Any progress made by the GOsC in considering requiring only a self-declaration in relation to an individual's health rather than a certified health declaration. However we are mindful that this would require a change in legislation and therefore is unlikely to occur quickly
- The outcomes of the GOsC's research on the preparedness for practice of newly qualified/registered osteopaths
- Any conclusions or action (for example the issuing of new guidance) arising from the GOsC's review of osteopathic web based advertising
- The outcomes of the remaining two strands of the GOsC's adverse events research, which are:
 - Communicating risk and obtaining consent in osteopathic practice (due for completion in June 2011)
 - Investigating osteopaths' attitudes to managing and assessing risk in clinical settings and patients' experiences and responses to osteopathic treatment (due for completion in November 2011).

Guidance and standards

- 13.9 The GOsC is required by legislation to determine the standards of proficiency for osteopaths, and to publish a code of practice laying down the standards of conduct and practice expected of osteopaths and giving guidance in relation to the practice of osteopathy. The GOsC currently publishes separate documents detailing the standards of proficiency and the code of practice. The GOsC is currently revising these, after wide-ranging public and stakeholder consultation, and intends that they should be merged into one document under the title *Osteopathic Practice Standards* (OPS). The GOsC's current review of the standards and code will be informed by the findings of its patients' expectations research so there should be appropriate emphasis on patient needs and patient centred care. It is expected that the proposed OPS will be considered by the GOsC's council in April 2011 and published in summer 2011. The OPS would then take effect from summer 2012. We see the approach of merging these documents as having benefits to patients, complainants and registrants, as the OPS should provide greater clarity and transparency and help avoid confusion.
- 13.10 We were interested to learn of the GOsC's work with the National Council for Osteopathic Research (NCOR) to promote clinical audit in osteopathic practice as a quality improvement tool and a means through which osteopaths could provide supporting information for the purposes of their revalidation. Registrant involvement in clinical audit (and the other work of NCOR) is encouraged through editorials in the GOsC's magazine, *The Osteopath*, which also contains links to further resources on clinical audit. NCOR is due to complete the first audit handbook by May 2011, which will be accompanied by standard presentations to help registrants access and complete audits. The handbook, which is due for publication in 2011, will guide osteopaths through the process of auditing key aspects of their practice – for example legibility and completeness of patient notes, clinic hygiene standards and appointment management.

We agree with the GOsC that audit could prove to be a very useful tool to maintain and improve standards and therefore protect patients. We would be interested to follow up on any progress in this area in our next report.

- 13.11 We note the GOsC's efforts to maintain and increase professional awareness among osteopaths. This year, the GOsC introduced a quarterly fitness to practise e-bulletin, which routinely reminds registrants of aspects of the code of practice, highlights ethical and practice issues, and aims to improve understanding of fitness to practise processes in general.
- 13.12 The GOsC currently distributes the quarterly *International Journal of Osteopathic Medicine* to all osteopaths free of charge and, from 2011 it will provide free or subsidised online access to a range of relevant medical research journals. We agree that this service contributes to the quality of patient care and continuing professional development, particularly as most osteopaths are in private practice and might otherwise have limited access to these resources.
- 13.13 We note that the preliminary findings of the GOsC's adverse events research, along with those from the separate research on patients' expectations, have fed into revisions made to the code of practice and standards of proficiency, prior to their combined re-issue as the OPS this summer. We also note that the research results have informed guidance for education providers and have fed into the GOsC's quality assurance process (which will be based on the OPS). We welcome the GOsC's commitment to publish all the research results and to ensure that learning from this work is fed into each of the relevant regulatory functions, and are encouraged by the GOsC's open and inclusive approach, which should help to ensure that patient views and interests are appropriately represented.
- 13.14 The Advertising Standards Authority's (ASA) British Code of Advertising (the ASA code) requires that all health promotion claims are based on sound clinical evidence. The GOsC has expressed a concern that some of the osteopathic practice information that is currently available online may be based on anecdotal, rather than empirical, evidence, and therefore falls short of the required standard. To manage this matter, we note that the GOsC has sought legal advice about the way in which it could best deal with a bulk complaint similar to that received by the GCC, should one arise, without jeopardising its operational performance. It is also conducting a review of online advertising published on osteopathic websites in order to assess compliance with the ASA's code. With collaborative input from the British Osteopathic Association, NCOR and ASA, the GOsC has developed a strategy to assist registrants to comply with ASA's code by using direct correspondence and profession-specific media. As already mentioned in paragraph 13.12, the GOsC is also raising awareness of research and disseminating information about evidence based osteopathic practice by providing registrants with free or subsidised access to scientific and professional research journals. We welcome this work and see it as important in helping to promote professional standards and maintain public confidence in the profession.
- 13.15 We were interested to learn that the GOsC's patients' expectations research included a survey that indicated that around two thirds of registrants are failing to ensure that patients are aware of the existence of a formal complaints process, should they need it. Although this is a concern, we acknowledge that the GOsC has said that it intends to develop a range of public information leaflets that will raise public and patient awareness of: osteopathic regulation and standards of practice,

what to expect from osteopathic treatment, and the potential risks associated with treatment. Patient and public information on the website will be also be reviewed by the GOsC.

- 13.16 The GOsC will also use its registrant publications (the bi-monthly magazine *The Osteopath*, and its quarterly fitness to practise e-bulletin) as well as its registrant website and regional registrant engagement events to raise registrants' awareness of the key themes emerging from the patient feedback and the systematic analysis of osteopathic practice that forms part of current GOsC research.

We welcome the GOsC's responsiveness to its research findings and would be interested to follow up on further developments in these areas in our next performance review.

Education and training

- 13.17 The GOsC has a statutory duty to set and monitor the standards for pre-registration osteopathic education. Both the standards of proficiency and code of practice are integral parts of the design and content of osteopathic training courses that lead to Recognised Qualifications (RQs). In order to ensure that this is clear and understood by students, the GOsC has maintained good levels of communication with them. It provides on-campus presentations on the code of practice both at the beginning and end of their clinical training, as well as providing final-year osteopathy students with access to its dedicated registrant website.

- 13.18 In last year's report we indicated that we wanted to follow up on the results of the preliminary quality assurance (QA) review that the GOsC was conducting, prior to a major review in April 2011. We understand that the preliminary review is ongoing, but that progress so far includes:

- A policy statement that articulates the aims of the QA process and highlights the importance of patient safety and student fitness to practise considerations in the assessment and approval of educational programmes
- A revised QA handbook to make the process clearer and more transparent
- An analysis of the osteopathic educational institutions' (OEl's) previous annual reports.

- 13.19 The findings have been fed back to the individual education providers, highlighting both areas for development and areas of good practice. In September 2010 the GOsC held its first joint seminar with the OEl's, which provided a forum for the exchange of information on good practice. The GOsC intends to make this a regular event.

- 13.20 We note the GOsC's observation that its preliminary QA review identified that there may be a need to give more prominence to professional issues as part of pre-registration osteopathic education. The GOsC's student fitness to practise working group (which includes osteopathic and public representatives of the OEl's, students, and public members) has therefore developed specific student fitness to practise guidance to be shared informally with OEl's ahead of the formal stakeholder consultation that will take place after April 2011. The GOsC advises that it has also published a statement emphasising that both the clinical requirements in the standards of proficiency and the ethical requirements in the code of practice must be met in order to be awarded an RQ. In practice, the OEl's are providing additional course modules around professional behaviours and professional development.

The GOsC will also be working with the Quality Assurance Agency to establish how to more effectively consider professional requirements as part of the QA process. We recognise this is activity that will enhance public protection, as it should help to ensure that only those students who are fit to practise become entitled to register with the GOsC.

- 13.21 As well as the review of the QA processes, the GOsC has supplied evidence that complaints about the quality of educational provision have led to improvements. The GOsC ensures that such complaints are investigated thoroughly, appropriately, and with patient safety being properly addressed. For example, a recent substantive complaint relating to the QA process within an institution prompted an unscheduled visit. The GOsC's education committee subsequently made recommendations to address the issues that had been identified, and monitoring by the GOsC has confirmed that these recommendations have been adopted.
- 13.22 The GOsC has also acted on feedback from newly-qualified graduate registrants which suggested that they needed more support when they begin their osteopathy career – many will make the immediate transition from supervised student to independent sole practitioner. The GOsC has therefore commissioned research on the preparedness for practice of newly-qualified/registered osteopaths. One possible outcome of this research will be to identify ways in which the GOsC, OEIs and the profession should work together to address these problems. We would be interested to follow up on the outcomes of this research in next year's review, particularly with regard to how the GOsC might mitigate any risks to patient care that are identified.
- 13.23 The GOsC is currently reviewing its continuing professional development (CPD) scheme and has identified some emerging issues. These include: how it should ensure osteopaths acknowledge and implement research findings, and how it can help registrants to identify suitable ways of meeting their identified learning needs and to undertake learning that involves reflection, review and self assessment. The GOsC has identified some potential solutions, including proposals to introduce core CPD subjects and mandatory tools such as clinical audit (with appropriate support and training). We would be interested to learn of further developments in this area in the next review. We consider that this information could be useful for other regulators who are also reviewing their approach to CPD.

Registration

- 13.24 The GOsC's registration requirements are available on the GOsC website and in paper format, supplemented by telephone support from trained members of the registration team. We note that improvements to the GOsC's registration function this year include the facility for online renewal of registration, payment of fees and recording of CPD activity. We welcome these developments, which improve the efficiency of the registration process.
- 13.25 Registrants are obliged to provide a health reference on initial registration (although the GOsC will accept appropriately witnessed self-declarations from those who are not registered with a doctor, or who have difficulty in obtaining a reference from a GP). We are encouraged that the GOsC has said it will review this requirement in line with its own legislation and our 2009 policy paper³³ (in which we recommend

³³ CHRE, 2009. *Health Conditions*. London: CHRE.

that the regulators should require applicants to provide only a self-declaration in relation to health). Although we fully appreciate that any alterations to the GOsC's current arrangements would require legislative change which is unlikely to be imminent, we believe it is disproportionate to require a health declaration that is signed by a registered doctor, and that a move towards accepting a self-declaration would help to ensure fairness and emphasise that being competent and fit to practise are the necessary criteria for registration. We are pleased to note the GOsC's current project for the development of dedicated guidance on health and disability to explore the challenges of making reasonable adjustments during education and independent practice, which it aims to put in place in 2011.

- 13.26 Under new GOsC powers, individuals who did not apply for registration in the initial two-year transition period (1998-2000) could apply to join the register up until December 2010. Applications for registration had to be received by the GOsC between January 2009 and December 2010, and therefore the GOsC developed a communication strategy to raise awareness of the particular eligibility requirements. It also provided clear information/guidance about the registration process to help guide applicants through the application process. Since January 2009 the GOsC has written to approximately 900 individuals who might have an interest in registering under these powers, and has included relevant information in communications with osteopathic stakeholder organisations, on its website and in *The Osteopath* magazine. The GOsC received 37 applications for registration, which will be assessed to ensure the applicants meet the GOsC's criteria for entry onto the register. We recognise that this initiative is in the interests of patients and the public as it will help to minimise the risk that patients may be treated by an unregistered (and therefore uninsured) practitioner. (We note that indemnity insurance is a mandatory requirement for all registered osteopaths.)
- 13.27 The GOsC operates an effective system of monitoring and taking appropriate action against individuals who are using the title of osteopath unlawfully. For example, this year the GOsC has for the first time successfully used the civil courts in Scotland to obtain an order preventing unlawful use of the title 'osteopath'. In September 2010, one individual was also prosecuted and fined £800 for fraudulent use of the title osteopath; 26 'cease and desist' letters were sent to individuals to remind them of the need to either register with the GOsC or cease misusing the title of osteopath. Eight of these cases have now closed as the individuals immediately took appropriate corrective steps and are no longer in breach of the law. The GOsC continues to correspond and/or monitor the activities of the remaining individuals to ensure that appropriate corrective steps are taken, or that, if necessary, cases are escalated for prosecution. We believe that this is important work.

Fitness to practise

- 13.28 The GOsC continues to make improvements to its fitness to practise processes. We note that it has recognised and responded to a need for further training for its new investigating committee members by producing guidance on imposing interim suspension orders and providing training to committee members on the matter. We believe that it is important that interim suspension orders are imposed appropriately, and that the GOsC's guidance should help ensure public protection and provide consistency and proportionality in decision making. As reported last year, the GOsC has also been seeking changes to its fitness to practise processes by way of a Section 60 order. It would like an extension of the maximum period that

interim suspension orders can be imposed by the investigating committee - to longer than two months. We understand that this matter is still under consideration by the Department of Health.

- 13.29 We recognise that the GOsC has made progress in reducing the time taken to deal with fitness to practise cases. We consider that this improvement reflects the outcome of the actions detailed in last year's performance review, namely a reduction in the size of the panels hearing cases from five to three members, which has allowed the scheduling of additional hearings, as more panelists are available. In 2010 the median time taken for a complaint to be screened was two weeks, and for a complaint to be considered by the investigating committee the median time was just under four months. The GOsC's targets for each stage are three weeks and four months respectively. The target for cases to reach a final hearing is 13 months (from receipt of the complaint) and we acknowledge that this target is close to being met, with the median time for cases heard in the last six months of 2010 reducing to 13.5 months (compared to 15 months for the 2010 calendar year as a whole). We acknowledge this improved efficiency which we believe is in the interest of registrants and the public.
- 13.30 The GOsC does not publish separate guidance for witnesses. However, it states that it aims to provide a high level of assistance to all witnesses, including vulnerable witnesses, depending on their individual needs and circumstances. This includes (similar to other regulators) bearing the cost of travel and accommodation for the witness, and, if requested, those of a relative or friend and providing support and accompanying them during the hearing process. The GOsC conducts regular case reviews with its external solicitors, during which contact with complainants and witnesses is discussed. Any special measures are also considered if a witness is vulnerable, such as enabling them to provide evidence from behind a screen. We note that the GOsC is carrying out ongoing research relating to the experience of participants in fitness to practise hearings. However, as it has received only a small number of responses, the GOsC considers this has made it difficult to draw any conclusions. We would suggest that this is kept under review, as this information may be valuable in determining whether witnesses' needs are being met.

14. The General Pharmaceutical Council (GPhC)

Overall assessment

- 14.1 Before discussing our views of the performance of the GPhC, we outline below some key information in paragraph 14.2 about the GPhC's activities for the financial year 2010/11 (from 27 September 2010 to 31 March 2011). When reading this data for each of the regulators, care should be taken to ensure that misleading comparisons are not made. There are differences in the size of the regulators both in terms of staff numbers and registrants, they all work to differing legislation, rules and processes, they have a varying caseload in terms of registration applications and fitness to practise referrals and are dependent to a greater or lesser extent on information from third parties which can impact on the timeliness of their work.

- 14.2 The General Pharmaceutical Council (GPhC) regulates one profession: pharmacists. It also regulates pharmacy premises. The GPhC currently operates a voluntary register for pharmacy technicians; this will become compulsory on 1 July 2011. The GPhC is responsible for the quality assurance of 11 types of pharmacy educational programme, totalling 108 programmes. It has 43,756 current registrants, 12,772 pharmacy technician registrants and 13,612 registered premises. The median times taken to process initial registration applications for UK graduates, international non-EU applicants and EU applicants are, respectively, two weeks, three months and six weeks for the EU automatic route and four months for the EU General Systems route. The GPhC received one registration appeal between 27 September 2010 and 31 March 2011. This appeal has not yet been heard. The GPhC has an annual retention fee (outside of any initial discount period) of £262 for pharmacists, £142 for pharmacy technicians and £217 for premises. The GPhC's investigating committee considered 55 cases and its final fitness to practise committees 28 cases. Since assuming responsibility for regulation on 27 September 2010, the GPhC has not progressed any cases from initial receipt to final decision by the investigating committee. When the GPhC assumed regulatory responsibility the median time taken by the predecessor body, the Royal Pharmaceutical Society of Great Britain (RPSGB) from receipt of initial complaint to the final investigating committee decision was 141 days. Throughout this performance review period the median time taken from the final investigating committee decision to final fitness to practise hearing decision was 608 days. The median time taken from referral of a matter for an interim order to an interim order decision was 16.1 days. There have been no successful registrant or CHRE appeals against final fitness to practise decisions.
- 14.3 The GPhC assumed responsibility for the regulation of practising pharmacists and pharmacy premises from the RPSGB on 27 September 2010. We consider that the GPhC's vision and strategy clearly places the protection and promotion of the health and safety of patients and the public at the core of all its activities. It will do this through the maintenance and development of safe and effective pharmacy practice and by contributing to the development of trust and confidence in pharmacy in Great Britain.
- 14.4 Uncertainty around the timeframe for the transfer of regulatory responsibility from the RPSGB to the GPhC meant that the GPhC had to prioritise which developments it considered were crucial to have in place on the date of transfer. Therefore the GPhC focused its pre-transfer communications activity on raising awareness of the regulatory transfer amongst pharmacists. It identified that awareness of the GPhC's existence and standards by pharmacists would be the most important component in ensuring effective public protection.
- 14.5 The GPhC is committed to ensuring that public and patient engagement is a core part of all of its work, including policy development. The GPhC intends to tailor its engagement activities appropriately according to individual workstreams. We welcome this public and patient centred approach, and look forward to reviewing the outcome of this approach on the GPhC's development of its policies and procedures during next year's review.
- 14.6 The GPhC has made some progress in dealing with the fitness to practise caseload that it inherited from the RPSGB on the transfer of regulatory responsibility. The GPhC inherited 589 active cases from the RPSGB. By the end of December 2010,

this had reduced to 422 cases and, by the end of March 2011, to 311 cases. Of these, 188 continue to be investigated; 24 have been referred to the investigating committee, and 99 cases have been referred for a final hearing. The GPhC has also introduced interim measures to enable it to collect and report information on the age profile of its cases, the number of cases in its process and the stage that cases have reached in the process. The legacy caseload clearly has implications for the GPhC's effectiveness as a regulator and we therefore intend to monitor progress and to report further on this in the next performance review.

