



Trust, Assurance and Safety –
The Regulation of Health Professionals
in the 21st Century

Presented to Parliament by
the Secretary of State for Health
by Command of Her Majesty
February 2007



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Foreword

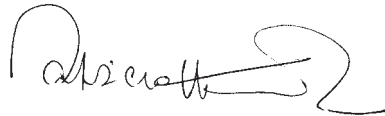
The Rt Hon. Patricia Hewitt, MP Secretary of State for Health



1. Patients in the United Kingdom rightly have great confidence in their health professionals. When we need care, we entrust ourselves to doctors, nurses and a range of other skilled and dedicated professionals because we know from our own experiences and the experiences of others that our trust is well placed and will not be abused.
2. For any consideration of the regulation of health professionals, the preservation of that trust has to be the starting point. Professional regulation must create a framework that maintains the justified confidence of patients in those who care for them as the bedrock of safe and effective clinical practice and the foundation for effective relationships between patients and health professionals.
3. The danger is that in addressing the issue at all we risk highlighting too much the poor practice or unacceptable behaviour of a very small number of health professionals. It is all too easy to focus on the incompetent or malicious practice of individuals and seek to build a system from that starting point, instead of recognising that excellent health professionals far outnumber the few who let patients down substantially. For every time that Harold Shipman and Beverley Allitt are mentioned, we must recall the hundreds of thousands of extraordinary individuals who dedicate themselves impeccably to their patients every day. Most health professionals meet high standards routinely and have a lifelong appetite to be even better. That professionalism is an unquantifiable asset to our society, which rules, regulations and systems must support, not inhibit.

4. The question is therefore how to deal with the small number of professionals who, at some time in their working lives, provide poor quality care to patients, and who cause concerns for patients, their families and professional colleagues, while supporting the overwhelming majority in their commitment to better clinical care and higher professional standards. We need a system that understands the pressures and strains under which all professionals operate and shows understanding, compassion and support where these are appropriate. It also means a system that is better able to identify people early on who are struggling – perhaps with personal problems of mental health or addiction – and supporting them, showing the same care to them that they have shown to their patients, so that they have a fair chance to improve and return to practice, if that is possible. It means a system that is better able to detect and act against those very rare malicious individuals who risk undermining public and professional confidence.
5. Sustaining confidence also means patients need to be assured that, when there are problems with health professionals, their concerns will be listened to and acted upon and that they will receive timely explanations. Just as a very small minority of health professionals need to be supported when they are struggling, a very small minority of patients need proper support in seeking explanations, a fair hearing of their views and concerns, and positive action to ensure that lessons are learned and that their trust in health professional is restored. Professional regulation is about fairness to both sides of the partnership between patients and professionals. To command the confidence of both, it must also be *seen to be fair*, both to patients and to health professionals.
6. For that to be the case, there are a number of key principles that should underpin statutory professional regulation.
 - First, its overriding interest should be the safety and quality of the care that patients receive from health professionals.
 - Second, professional regulation needs to sustain the confidence of both the public and the professions through demonstrable impartiality. Regulators need to be independent of government, the professionals themselves, employers, educators and all the other interest groups involved in healthcare.
 - Third, professional regulation should be as much about sustaining, improving and assuring the professional standards of the overwhelming majority of health professionals as it is about identifying and addressing poor practice or bad behaviour.
 - Fourth, professional regulation should not create unnecessary burdens, but be proportionate to the risk it addresses and the benefit it brings.
 - Finally, we need a system that ensures the strength and integrity of health professionals within the United Kingdom, but is sufficiently flexible to work effectively for the different health needs and healthcare approaches within and outwith the NHS in England, Scotland, Wales and Northern Ireland and to adapt to future changes.