- 14.7 The GPhC has only had responsibility for the regulation of the pharmacy workforce for seven months, and has therefore not yet had an opportunity to fully develop all its own policies and procedures or to develop appropriate outcome measures to evaluate their impact. The GPhC expects to do that work during 2011, alongside continuing to promote its identity as the new pharmacy regulator (in the interim, the GPhC has adopted some of the policies and procedures used by the former regulator). In this report we have therefore only been able to report on the GPhC's intentions in some areas, rather than to provide our views about established policies/procedures and their outcomes.
- 14.8 In next year's performance review, we would like to see progress in the following areas:
- The development of GPhC's working practices and approach to regulation
 - The application of the GPhC's approach to patient and public engagement
 - The development of the GPhC's standards and guidance
 - The outcome of the revalidation group's work
 - The management of the registration of pharmacy technicians
 - The action taken to progress the 'legacy' fitness to practise cases
 - The publication of fitness to practise data against service standards.

Guidance and standards

- 14.9 We consider that the GPhC has an appropriate framework in place to enable it to develop, revise and disseminate guidance and standards which prioritise patient safety and patient centred care. This is set out in its published regulatory standards policy. This document also details the status of the standards and guidance documents and the way in which they should be used by pharmacy professionals. We consider that it is sensible to take a transparent approach to this work. By setting clear parameters staff developing the standards have clear guidance about the principles that underpin their work and registrants who have to follow the standards understand what is expected of them.
- 14.10 The GPhC considered it critical that its standards for conduct, ethics and performance were in place on the date of transfer of regulatory responsibility from the RPSGB. These are the core standards that pharmacy professionals must meet in order to practise safely and effectively. We note that these standards:
- Prioritise patient centred care and safety
 - Have been influenced by the views of the profession and others
 - Are focused on outcomes, rather than providing technical guidance which can stifle innovative practice
 - Can be applied to the different settings that pharmacy professionals work within.

- 14.11 The GPhC has now had an opportunity to review its approach to producing standards and guidance. It has developed a consultation policy which ensures that stakeholders will be engaged at the early stages of standards and guidance development, rather than just at the formal consultation stage. The GPhC intends to use learning from across its regulatory functions, queries received by the standards advisory team, as well as organisational complaints to inform the development and revision of its standards and guidance. We support the GPhC's intended approach to its standards and guidance work.
- 14.12 Under the Pharmacy Order 2010, the GPhC has a new role in relation to setting standards for pharmacy premises. The GPhC has established a 'premises project' and will be developing its standards. In the meantime we note that the GPhC has adopted interim standards for pharmacy owners and superintendent pharmacists.
- 14.13 The premises standards will include those relating to the sale of homeopathic products in pharmacies. The premises project will consider the development of registration criteria specifically for those premises that are currently registered, but where the principal activity at the premises is not the retail sale or supply of Pharmacy (P) medicines and/or Prescription Only Medicines (POMs). Any new criteria could cover (amongst other issues) those premises where supply of homeopathic products is the main business activity. We note that the sale of homeopathic products in pharmacies is an issue that has recently attracted media attention because of the lack of a consensus about the efficacy of those products and the potential implications for patients who take them in preference to conventional medicines. It is therefore a significant issue for the pharmacy regulator to consider.
- 14.14 To date the GPhC has published three pieces of guidance to supplement its standards, including provision of pharmacy services affected by religious and moral beliefs. We note that the GPhC is in the process of producing guidance on other topics, including consent, confidentiality and maintenance of sexual boundaries. These are clearly areas of critical importance to patients, and we will wish to see that they are developed as soon as possible. This is something we will review in our next performance review. We will also want to see evidence that the GPhC has undertaken an appropriate evaluation to ensure that adequate guidance is in place to support its standards.
- 14.15 The GPhC is undertaking a range of activities to ensure that its standards are accessible to the profession and others. It has published them on its website, sent hard copies to registrants and pre-registration trainees, and given presentations to pharmacy students and pre-registration trainees on the importance of the standards and how they should be applied in practice. It also has a standards advisory team in place. This team is comprised of pharmacists whose main role is to provide the profession and others with advice about the application of the standards. We note that the GPhC also plans to prepare and publish case studies to explain how the standards and guidance should be applied to practical day-to-day situations. We support this plan and have previously highlighted the use of such case studies as good practice.
- 14.16 We will want to see how the GPhC's work in standards and guidance evolves over the coming months and will report on this in the next performance review.

Education and training

- 14.17 The GPhC is undertaking a significant amount of work across the spectrum of education and training of pharmacy professionals. The GPhC is in the process of developing new standards for education, revising its quality assurance processes, and developing standards for registrants undertaking CPD and, working with qualification bodies, has agreed new minimum registration criteria for pharmacy technicians prior to their statutory regulation by the GPhC (from 1 July 2011). In the meantime it has adopted the RPSGB's standards and processes in all these areas.
- 14.18 One of the objectives of the new standards for education is that there should be a clear link between the conduct, ethics and performance required of students, trainees and registrants, so that students and trainees are aware from the start of their training of the requirements they need to meet to be a registrant. The GPhC aims to achieve this by using consistent language throughout all the standards documents, and by merging the standards for undergraduate education and pre-registration training. We note that the GPhC has engaged with patients and the public across Great Britain as part of its development of these standards. It has used external organisations to run the engagement events. It has received anecdotal feedback that the events have been effective and resulted in meaningful engagement with particular patient groups (such as methadone users and homeless people) and the public.
- 14.19 The GPhC is also revising its quality assurance process to bring it in line with current regulatory approaches. It wants to move to a process that focuses on evidence based outcomes, and that is risk-based. It also wants to increase the level of involvement of patients, the public and students in accreditation events. It is currently consulting with its key stakeholders on its proposed changes. We support the overarching principles that the GPhC intends the quality assurance process to adhere to.
- 14.20 We note that the GPhC is aiming for a facilitative relationship with the pharmacy education providers. As part of this, it is now sharing with education providers the information it collects about the registration examination, and through the annual survey of education providers. This has enabled the education providers to identify improvements in their processes. For example, following the results of the registration examination being shared, two providers raised the standard for entry to their courses and another provider is reviewing its curriculum design to see if it can better support and assist trainees during the pre-registration year. Resources permitting, the GPhC also intends to survey all tutors and trainees annually from the 2012 pre-registration cohort. This is so it can assess general satisfaction with the training. We consider that improvements in gathering and using information should help to drive up standards of education and training.
- 14.21 The GPhC is working with vocational qualifications awarding bodies to agree new competence and knowledge standards for pharmacy technicians. The GPhC will assure pharmacy technician qualifications by recognising them. Recognition is a scrutiny process which looks at content of the vocational courses and the processes used by the vocational qualification awarding bodies to ensure that qualifications are only awarded when the student has meet the required standard. As there are differences in the content of the English/Welsh and Scottish vocational qualification courses, we note that the GPhC has developed a uniform

underpinning knowledge requirement to ensure that technicians with either qualification are safe to work across Great Britain.

- 14.22 Under the Pharmacy Order 2010, it is now mandatory for pharmacy professionals to undertake CPD whilst they are registered with the GPhC. As a consequence the GPhC has responsibility for setting standards for CPD. The GPhC has developed and consulted on its CPD framework and rules and is currently analysing the responses received. In the interim it has adopted the RPSGB's CPD standards which its registrants are required to meet. The GPhC has begun its review of CPD records and will review all its registrants' CPD records over a five year cycle. We note that initial findings suggest that there is a low non-submission rate and that, so far, those records that have been reviewed have met the required standards. The GPhC is therefore confident that its registrants are generally taking appropriate action to ensure they remain fit to practise.
- 14.23 However, the GPhC considers that mandatory CPD reviews have already become an important regulatory tool for another reason. It considers that receiving a registrant's reasons for non-submission or incomplete submission of their CPD records has helped it to identify registrants with potential health and/or personal problems and enabled the GPhC to offer appropriate help and support to them. The GPhC considers that by exercising legitimate and proportionate discretion to help these individuals it avoids matters escalating and becoming fitness to practise concerns.
- 14.24 The GPhC's work to consider any future model for revalidation in pharmacy is continuing. The research programme organised by the RPSGB has reported, and the GPhC's council has had preliminary discussions about the findings. The GPhC has established a 'task and finish' working group which will be responsible for establishing a clear view on the purpose of revalidation in relation to the risks posed by the pharmacy professionals to patients and the public. In undertaking this work it will consider the findings of the research, and the view expressed by the government in *Enabling Excellence* that '*there must be evidence of significant added value in terms of increased safety or quality of care for users of health care services from additional central regulatory effort on revalidation*'. We will want to see the GPhC's plans for delivery of revalidation in light of the work of the group at the next review.

Registration

- 14.25 The GPhC only has powers to register practising pharmacy professionals and pharmacy premises. It is not empowered to hold a non-practising register, unlike the former regulator.
- 14.26 The GPhC is changing its approach to renewals of registration owing to the requirement in the Pharmacy Order 2010 that it operates a system of rolling registration. This means that when a registrant first enters the register they will be registered for a full year, rather than just to the end of the year in which they entered the register. This will be fairer to registrants, and should also remove the operational challenges that arise from having one registration/renewal period each year during which all applications have to be received and processed.
- 14.27 We acknowledge that, unfortunately, the GPhC's legislation did not permit it to stagger the initial registration process on the transfer of regulatory responsibility from the RPSGB. This meant it had to ask all registrants and premises to register

within two months - which was not ideal in terms of fostering good relationships with the profession. However, it did enable the GPhC to quickly establish its identity amongst its registrants. The GPhC says that as a result of its effective communications strategy, the bulk of the registration applications were received on time.

- 14.28 We consider that the GPhC is managing an effective and transparent registration process. It has enhanced the process used by the RPSGB by implementing new registration criteria which ensure the currency of the pharmacist's qualification and training, and by widening the fitness to practise declaration so that it requires information that the pharmacist has appropriate indemnity insurance to cover their practice. We would also suggest that the GPhC should consider whether it should continue to require a health declaration that is signed by a registered doctor. In our report on health requirements for registrants,³⁴ we recommended that the regulators move to a requirement that applicants provide a self-declaration. This was in order to ensure that fitness to practise is being assessed on the basis of functional capacity, rather than on a diagnostic view of health and disability. We regard it as disproportionate to require a health declaration signed by a registered doctor in every case.
- 14.29 The GPhC is considering redeveloping its registration IT system to enable more efficient application processing and to enable registrants' equality and diversity data to be analysed and used to monitor trends in the registration process. We note that there may be further enhancements to the registration process once the IT review is complete.
- 14.30 The GPhC is also currently consulting on amendments to the initial registration standards for pharmacy technicians. These will clarify the training and vocational standards (eg number of hours worked) that technicians need to demonstrate that they meet.
- 14.31 We note that generally the registration process managed by the GPhC is efficient. However, due to an unprecedented and unanticipated level of pharmacy technician registration applications received by the RPSGB in the final three weeks of its existence, the GPhC has not been able to process pharmacy technician applications in line with its service standards. When the GPhC took over regulatory responsibility from the RPSGB there were approximately 3,500 applications to process. To manage this workload, the GPhC changed the structure of the registrations team, increased staff resource and set up a helpline to enable queries to be dealt with by staff who were not processing the applications. The GPhC also kept the profession up to date about the progress being made on the processing of their applications. The GPhC, while aiming to clear the backlog of applications as quickly as possible, has remained focused on ensuring only those registrants who meet its standards are registered. We note that the GPhC was hindered by the lack of automation in its registration process. We would recommend that this functionality is carefully considered during the IT review, as online registration processes help improve efficiencies and reduce the number of data errors.

³⁴ CHRE, 2009. *Health Conditions*. London:CHRE.

- 14.32 We acknowledge that the GPhC took account of our report³⁵ on how to maximise public protection from regulators' registers and the views of patients, the public, employers and others when it developed its register. We are pleased that the register includes the fitness to practise history of its registrants, details of registrants who have been struck off within the last five years and the expiry date of a registrant's registration. We consider that this information will help patients and the public to make informed decisions about their healthcare professionals. It will also help employers' decision making when recruiting staff and help them to ensure that they are not employing professionals whose registration has lapsed, whether accidentally or not. In terms of informing patients, public and employers about the importance of checking that a professional is registered, the GPhC has signposted its register prominently on its homepage. It also emailed superintendent pharmacists at the end of the registration process with a list of those individuals that had been removed from the register. We will look to see what further action the GPhC has undertaken to emphasise this message in our next performance review.
- 14.33 The GPhC is also revisiting the internet pharmacy logo scheme. It is considering whether this is a scheme (which was implemented by the RPSGB) that it wishes to continue and if so, how it can make it more robust to ensure that it is not open to misuse. As part of this work, it will be carrying out an audit of the use of the logo. We consider that this is a sensible approach.

Fitness to practise

- 14.34 From work undertaken prior to the GPhC assuming responsibility for the regulation of pharmacy professionals and premises, it identified five risks that it would need to manage. These were:
- Time taken to progress cases through the fitness to practise process
 - The time and related costs of investigating cases after a substantive investigation committee decision
 - Difficulties with scheduling hearings – previously hearings were scheduled according to a pre-determined hearing timetable, rather than scheduling them according to the cases that needed to be considered
 - The lack of accurate and comprehensive performance information
 - The lack of a case management system that was fit for purpose for each stage of the fitness to practise process.
- 14.35 The GPhC has established a 'fitness to practise legacy project group' to manage the workstreams associated with these five risks. We detail below the work that has been undertaken thus far to deal with these risks.
- 14.36 When the GPhC assumed responsibility for the regulation of pharmacy professionals and premises, all the RPSGB's 'open' cases were transferred to it. This equated to 589 cases which were either awaiting consideration by the investigating committee, were awaiting a final fitness to practise hearing, or were part-way through a hearing. We note that under the GPhC's legislation it is empowered to assess and close such cases under its 'legacy criteria', for example cases can be closed if there is insufficient evidence to proceed.

³⁵ CHRE, 2010. *Health Professional Regulators' Registers: Maximising their contribution to public protection and patient safety*. London: CHRE.

- 14.37 We consider that the GPhC has implemented appropriate oversight and scrutiny mechanisms to manage any potential public perception that the 'legacy criteria' may be misused to reduce the caseload. All recommendations to close cases are reviewed by the 'legacy determination group' (made up of the director of regulatory services, the head of fitness to practise, the legal adviser and the interim chief pharmaceutical adviser) prior to referral to the registrar for decision. The 'legacy determination group' also reviews a sample of decisions to refer cases onto a hearing. We support the rationale for the legacy criteria - which is to ensure that cases are handled proportionately according to risk. In our recent audit, we concluded that the 'legacy criteria' had been applied appropriately in the sample of cases that we reviewed.
- 14.38 The GPhC has also developed threshold criteria to be used to screen out allegations it received on or after 27 September 2010 that do not give rise to risks to patients/the public, to professional standards or to public confidence in the profession. Staff deciding whether or not allegations meet the threshold criteria will base those decisions on the outcomes of investigations carried out by the pharmacy inspectorate. We consider that this is a sensible approach, as it enables the GPhC to focus its resources on cases where there are serious concerns. However, to ensure that: these criteria are being used by staff consistently, the right decisions are reached, and public confidence is maintained in the GPhC's processes, we would suggest that the GPhC should implement internal quality assurance processes.
- 14.39 Timeliness of case progression of the cases inherited from the RPSGB is an issue for the GPhC. To help improve the timeliness of case progression, the GPhC has developed case management directions, which should expedite the service and scheduling of cases, and it has amended the way it schedules cases so that cases are listed for hearing as soon as they are ready to be heard. However, it is not clear to CHRE that the GPhC's change in approach to scheduling cases will result in an increase in the throughput of cases. We look forward to following up with the GPhC, as part of next year's review, on any improvements to throughput which have been achieved. The GPhC has also introduced monthly meetings in which case progression will be discussed, and it is reviewing how cases are investigated by its external solicitors post-investigating committee. We would suggest that the GPhC undertakes an evaluation of the measures it has introduced to improve case progression to ensure that they will clear the legacy caseload rather than just maintain its current performance.
- 14.40 We note that the GPhC also considers that its ability to manage cases in a timely manner has been affected because the electronic case management system that was developed by the RPSGB does not meet all of the GPhC's needs. This means that, in part, the GPhC is reliant on paper records and manual processing. The GPhC plans to develop a case management system which will enhance its ability to track the progress of cases, to identify those which have become delayed, to produce accurate and comprehensive performance management data, and to analyse whether its processes adversely impact on particular groups. The GPhC does not have a set timeframe for the development of the new case management system or service standards. It is our view that the development of the new case management system should be considered a priority, alongside the development of service standards, against which the GPhC should publish its performance. As an interim measure, the GPhC is developing a database on which to capture key

management information, enabling it to track the end-to-end progress of cases through each stage of the process. The GPhC has developed a template for reporting on: case volume, the stage cases have reached within the process, and the age profile of cases. The reports are considered at each council meeting, and are then published on the GPhC's website. We consider that transparency about timeliness of case progression is important to the maintenance of public confidence in a regulator. We will therefore want to see in next year's review that the GPhC is able to report on the time taken for cases to progress throughout the fitness to practise process.

- 14.41 We note that the GPhC has developed guidance and forms for staff and decision makers to use when recording decisions, to ensure that processes are applied and decisions are made consistently. It has also provided training to staff and committee members on the practical application of these new documents, and on the legislative changes associated with the establishment of the GPhC. Some of the training events are available as audio recordings, which staff can use as refresher training. We consider that these activities should help to maintain the quality of the GPhC's casework. We are aware that the GPhC needs to develop its own indicative sanctions guidance (it has adopted the RPSGB's in the interim) and a disclosure policy. We consider that these documents are important, as they guide decision makers in making consistent, transparent and fair decisions. Given the importance of these documents to public confidence in the decisions of the GPhC, we encourage the GPhC to consider their development as a priority.
- 14.42 The GPhC has processes in place to ensure that serious cases are prioritised. It aims to review all complaints within 24 hours so that serious cases can be identified quickly. It has also developed guidance for identifying cases that should be referred for an interim order, and a form on which staff record their reasons for making such a referral. We consider that this should encourage consistent and transparent decision making and help to ensure that timely action is taken on serious complaints. To ensure that is the case, we would recommend that the GPhC introduces a quality assurance process to enable decisions to refer/not to refer cases for an interim order to be reviewed.
- 14.43 Now that the GPhC has its basic fitness to practise framework in place and information about its processes on the website, we note that it is considering what other communication activities it should undertake. It has begun work on a patient information leaflet, it is revising its witness care leaflet, and it is developing a process to analyse the information it receives from its complainant feedback forms. We consider it is important that parties are given clear information throughout the fitness to practise process, and that regulators listen to the views and experiences of those who have used the system, so that improvements can be made. We have concerns about the extent of the information that is available on the GPhC's website about its fitness to practise processes and the accessibility of the information that is available (including the accessibility of fitness to practise determinations made prior to the transfer of regulatory responsibility from the RPSGB). However, we note that the GPhC is aware of difficulties with its website and is undertaking a review of its content and accessibility. We will want to see the progress made on the initiatives noted above and the outcome of the website review in the next performance review.

14.44 The GPhC has met and shared information with a number of stakeholders including the NHS Counter Fraud and Security Management Service to improve information sharing and facilitate joint working on cases that raise concerns about the performance of individual registrants or pharmacy premises. It hopes that this will result in information which raises concerns about registrants' fitness to practise being shared at an earlier time, so that action can be taken. We welcome this engagement activity.

15. The Health Professions Council (HPC)

Overall assessment

- 15.1 Before setting out our views of the performance of the HPC, we outline below some key information in paragraph 15.2 about the HPC's activities for the financial year 2010/11. When reading this data for each of the regulators, care should be taken to ensure that misleading comparisons are not made. There are differences in the size of the regulators both in terms of staff numbers and registrants, they all work to differing legislation, rules and processes, they have a varying caseload in terms of registration applications and fitness to practise referrals and are dependent to a greater or lesser extent on information from third parties which can impact on the timeliness of their work.
- 15.2 The Health Professions Council (HPC) regulates 15 professions: arts therapists, biomedical scientists, chiropodists / podiatrists, clinical scientists, dieticians, occupational therapists, operating department practitioners, orthoptists, paramedics, physiotherapists, prosthetists / orthotists, radiographers, speech and language therapists, practitioner psychologists and hearing aid dispensers. The HPC is responsible for the quality assurance of 631 health professional educational programmes. It has 215,083 current registrants and received 15,624 new registration applications since the last review. The median times taken to process initial registration applications for UK graduates, international non-EU applicants, EU applicants and those in a grandparenting period were five days, 80 days, 80 days and 41 days respectively. There were 37 registration appeals and 21 appeals were allowed. The HPC has an annual retention fee (outside of any initial discount period) of £76. The HPC's investigating committee considered 532 cases and its final fitness to practise committees 504.³⁶ The median time taken from receipt of initial complaint to the final investigating committee decision was five months. The median time taken from final investigating committee decision to final fitness to practise hearing decision was nine months. The median time taken from receipt of a complaint/information indicating the need for an interim order referral to an interim order decision was 13 days. The number of successful registrant appeals against final fitness to practise decision was two and there were no successful CHRE appeals.

³⁶ 314 cases were concluded at final hearing, a further 88 cases were part heard, referred to another committee or adjourned on the day of the hearing. There were 99 review hearings, two cases were considered for restoration and one case considered under article 30(7) (new information relevant to a striking off order).

- 15.3 The HPC has performed as an effective and efficient regulator for the diverse range of professions that it regulates. This is particularly notable as it has had to manage the challenges associated with the likely expansion in the number and type of professions that it will regulate in future.
- 15.4 The HPC is also considering the implications of moving from a traditional health regulator model to that of a health and social care regulator with a regulatory role in complementary medicine. In July 2010 the government announced the transfer of the regulation of social workers in England to the HPC, which is anticipated to happen by 1 July 2012. Preparation for the transfer of the register of social workers to the HPC has created a large amount of new work.
- 15.5 In April 2011 European legislation that requires manufactured herbal medicines to be licensed in the same way as conventional medicines will come into force, with the only exemption from this being where a practitioner is regulated. On 16 February 2011 the government announced its intention that in order to comply with this legislation, practitioners of herbal medicine will be regulated by the HPC. The HPC has undertaken a number of activities in relation to these forthcoming changes, which are outlined in more detail at paragraphs 15.15 to 15.17.
- 15.6 We acknowledge the HPC's positive response to the points we raised in last year's performance review. The HPC has:
- Implemented a programme of work to improve its fitness to practise processes in the light of the results of research into complainants' expectations. This includes:
 - The provision of clearer and more accessible information about fitness to practise on the HPC website
 - Updating relevant publications
 - Producing an audio visual presentation about the process including what participants in fitness to practise hearings should expect.
 - Reviewed how it involves service users in the design and delivery of education provision across the professions, including:
 - Commissioning external research to look at this area
 - Planning to pilot the use of public partners on education programme approval visits.

We also acknowledge that the HPC has:

- Progressed work towards the inclusion of details of suspensions and interim suspensions on the HPC register
- Reduced the time taken for fitness to practise cases to conclude, from the receipt of an allegation to the final hearing stage and from the committee stage to the final hearing stage, by two months and one month respectively
- Introduced registrant assessors to give advice to fitness to practise committees on matters of professional practice.

15.7 In next year's review we would like to follow up on:

- Any progress or further developments with regard to the HPC's assumption of regulatory responsibility for social workers in England and for practitioners of herbal medicine

- The outcomes of the external research on the involvement of service users in the design and delivery of educational programmes, and the proposed pilot to include public members as part of educational visit teams
- Any further findings from the studies by Durham University to develop a quantitative approach for measuring professionalism
- The impact of the introduction of registrant assessors to advise fitness to practise committees
- Any progress or further developments made in the HPC's current and continuing work on alternative mechanisms for resolving disputes.

Guidance and standards

- 15.8 The HPC continues to communicate effectively with, and provide appropriate information to, stakeholders about the standards of proficiency, conduct, performance and ethics that its registrants are required to meet. It also produces additional guidance as required.
- 15.9 One example of this is the HPC's publication of guidance about escalating concerns. Following recent concerns raised in the wider healthcare environment about whether registrants are supported to raise concerns which have implications for public protection, the HPC developed appropriate guidance, which it published both on its website and in its dedicated registrant newsletter. More generally, the HPC makes its patient information leaflet, *How to Raise a Concern*, available to the public in 13 languages.
- 15.10 The HPC conducts ongoing and periodic reviews of its standards and guidance to ensure that they continue to reflect best practice. The HPC engages with its stakeholders in developing and reviewing its standards and guidance. For example, in 2009/10 the HPC consulted on a minor change to the standards of proficiency for health psychologists. Feedback from stakeholders suggested that the existing standard was confusing. Respondents said that by referring specifically to cognitive behavioural therapy (CBT) the standard implied that techniques used by health psychologists must include CBT, rather than CBT simply being an exemplar. Feedback also suggested that education and training providers might not be able to meet the requirement, as not all offered CBT options to students. As a result of that feedback the HPC removed the reference to CBT and the amended standard took effect from 1 October 2010.
- 15.11 A thorough and comprehensive periodic review of the HPC's standards is conducted approximately every five years, although ongoing review may signal that an earlier periodic review is necessary. The next periodic review of the HPC's standards of conduct, performance and ethics is scheduled for 2012/13. The HPC is currently looking at alternative ways of consulting with the public and patients, and will consider the options for such consultation before embarking on the periodic review. We recommend that the HPC takes account of other regulators' experiences of consulting with patients and the public in deciding how to progress this area of work.
- 15.12 The HPC has recently consulted on changes to its generic standards of proficiency. The consultation arose out of stakeholder feedback obtained in earlier consultations, and out of other engagement events about the profession-specific standards. Particular concerns that arose were that not all of the current generic standards are easily applicable to all the professions that the HPC regulates, and

that some of the terminology used did not reflect the practice of, or apply to, all of the HPC's registrants. Some generic standards are targeted at those professions where the service user is a patient – which is not the case for all HPC regulated professions. For example, the service users of biomedical scientists may be the health professionals that rely on the tests that they perform, rather than patients or carers.

- 15.13 In March 2011 the HPC agreed amendments to reduce the number of overarching standards from 26 to 15 standards that are broader in scope, with a rolling implementation of revised profession-specific standards thereafter. Under the new model the majority of standards will be profession-specific; allowing professions to use their own language and ensure that the standards are relevant and unambiguous.
- 15.14 The HPC has said that the flexibility that the new structure offers means that the standards could be applied more easily to any additional professions it might regulate in future (eg social workers in England). Each profession will have a new set of profession-specific standards that fit beneath the overarching standards. We believe that the HPC's approach to the maintenance and development of standards is one that prioritises patient safety and patient centred care and therefore helps to maintain public protection.
- 15.15 In March 2010 the HPC agreed to reconvene its Psychotherapists and Counsellors Professional Liaison Group (PLG). This was done in order to explore the issues that were identified in a consultation that ran from July to October 2009 relating to the original PLG's draft proposals on the regulation of psychotherapists and counsellors. The outstanding issues concerned how the HPC would: differentiate between psychotherapists and counsellors on its register, differentiate between those qualified to work with children and those qualified to work with young people, set the standards of proficiency that registrants would be required to meet, and set the threshold level of qualification for entry to the register. The PLG met on several occasions during 2010 and again in February 2011. Throughout this period the HPC also continued to meet with interested stakeholders, including attendance and presentations at events on regulation. We acknowledge that the hearing of a judicial review application concerning the HPC's recommendation to the Department of Health that it should regulate psychotherapists and counsellors was approved in December 2010, and that the hearing was pending as at the end of the period covered by the performance review. However, the government has now given a clear indication to the HPC that statutory regulation will not be progressed at this time, in light of the move toward voluntary assured registration.
- 15.16 In July 2010 the government announced the transfer of the regulation of social workers in England to the HPC. The HPC has undertaken a number of activities to prepare for this forthcoming change and to ensure that public protection remains central to any agreed standards of proficiency to be met for entry onto the HPC register. These include: formulating a project plan to cover the transfer of the General Social Care Council (GSCC)'s register, holding meetings and discussions with stakeholders, participating in relevant working groups, and establishing a professional liaison group (PLG) with representatives from the social work field for the purpose of drafting the standards of proficiency. The first PLG meeting was held in January 2011. In the 2011/12 financial year the HPC intends to consult on the standards of proficiency and on the threshold level of the social work qualification for entry to the register.

It also intends to consult on the issue of student registration for the professions it regulates, including considering whether the HPC should continue the GSCC's practice of registering student social workers, giving regard to CHRE's published advice on this topic.³⁷

- 15.17 As yet there is little detail about how practitioners of herbal medicine and traditional Chinese medicine will be regulated, but the government has said that the focus will be '*solely on minimising risk to the public*'. The HPC register will be a register of people who are able to dispense unlicensed herbal medicines. The Department of Health in England will discuss this proposal with the governments in Wales, Scotland, and Northern Ireland, with a view to agreeing the necessary enabling legislation. We note that the HPC has stated that it will discuss these issues further with the Department of Health and other stakeholders, and that further information will be provided on the HPC website once it becomes available.

Education and training

- 15.18 All new and existing programmes must satisfy the HPC that students understand the standards of conduct, performance and ethics; are able to meet the standards of proficiency; and are assessed in both the education and practice placement settings. This includes requirements about the level of English language proficiency attained by the end of the programme. Educating and training providers must also have procedures in place that address any student fitness to practise concerns, along with safeguards that ensure service users are protected from harm and that students are safe to practise. Any proposed changes to the HPC's standards of education and training involve public consultation, including the involvement of a professional liaison group made up of relevant stakeholders. We believe that this approach helps to maintain and improve standards, and therefore enhances public protection.
- 15.19 In last year's report we outlined our view that patients should be more involved in the design and delivery of education programmes, and that course evaluation should take patient views into account. We are pleased to report that the HPC is currently examining the levels of service user involvement in the design and delivery of education provision across the professions. In March 2011 the HPC's education and training committee (ETC) decided to commission research to inform any future decision about whether to amend the standards of education and training/guidance to make service user involvement in design and delivery of education and training programmes compulsory. The research will be commissioned in May 2011 and the outcome will be reported to the committee's meeting in November 2011. We will be interested to follow up on the results in our next review.
- 15.20 Additionally, we note that in September 2010 the ETC considered whether a pilot study including the use of public partners on approval visit panels represented true service user involvement. The ETC made a distinction between a pilot of this type and any other future action to address service user involvement. It concluded that discussion about such a pilot should be separated from any further discussion about service user involvement in the education approval process.

³⁷ CHRE, 2008. *Advice on Student Registration*. London: CHRE.

We agree that this is a reasonable approach, and note that the inclusion of public partners on approval panels would bring this activity in line with other HPC functions (eg fitness to practise panels).

- 15.21 The HPC has stated that its work on revalidation is continuing and that no decisions in relation to its revalidation proposals will be made until the end of 2011. However, we were particularly interested to note two external studies commissioned as part of the HPC's research into revalidation. The first study explored any links between conduct during pre-registration education and training and subsequent fitness to practise action. An analysis of the HPC's fitness to practise data indicated that complaints are overwhelmingly prompted by registrant conduct, rather than concerns about competence. Research from the United States indicates that doctors who had concerns raised about their professionalism whilst students were more likely to be subject to disciplinary action once qualified than those without any such history. The HPC concluded that it should therefore focus its efforts on professionalism, and build the evidence base in this area, as it found no comparable UK studies relating to the professions it regulates. The second study is a qualitative study that looked at educator and student perceptions of professionalism and what constitutes professional or unprofessional behaviour. The research involved three professions; paramedics, occupational therapists and podiatrists. The initial results, along with an annual progress report, will feed into ongoing research aimed at the development of a tool to assess levels of professionalism. This research is due to be completed in March 2015. We believe that this work has obvious potential public protection benefits, and that the outcomes could be usefully shared with all healthcare regulators and other interested stakeholders.
- 15.22 More generally, the HPC is also considering whether its revalidation model should focus on quality improvement or quality control. Its current thinking is that revalidation should aim to improve the quality of all registrants' practice, rather than solely aiming to identify those practitioners who do not meet the basic acceptable threshold for practice.

Registration

- 15.23 We consider that the HPC manages registration effectively and efficiently and that it has demonstrated a commitment to continuous improvement through its work on improving its verification processes for international applicants. This is particularly important given the flow of healthcare workers across European and international boundaries.
- 15.24 The HPC has placed a particular focus on verifying the identity, qualifications and registration of international applicants with overseas regulators. This has included checks of all passports using an online database, and contacting awarding institutions to confirm the authenticity of applicants' qualifications. Two further online databases are used to verify education providers and programmes, and checks are also carried out with overseas regulatory bodies to establish applicants' professional status. The HPC also has an arrangement with a background screening organisation with global capabilities to undertake further checks if necessary. A fraud measurement exercise by the NHS Counter Fraud and Security Management Services (referred to in last year's review) has been completed. The exercise was aimed at validating the qualifications of a sample of HPC registrants.

The exercise found that generally the HPC had appropriate processes in place to validate the qualifications of applicants - however, one case involving a false qualification was identified. The HPC is planning a follow up study to clarify whether this is a more widespread issue. We believe that these activities help the HPC to minimise the risk of fraudulent applications and entries to the register while preserving public confidence in the integrity and role of the HPC registers in maintaining public protection.

- 15.25 The HPC introduced its new online facility for renewals in March 2010 and around 50 per cent of registrants have used the service. The HPC has plans to further raise the profile of the online renewal system: in renewal letters sent to registrants and employers, by HPC staff on the telephone, and in communications with professional bodies (for onward dissemination to registrants). The HPC therefore expects the proportion of online registrant renewals to increase over time. We note that the benefits of increasing registrants' use of the online facility are that it improves the efficiency of application processing and reduces data entry errors by HPC staff. More generally, the HPC reports that its work with stakeholders to communicate the importance of registration renewal (using the online facility or otherwise) has resulted in fewer registration lapses, with a record number of registrants having successfully renewed this year. This has positive implications for public safety, as it reduces the risk that patients might be treated by unregistered practitioners.
- 15.26 We are pleased to report that in the coming year the HPC intends to improve the information available on its register. The register will indicate when a registrant is subject to a substantive or interim suspension order and a clear statement to explain that the names of registrants who have been struck off are not shown will be included on the 'search the register' pages. The HPC has indicated that it will also consider adding a 'sounds like' search function to the online register. As indicated in our February 2010 report on registers,³⁸ we take the view that these improvements will enhance public protection, as the added clarity should help the public to make an informed choice when identifying professionals who are qualified and fit to practise. The HPC has previously consulted with stakeholders regarding improvements to the way data is displayed and accessed, and plans to seek stakeholder views on the online register in its next round of opinion polling, which will take place in the autumn of 2011.
- 15.27 As we reported last year, the HPC consulted on the removal of a health reference as a requirement for registration. We are pleased to report that the HPC, having considered the consultation responses, has concluded that this requirement should be removed and replaced with a self-declaration, which is in line with our recommendation that regulators should employ the most proportionate means to obtain the information required to decide whether prospective registrants are fit to practise.³⁹ We understand that the HPC's health reference requirement was removed from 1 April 2011, when the relevant amendment rules became effective.
- 15.28 The HPC has also advised that it has considered the issue of indemnity insurance for its registrants at length. As the policy and legislative timetable is currently unclear, the HPC is not undertaking any work on indemnity insurance at present.

³⁸ CHRE, 2010. *Health Professional Regulators' Registers: Maximising their contribution to public protection and patient safety*. London: CHRE. [page 1]

³⁹ CHRE, 2009. *Health Conditions*. London:CHRE. [page 16]

The HPC intends to start work on developing its policy around indemnity insurance shortly before the legislation is published for consultation.

- 15.29 In August 2010 the HPC launched an online referrers' campaign to highlight the importance to other health professionals of checking the registration status of a member of an HPC-regulated profession. This followed commissioned research results which indicated that there was low awareness of the HPC amongst health professionals (such as GPs and practice nurses) who might refer patients on to other professionals such as chiropodists or physiotherapists regulated by the HPC. The main focus of the campaign was an HPC micro site on Doctors.net.uk. This gave the HPC access to over 173,000 primary and secondary care GMC-registered doctors. The HPC also exhibited at the Royal College of General Practitioners' annual conference where it met GPs, answered queries, and distributed relevant literature (including the updated referrers' guide). We welcome this approach, which we believe could contribute to patient safety and public protection by reducing the risks of a healthcare professional referring a patient to an unregistered practitioner.