7. The quality of the professional, public and patient responses to Sir Liam Donaldson's report (*Good doctors, safer patients*) and to the departmental review ('The regulation of the non-medical healthcare professions') has been heartening. Just as we in Government have been persuaded by committed and well-informed arguments in consultation responses, so too have the professionals and their regulators shown an open and progressive mind on many issues. Some have moved significantly and in doing so are leading and shaping a new and sustainable consensus for professional regulation in the 21st century. All important changes on issues as vital as this will be tested carefully and vigorously by everyone with an interest. I am confident that the proposals in this White Paper set out a framework through which patients, the public, the professions and the Government can secure a new settlement that assures the safety of patients and their continuing confidence in the professions while treating dedicated health professionals fairly and independently.



Executive summary

Introduction

1. This White Paper sets out a programme of reform to the United Kingdom's system for the regulation of health professionals, based on consultation on the two reviews of professional regulation published in July 2006: *Good doctors, safer patients* by the Chief Medical Officer (CMO) for England and the Department of Health's 'The regulation of the non-medical healthcare professions'. It is complemented by the Government's response to the recommendations of the Fifth Report of the Shipman Inquiry and to the recommendations of the Ayling, Neale and Kerr/Haslam Inquiries, *Safeguarding Patients*, which sets out a range of measures to improve and enhance clinical governance in the NHS.

Chapter 1: Assuring independence: the governance and accountability of the professional regulators

2. Chapter 1 sets out a series of measures to ensure the independence of the national professional regulators. In order to exercise their functions effectively and command the confidence of patients, the public and the professions, they need to be seen to be independent and impartial in their actions. To ensure that this is the case, the White Paper proposes that:
 - the councils that regulate health professionals have, as a minimum, parity of membership between lay and professional members, to ensure that purely professional concerns are not thought to dominate their work;
 - the Government will agree arrangements to ensure that all councils become more accountable to Parliament, presenting annual reports to the UK Parliament and, for those councils that regulate professionals whose regulation is a devolved matter, to the Devolved Assembly legislatures;
 - to dispel the perception that councils are overly sympathetic to the professionals they regulate, council members will be independently appointed;
 - to enable councils to focus more effectively on strategy and the oversight of their executives, they will become smaller and more-board like, with greater consistency of size and role across the professional regulatory bodies;

- similar changes will be made to the Council for Healthcare Regulatory Excellence (CHRE), enabling it to take on a stronger and more independent role in providing expert advice on professional regulation;
- there will be no mergers, for the time being, of the professional regulatory bodies and the Government will review these arrangements in 2011; and
- the Government will work with the pharmacy profession to establish a General Pharmaceutical Council responsible for the regulation of pharmacists and pharmacy technicians, and the registration of pharmacy premises. The profession will need a strong and clear voice to assume the critical responsibility of undertaking a role akin to that played by a Royal College, supporting clinical excellence in the profession. A working party will be established to take forward detailed proposals. Its work will help inform future decisions about the regulation and leadership of pharmacy in Northern Ireland.

Chapter 2: Revalidation: ensuring continuous fitness to practise

3. Chapter 2 sets out new proposals to ensure that all the statutorily regulated health professions have in place arrangements for the revalidation of their professional registration through which they can periodically demonstrate their continued fitness to practise.
4. For doctors, the Government endorses the revalidation proposals set out in the Chief Medical Officer's report, *Good doctors, safer patients*. Medical revalidation will have two core components: relicensure and specialist recertification.
5. For relicensure, all doctors will have a licence to practise that enables them to remain on the medical register. This licence to practise will have to be renewed every five years. In order to bring objective assurance of continuing fitness to practise, the appraisal process will include 'summative' elements which confirm that a doctor has objectively met the standards expected. Specialist recertification will apply to all specialist doctors, including general practitioners, requiring them to demonstrate that they meet the standards that apply to their particular medical specialty. These standards will be set and assessed by the medical Royal Colleges and their specialist societies, and approved by the General Medical Council (GMC). The Department will discuss with stakeholders ways of ensuring that revalidation can be applied appropriately to all practising doctors, not just those who work in the NHS.
6. For the other health professionals, this White Paper sets out new arrangements to ensure that they also have the opportunity to demonstrate their continuing fitness to practise through appropriate revalidation arrangements. The Department will discuss with each profession and its regulator the most appropriate arrangements.