Fitness to practise

- 15.30 In our previous review we indicated our interest in any future improvements made to the HPC's fitness to practise process based on the outcomes of its commissioned research into the expectations of complainants. That research was published in February 2010 and we recognise that the HPC has undertaken a range of activities in 2010 in response to the outcomes from it, including:
- Updating the complaints section of its website and providing clearer and more accessible online information about the fitness to practise process, which includes an audio-visual presentation for anyone attending, or interested in finding out about, fitness to practise hearings
 - Updating standard letters so that they now provide information regarding the length of time a case is likely to take and the reasons for this, as well as details of how to make a complaint about the HPC
 - Updating its 'Raising a Concern' form
 - Updating relevant publications for patients, employers and registrants
 - Publishing an *Information for Witnesses* leaflet in March 2010.
- 15.31 Another outcome of the complainants' expectations research was the HPC's consideration of the potential role within its fitness to practise process of alternative mechanisms for resolving disputes. As part of this work the fitness to practise committee considered a literature review looking at mediation and other alternative mechanisms for resolving disputes. The fitness to practise committee will consider the outcomes of the commissioned research in October 2011, and the HPC anticipates beginning a pilot study in October 2012 which is likely to run alongside its existing fitness to practise process. We would be interested to learn of any developments or progress made in the HPC's continuing work on alternative mechanisms for resolving disputes as part of next year's review.
- 15.32 The HPC has also made improvements to its processes which were not prompted by the complainants' expectations research. Historically, registrant self referrals were automatically considered by the registration panel to determine whether they should be dealt with under the fitness to practise process. Following our 2009 audit

of initial decisions and to ensure consistency in investigation standards and decision making, the HPC has changed the way it deals with self referrals. When the HPC receives a self-referral it now considers whether the information raises the possibility that the registrant's fitness to practise may be impaired and should therefore be investigated as a fitness to practise allegation. If it does raise that possibility the case is referred to the fitness to practise department immediately, without referral to the registration panel. We believe that the HPC's response in these areas demonstrate a drive towards continuous improvement and should help ensure that concerns are raised and dealt with efficiently, effectively and consistently in the interests of patient safety.

15.33 We welcome the HPC's introduction of internal auditing of the fitness to practise procedures used by its caseworkers and panelists. We note that an internal HPC review of the decisions made by the investigating committee between April and August 2010 identified key learning for panelists, including:

- The need to provide reasons for their decisions that can be understood by all in every case
- The need to ensure consistency in the application of the 'realistic prospect' test
- The possibility that panelists should issue registrants with learning points where there is no realistic prospect that impairment of fitness to practise will be established, but where the registrant's behaviour did not reflect good practice.

15.34 The HPC has addressed these findings by improving the template that is used by the panelists when drafting their decisions, and by providing better guidance on how to apply the realistic prospect test. Panelists have received training on these improvements and have also had refresher training.

15.35 The audit identified eight cases in which seeking clarification from the complainant might have assisted in the decision making process. In our view⁴⁰ and in the interests of fairness and transparency, there should be a presumption that registrants' responses will be shared with the complainants. This can lead to such clarification emerging before the investigating committee reaches its decision. We would urge the HPC to reconsider our recommendations about this, given the audit findings. However, we recognise that the HPC has taken steps to minimise the risk of recurrence by providing further training to case managers and by introducing case investigation reports.

15.36 Notable improvements in the HPC's fitness to practise function this year involve:

- The reduction in the time taken for cases to conclude, from the receipt of allegation to final hearing stage, and from the investigating committee stage to the final hearing stage, by two months and one month respectively
- The introduction of arrangements for registrant assessors to provide advice to the investigating committee on profession-specific matters, where appropriate.

15.37 We welcome these developments, which should help to ensure fairness, consistency and greater reliability in decision making, while enhancing patient safety and public confidence by reducing the time needed to arrive at a conclusion.

⁴⁰ CHRE, 2009. *Handling Complaints: sharing a registrant's response with a complainant*. London: CHRE.

- 15.38 The HPC has reported that during 2010 its fitness to practise team had a series of meetings with various UK ambulance services and relevant trades unions. Issues discussed included:
- The high number of cases involving paramedics
 - The type of information that employers should provide to the HPC and at what stage this needs to be done, so that fitness to practise matters can be dealt with as quickly as practicable
 - The purpose of fitness to practise proceedings - making it clear that they are not a form of employment tribunal.
- 15.39 A lead case manager has been designated as the specific point of contact for ambulance services within the HPC. The HPC is also developing a policy position for consideration by its council in July 2011 concerning whether paramedics are obliged to provide care and treatment to patients during meal-breaks which are stipulated under their employment contracts. Given recent highly publicised cases in which the lack of care and treatment provided was a matter for concern, we welcome the measures taken by the HPC, which should address a recognised risk to patient safety and public confidence.

16. The Nursing and Midwifery Council (NMC)

Overall assessment

- 16.1 Before setting out our views of the performance of the NMC, we outline below some key information in paragraph 16.2 about the NMC's activities for the financial year 2010/11. When reading this data for each of the regulators, care should be taken to ensure that misleading comparisons are not made. There are differences in the size of the regulators both in terms of staff numbers and registrants, they all work to differing legislation, rules and processes, they have a varying caseload in terms of registration applications and fitness to practise referrals and are dependent to a greater or lesser extent on information from third parties which can impact on the timeliness of their work.
- 16.2 The Nursing and Midwifery Council (NMC) regulates two professions: nurses and midwives. There are 1,043 education programmes that the NMC approves, however, this number is frequently subject to change. It has 669,677 registrants and received 30,687 new registration applications since the last review. Once an application was accepted, and the necessary documentation and payment received, the registration process was completed within five days. The median time taken to process initial registration applications for UK graduates, international non-EU applicants and EU applicants was 1.2, 1.3 and 1.5 days respectively. The NMC received six appeals against registration decisions. Two of these were concluded with the decision being upheld and the remainder are ongoing. The NMC has an annual retention fee (outside of any initial discount period) of £76. The NMC's investigating committee considered 4,058 cases and its final fitness to practise committees 1,294. The median time taken from receipt of initial complaint to the final investigating committee decision was 14.8 months. The median time taken from final investigating committee decision to final fitness to practise hearing

decision was 9.5 months. The median time taken from receipt of a complaint/information indicating the need for an interim order referral to an interim order decision was six weeks. There was one successful registrant appeal against a final fitness to practise decision and one successful CHRE appeal.⁴¹

- 16.3 The NMC has undergone a series of significant changes during this performance review period. It has restructured its organisation, and there have been changes in key senior personnel (such as the director of fitness to practise in August 2010). It has undertaken a strategic review of the work of each of its functions to consider where improvements can be made. This has resulted in a number of changes, for example, the development of a more systematic, evidence based approach to the review of standards and guidance. It has also acted on feedback from its stakeholders. One outcome of this work was greater engagement with employers of nurses and midwives. It has held regular engagement events, and set up a dedicated helpline for employers considering making fitness to practise referrals. We note that it has also considered how it can improve the use of its own data. It is developing a critical standards intervention system, which will collate and analyse legitimate sources of information such as organisational complaints, fitness to practise data and information collected through the quality assurance of education providers and the local supervising authorities. This will be used as an indicator to identify possible concerns relating to fitness to practise. The NMC will then take appropriate action to address these concerns such as initiating an investigation.
- 16.4 As well as experiencing a number of changes, the NMC has built on its good performance in the development, revision and communication of standards and guidance. This is illustrated in the range of consultations carried out during the final stages of the development of the new pre-registration nursing education standards. When consulting on its draft standards, the NMC produced a generic survey and also specific surveys for particular groups of patients such as those who are older or have dementia.
- 16.5 In April 2010 the NMC invited CHRE to undertake a review of its progress since the publication of our *Special Report to the Minister of State for Health Services on the Nursing and Midwifery Council* published in June 2008 ('Special Report') and our *Fitness to Practise Audit Report* published in February 2010 ('Audit Report'). We published our progress review in January 2011.⁴² We found that the NMC had made some significant improvements, such as the introduction of a case management system, and use of fit-for-purpose premises for fitness to practise hearings. However, we remained concerned about the number and nature of the improvements that the NMC still had to make, particularly around its customer care, its management of serious cases and the timeliness of its case progression. We were satisfied that the NMC had a good understanding of the areas in which it still needed to improve and that it recognised that its current performance impacted on the public's confidence in its ability to be an effective regulator and could adversely impact on public protection and patient safety. Due to the importance of the areas that are still in need of considerable improvement, we agreed with the NMC that we would work alongside it over the coming months to ensure that improvements

⁴¹ We lodged three appeals against NMC final fitness to practise decisions in 2010/11. A hearing was heard for one case in February 2011, and our appeal was granted in April 2011. The two other appeals are outstanding.

⁴² The three reports can be found on our website, www.chre.org.uk

continued to be made. We report on the further progress the NMC has made since publication of the progress review in the fitness to practise section of this report.

16.6 In last year's report, we noted a number of areas where we wanted to see evidence of progress. We report the following:

- Improvement to the consistency and quality of decisions made and recorded – from the evidence collected from our two audits of initial decisions and our ongoing review of final fitness to practise decisions, we do not consider that the consistency or quality of decisions has significantly or consistently improved. We report at paragraphs 16.63-16.69 on how the NMC is attempting to improve this aspect of its work
- Improvement to the culture of customer care and the content and use of standard letters – the newly appointed corporate complaints manager will be responsible for the development of organisational customer relations standards and the promotion of a culture of customer focus in all the NMC's dealings with service users. We report at paragraphs 16.70-16.76 the specific work undertaken on this concern in the fitness to practise function
- Outcomes of internal audits and the external review of the NMC's fitness to practise hearings, processes and decisions – the external review was undertaken in early 2010 and indicated a number of areas for improvement, particularly around the administration of the fitness to practise process. The NMC accepted the findings of the audit and the actions to address these findings were signed off by the fitness to practise committee in October 2010
- Progress on the wider public involvement in the quality assurance of education providers – the NMC's quality assurance process now measures patient and public input into curriculum design, development and student assessment
- Implementation of an organisational complaints process – the NMC has appointed a corporate complaints manager and an organisational complaints process has been developed (based on the NHS complaints model). The corporate complaints manager will be responsible for identifying trends and learning from complaints in a systematic way. Guidance has also been produced specifically for fitness to practise staff on how to manage complaints. We hope to see an improvement in the NMC's complaints handling in the future.
- Implementation of information governance and assurance arrangements to protect personal data – an information governance review is underway, information governance policies have been drafted, staff have received training, all data breaches and losses have been reviewed, and an information and data governance manager has been appointed.

16.7 We would like to see progress by the NMC in the following areas:

- The effectiveness of the NMC's quarterly monitoring tool for managing and identifying risks in the performance of the local supervising authorities responsible for the statutory supervision of midwives
- The outcome of its review of the quality assurance framework for education providers
- The outcome of its review of the good character and health guidance

- The development of its revalidation scheme
- The use of its equality and diversity data to improve its performance
- Its review of its policy on professional insurance and indemnity. We note that it will begin this once it is clear what is to be included in the relevant legislation.
- Its information security review
- The review of its policy of only listing those with effective registration on its public register - this will include consideration of whether details of the registrants who have been suspended or struck off the register should be included on the public register
- Continued improvement of the work of the fitness to practise directorate.

Guidance and standards

- 16.8 The NMC has undertaken a range of activities to refine and enhance its guidance and standards function. This includes taking a strategic approach to the development and revision of standards and guidance, using stakeholder feedback and data collected from the organisation to greater effect, and diversifying how it publishes standards and guidance to ensure that different groups have access to information in a format that is most useful to them. We welcome these enhancements. We consider that they can only be beneficial to patient safety, as they should enable the NMC to meet registrants', the public's and patients' needs more effectively.
- 16.9 The NMC has established a single directorate that oversees nursing and midwifery policy and standards. The directorate's work will be guided by the NMC's *Strategic Context* report, which provides an overview of all the policy drivers that affect the regulation of nurses and midwives. These policy drivers include demographic trends that affect the delivery of care (eg the growing population of older people), implications for public health (eg the need to reduce obesity), legislative requirements and training, and mobility of the profession (eg ensuring competency in communication and practice). The NMC is developing criteria, methods and tools to use in its standards and guidance review and evaluation, including a framework for the commissioning of research. This framework will ensure that research is focused on the relevant issues required for each workstream.
- 16.10 The above work will build on the evaluation already carried out by the NMC of its *Guidance for the Care of Older People*. The most recent evaluation looked at qualitative feedback from nurses who had used the guidance over the year since its publication. The feedback received indicated that the guidance was a positive resource, which enabled benchmarking of practice. We are pleased with this outcome, as it indicates that the guidance is a tool through which standards of care can be improved.
- 16.11 Alongside the development of a new approach to the work of this function, the NMC has continued to review its core standards, and to provide additional guidance and advice to registrants on the application of its standards to specific issues.
- 16.12 The NMC's update of its Midwives' Rules and Standards, the Standards for Preparation and Practice of Supervisors of Midwives and Standards for the Supervised Practice of Midwives is ongoing. The timeframe for the delivery of these standards is being reviewed, to take account of the impact of the current policy

changes within the NHS. These include the dissolution of the strategic health authorities in England, which currently hold the function of the local supervising authority.

- 16.13 The NMC has continued its extensive engagement strategy with key stakeholders. During the review of the *Midwives' Rules and standards* it piloted a new approach to obtaining views during the formal consultation period. It approached representative groups and asked which parts of the consultation document would be of particular interest to the people that each group represented. The NMC then adapted the supporting information within the consultation document, to make it more accessible to that particular audience. This made it easier for the NMC to understand the views of all stakeholders about the same issues. We consider that there is value in taking such an approach during consultations.
- 16.14 We note that the NMC has also made improvements to the way it monitors the performance of the local supervising authorities for the statutory supervision of midwives. It has developed a quality monitoring tool which enables it to more closely monitor and take prompt action about any performance issues or perceived threats that may have implications for the health and well-being of women and their babies. We consider that this could be an important tool in ensuring the safety of women and their families. The quarterly reporting of performance by the local supervisory authorities to the NMC began in January 2011, and we look forward to discussing the effectiveness of this tool in the next performance review. We share the NMC's concern at the lack of clarity about the place of local supervising authorities for the statutory supervision of midwives in the restructured NHS that is proposed in the Health and Social Care Bill and the potential risk to patient safety.
- 16.15 We note that the NMC has made a concerted effort to develop and revise guidance and advice on specific issues as a result of changes in legislation, feedback from stakeholders, trends identified in fitness to practise referrals, and external events.
- 16.16 In response to changing legislation, the NMC has included an update on those medicines that can be supplied and administered by midwives in its circular *Changes to Midwives' Exemptions (06/2010)*. As a result of using its fitness to practise data, it has identified that its guidance on record keeping could be enhanced as this was a common area of poor performance. Alongside this, it has also identified that there might be a need for additional material to support registrants in leadership roles, as well as those who work in the armed forces. Its aim is to publish advice that promotes effective practice through illustrative case studies. We consider that such a practical approach will help registrants apply the standards and guidance to their everyday practice.
- 16.17 The Department of Health requested that the NMC clarify the role of nurses and midwives in safeguarding adults. The NMC responded to this by carrying out a range of activities to understand its registrants' awareness of such matters and engaged with groups including Action on Elder Abuse. The information obtained was used to shape the NMC's subsequent advice on recognising and effectively managing situations where a registrant suspects a person in their care may be at risk of harm. Advice has been published for: midwives providing antenatal care, nurses providing care for older people in care homes, and registrants caring for people with learning disabilities. The NMC has devised a toolkit of resources to support the advice. We consider that this advice should help to protect the safety of some of the most vulnerable patients.

- 16.18 We welcome the publication of the NMC's advice to registrants, *Raising and Escalating Concerns*. This came about as a result of a high profile fitness to practise case and subsequent media attention focusing on whether those health professionals who raise concerns are sufficiently supported. Advice has been provided to NMC registrants on how to raise concerns about the safety and well-being of patients in their care without endangering their registration. The advice has benefited from a wide range of input from professional bodies, interest groups, registrants and Public Concern at Work. We consider that this advice should contribute to improvements in patient safety.
- 16.19 As well as using the results of its engagement activities in individual pieces of work, the NMC has begun to make greater use of the wider feedback it receives as a result of its engagement work. For example, from its work with the Alzheimer's Society on the pre-registration nursing standards, the NMC identified the need for some additional material for nurses who care for people with cognitive impairment and dementia. It is now considering how it can take this forward.
- 16.20 We note that the NMC has put considerable effort into diversifying its communication channels. We agree with the principle behind this work – to ensure that the NMC's communications are targeted, cost-effective and reach those stakeholders who require the information.

Education and training

- 16.21 The primary purpose of the NMC's standards for education is to ensure the safe and effective practice of students at the point of registration (or when adding a recordable qualification to an existing registration). Public protection is central to these standards and to the guidance for student nurses and midwives. This is illustrated in the NMC's recently published standards for pre-registration nursing education. The standards set out that all pre-registration students, irrespective of their field of practice, have to be able to meet the essential care needs of people of all ages, as well as being able to meet the more complex needs of people within their particular field of practice.
- 16.22 The NMC's focus on ensuring that students are fit to practise at the point of registration is also evident in other strands of its work. For example, it has strengthened the standards to support learning and assessment in practice, to ensure that safe judgments are made about nursing and midwifery students' developing competence in the practice setting, and that any concerns are promptly addressed. The NMC is also about to undertake a comprehensive review of its guidance on good character and health. This will also incorporate issues relating to programme access, making reasonable adjustments, and the provision of appropriate support for people with disabilities who wish to become a nurse or midwife. We are supportive of this work, as it will have obvious benefits for public protection. We look forward to seeing the outcomes of this work in the next performance review.
- 16.23 Another strand of this work is the NMC's consideration of student indexing. Indexing would mean that the NMC would record the name and education course of each student, and the student would be issued with a unique reference number. This would enable the NMC to track and communicate with students more easily. We would want to be sure that this approach deals with genuine risk and is effective in achieving the outcome that the NMC intends. We would ask the NMC to

be mindful, when considering this option, of the eight elements that sit at the heart of right-touch regulation.

- 16.24 We note that the NMC has introduced an internal oversight and scrutiny group which provides a forum for the discussion of education issues, together with expertise to support the registrar in the approval process. It is also reviewing its quality assurance framework, to ensure that it is meeting its objectives and is fit for purpose. We hope that any changes will improve the proportionality of the NMC's quality assurance process. We will look to see the progress made on the changes, and any evidenced impact, in next year's performance review.
- 16.25 Whilst changes are being made to the quality assurance process, we are pleased to see that the NMC now has measures in place to ensure that stakeholder and wider public engagement inform curriculum design and development, and, where appropriate, the assessment of students. For example, midwifery programme providers (which have students with their own caseloads) obtain feedback from women about the care that they have received from their student midwife, which inform the students' assessments.
- 16.26 The NMC has completed the information-gathering phase of its revalidation project. It has undertaken a range of activities, such as conducting interviews, workshops and surveys of key stakeholders, reviewing documentation and assessing the NMC's Prep (post-registration education and practice) standard. The outcomes of this work will feed into the next stages of the revalidation work. This will culminate by the end of 2011 in the development of revalidation options which will then undergo cost/benefit analysis, followed by the approval of a preferred option, which will then be subject to consultation and piloting in 2012/13.
- 16.27 A key part of the next stage of the revalidation work for the NMC is the redevelopment of its Prep standard. The NMC wants to incorporate the Prep standard within the new revalidation standard so that it is clear to registrants that Prep is a key component of maintaining their fitness to practise. The NMC wants to introduce a more rigorous validation process through the new revalidation system, which enables it to identify the outcomes of learning activities and their impact on the registrants' ability to remain fit to practise in their current areas of practice. In other words, to ensure that its registrants are undertaking relevant continuing professional development (CPD) which will improve their practices and patient safety. It also wants to introduce a risk-based process for auditing CPD. This would allow the NMC to require registrants to submit evidence of their CPD. The NMC would then assess those records, and take appropriate action depending on the quality of the CPD undertaken by the registrant. The NMC considers that by incorporating a contemporary record of the learning a registrant has undergone in a three-year registration period into the renewals process, it could enhance the assurance it provides to the public about a registrant's current fitness to practise. We look forward to seeing the progress that the NMC has made on its revalidation work in next year's performance review.

Registration

- 16.28 The NMC has begun a long-term project to improve the customer experience in registration. It has begun to do this by identifying and using learning from appeals against registration decisions. For example, the NMC acknowledges that it needs to give greater detail about why a decision has been reached to reject an application,

and that it needs to improve the documentation provided to appellants. It is also considering how to improve the clarity of the information it provides to applicants. For example, it is developing member state specific guidance on routes to registration for European Economic Area applicants. This will provide generic information about the registration process, as well as specific European Union member state guidance on the documentation required.

- 16.29 As part of this work, the NMC has also engaged with the NHS Counter Fraud and Security Management Service to improve its identification of fraudulent applications to the register. This engagement has led the NMC to engage with other enforcement agencies including the Serious Organised Crime Agency and the Multi Agency Intelligence Network. We consider that this engagement should lead to improvements to patient safety, through improved intelligence sharing.
- 16.30 In response to our last audit report⁴³ the NMC has strengthened its registration and renewal processes for managing convictions and cautions arising from alcohol and drug related offences. It has introduced a process whereby, on notification of a first caution/conviction, the NMC will ask the applicant/registrant to provide a health reference from their GP. On notification of a second caution/conviction the NMC will ask the person to undergo a health assessment. A similar process is now also being used in fitness to practise cases. We welcome this development, as it should help the NMC to identify individuals whose fitness to practise may be impaired as a result of ill health, with the effect that appropriate and prompt action can take place to help the registrant and protect the public. We hope that other regulators which do not currently take this approach to alcohol and drug related offences will take account of the value of the NMC's approach.
- 16.31 In January 2011 the NMC agreed that it would commence a review of its policy on professional insurance and indemnity, once it was clear what was to be included in the legislation that would make indemnity insurance a condition of registration. Although the majority of the NMC's registrants are covered by an employer's indemnity insurance scheme, independent midwives are not. To look into what indemnity arrangements could be implemented for independent midwives the NMC has jointly funded a project with the Royal College of Midwives. Whilst we recognise that the lack of insurance only affects around 250 out of 34,000 midwives, we consider that it is appropriate for the NMC to focus on this matter as it is an important patient safety issue. There are significant risks involved in childbirth for women and babies and when there are incidents of negligence, individuals should be able to claim some redress. That said, if the government is committed to providing women with choice during their pregnancies, then we consider that the Department of Health also has a key role to play in this work.
- 16.32 The NMC has now completed its initial collection of equality and diversity data from its registrants. It has achieved an overall response rate of 60 per cent. It is now analysing this data, and will use it to identify any barriers to registration and ensure that its registration outcomes are consistent and its processes non-discriminatory. We recognise the efforts that the NMC has made in obtaining this data and look forward to seeing how it is used to improve its work.
- 16.33 The NMC is working to improve the security of its information across the organisation, particularly in the registration and fitness to practise departments. It has developed policies, provided staff training, reviewed all its data losses and

⁴³ CHRE, 2010. *Fitness to Practise Audit Report*. London:CHRE.

breaches, and is improving the security of its IT systems. It should have completed the initial review of its information security risks by the end of 2011. We consider that this work is important in order for the NMC to maintain the confidence of its registrants, the public and others.

- 16.34 The NMC has integrated data on its register with the NHS electronic skills record. This means that the NHS in England and Wales (which employs around 60 per cent of registered nurses and midwives) will now have access to up-to-date and accurate data about the qualifications, registration status and fitness to practise history of its employees. Employers will also receive notification from the NMC if an individual's registration has lapsed. We consider that this improvement will help to reduce the risks associated with unregistered nurses and midwives practising in the NHS, and improve the decision making of employers, thereby improving patient safety. We are also pleased that the NMC is considering reviewing its policy of only listing those with effective registration on its public register - this will include consideration of whether details of the registrants who have been suspended or struck off the register should be included on the public register. A change to annotating its public register with details of individuals who have been suspended or struck off would be in line with recommendations we have previously made⁴⁴ and we consider that it is essential to maintain public confidence in the NMC's regulatory processes.

Fitness to practise

- 16.35 From our progress review published in January 2011 we identified that the NMC had made significant progress in some areas of its fitness to practise work since our Special Report in 2008. This included:
- New premises that have facilities suitable for fitness to practise hearings
 - The introduction of an electronic case management system
 - Improved recruitment, training and appraisal of its fitness to practise panellists
 - The introduction of new posts that will assist with the development of an effective fitness to practise function
 - Development of systems for reviewing and learning from errors.
- 16.36 We remained concerned about the number and nature of the improvements that the NMC had to make. The necessary improvements spanned the areas of case handling, customer care, decision making, timeliness of case progression, record keeping and the overall management of the fitness to practise process. We recognised that the NMC understood the areas for improvement, and had plans in place to address them. However, due to the importance of the areas that were still in need of considerable improvement, we agreed with the NMC that we would monitor the implementation of the planned changes and their effect on the NMC's performance. Our findings in this section of the report are based on the information we have received from the NMC in the first quarterly update that it has provided to us, following the publication of the progress review. We also incorporate our brief

⁴⁴ CHRE, 2010. *Health Professional Regulators' Registers: Maximising their contribution to public protection and patient safety*. London: CHRE.

comments about other aspects of the NMC's performance which have been highlighted through the performance review submission to CHRE.

Case handling

Resources

- 16.37 In our progress review we noted that the NMC was evaluating whether it used its existing resources effectively. It planned to change the structure of the teams in its fitness to practise directorate and to pilot in-house investigation. The NMC asserted that it had been working to better support and manage existing staff, through creating a culture of learning and development, and setting out the standards expected of all staff and managers. It had also improved internal communications with staff, to improve their knowledge, understanding and engagement with the work of the directorate. We recognised that these were positive initiatives, but raised our concerns that without sufficient support for staff, a reduction in their caseloads, robust monitoring arrangements being implemented, and a move to 'can do' positive working culture, NMC staff would continue to struggle to reach the standards needed to work effectively.
- 16.38 The NMC has assured us that there has been a reduction in caseloads, that very clear and robust monitoring arrangements are in place for dealing with consistently poor performance, and that there has been a significant increase in resources to support the case teams.
- 16.39 In April 2011 the NMC informed CHRE that its new screening team had become operational on 11 January 2011. That team of caseworkers is supported by a lawyer and two part-time clinical advisers. It manages cases from the point of initial receipt to their first consideration by an investigating committee. Staff in the team have received training on the use of the devolved decision making criteria and on the standard operating procedures for their work. Compliance with the appropriate processes is monitored by managers (and will be monitored through the quality assurance programme once it is implemented). Weekly meetings (attended by the director and the assistant director – operations) are also held to monitor progress of these cases. The NMC reported on its post-implementation review of the screening team to its council in May 2011. The NMC reported that the early indications were extremely positive. It believed that the screening team had helped to improve the standard of customer service and had enabled cases to progress more efficiently in the initial stages of the fitness to practise process.
- 16.40 The NMC has informed us that the escalation team (which will concentrate on progressing specific types of cases once the investigating committee has decided that there is a case to answer) is fully resourced and almost working at capacity. It will work to progress these cases using the NMC's high profile case strategy. Those senior case officers who are already in post have already started to deal with high profile casework, including referrals from the Mid Staffordshire NHS Foundation Trust inquiry. The team manager provides an update to the senior management team on a weekly basis on the progress of high profile and complex cases.

- 16.41 A new allocation process for cases on referral for investigation is now part of the directorate's standard operating procedures. We also note that a pilot of in-house investigations is due to begin on 27 June 2011.
- 16.42 As well as restructuring the teams, the NMC has said that it has begun work to improve the recruitment process for, and the support given to, new caseworkers. It has reviewed the competencies, job role and interview requirements for its caseworker roles. Customer service skills and experience are now an important element of the person specification and are tested at interview. The NMC has also recruited a process and induction manager to lead on induction planning and implementation and delivery to all staff across case management. The postholder will be responsible for certifying the competence of each caseworker in all stages of case progression before they pass their probation period.
- 16.43 In terms of its current staff, the NMC, as part of its personal development process has incorporated a training needs analysis - using both the generic NMC competency framework and specific fitness to practise competencies. It aims to ensure that each existing staff member assesses their individual level of knowledge against the expertise required for their role. This analysis will inform the training plan for the fitness to practise directorate. Evaluation of recent training is being undertaken through work-sampling and monitoring the causes of any critical incidents. Managers are being provided with training on developing staff and managing their performance. The NMC has told us that robust monitoring arrangements have now been put in place for tackling poor performance and for ensuring that standards are raised across the directorate.
- 16.44 As at August 2010 the NMC casework team staff each managed an average caseload of 121 cases, and the triage stage staff managed an average caseload of 135 cases. By the end of March 2011, the new screening team members were managing an average of 82 cases each, and the casework team members were managing an average of 110 cases each. Whilst we consider that this average caseload is still too high, we do recognise that due to a 57 per cent increase in complaints received in January and February 2011 compared to the same period in 2010, and the time needed to make the changes necessary to improve the timeliness of fitness to practise case progression, a greater reduction of caseloads within this period was unlikely. In addition to this we recognise that as the NMC has only just recruited the new escalation team, the benefits of having this additional resource to deal with the more complex cases has yet to be realised.
- 16.45 We will want to see evidence of how these changes are impacting on the quality of the NMC's casework in our next audit, and in the next quarterly update (which we expect to receive in July 2011).

Case management system (CMS)

- 16.46 In our progress review we highlighted our concerns that the CMS was still subject to technical difficulties, that data accuracy of case records remained a problem, and that staff were not using the CMS appropriately. We considered that these difficulties had a significant impact on the NMC's ability to manage and prioritise cases.
- 16.47 We have seen the NMC's CMS action plan, detailing the work that is to be done to improve the performance of the CMS. An update on the progress of the CMS was reported to the NMC's corporate leadership board in May 2011. The NMC

acknowledges that there are still problems with the data accuracy of case files and computerised records. However, it says that it has a process in place to ensure that the CMS reflects the correct stage that each case has reached, and that staff check the data accuracy of case files on a daily and weekly basis to ensure that any anomalies or errors are dealt with quickly and effectively. The NMC is confident that the vast majority of its cases are at the correct stage, even though there are problems with workflows for individual cases. The NMC says that these workflow problems do not impact on its ability to know what stage a case has reached, and what needs to be done to progress it.

- 16.48 The NMC does not believe that it will have full confidence in the system and the staff who use it until the system is working in the way that meets the need of the fitness to practise process. We understand that the NMC is committed to the principle of every member of the directorate fully utilising the CMS as the only tool for managing cases, and it is working to ensure 100 per cent compliance. We are also aware that the NMC is recruiting a full-time trainer who will have responsibility for training (and retraining) staff on using the CMS. We note the NMC's views about the effectiveness of its CMS, and recognise the initiatives undertaken by the NMC to improve the accuracy of the data held on the CMS. The effective use of the CMS is critical to improving the NMC's performance in fitness to practise, and we will expect the NMC to provide evidence of how the improvements that they have recently put in place or are currently implementing have impacted on performance in the quarterly update that they will provide to us in July 2011. We will also look for evidence of the impact of these changes in our next audit of the NMC's initial stages of the fitness to practise process.
- 16.49 The NMC has developed a protocol for the sharing of fitness to practise information with the registrations team - so that fitness to practise information about applicants to the register is consistently shared. We consider that this should improve the integrity of the register and public protection.

Guidance for staff and panel members

- 16.50 In our progress review we discussed the NMC's approach to a recommendation made in our initial stages audit report in 2010, namely that the NMC should develop a comprehensive manual of guidance covering all aspects of its consideration of cases. We noted that work had begun on drafting guidance for staff and committee members, and that a comprehensive manual was going to be produced. We considered that the lack of comprehensive and accurate guidance had led to inconsistencies in case handling by staff, and we were concerned that such matters could affect patient safety.
- 16.51 The NMC has provided CHRE with a copy of the first version of its new casework manual. The manual is currently undergoing user-testing. Amendments and additions are being collected and will be incorporated into a revised version once testing is complete. The NMC says that feedback from staff so far has been positive. The manual covers each stage of the fitness to practise process from initial receipt of a complaint to a final hearing decision; it includes case management processes, business support arrangements (such as administrative tasks and financial payments) scheduling, the liaison with the legal team and useful information (such as the archive and retention policy). We look forward to seeing the impact of this manual on the quality of case handling by staff.

16.52 The NMC has said that it has also improved its 'case to answer' guidance, so that it is clear that panel members should not place undue reliance upon other organisations' investigations, and should ensure that sufficient evidence has been obtained before the panel makes a decision. Panel members are currently being retrained on the application of the 'case to answer' test. We look forward to reviewing this guidance and seeing evidence of its use in practice. We consider that this will improve the quality of the NMC's investigations and decisions and therefore improve patient safety as well as public confidence.

Expert advice

16.53 We noted in our progress review that the NMC was in the process of recruiting clinical advisors who would provide advice at the screening stage of the process. We understand that these are now in post. They will develop standard operating procedures to ensure that requests for, and the use of, clinical advice is consistent. It is hoped that once they are established, they could also provide advice to other parts of the directorate. We are pleased that these advisers are in place, and in our next audit, we will want to see that requests for advice and the use of the advice are consistent throughout the screening team, and that the quality of decision making has improved. We consider that expert advice could improve the quality of decision making at the early stages of the fitness to practise process.

Cautions/convictions for alcohol or drug offences

16.54 As we noted in paragraph 16.30 the NMC has adopted a new approach to dealing with registration and fitness to practise cases which involve a conviction or caution for alcohol or drug offences. This process has been applied since 31 March 2011. We are pleased with the progress made on the development of this policy. We will look to see evidence of its consistent use in our next audit.

Prioritisation of serious cases

- 16.55 We identified significant concerns in our progress review about the identification, prioritisation and subsequent management of serious cases. We considered that the NMC's failure to do any of these tasks in a consistent or appropriate manner had obvious implications for public protection. We reported that the NMC had recognised this as significant risk and was working towards remedying these failures.
- 16.56 We recognise that the NMC has adopted a multifaceted approach to improving its performance in this area. It has in place a high profile case strategy for identifying, processing and monitoring the most serious and complex cases.
- 16.57 The screening team carries out an immediate assessment of new referrals to establish at the outset if any of them could adversely affect patient safety. This high risk assessment is carried out by the screening manager and screening lawyer, with input from a clinical adviser. The NMC says that it is prioritising interim order cases, and this is evidenced through the work that the scheduling team is doing to monitor cases with interim orders so that those cases can be promptly progressed.
- 16.58 The NMC's new key performance indicator measures its performance in achieving holding an interim order hearing within 28 days of receiving a complaint. The average time taken for an interim order hearing to be held (between January and

March 2011) was 27 days. This is a very significant improvement on the NMC's performance in December 2010, - when it was taking 210 days from receipt of a complaint for an interim order hearing to be held. We will continue to monitor the NMC's progress, and look forward to seeing evidence of improvement in its management of fitness to practise cases throughout the process.

- 16.59 In particular, we expect to see: that no interim orders have lapsed before a final fitness to practise hearing is concluded, a reduction in the number of high court extensions of interim orders, quality assurance of decisions not to refer for an interim order, and continual risk assessment throughout the life of a case so that staff can make a referral for an interim order at any point. We also expect to see consideration of how to strengthen panel guidance so that cases which may require an interim order to be put in place to cover the appeal period following the imposition of a final sanction are considered at a hearing rather than at a committee meeting (at which such orders cannot apparently be made).
- 16.60 As of 1 April 2011 the NMC has changed its approach to the consideration of interim orders. It intends to have a specific pool of panel members who will only consider interim order applications. This should help to build expertise, and avoid any overlap between panel members who consider an interim order and those who consider the fitness to practise case at any other stage of the process.

Review of its legislative framework and rules

- 16.61 We reported that the NMC recognised that its rules and legislation hampered its ability to work effectively. To address this, it was working with a legal firm to see how it could use its current powers more effectively. It is also carrying out a fundamental review of its legislation and rules to identify improvements.
- 16.62 The outcome of this work so far is liaison with the Department of Health on two proposed changes to the NMC's legislation. One of these would empower the registrar to refer cases to an interim order hearing (rather than the current two-stage committee process which impacts on the timeliness of the process). The NMC also wants to be able to offer registrants the option to apply for voluntary erasure from its register during the course of an investigation. It considers that the ability to accept applications for voluntary erasure would allow it to deal with health and competence cases in a fairer and less harmful way for registrants, while at the same time protecting the public. We await further outcomes from the NMC's review of its legislative framework and rules.

At this time we do not have sufficient information about the NMC's plans in this area to comment on the intended voluntary erasure powers. We will be concerned to ensure that such powers do not enable registrants to avoid their fitness to practise being scrutinised appropriately.