7. Professionals in England will fall broadly into one of three groups for revalidation:
 - For employees of an approved body, for example nurses, dietitians or paramedics working in an NHS organisation or a licensed private or independent sector provider, evidence to support revalidation will be provided as part of the normal staff management and clinical governance systems, with employers providing recommendations to the professional regulators.
 - For those, including self-employed contractors, performing services commissioned by NHS primary care organisations (such as dentists or optometrists), the revalidation processes will be carried out under the supervision of either the NHS commissioning organisation or, particularly where it is necessary to take an overview of both NHS and private work, the regulatory body, but in either case with appropriate collaboration between the two bodies.
 - For all others, for example osteopaths, the relevant regulatory bodies will develop direct revalidation arrangements.
8. The responsibility for revalidation arrangements for staff directly employed by primary care contractors, for example practice nurses or dental hygienists, will be discussed with the relevant professions and regulators.
9. The appraisal process, which will be a central component of revalidation, should be both formative and summative, to ensure objectively that required standards are met. Within the English NHS, information gathered under the Knowledge and Skills Framework should be used as far as possible as the basis of revalidation, with any additional requirements justified by risk analysis. Scotland, Wales and Northern Ireland will consider how they wish to take this forward within their particular contexts.

Chapter 3: Tackling concerns: the local role

10. For doctors and other relevant health professionals working in primary care, the Government will review the current Performers List arrangements to consider whether or not they are being used effectively. In particular, following the GMC's introduction of the GP register in April 2006, the Government will consider the regulatory burden of separate lists being held by each primary care trust (PCT).
11. For all doctors working in the UK, the Government will seek parliamentary approval to establish a UK network of GMC Affiliates at a regional level in England and at a national level in Scotland, Wales and Northern Ireland. In some larger regions with a large number of doctors, sub-regional arrangements may provide more effective engagement with local services. The Government will pilot these approaches at different levels of engagement in England prior to full-scale rollout. The Devolved Administrations will consider implementation of the Affiliates measures in the light of learning from these pilots.

12. Appointed by, and accountable to, the GMC, the Affiliates would lead and establish devolved GMC offices in England and work within existing structures in Scotland, Wales and Northern Ireland. In England, they would lead regional medical regulation support teams, including the strategic health authority (SHA) the director of public health, the SHA clinical governance lead, the National Clinical Assessment Service (NCAS), the Healthcare Commission (or its successor), the postgraduate dean and four lay GMC Affiliates.
13. Advised and assisted by the regional medical regulation support teams, the GMC Affiliates would provide support, advice and guidance to employers in managing concerns about doctors and would quality assure the processes for revalidation of doctors.
14. These changes mean that medical directors, and others in similar roles, will take on the organisational roles originally envisaged for GMC Affiliates in *Good doctors, safer patients*. In England, all practising doctors on the medical register will need to relate to a responsible officer approved by the GMC Affiliate. Where medical directors are in place, they will generally take on this role.
15. The Department will lead a project to establish more explicit competencies for the role of medical directors as well as measures to enhance their direct accountability to boards for actions relating to their new responsibilities and powers for regulation and revalidation. In England, all PCTs will be expected to have in place, at board level, a responsible officer.
16. *Good doctors, safer patients* also proposed a new measure, Recorded Concerns, for the local regulation of concerns about doctors' conduct or practice, that will facilitate proportionate local responses to problems and allow patterns of misconduct or behaviour to be tracked over time and place. The Department will discuss with key stakeholders from across the UK how to frame detailed proposals on the practical implementation of the new system of GMC Affiliates and Recorded Concerns through a piloted approach in England, with the Devolved Administrations considering local arrangements in the light of learning from these pilots. The Department will invite stakeholders covering appropriate UK interests to participate.
17. In order to provide assurance of the quality of all health professionals who work as locums, the Department will consider, with stakeholders, the regulatory and other impacts of developing a more effective system of registration and inspection for agencies supplying health professionals.

Chapter 4: Tackling concerns: the national role

18. Chapter 4 sets out proposals to ensure public and professional confidence in the handling of cases in which a health professional's fitness to practise is called into question. To ensure greater fairness and openness in the handling of such cases, the White Paper includes the following proposals:
 - in the adjudication of fitness to practise cases for all health professionals, panels should use the civil standard of proof, with its sliding scale, rather than the criminal standard;

- CHRE should have enhanced powers to scrutinise the regulators' handling of fitness to practise cases;
 - CHRE should develop common protocols for local investigations across all the regulators, with guidance to employers on when such cases should be referred to the national regulator;
 - the Department should work with the NCAS, the GMC and the General Dental Council to agree protocols to ensure that, in England, full use is made of the NCAS in its investigations; and
 - the Department should work with the NCAS and with stakeholders to review the cost-effectiveness of extending its scope to other health professionals, as suggested by the Public Accounts Committee.
19. To ensure an integrated, affordable and cost-effective approach to the health of all health professionals, the Department will establish a wide-ranging and inclusive national advisory group to inform the development of a national strategy. Including UK stakeholders, the group will advise on measures to ensure appropriate prevention and early intervention for health professionals; the role of health in revalidation arrangements; enabling easier and confidential uptake of services; the roles and responsibilities of employers, regulators, professionals themselves and others in ensuring the health of professionals; and more effective arrangements for the rehabilitation of health professionals whose actions have led to regulatory involvement.
20. For doctors, the Government agrees with Dame Janet Smith and with the CMO that the separation of investigation and prosecution from adjudication is essential to ensure complete public and professional confidence in the independence of the decisions made by the adjudicator. Working closely with the GMC, the Government will seek legislative agreement to establish an independent body to adjudicate on fitness to practise cases involving the medical profession. Doctors and the GMC will have a right of appeal against the decision of the independent body to the High Court or the Court of Session.
21. For all the other regulators, the Government will charge the new independent body with establishing a central list of people, vetted and approved for all adjudication panels, chosen by the Appointments Commission for their expertise and specifically trained to undertake these duties in a fair and impartial manner. Regulatory bodies will be able to draw on this list in order to conduct independent adjudication panels within their own organisations. Over time, and in the light of the experiences of fully independent adjudication for the medical profession, other regulators may wish to adopt the independent body to provide further assurance of independence to the public.

Chapter 5: Education: the role of the regulatory bodies

22. The Government agrees that the non-medical professional regulatory bodies should continue to be responsible for the educational standards of the professionals they regulate.

23. The Government recognises the gains to be secured from single oversight of medical education, but believes that change should be introduced in such a way as to preserve the expertise and experience of the present organisations that undertake this role. The Government agrees with the proposal, set out in the GMC's response to consultation, for a three-board model covering undergraduate education, postgraduate education and continuing professional development. The Department will work with the GMC to establish an undergraduate board and a continuing professional development board in the GMC. The Postgraduate Medical Education and Training Board will continue as a separate legal entity, fulfilling the role of the postgraduate board within this three-board approach. Both organisations will continue to have a duty of co-operation.
24. The Department will ask UK professional regulatory bodies to work with NHS employers to develop arrangements for selective language testing for applicants to posts, where appropriate.