Decision making

Panel members

- 16.63 We reported on our concerns about the quality of the NMC's panel members' decision making. We noted that the NMC was addressing these concerns in three ways: the roll out of the appraisal system for panel members, the development of

tools to support decision making and the development of a quality assurance process to identify and address poor decision making.

- 16.64 The NMC has completed its appraisals of its panel members. We have been told that eight appraisals have not been completed for reasons that are outside of the NMC's control. We note that this represents a slight delay from the anticipated date of completion. The NMC has taken account of the feedback provided by panel members about the appraisal process, the work of the directorate, and their training needs, and that it will implement changes to the appraisal process shortly. During this round of appraisals, panel members were asked to give 360 degree feedback about colleagues, many commented that it had been a long time since the hearing or meeting, making recall difficult. The NMC will adopt the GMC's process of requesting 360 degree feedback immediately after each panel hearing or meeting. We note that this should improve panel members' recall of events and also enable performance issues to be dealt with in a timely manner. The NMC is also working with other regulators to see if learning can be shared on panel member appointments and management.
- 16.65 Future training events will be based on the competencies required of panel members. This will build on the training needs identified through appraisals. Refresher training has been held for investigating committee panel members on the 'case to answer' test, this covered, amongst other things, what should and should not be decided at the investigation stage (ie that it is not the investigating committee's role to reach a decision about impairment or mitigation). Ongoing training is being provided on how to draft clear and well-reasoned decisions. As previously noted, we consider that our learning points bulletin⁴⁵ on drafting determinations should be used as a reference tool during these training sessions. A monthly e-newsletter will shortly be issued to all panel members highlighting any key changes to the fitness to practise processes and any learning points identified. We also consider that our progress review, our 2010 audit report, this performance review report, and our learning points should be brought to the attention of panel members. We consider that these would be valuable learning tools for those decision makers.
- 16.66 As well as enhancing the panel members' skills and knowledge, the NMC has continued with the development of determination toolkits for its committees. The effectiveness of the toolkit at improving the quality of decisions of the conduct and competence committee is currently being evaluated. We hope that the NMC will take account of the learning points we have identified from our review of final fitness to practise decisions when it carries out this evaluation. The determination toolkit for its health committee hearings and one to be used at restoration hearings is being piloted, and a toolkit for interim order hearings will be developed. A similar support mechanism for investigating committee meetings is also being considered. Additionally, training has been provided for legal assessors, part of which includes training about their role in supporting the panel to provide clear reasons for their determination. The NMC also plans to carry out a review of its indicative sanctions guidance later this year. We consider this to be desirable.
- 16.67 The NMC manages a high volume of fitness to practise complaints and as reported in paragraph 16.2 above, in 2010/11, its investigating committee considered 4,058 cases and its final fitness to practise committees issued decisions in 1,294 cases.

⁴⁵ CHRE, 2009. Learning points bulletin. CHRE: London.

We remain concerned about the quality of the NMC's panels' decisions. We have seen no general improvement in their quality, and regularly issue learning points on this topic to the NMC. We note that the NMC has introduced a new process for logging, monitoring and acting upon our learning points, which are reported to the council on a quarterly basis. We hope that this, together with the initiatives identified above will result in real improvements to the quality of recorded decisions.

Audit

- 16.68 The NMC's council has approved the directorate's quality assurance programme which should begin shortly. The programme is designed to review cases to assess: compliance with processes, timeliness through the process, customer service and care, file management, data integrity, and decision making. Cases closed at each of the decision points will be reviewed and the case file and any feedback from the registrant, complainant, witnesses or others will be considered. Work is also continuing on the 'cause and effect' process and critical incident reviews. The outcomes of the quality assurance and review work will be used as training and feedback tools to drive operational change and improve standards of performance.
- 16.69 We hope that the quality assurance programme begins promptly as we consider that it will provide a valuable extra layer of oversight to a directorate that is undergoing such significant change. We will want to see evidence of the impact of this work in the NMC's next quarterly update.

Customer care

Quality of communications

- 16.70 We reported that customer care was a significant area of deficiency in the NMC's performance. We were concerned that customer care had been sacrificed for speed of case resolution. We were particularly concerned about the quality and timeliness of communications, and the lack of consistency in the identification and response to complaints. We considered that this poor performance was frustrating for registrants, complainants and others, and that it also impacted adversely on the public's perception of the thoroughness and accuracy of the NMC's work. However, the NMC tells us that it is receiving regular feedback from stakeholders on how much the quality of its communications has improved. We look forward to seeing evidence of this at the next review.
- 16.71 The directorate has introduced a number of initiatives to improve its customer care. From April 2011, new customer service standards were put in place. The NMC has developed a public-facing standards document as well as internal guidance which details what is expected of staff and how they are expected to meet those standards. This was supported by three training sessions held during April and May 2011. The standards will also form part of the induction training for any new staff members. We consider that this is a positive initiative, but would reiterate our previous concerns that without robust monitoring across the directorate, these standards may not have the desired impact.
- 16.72 An illustration of the impact that monitoring can have on performance is detailed below. As previously reported, the NMC has introduced a system of checking the quality and timeliness of its letters. The NMC has said that this has led to a marked improvement in the letters produced by the screening team. In September 2010,

the screening team was achieving 87 per cent of its letters being 'right first time'; this had improved to 97.7 per cent by March 2011. We are pleased that the NMC is able to demonstrate improvement in this area. We would like to see it implemented across all of the teams, and to see evidence of these improvements in our next audit.

- 16.73 In addition, we note that the NMC's new standard operating procedures make it clear when communication with relevant parties is required, and sets out what should be said. We consider that this should help make communications clearer and more consistent.
- 16.74 Feedback forms for complainants and others should provide a mechanism for the NMC to monitor the impact of its customer care initiatives. We look forward to seeing the impact of these changes over the coming months, and in our next audit.

Building relationships

- 16.75 We reported that the NMC had begun to undertake a range of activities to build relationships with its key stakeholders. We noted that this appeared to be having a positive impact on the stakeholders' perception of the effectiveness of the NMC. The engagement events for employers have continued, and have been supported by the introduction of a dedicated helpline. The helpline enables directors of nursing to obtain advice on potential and actual fitness to practise referrals. An improvement in relationships with employers should (subject to council's approval of a change in process) enable the NMC to adopt a process similar to the GMC's, whereby it refers complaints back to the employer to identify whether there are any wider concerns, before deciding whether to take any action.
- 16.76 In addition, the NMC has developed leaflets for registrants and complainants about the standard fitness to practise process. We consider that this should help registrants and others to understand the process better, which may prevent unnecessary queries being raised with the NMC as well as preventing any misunderstandings about the rationale for the NMC's actions.

Timeliness

Reduction in time taken to progress cases

- 16.77 We reported in our progress review that timeliness of case progression was still a significant area of concern. We had received overwhelming third party feedback that timeliness had not improved since 2008, and we had seen evidence of long delays in both our audits. Delays in the process adversely impact on all involved and can have implications for patient safety. We note that many of the measures already mentioned in this report will help to reduce delays, but also that the NMC has also introduced some other initiatives. The NMC has introduced regular case audits which take place at intervals of between two and four weeks and which are documented. At those case audits caseworkers are required to confirm that they have looked at each of their cases, and to identify the next action to be taken. The NMC considers that, as a consequence, it has seen a significant improvement in case management, which has led to a reduction in the number of cases at the stage between the two investigating committees.

16.78 In October 2010 the NMC targeted the 250 oldest cases in its system. By the end of February 2011, 69 of the oldest cases had been concluded, and there was evidence of significant progress having been made in the other cases (such as the scheduling of hearings). As of 1 April 2011 the NMC has changed the composition of its fitness to practise panels, by removing the need for a 'due regard' panelist (a panelist with experience of the same field of practice as the registrant). This should reduce the difficulties of scheduling hearings. We welcome the changes made by the NMC to improve the timeliness of its case progression. We will want to see evidence of the outcomes of these changes in our next audit, and also in the next quarterly review.

Proactive management of cases with external solicitors

16.79 We reported that delays in the investigation stage of the fitness to practise process had been, in part, caused by the time taken by the NMC's external solicitors to investigate cases. The NMC had not proactively monitored the progress of cases being externally investigated by its solicitors, and this had the effect of creating a backlog of delayed cases. The NMC began to manage this aspect of the process during the summer of 2010 and the external investigations into all 157 outstanding cases had been concluded by the end of May 2011. Having reflected on the lessons learned, the NMC has now contracted with new external solicitors. It has established a schedule of monthly operational meetings, and has clearly set out its expectations for quality and timeliness of casework. Any extension to the agreed 13 week deadline for the turnaround of cases can only be granted if certain criteria are met, and if any case exceeds 21 weeks, then it will be escalated for discussion at an operational meeting. We are pleased that the NMC has applied this learning from its previous experiences. We hope that this will contribute to the improvement of the timeliness of case progression at the investigation stage of the process.

Development of new key performance indicators

16.80 The NMC introduced new performance indicators in January 2011. These relate to the time taken:

- From initial receipt of the complaint to an interim order hearing – 28 days
- From initial receipt of the complaint to its first consideration by the investigating committee – 16 weeks for 80 per cent of cases
- From the first investigating committee decision to the final consideration by the investigating committee – 28 weeks in 80 per cent of cases
- From initial receipt of the complaint to conclusion of the case – 15 months in 90 per cent of cases.

16.81 All cases received by the NMC since January 2011 will be monitored against these indicators, and its older caseload will continue to be monitored against its previous performance indicators. We consider that the new indicators will enable the NMC to understand its performance at each stage of the process better. This should ensure that resources can be targeted at the areas most in need of improvement, and that the NMC can identify any other changes that need to be made. We look forward to seeing evidence of the NMC's performance against the second and third key performance indicators in the next quarterly update, as well as the performance data in relation to its older caseload. In terms of its older caseload, the NMC

performance against the key performance indicator of 90 per cent of cases concluded within 15 months was 62 per cent at 31 March 2011. We acknowledge that there is a difficult balance for the NMC to achieve in clearing its older caseload and efficiently progressing its new caseload so that it can meet its key performance indicators.

Record keeping

- 16.82 In our progress review, we highlighted that although record keeping had improved since 2009, our second audit had identified that there were still a number of errors which indicated that further improvements needed to be made. These included no records of why decisions had been taken for key actions such as closing cases and no records of police national computer or previous fitness to practise history checks having been undertaken. We consider that poor record keeping impacts on the effectiveness of case management, as it prevents clear understanding of what decisions have been taken and the rationale behind them and makes it difficult to manage case progression.
- 16.83 The NMC considers that there is emerging evidence of improvement regarding the quality of its record keeping. This is being identified through case audits, oldest cases review and in analysis of the outcomes of critical incidents investigation. We note the NMC's assertion, and look forward to seeing evidence of this in our audit.

Administration of the fitness to practise process

- 16.84 Third party feedback we received, feedback from the NMC's own panel members and the external audit the NMC commissioned on the quality of its panels' decision making clearly showed that the administration of the fitness to practise process was poor. Examples of this included bundles of papers for the committees containing incorrect or incomplete information, poor witness liaison and inaccuracies in notices sent to registrants meaning that cases had to be adjourned. We considered that improvements in this area could have a significant impact on the NMC's workload and on public perception of the effectiveness of the NMC and could result from relatively simple adjustments. The NMC planned to address these deficiencies through improving administration support for hearings, reviewing the process of allocating panel members to cases, and improved witness liaison.
- 16.85 The NMC has taken steps to improve the administration of hearings and meetings. The role of the council officer (who currently supports the panel at a hearing) has been externally reviewed. It has been recommended that the NMC introduces a new role of panel secretary, who should be better able to support, guide and advise panel members. The NMC is taking steps to recruit for this role and has recently recruited a hearings manager. It believes that there is a considerable amount of work to do to recruit and train staff alongside communicating a significant change to its hearings process. We welcome this change, and acknowledge that as recruitment to these new roles is either ongoing or has only taken place recently, it will take some time for its impact to be evident. We will continue to monitor any improvement in the quality of the NMC's administration of fitness to practise committee hearings and meetings through the quarterly updates that the NMC will provide to CHRE as set out in our progress review.

- 16.86 We note that the technical difficulties with the CMS's ability to compile the necessary papers for a hearing have not yet been permanently resolved. The effective use of the CMS's bundling functionality would help to ensure that the correct and complete papers are available for hearings/meetings, which would minimise the number of adjournments or delays in the consideration of cases caused by administrative errors. We recognise that the introduction of the new panel secretary role should also help to improve the administration of the hearings process in due course. The NMC has begun piloting a new bundling function within the CMS, and we hope that the outcome of that pilot will be a permanent solution to the current difficulties. We look forward to seeing evidence of any outcomes from this pilot in the next quarterly update from the NMC. We would expect the NMC to keep the progress of resolution of these technical difficulties under regular review. If the pilot does not result in a permanent solution to the problem, we would expect the NMC to consider whether it is possible to take any other temporary measures to improve the administration of hearing papers, pending the implementation of a permanent solution.
- 16.87 The NMC has allocated responsibility for witness liaison to the scheduling team. A standard operating procedure has been developed which sets out when and how witnesses should be contacted. The standard operating procedure is supported by the NMC's leaflets for witnesses. The three leaflets cover the investigation stage, the hearings stage and what happens after a hearing.
- 16.88 From the evidence that we have received from the NMC, we can see that it is taking the necessary steps to address the areas of concern in our progress review. We welcome the number of new initiatives that the NMC has introduced in 2011 to improve its performance. As these initiatives have only recently been introduced, we have as yet seen little evidence of their impact on the NMC's performance. However, we recognise that it will take time for the full impact of some of the improvements to become evident. We support the NMC's intentions and recognise that the NMC is committed to improving its performance. We look forward to seeing evidence of how these various initiatives have improved the quality of the NMC's casework in the next quarterly update that will be provided by the NMC, our next audit of the initial stages of the NMC's fitness to practise process and through our reviews of final fitness to practise determinations made by NMC panels as well as in next year's performance review.

17. The Pharmaceutical Society of Northern Ireland (PSNI)

Overall assessment

- 17.1 Before setting out our views of the performance of the PSNI, we outline below some key information in paragraph 17.2 about the PSNI's activities for the financial year 2010/11. When reading this data for each of the regulators, care should be taken to ensure that misleading comparisons are not made. There are differences in the size of the regulators both in terms of staff numbers and registrants, they all work to differing legislation, rules and processes, they have a varying caseload in

terms of registration applications and fitness to practise referrals, and are dependent to a greater or lesser extent on information from third parties, which can impact on the timeliness of their work.

- 17.2 The Pharmaceutical Society of Northern Ireland (PSNI) regulates one profession: pharmacists in Northern Ireland. The PSNI is responsible for the quality assurance of two pharmacy educational programmes. It has 2,092 current registrants and received 163 new registration applications since the last performance review. The median times taken to process initial registration applications for UK graduates, international non-EU applicants and EU applicants were 1, 0⁴⁶ and 1 day respectively. The proportion of successfully appealed-against registration decisions was nil, (there were no appeals). The PSNI has an annual retention fee (outside of any initial discount period) of £372. The PSNI's scrutiny committee considered 14 cases and its statutory committee 4. The median time taken from receipt of initial complaint to the final scrutiny committee's decision was 70 days. The median time taken from the final scrutiny committee's decision to the final statutory committee's decision was 87 days. The number of successful registrant or CHRE appeals against final fitness to practise decisions was nil.
- 17.3 The PSNI has maintained its performance as an effective and efficient regulator within the limitations of its legislation. It has also made a number of improvements to its performance, including:
- Reducing the risks associated with unregistered practice by improving employers' and the public's awareness of the importance of checking that a pharmacist is registered and by cross-checking premises' employee data against individual registrants to identify any person practising whilst unregistered
 - Enhancing its registration processes, for example through increased checks on whether registrants have indemnity insurance
 - Ensuring that the public's and students' views are taken into account during the education quality assurance process.
- 17.4 It has also progressed the three areas which we identified in last year's review:
- The continued separation of the regulatory and professional functions – progress has continued. The board of the new professional forum has been established, with eight members elected by the profession. The first board meeting took place in March 2011, when work began to devise a scheme of delegation between the council and the board
 - Its approach to managing its education function, after the establishment of the new pharmacy regulator in Great Britain (the GPhC) – the two regulators have met to discuss the development of a memorandum of understanding to cover operational matters such as quality assurance and approval of education providers, and fitness to practise information-sharing. Liaison between staff continues

⁴⁶ There were no international non-EU applicants in 2010/11.

- The progress made on establishing the PSNI's regulatory framework – the proposed legislation (the Pharmacy (Northern Ireland) Order 1976 (Amendment) Order (Northern Ireland) 2011) is currently subject to public consultation. We discuss the changes proposed in this legislation at paragraphs 17.14, 17.24 and 17.26.

17.5 We hope that the PSNI will continue to perform effectively leading up to the implementation of its new legislation. In next year's review we would like to follow up:

- The implementation of the changes that will take place as a result of the Pharmacy (Northern Ireland) Order 1976 (Amendment) Order (Northern Ireland) 2011. We would be particularly interested in considering the impact this will have on the PSNI's regulatory functions
- PSNI's consideration of moving from a health declaration that is certified by a doctor, to self-certification of health at the initial stages of the registration process.

Guidance and standards

- 17.6 The PSNI has used learning from its own work, discussions with patients and the public, external events and views of registrants to improve its guidance and standards. Ensuring that registrants have appropriate guidance and standards to steer their practice is a key part of the regulator's role in protecting the public.
- 17.7 The PSNI has used learning from the cases dealt with through its fitness to practise process to identify areas where registrants might benefit from additional or enhanced guidance. For example, it has developed and consulted on supplementary guidance for pharmacists on the provision of prescription collection and delivery services standards. We consider that the PSNI uses its fitness to practise data effectively to inform its guidance and standards work. However, as it has a small caseload, we would also recommend that the PSNI considers whether any learning from the GPhC's fitness to practise cases could be used to enhance its guidance and standards. The PSNI has agreed to consider this recommendation.
- 17.8 The PSNI has also used the views of patients and the public in its work on guidance and standards. As well as seeking their views as part of consultation exercises, the PSNI has used such feedback to identify where registrants may benefit from existing guidance produced by others. For example, the PSNI has disseminated information to pharmacists from the Royal National Institute for the Blind, the Royal National Institute for the Deaf and Parkinson's UK on specific disability matters and how they relate to pharmacists. It has also circulated information on complaints handling from the Patient Client Council (NI) to pharmacy owners and superintendent pharmacists.
- 17.9 Registrants raised concerns with the PSNI following the House of Commons Science and Technology Committee's review of the evidence base for homeopathy (which found that homeopathy is not an efficacious form of treatment). Supply of homeopathic products in pharmacies is legally permitted, and pharmacists have the right to sell them as part of their business. However, as there may be a risk to public protection if patients use such products in preference to conventional

medicines to treat serious health conditions without being aware that there is no consensus regarding the evidence base for the treatments, the PSNI developed, consulted upon and published guidance on the supply of homeopathic products in pharmacies. The guidance made it clear that when registrants provide a homeopathic product the patient should be advised that there is no consensus on the efficacy of homeopathy. The registrant should ensure that there is sufficient discussion with the patient so that they are able to advise the patient appropriately on the benefits and risks of using such products. We consider that PSNI has taken a sensible approach to this controversial matter.