Chapter 6: Information about health professionals

25. Chapter 6 sets out further proposals for the professional registers and the extension of the information held on them for patients, the public, employers and the professions.
26. Entry to the professional register depends ultimately on demonstrating fitness to practise by securing the educational qualifications and, in some cases, levels of competence, recognised by the relevant regulatory body. As 'The regulation of the non-medical healthcare professions' noted, however, the different regulatory bodies have similar, though not identical, requirements of people seeking new registration. The Government will ask CHRE to recommend a single standard definition of good character, working with the regulatory bodies, and encompassing wider work within Europe to promote information sharing on the good character of professionals who cross national borders.
27. The Government will also take forward the recommendation to ensure closer co-operation and co-ordination between regulators and employers when a health professional enters employment for the first time. The Department will ask CHRE to lead a programme of work with regulators and employers from across the UK to investigate the feasibility and practicability of these proposals, reporting to ministers by April 2008.
28. Both *Good doctors, safer patients* and 'The regulation of the non-medical healthcare professions' raised the issue of whether students and trainees should have closer relationships with their future regulators prior to qualification. The Government believes that each regulator should consider this issue on the basis of the risk presented to patients by trainees and students in particular professions. The Department will ask the regulators to report back with proposals by January 2008.

29. The Government agrees with the CMO's key proposals for changes to the medical register. The medical register should be the key national list of doctors entitled to practise in the UK. The Department will discuss with the GMC how the register can be further developed to become the single authoritative source of information on doctors, including disciplinary action by employers and alert notices. In reviewing such arrangements, the Department will ask the regulators what other changes could be made to provide better access to information for patients, the public and employers.

Chapter 7: New roles and emerging professions

30. Some existing professionals who are not statutorily regulated have been in practice with patients for many years; practice that carries at least the same potential risk to members of the public who use their services as that of the statutorily regulated professions. The Government believes that these professionals should also be subject to a system of regulation that is proportionate to the risks and benefits entailed.
31. The Government is planning to introduce statutory regulation for applied psychologists, several groups of healthcare scientists, psychotherapists and counsellors and other psychological therapists. These are the priorities for the introduction of statutory regulation.
32. For emerging professions, the Department will establish a UK working party to develop criteria to determine which roles should eventually be statutorily regulated. The regulation of emerging and existing unregulated professions will be managed by the existing statutory regulatory bodies and the proposed new General Pharmaceutical Council. This will help to foster consistency where appropriate and the application of best regulatory practice across all regulated professions. With the exception of the new arrangements for the regulation of pharmacy, the Government will not establish any new statutory regulators.
33. The Government will consider areas in which regulatory practice and legislative provisions should be harmonised across the regulators so that they all have the most up-to-date and comprehensive duties and powers.
34. Where a health professional joins a new regulated profession from within an existing regulated profession, it might be possible for them to remain registered with their existing regulator, in a system of distributed regulation, to avoid costly dual regulation.

Chapter 8: Implementation

35. The Government will consult with the Devolved Administrations, the regulators, the professions, employers and other key stakeholders on the development of a detailed implementation programme that encompasses both this White Paper and the Government's response to the recommendations of the Fifth Report of the Shipman Inquiry and the recommendations of the Ayling, Neale and Kerr/Haslam Inquiries, *Safeguarding Patients*.

36. Many of the reforms set out in this White Paper will require primary legislation. Other measures need to be enabled by seeking parliamentary approval for secondary legislation. On specific matters where there is clear public, professional and parliamentary agreement on the need for change, the Department will consider with stakeholders whether it would be appropriate to seek Parliament's agreement in primary legislation to enable these issues to be addressed through secondary legislation. These legislative proposals will be developed in close consultation with the Devolved Administrations to ensure that they are appropriate to the whole of the UK.
37. The White Paper sets out the key principles for a lasting settlement for professional regulation, but putting those principles into practice will require the advice and participation of a wide range of stakeholders to ensure effective delivery. The Government will establish an inclusive national advisory group on professional regulation to advise the Department and the Devolved Administrations on the detailed implementation of the White Paper and the response to the Shipman Inquiry, and related inquiries.

Introduction by the Chief Medical Officer for England



Professional regulation in context

1. The primary purpose of professional regulation is to ensure patient safety. As such, it is a vital component of the overall framework in the United Kingdom for ensuring the highest quality healthcare for the public, but it is only one component of a much wider system to sustain and improve the standard of care that patients take for granted.
2. The Government is working on a comprehensive strategy to improve the quality of care that patients and the public can expect. In order to assure respectful, compassionate, caring and clinically excellent care as the norm, it would be inadequate to focus solely on the regulation of individual health professionals. The Government's programme for assuring the quality of healthcare is addressing a broad agenda to secure this goal in England, and there are similar strategies in Scotland, Wales and Northern Ireland. In England:
 - At the level of the healthcare system as a whole, a new system for regulating organisations that provide care for the public will be seeking to ensure that these organisations have high-quality care and patient safety as their priority.
 - Patients are being given the power of choice, supported by the introduction of payment by results and better information about services, to enable them to exert their individual and collective influence by choosing healthcare organisations that best deliver the quality of care that they expect.
 - Within clinical teams and healthcare organisations, clinical governance and better measurement of clinical results through clinical audit are supporting continuous improvement to the way in which patients are treated. Increasingly, health professionals are able to learn both from treatment that worked well and that could have been better.
 - An unprecedented programme of investment in buildings and equipment is enabling health professionals to work in environments that support high-quality care.
 - A new approach to patient safety, initiated by my report, *An organisation with a memory*, is focusing on how we can tackle human error by improving the systems to reduce its impact.

- Greater devolution of responsibility within the health service, and within healthcare organisations themselves, is resulting in greater flexibility and creativity in responding to local and individual needs.
3. Scotland, Wales and Northern Ireland are also addressing the quality agenda in ways that meet the needs of the populations that they serve and that are suited to the way their healthcare systems are organised. For example, NHS Quality Improvement Scotland shares good practice and monitors clinical standards and NHS Education for Scotland ensures effective educational approaches for workforce development. The Scottish Commission for the Regulation of Care regulates a range of services, including independent healthcare services. The Welsh quality strategy published in 2006 makes similar provisions and Northern Ireland has recently published a response to the Shipman Inquiry which has further strengthened arrangements for high-quality clinical care and patient safety.
 4. The modernisation of professional regulation set out in this White Paper complements the development of the regulatory framework for health and adult social care more broadly, as set out in the Department of Health's recent consultation document, *The future regulation of health and adult social care in England*. This proposes reforms to the health and social care system to help secure greater safety, quality, fairness and efficiency for patients and service users across the health and adult social care systems. The document also confirms the commitment to merge the three organisations currently responsible for regulating healthcare, adult social care and the operation of the Mental Health Act – the Healthcare Commission, the Commission for Social Care Inspection and the Mental Health Act Commission. As part of this work, the new registration system for NHS providers will help assure safety at organisational level. Subject to consultation, this will stipulate that all staff comply with appropriate professional regulation systems.
 5. The overall quality of the healthcare system that serves the public is ultimately dependent on the expertise, attitudes, behaviour and commitment of the individual health professionals and other staff who work within that system. Their pride and commitment to the primacy of their individual relationship with the patient and their fundamental desire to apply their clinical and professional expertise in that context are the human bricks and mortar from which our healthcare system is built and the reason why, as a society, we hold health professionals in such high esteem.
 6. The goal of any reform to the regulation of individual health professionals must be to support and maximise the power of that fundamental asset to society, while ensuring safeguards that identify problems quickly and minimise the impact on those rare occasions when individual health professionals fail to meet the high standards that the professions have set for themselves.

7. While the substantial majority of health professionals in the UK work primarily in the NHS, including NHS Foundation Trusts, or are employed by organisations commissioned to provide NHS services, there are a range of other organisations and contexts in which they work, and the new system set out in this White Paper has to work in these as well as in the NHS. In addition to those who work in the private and independent sectors, there are those who are engaged in education and training, research, public health, management, the development of new drugs and medical technology, clinical trials, expert testimony and humanitarian work overseas. All these professionals need to be able to participate easily in the new systems. It is also important to ensure that as new settings for the work of health professionals develop, the regulatory system is able to adapt without difficulty.