- 17.10 The views of registrants have been sought by the PSNI on four particular issues: the usefulness and relevance of existing standards and guidance to pharmacists' practice, what areas of practice could benefit from additional guidance, how they currently access standards and guidance (eg via the website) and how involved they feel in the process for developing standards and guidance. The information collated from pharmacists has been used by the PSNI to inform its 2011 standards and guidance work programme. It will also be used to benchmark the effectiveness of the PSNI's future activities.

For example, currently the majority of pharmacists rate the PSNI standards and guidance as either 'excellent' or 'good' and consider them to be very useful. The next time a similar survey is undertaken, the PSNI will be able to assess whether the work undertaken in the interim has continued to meet registrants' expectations and needs

Education and training

- 17.11 As reported in previous performance reviews, the PSNI has had a long-standing working relationship with the pharmacy regulator in Great Britain in relation to setting standards for pharmacy undergraduate education. With the establishment of the new pharmacy regulator in Great Britain (the GPhC) we note that the PSNI has had to develop a new working relationship. We understand that this is progressing effectively. A new framework for pharmacy undergraduate education standards, including a new quality assurance process, is being developed by the GPhC. The PSNI has provided its views on this framework based on its own experiences and learning.
- 17.12 The PSNI carries out quality assurance (QA) of the two undergraduate education institutions in Northern Ireland in partnership with the GPhC. We consider that an improvement has been made to the process previously used, as views of patients and the public (through the use of a patient representative on the QA panel and students on relevant courses) have been taken into account before a decision has been reached on whether to approve the courses.
- 17.13 The PSNI manages its own pre-registration year programme for pharmacy graduates. All graduates must undertake and pass this course before being admitted to the PSNI's register. The PSNI undertakes various workstreams to ensure that the programme is continuously improved. It reviews the syllabus and examination (including the results) annually; and it surveys trainees for their views on the programme and on tutor performance. Changes that have been made to the syllabus in 2010 include: a greater focus on the registration requirements that trainees need to meet before they can begin to describe themselves as pharmacists (following a misuse of title case that the PSNI considered in 2009),

and a compulsory training day on the appropriate management of complaints and the NHS complaints system. Changes have also been made to the pass mark of the calculations section of the examination to reflect the importance of registrants' competence in this area.

- 17.14 The PSNI's continuing professional development (CPD) scheme is not yet mandatory, so it is notable that through its informal voluntary system 74 per cent of its registrants have already had their CPD cycles audited. Following our suggestion that the PSNI should ensure that its registrants' CPD is focused on patient safety, the PSNI reported that in 2009/10 96 per cent of its registrants' CPD focused on patient safety/public protection. The PSNI has also undertaken a range of activities to help registrants understand the objectives of CPD, and how learning from such activities should be documented. These include holding training events, feeding back personalised learning points for individual submissions and the publication of an online CPD manual. We consider that the PSNI will be in a good position to launch its mandatory CPD scheme as soon as the proposed legislation is enacted. This legislation will give the PSNI powers to set standards for CPD, to require completion of an annual declaration that CPD requirements have been maintained, to require submission of records for review, and to deal with registrants who have not met the standards or who have made a false declaration.
- 17.15 The PSNI commissioned research in 2010 to inform its revalidation proposals. The research identified the relative risks in different parts of the pharmacy workforce and an evidence base for the training and support requirements for those who return to the register. It also made recommendations for the development of a risk-based revalidation model. We understand that the PSNI is currently considering the next steps that it should take in relation to its revalidation model.

Registration

- 17.16 The PSNI has continued to manage registrations efficiently. It has also undertaken a number of activities to enhance its processes and to improve public protection.
- 17.17 Following several cases of pharmacy trainees with self-declared convictions or conduct issues applying for entry onto the PSNI's register, the PSNI introduced a requirement that all pharmacy trainee applicants must be approved by their head of school at their graduating university. The PSNI considered that this would strengthen its registration processes by ensuring the capture of all relevant conduct issues.
- 17.18 It is a professional requirement of ongoing registration that registered pharmacists are appropriately indemnified to practise. The PSNI has changed its registration form - to include a request for the details of the registrants' indemnity insurance provider. This change was made to reinforce the message about the need to hold indemnity insurance in order to ensure appropriate cover in the event of negligence and to be compliant with the PSNI's code of ethics. Furthermore, we note that the PSNI held a training event for registrants to improve their understanding of the purpose of indemnity insurance and what such insurance does and what it does not cover.

- 17.19 We acknowledge that the PSNI has changed the format of its equality monitoring form, and that this has resulted in an increased registrant response rate (from 57.2 per cent in 2009/10 to 73.3 per cent in 2010/11). We consider that this increase is positive as it will enable PSNI to gain a greater understanding of the demographics of its registrants.
- 17.20 Whilst we note the improvements the PSNI has made to its registration processes, we would recommend that it gives consideration to moving away from requiring a health declaration that is certified by a UK registered doctor, to accepting a self-declaration for health. In our report on health requirements for registrants⁴⁷ we recommended that the regulators should allow applicants provide a health self-declaration, in order to ensure that fitness to practise of applicants is being assessed on the basis of functional capacity – their ability to carry out the role safely and effectively – rather than on a diagnostic view of health and disability. We have no evidence that the PSNI takes a diagnostic view of health declarations, nevertheless we regard it as disproportionate to require a health declaration to be signed by a registered doctor in every case, and we suggest that the PSNI reconsiders its requirements in this area. The PSNI has agreed to reconsider this matter, taking account of our report and its experience of the current arrangements.
- 17.21 The PSNI has undertaken a great deal of work to address the risks to public protection associated with unregistered practice. It has cross-checked the data collected through its premises retention form against those individuals on the register to establish if there are any non-registrants who are working as pharmacists. This work identified a very small number of non-registrants working as pharmacists, and enabled the PSNI to take appropriate action. We welcome this action, as it has obvious positive implications for public protection.
- 17.22 The PSNI has also written to all employers to gain a greater understanding of how frequently they check the registration status of their employees. Where the employer indicated that they never check the register, annually check the register, or only check the register when the person is first employed, the PSNI wrote to the employer and explained the risks of failing to regularly check the registration status of employees. This has resulted in employers developing standard operating procedures to ensure that employees' registration status is checked regularly. The PSNI has also worked to raise the public's awareness of the importance of checking that a pharmacist is registered. It has distributed an information leaflet for the public at conferences and exhibitions which sets out on the front page the importance of checking the register.
- 17.23 In addition, enhancements have been made to the security of the certificate provided to registrants once they successfully join the register. Although there was no evidence to suggest any misuse of the previous certificate, there are obvious risks to public protection should the certificates be forged and used by non-registrants.

Fitness to practise

- 17.24 We have reported in previous performance reviews the limitations the PSNI currently has to work within in respect of managing pharmacists' fitness to practise, due to its legislation. In particular, we have noted that the PSNI does not have the

⁴⁷ CHRE, 2009. *Health Conditions*. London: CHRE.

power to impose interim orders, nor does it have powers to impose the full range of fitness to practise sanctions. We have been concerned that these limitations impact on public protection because the PSNI is not able to take immediate action to prevent a pharmacist from continuing to practise, or to impose a sanction where there is evidence of misconduct that is not serious enough to warrant removal from the register. We have also been concerned that the PSNI does not have the powers to consider cases where a registrant's fitness to practise is impaired because of an adverse health condition, and that it is limited in its appointment of chairs and panelists. We note that all of these concerns could impact on public confidence in the regulator.

17.25 We are confident that the PSNI has taken appropriate steps to mitigate against these risks, for example, by implementing a system of voluntary undertakings in the place of interim orders. However, we are pleased that the proposed legislation that was published in March 2011 will address our concerns, once it is enacted. It is proposed in the draft legislation that the PSNI will, amongst other things, be empowered to:

- Impose interim orders
- Impose a full range of sanctions ranging from advice through to removal from the register (including imposing a suspension or conditions of practice)
- Consider cases where a registrant's fitness to practise is impaired as a result of ill health
- Use specialist advisers such as legal assessors and clinical assessors
- Disclose information about the fitness to practise of an individual (including placing fitness to practise concerns on its register) where it is in the public interest to do so.

17.26 We await the enactment of this legislation. We continue to consider that the PSNI's outdated legislation impacts on public confidence in its ability to act fairly and independently and to protect the public.

17.27 We recognise that the PSNI is beginning to undertake a number of activities to prepare for the legislative changes. It is working with the GPhC to ascertain if there is any learning it can gain from the GPhC's management of fitness to practise cases. It is reviewing its committee structure and functionality, to see if this can be improved. It also plans to recruit and train further panelists and to revise its indicative sanctions guidance so that it covers the full range of possible sanctions. We consider that it is important that the PSNI has a comprehensive workplan to address how it will accommodate the changes and mitigate the risks associated with the significant changes to its legislation.

17.28 We would also highlight the need for the PSNI to work with others to reduce the time taken for complaints to be investigated. Currently, 37.5 per cent of cases take longer than 100 working days (over five months) to close. This appears to be due to external agencies having a substantial input into the investigation stage. We recognise that the delays may be outside of the PSNI's control, however, in light of the forthcoming expansion of the PSNI's powers to investigate fitness to practise cases, we consider it will be important that the PSNI works with these agencies to reduce the time taken to investigate cases. We acknowledge that the PSNI is currently working with external agencies to establish a three month target for completion of investigation/prosecution considerations.

17.29 In relation to its current fitness to practise processes, the Pharmacy Network Group (comprised of the PSNI, the Health and Social Care Board and the Department of Health, Social Services and Public Safety Northern Ireland) has now been operational for a year. The PSNI consider that the group has continued to work well, and that there are clear benefits from the improved information-sharing between key regulatory bodies in Northern Ireland. The group has considered some changes to its format and to its processes. As a result the membership of the group will shortly be extended to include the pharmacy leads at the five hospital trusts. This will ensure that there is a comprehensive and dedicated complaints and concerns handling group for community and hospital pharmacy care. The threshold for referral has also been reviewed, as it was considered that the previous threshold meant that too many cases were being investigated that were not sufficiently serious. We agree that the focus of such a group should be on serious cases where regulatory intervention is likely to be required – this includes where there is a history of minor incidents which may indicate a more serious underlying problem.

18. Conclusions and recommendations

- 18.1 The performance review has identified that the regulators are generally fulfilling their responsibilities and are focused on public protection. This is notable considering the challenges faced by some, if not all, of the regulators in 2010/11 which have included the continuing rise in fitness to practise cases (affecting the GDC, GMC and the NMC); changes in leadership (the GDC, GOC, GOsC); and (in the case of GMC, GPhC and HPC) the assumption of new regulatory responsibilities.
- 18.2 However, we have also raised concerns about the performance of some of the regulators, particularly around the effectiveness and efficiency of their fitness to practise processes. We are satisfied that work is generally already underway to ensure that improvements are made but we will work with the regulators over the coming months to ensure that these improvements have a real impact on their performance.
- 18.3 In relation to the current issues and concerns affecting health professional regulation, we have discussed the changes that the Health and Social Care Bill and *Enabling Excellence* will bring. The next year is likely to be challenging for the regulators, with the preparation for implementation of changes set out in the proposed legislation in England and Northern Ireland and in *Enabling Excellence*. Whilst we recognise this, we expect to see the regulators continuing to meet their statutory responsibilities and for public protection and patient safety to be their overriding priority.
- 18.4 We have also highlighted the importance of a number of initiatives affecting health professional regulation including revalidation and the vetting and barring schemes in the UK. We hope that the regulators and the Departments of Health and, in the case of PSNI, the Department of Health, Social Services and Public Safety Northern Ireland, take account of our views on these matters when going forward with these initiatives.

Recommendations

- 18.5 We have identified a number of issues which require further consideration by either CHRE, the Department of Health and (in the case of PSNI) the Department of Health, Social Services and Public Safety Northern Ireland.

For CHRE

- 18.6 *Enabling Excellence* requires CHRE to provide advice to the government on a number of issues which have a bearing on the matters highlighted in the performance review. In next year's performance review we will summarise the advice we have provided to the government on the following matters:
- The implementation of our powers to investigate certain complaints about the regulators
 - Modern and efficient fitness to practise adjudication
 - Standards for the appointment of members to the regulators' councils.
- 18.7 We aim continuously to improve the quality of our performance review; as part of this work we will liaise with the regulators to refine and improve the quantitative (numerical) data provided in the regulators' individual reports about the core activities.
- 18.8 We will also continue to develop our relationships across the devolved administrations and governments.

For the Department of Health

- 18.9 We recommend that the Department of Health should:
- Continue to progress the legislative changes required for ensuring that indemnity insurance becomes a condition of registration
 - Take into account our views about the importance of the notifiable occupations scheme in protecting the public when contributing to the Ministry of Justice's review of the scheme

For the Department of Health, Social Services and Public Safety Northern Ireland

- 18.10 We hope that progress continues to be made on implementing the proposed legislation (the Pharmacy (Northern Ireland) Order 1976 (Amendment) Order (Northern Ireland) 2011).

For the regulators

- 18.11 We recommend that the regulators should:
- Address the highlighted areas of concerns identified in their individual regulators reports
 - Review this document as a whole, taking into account of our views, and consider whether they can learn and improve from the practices of the other regulators

- Adopt the practice of requiring a registrant who has been convicted or cautioned for a drink or drug related offence to undergo a routine medical examination, in order to establish whether or not their fitness to practise is impaired as a result of an underlying drink or drug dependency
- Ensure that they have a proportionate system of quality assurance which enables them to review cases that have reached key decision points in the fitness to practise process. This is to ensure that processes are being followed consistently and that appropriate decisions are being made
- Work with the Scottish Government to develop a consistent approach in publicly reporting on Scottish barring decisions which prioritises public protection and confidence in regulation, and work with the Department of Health and Ministry of Justice to improve the Independent Safeguarding Authority's management of the vetting and barring scheme in England and Wales
- Review their processes for handling complaints about themselves to ensure that they have allocated sufficient resources to enable complaints to be managed effectively and efficiently and, where necessary, to enable them to systematically identify learning which could be used to improve overall performance. The regulators should also review whether they have appropriate governance and oversight arrangements in place in relation to the organisational complaints processes.

19. Annex A: List of regulated health professions

Health professional regulator	Regulated health profession
General Chiropractic Council	Chiropractors
General Dental Council	Dentists Dental hygienists Dental therapists Clinical dental technicians Orthodontic therapists Dental nurses Dental technicians
General Medical Council	Doctors
General Optical Council	Dispensing opticians Optometrists
General Osteopathic Council	Osteopaths
General Pharmaceutical Council	Pharmacists Pharmacy technicians*
Health Professions Council	Arts therapists Biomedical scientists Chiropodists Clinical scientists Dieticians Hearing aid dispensers Occupational therapists Operating department practitioners Orthoptists Orthotists Paramedics Physiotherapists Podiatrists Practitioner psychologists Prosthetists Radiographers Speech and language therapists
Nursing and Midwifery Council	Nurses Midwives
Pharmaceutical Society of Northern Ireland	Pharmacists

*Pharmacy technicians are currently registered with the GPhC on a voluntary basis. On 1 July 2011 registration will become mandatory.

20. Annex B: The standards of good regulation

Introduction

- 20.1 Our *Standards of Good Regulation* cover the regulators' four core functions. These are:
- Setting and promoting guidance and standards for the profession(s)
 - Setting standards for and quality assuring the provision of education and training
 - Maintaining a register of professionals
 - Taking action where a professional's fitness to practise may be impaired.
- 20.2 The *Standards of Good Regulation* are the basis of our performance review process. They describe the outcomes of good regulation for each of the regulators' functions. They also set out how good regulation promotes and protects the health, safety and well-being of patients and other members of the public and maintain public confidence in the profession.

Using the *Standards of Good Regulation* in the Performance Review

- 20.3 We ask the regulators to submit evidence on whether they meet the standards and how they have evaluated the impact of their work in promoting and protecting the public and maintaining public confidence in the profession. To help the regulators in drafting their submission we have suggested examples of the type of evidence that they could provide us with. We will also provide an evidence template for the regulators to complete. The suggested evidence may change over time.
- 20.4 Once we have received the regulators' evidence, we assess their performance against the standards by:
- Identifying each regulator's strengths
 - Identifying any areas for improvement
 - Identifying good practice and excellence.
- 20.5 We also ask the regulators at the beginning of their evidence (Section 1) to comment on their overall performance by answering a set of questions.

21. Section 1: Overview

Introduction

- 21.1 This section covers general issues relating to the regulators' performance, including how they have responded to last year's review, how they comply with the principles of good regulation and their liaison with other bodies.

Response to last year's performance review

- What consideration have you given to issues raised in the previous year's performance review report including the adoption of any good practice?
- How have you addressed the areas for improvement identified in your individual performance review report?
- Where has your performance improved since last year?
- What areas for concern have you identified in each of the four functions and how have these been addressed?
- What areas of good practice have you identified in each of the four functions?

Responding to change, learning and information

- How is learning from the following five areas taken into account in each of the functions:
 - other areas of your work such as fitness to practise, policy development or quality assurance of educational institutions
 - organisational complaints
 - the outcomes of CHRE's work
 - feedback from stakeholders from the four UK countries
 - public policy programme reports from the four UK countries
- How have you addressed information, other than formal fitness to practise complaints, which you may have received from other sources on possible failures in performance of organisations or individuals?
- How have you responded to changes in regulation or forthcoming changes in regulation?

Liaison with other bodies

- How have you worked with service regulators, other regulatory bodies or other bodies with shared interests to:
 - ensure that relevant intelligence is shared, within legislative requirements, on individuals or organisations?
 - ensure that cross regulatory learning is shared?