Shipman, Neale, Ayling, Haslam and Kerr

8. It would be all too easy for proponents of the reforms set out in this White Paper to point simply to the actions of Harold Shipman, but this is not the sole basis on which we seek to move forwards. The Government's response to the fifth report of Dame Janet Smith's rigorous and painstaking inquiry, *Safeguarding Patients*, sets out a wide-ranging plan of action to put in place new safeguards for society. It also addresses the recommendations of the inquiries into the conduct of Richard Neale, Clifford Ayling, Michael Haslam and William Kerr. At the same time, the Department of Health is publishing an overview of the Government's proposals and actions in relation to all the recommendations in the reports of the Shipman Inquiry, *Learning from tragedy, keeping patients safe*. This White Paper sets out a future strategy based on a system that sustains confidence in all professionals. It is not solely focused on the extreme behaviour of those whose conduct has been criminal, malicious, abusive or reckless.

The case for change

9. As the inquiries into these cases have made clear, there are important lessons to be learned, but with health professionals continuing to enjoy high levels of public confidence, some have questioned the need for change. With the knowledge we now have from bitter experience, positive learning and a growing professional and public recognition of the need for change, complacency would be unforgivable and would only delay the essential changes that are needed to adapt to the realities of healthcare in the modern world.

10. First, we live in an age where traditional social deference is increasingly being challenged and questioned by a better-informed and more assertive public. There has been a shift away from the relatively passive acceptance of authority and establishment institutions by society since the Second World War. Informed by access to health information that was once the sole preserve of the professions, the public are more likely to challenge received opinion. Greater media scrutiny of once privately managed difficulties is subjecting the professions to closer examination. There is emerging and growing public pressure for the relationship between the health professional and the patient to be an open, honest and active partnership, and a declining public willingness to accept passively and unquestioningly the clinical judgements that are made for them. The system that regulates health professionals, in its governance and its ability to provide objective assurance, needs to respond to these pressures, which will increase as the global economy and the open information society gather pace.
11. Second, as the technical ability to intervene effectively continues to accelerate, patient and public expectations of health professionals are rising proportionately and the work of health professionals is becoming more complex and specialised. Accordingly, the scope for human error increases, putting growing pressures on health professionals who strive to fulfil their fundamental ambitions and instincts to deliver clinical excellence. Our system of regulation needs to adapt and respond to those pressures. It needs to put in place mechanisms that deal with honest mistakes fairly, supportively and sympathetically. It needs to ensure that professional education adapts to this new context so that health professionals are properly prepared for the complexity they face when they enter their profession. It needs to ensure that health professionals keep themselves up to date with the state-of-the-art clinical interventions that are available to them. The system needs to provide safeguards so that health professionals do not feel pressurised to operate outside their safe sphere of competence either through a desire to deliver the most effective care or through unreasonable patient expectations of what they can do.
12. The reforms set out in this White Paper ensure that health professionals are given the opportunity throughout their careers to assure themselves, their patients, their colleagues and their employers that their continuing commitment to practise to the highest standard is underpinned by objective confirmation of their continuing competence to do so. Public trust in the professions needs to be sustained and enhanced by ensuring that the regulators provide effective and objective scrutiny of practitioners from the perspective of reasonable patient expectations, free from any doubt that the regulators are overly sympathetic to lapses in conduct or competence through a sense of professional loyalty.