Section 2: Guidance and standards

Introduction

- 21.2 All of the regulators are responsible for publishing and promoting standards of competence and conduct. These are the standards for safe and effective practice which every health professional should meet to become registered and to maintain their registration. They set out the quality of care that patients and service users should receive from health professionals.
- 21.3 Regulators also publish additional guidance to address specific or specialist issues. These complement the regulators' standards of competence and conduct.

The standards of good regulation relating to guidance and standards

- Standards of competence and conduct reflect up-to-date practice and legislation. They prioritise patient safety and patient centred care
- Additional guidance helps registrants apply the regulators' standards of competence and conduct to specialist or specific issues including addressing diverse needs arising from patient-centered care
- In development and revision of guidance and standards, the regulator takes account of stakeholders' views and experiences, external events, developments in the four UK countries, European and international regulation and learning from other areas of the regulators' work
- The standards and guidance are published in accessible formats. Registrants, potential registrants, employers, patients and members of the public are able to find the standards and guidance published by the regulator and can find out about the action that can be taken if the standards and guidance are not followed.

How does good regulation through standards and guidance promote and protect the health, safety and well-being of patients and other members of the public and maintain public confidence in the profession?

- Provides a clear framework that health professionals should meet when providing care, treatment and services to patients
- Provides a clear framework so that members of the public and patients can hold registrants to account by raising concerns when the standards and guidance are not followed
- The standards and guidance meet the needs of relevant stakeholders.

What evidence could be provided?

- 21.4 We need to know:
- How the regulators have met the *Standards of Good Regulation*
 - How they have evaluated the impact of their work in this area.

21.5 The following evidence could be provided:

- The standards of competence and conduct and information on how they reflect up-to-date practice and legislation, prioritise patient safety and patient centred care
- Guidance produced or being developed and how this will help registrants apply the regulators' standards of competence and conduct to particular issues
- Plans for reviewing or developing guidance and standards, including what stakeholders were approached and how their views and experiences were taken into account alongside external events and learning from other areas. The outcomes of the revision or development and how the learning from this work is used within and outside of the standards and guidance function
- Details of how the regulators ensure that the documents are understandable and accessible. For example, publication in different languages, easy read, plain English and circulation in GP practices and Citizen Advice Bureaux
- Evidence of work undertaken to take account of the developments in European and international regulation
- The mechanisms used by the regulator to assess how they are performing and how they use the results to improve their practices.

Section 3: Education and training

Introduction

- 21.6 The regulator has a role in ensuring that students and trainees obtain the required skills and knowledge to be safe and effective. They also have a role in ensuring that, once registered, professionals remain up to date with evolving practices and continue to develop as practitioners.
- 21.7 As part of this work, the regulators quality assure and, where appropriate, approve educational programmes which students must complete in order to be registered. Some also approve programmes for those already on the register who are undertaking continuing professional development, a particular qualification or specialist training.

The standards of good regulation relating to education and training

- Standards for education and training are linked to standards for registrants. They prioritise patient safety and patient centred care. The process for reviewing or developing standards for education and training should incorporate the views and experiences of key stakeholders, external events and the learning from the quality assurance process
- Through the regulator's continuing professional development/revalidation systems, registrants maintain the standards required to stay fit to practise
- The process for quality assuring education programmes is proportionate and takes account of the views of patients, students and trainees. It is also focused on ensuring the education providers can develop students and trainees so that they meet the regulator's standards for registration

- Action is taken if the quality assurance process identifies concerns about education and training establishments
- Information on approved programmes and the approval process is publicly available.

How does good regulation through education and training promote and protect the health, safety and well-being of patients and other members of the public and maintain public confidence in the profession?

- Assures the public that those who are registered have and/or continue to meet the regulator's standards
- Assures the public that those providing education and training to students, trainees and professionals give them the required skills and knowledge so that they can practise safely and effectively
- Effective stakeholder involvement in the education and training process increases everyone's trust, confidence and knowledge of health professional regulation.

What evidence could be provided?

21.8 We need to know:

- How the regulators have met the *Standards of Good Regulation*
- How they have evaluated the impact of their work in this area.

21.9 The following evidence could be provided:

- The standards to be met by students and how they link to the standards of competence and conduct for registrants
- Where available, evidence of the regulator's mechanisms, which enable them to be aware of action taken by training establishments against students on fitness to practise issues and a system for learning from these outcomes. For example, are outcomes taken into account in the quality assurance process and revision of standards?
- The standards to be met by education and training providers, how these reflect patient centred care and protect the public, and how they link to standards of competence and conduct for registrants
- Guidance given to education and training establishments to help ensure that disabled students do not face unnecessary barriers to successful careers in health
- The plans for reviewing or developing standards for students and education and training providers, including what stakeholders were approached, how their views and experiences and other areas of learning are taken into account. The outcomes of this work and how the learning from this work is used within and outside of the education function

- Details of the monitoring and approval processes for the education and training providers including how the views and experiences of stakeholders and other quality assuring bodies are taken into account
- Details of how many assessments were undertaken, how many concerns were identified through the quality assurance process and what action was taken to address these concerns
- Details of how stakeholders can access the regulator's final assessments of education and training providers and the regulator's approval process, for example, through publication on its website
- Details of the regulator's revalidation proposals
- Details of how the regulator ensures that continuing professional development is targeted towards the professional developing their skills and knowledge in their areas of practice and that public protection is prioritised. For example, how many audits were carried out, were issues identified and how were these addressed?
- The mechanisms used by the regulator to assess how they are performing and how they use the results to improve their practices.

Section 4: Registration

Introduction

21.10 In order for a health professional to practise legally in the UK, they must be registered with the relevant regulator. The regulators only register those professionals who meet their standards. The regulator is required to keep an up-to-date register of all the professionals it has registered. The register should include a record of any action taken against a professional that limits their entitlement to practise.

The standards of good regulation relating to registration

- Only those who meet the regulator's requirements are registered
- The registration process, including the management of appeals, is fair, based on the regulators' standards, efficient, transparent, secure, and continuously improving
- Through the regulators' registers, everyone can easily access information about registrants, except in relation to their health, including whether there are restrictions on their practice
- Employers are aware of the importance of checking a health professional's registration. Patients and members of the public can find and check a health professional's registration
- Risk of harm to the public and of damage to public confidence in the profession related to non-registrants using a protected title or undertaking a protected act is managed in a proportionate and risk-based manner.

How does good regulation through registration promote and protect the health, safety and well-being of patients and other members of the public and maintain public confidence in the profession?

- Assures the public that professionals are regulated and are required to meet certain standards before they are able to provide care, treatment or services to them
- Informs the public of any limits imposed on the way a registered professional is allowed to practise
- Helps the public and others to identify and report those who practise illegally.

What evidence could be provided?

21.11 We need to know:

- How the regulators have met the *Standards of Good Regulation*
- How they have evaluated the impact of their work in this area.

21.12 The following evidence could be provided:

- Details of the checks carried out by the regulator to ensure that only those who are fit to practise are registered including revalidation/CPD checks
- Details of the registration process, including the management of appeals and how the regulator ensures that applications are processed efficiently
- Evidence of activity undertaken to ensure that only EEA and international registrants that meet the regulators' standards, within the legal framework, are registered
- The number of registration applications considered. The number of appeals considered. The number of appeals upheld
- How the case management system/process enables the collection and analysis of reliable data to ensure that there is no bias in the process, with evidence of this testing being carried out by the regulator
- How the processes and procedures in place are fair, objective and free from discrimination
- The level of detail included on the register and the reasons for this, for example, a council decision, legislation, rules or the regulator's disclosure policy
- Evidence of the regulator's compliance with its information security policies and with the relevant legislation. The number of data loss/breach incidents which have occurred
- The activities undertaken to communicate to employers the importance of checking that a professional is registered. Evidence of employers informing the regulators that a professional is no longer registered or not registered

- How the regulators make their registers available to the public and patients. Evidence of the amount of contacts from public and patients about the regulators' registers
- Activities undertaken to identify non-registrants using a protected title or undertaking a protected act. Details of proportionate and risk-based action taken to reduce the risk of harm to the public and damage to public confidence in the profession of non-registrants using a protected title or undertaking a protected act. For example, increasing public awareness of the importance of health professional registration and regulation, sending 'cease and desist' letters, and fostering relationships with organisations that have a shared interest in preventing title misuse
- The mechanisms used by the regulator to assess how it is performing and how it uses the results to improve their practices.

Section 5: Fitness to practise

Introduction

21.13 Anyone, including members of the public, employers and the regulators themselves, can raise a concern about a registered health professional's conduct or competence that calls into question their fitness to practise. The regulators are required to take action under their fitness to practise procedures where they receive such concerns. This can lead to a variety of outcomes including no further action, a health professional being prevented from practicing or restrictions being imposed on their practice.

The standards of good regulation relating to fitness to practise

- Anybody can raise a concern, including the regulator, about the fitness to practise of a registrant
- Information about fitness to practise concerns is shared by the regulator with employers/local arbitrators, system and other professional regulators within the relevant legal frameworks
- Where necessary, the regulator will determine if there is a case to answer and if so, whether the registrant's fitness to practise is impaired or, where appropriate, direct the person to another relevant organisation
- All fitness to practise complaints are reviewed on receipt and serious cases are prioritised and where appropriate referred to an interim orders panel
- The fitness to practise process is transparent, fair, proportionate and focused on public protection
- Fitness to practise cases are dealt with as quickly as possible, taking into account the complexity and type of case and the conduct of both sides. Delays do not result in harm or potential harm to patients. Where necessary the regulator protects the public by means of interim orders

- All parties to a fitness to practise case are kept updated on the progress of their case and supported to participate effectively in the process
- All fitness to practise decisions made at the initial and final stages of the process are well reasoned, consistent, protect the public and maintain confidence in the profession
- All final fitness to practise decisions, apart from matters relating to the health of a professional, are published and communicated to relevant stakeholders
- Information about fitness to practise cases is securely retained.

How does good regulation through fitness to practise promote and protect the health, safety and well-being of patients and other members of the public and maintain public confidence in the profession?

- Assures the public that action is taken against those professionals whose fitness to practise is impaired
- Assures the public that those whose fitness to practise is impaired are not able to continue practising or practising unrestricted
- Helps the public to understand why action is and is not taken to limit a health professional's practice
- A joined up approach to fitness to practise mitigates the risk to public protection from regulators working independently of each other
- Effective involvement of all parties in the fitness to practise process increases trust, confidence in and knowledge of health professional regulation.

What evidence could be provided?

21.14 We need to know:

- How the regulators have met the *Standards of Good Regulation*
- How they have evaluated the impact of their work in this area.

21.15 The following evidence could be provided:

- Activities undertaken to publicise how all individuals, including those with particular health or language needs, and organisations can raise concerns about the fitness to practise of health professionals and the evaluation of this work. For example, publication of public information/employer leaflets, information available via the telephone or email and liaison with other organisations
- Examples of where the regulator has raised and taken forward a fitness to practise concern itself. For example, the number of cases taken forward and the reasons for this
- Examples of the regulator's work with other relevant bodies on when to refer fitness to practise complaints. For example, evidence of liaison with other organisations and feedback from those organisations on the effectiveness of this help

- Examples of information that has been shared between the regulators and other relevant bodies, within legal requirements, on the fitness to practise of individuals and the results of this work. For example, exchange of information through memoranda of understanding and, where possible, discussion on what use was made of this data
- Examples of where serious cases have been identified, prioritised and, where possible, referred to an interim orders panel. For example, the number of cases identified and the process for how this is carried out
- Examples of how the case management system and case management process helps prevent excessive delay and manages identified delays. Information on current timeframes and/or delays in the system
- Examples of how the regulator ensures that all parties are regularly updated on progress of the fitness to practise case. How many complaints were received about lack of update notification?
- How the case management system/processes enables the collection and analysis of reliable data to ensure that there is no bias in the process, with evidence of this testing being carried out by the regulator
- How the processes and procedures in place are fair, objective and free from discrimination
- Activities undertaken to meet the individual needs of parties to the fitness to practise process, particularly those who are vulnerable, and the outcomes of this work. For example, use of video link facilities, witness support arrangements, participant feedback surveys and number of complaints from participants about lack of support
- The appointment and appraisal process for committee members, panelists and advisors to fitness to practise cases. Relevant training, guidance and feedback provided to committee members, panelists and advisors to fitness to practise cases. How this has helped improve decision making
- Evidence of steps taken to identify and mitigate risks in fitness to practise decisions, for example, outcomes of the regulator's quality assurance of decisions, number of appeals and their outcomes. How learning from this process is used to improve decision making
- The regulator's disclosure policy in relation to fitness to practise proceedings and the disclosure of fitness to practise information to third parties
- The regulator's information security policies and compliance with the relevant legislation. The number of data loss/breach incidents which have occurred
- The mechanisms used by the regulator to assess how they are performing and how they use the results to improve their practices.

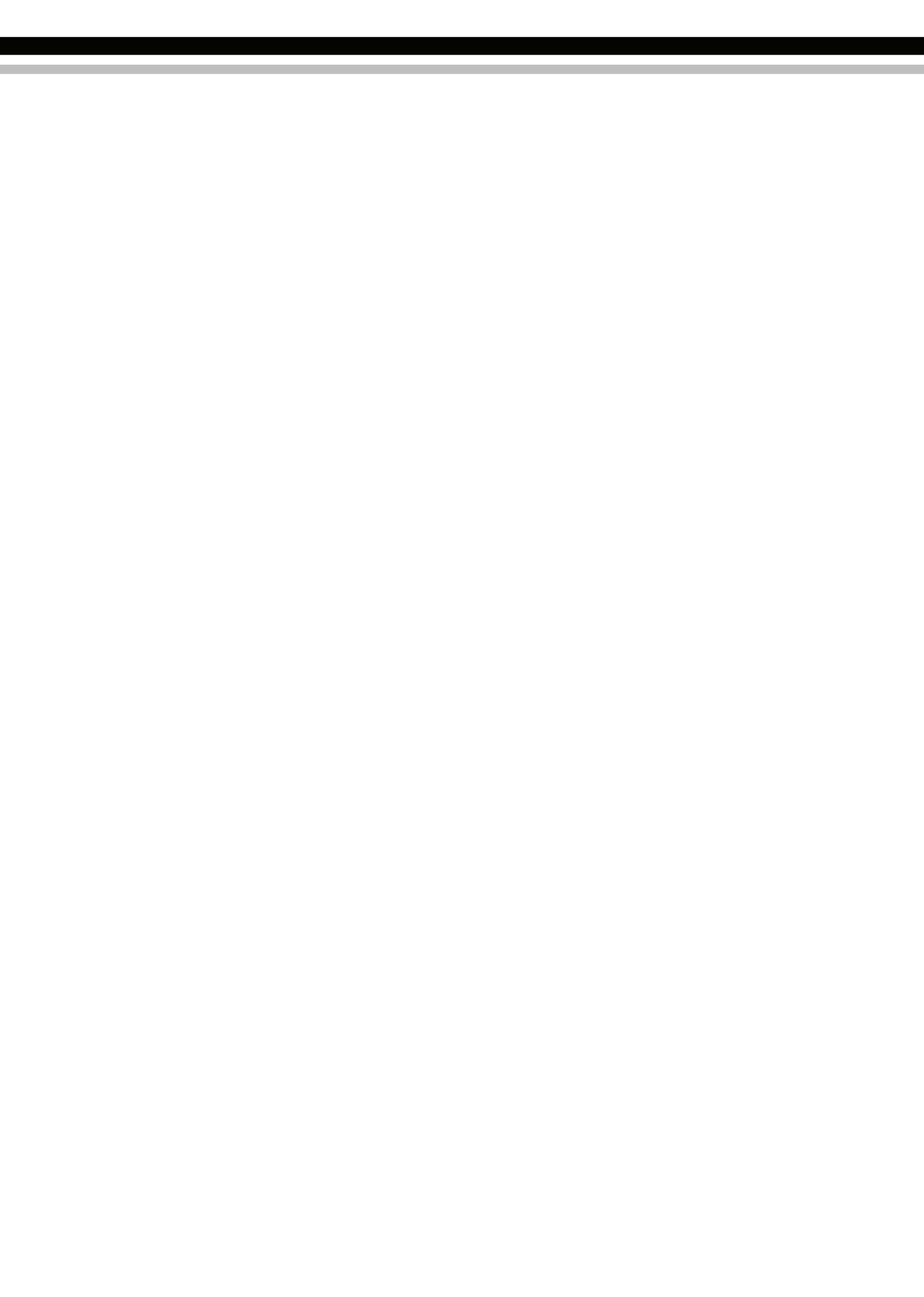
22. Annex C: Third party feedback

22.1 As part of this year's performance review, we wrote to a wide range of organisations who we considered had an interest in how the regulators performed against the *Standards of Good Regulation*, and to our public and professional stakeholder networks. We invited them to share their views with us on the regulators' performance in relation to the standards. We explained that we would use the information provided to challenge the regulators' evidence to ensure that we had a more rounded view of the regulators' performance. We also placed a general invitation to provide views on the regulators' performance on our website.

22.2 Below is a list of the third party organisations' feedback that we took into account:

- Association of Optometrists
- Aviva
- British Chiropractic Association, McTimoney Chiropractic, Scottish Chiropractic Association/ United Chiropractic Association
- British Osteopathic Association
- Camden and Islington NHS Foundation Trust
- Chief Nursing Officer, Northern Ireland
- College of Optometrists
- Complementary and Natural Healthcare Council
- Council of Deans of Health
- Cwm Taf Local Health Board
- Dental Protection Society
- Dental Schools Council
- Federation of Dispensing Opticians
- Independent Midwives UK
- Institute of Pharmacy Management International
- Medical Protection Society
- Medical Schools Council
- NHS Education for Scotland
- NHS Employers
- NHS Greater Glasgow and Clyde
- NHS North East
- NHS Shetland
- NHS Tayside
- Northern Health and Social Care Trust
- Patient and Client Council (Northern Ireland)

- Royal College of Midwives
- Royal College of Nurses
- Royal College of Pathologists
- Royal College of Physicians of Edinburgh
- Royal College of Radiologists
- South Eastern Health and Social Care Trust
- South West Strategic Health Authority
- Tees, Esk and Wear Valley NHS Foundation Trust
- The Society of Chiropractors and Podiatrists
- Unison
- 12 individuals









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