13. Third, prior to the rapid advances in technical ability, the historic interactions between patients and health professionals were as much concerned with relationships, support and traditional bedside manner as they were with treatment. Good communications and mutual respect were at a premium and remain an enduring part of our expectations of the relationship between health professionals and patients. As demands on clinical time and emphasis on technical competence have grown, there has been a shared concern among patients and health professionals that the central human dimension of this relationship has been weakened. Both sides have a desire for a system that supports and strengthens its important role in good patient care and high-quality professional practice.
14. Fourth, the increasing complexity of modern clinical practice demands a new and more understanding relationship with professionals about the pressures they face. Where appropriate and justifiable, there needs to be a greater emphasis on remediation, rehabilitation and support for those health professionals who have struggled to cope. This White Paper seeks to set out a new settlement for that environment in which valued health professionals are given the support and second chances that we all expect, if it is fair and reasonable to do so.
15. Finally, both nationally and internationally, the past decade has seen a series of high-profile and controversial cases which have sent shockwaves through both professional and public thinking about the future of professional regulation. However atypical their behaviour, names like Beverley Allitt and Harold Shipman are now fixed in the public memory. The mounting pressure of scrutiny from the Bristol Royal Infirmary Inquiry, Alder Hey, Neale, Ayling, and the Kerr and Haslam inquiries, and other cases, has led to growing doubt in the public's mind about the adequacy of our arrangements for professional regulation. While, in the past, in a more deferential age with a more passive media, such incidents might have escaped public attention, today there is no hiding place. Society and the professions need a new system which is able to detect problems early, provide open assurance of competence and good conduct, and is seen to deal fairly and independently with poor practice and poor behaviour when it occurs.
16. In *A first class service: Quality in the new NHS*, clinical governance was defined as the framework through which NHS organisations in England are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish. The introduction of clinical governance is the key underpinning change to health service culture and practice that is seeking to address powerful social, technological, professional and organisational challenges. Through the implementation of clinical governance, the quality of patient care has increasingly become a shared responsibility for organisations, the teams within them and the individual health professionals within those teams.

17. The Government's response to the Shipman Inquiry sets out a programme of action to ensure that more rigorous and consistent clinical governance, as an integral component of routine organisational, team and individual day-to-day work with patients, will ensure effective systems to assure acceptable standards of clinical practice and to promote continuous improvements in the quality of care. This White Paper sets out a programme of reform to ensure that where such systems identify problems with individual health professionals that cannot be fully addressed through clinical governance, there are systems in place to deal fairly, quickly and effectively with potential threats to patient safety and high-quality care.
18. I believe that both the public and the professions support the need for change in this new context. While public opinion research continues to show a high degree of trust in our health professionals, we are all familiar with the informal and anecdotal accounts of dissatisfaction among family, friends and professional colleagues about the capability and conduct of individual professionals. Those of us who work closely with health professionals will have heard such accounts from health professionals themselves. In relation to doctors, the research I commissioned to inform *Good doctors, safer patients* suggested that although the public said that they were satisfied with the regulatory system, many believed, wrongly, that doctors were tested regularly to demonstrate their continuing abilities. The intense media scrutiny and coverage of cases where health professionals harm or let down their patients suggests a very low public tolerance of such cases and would mean that the price of minimal regulation would be a debilitating attrition of the collective reputation of the health professions in the UK.

Regulation in the context of multi-professional care

19. Effective healthcare in the 21st century is usually dependent on multi-professional teams and the contributions of many health professions. Good quality healthcare depends on a large and diverse team of professionals.
20. In order to assure a safe and high-quality experience for patients across the spectrum of their encounters with health professionals, we need to ensure proportionate arrangements for all the professions involved. There can be no weak links in the chain of care. In a multi-disciplinary environment where health professionals frequently work together, their ability to work co-operatively in the best interests of their patients is as much a measure of clinical quality and good patient care as the individual strengths and weaknesses of the professionals within the team.
21. The process of reform has already been far reaching. New professions and new regulatory arrangements have meant new and more flexible fitness to practise procedures and the introduction of new requirements for continuing professional development. It is important to recognise that the regulators themselves have made many improvements to the way in which they work and they are to be congratulated for these changes. The issue is whether these changes have been sufficient.

Consultation

22. Consultation responses to *Good doctors, safer patients* and to 'The regulation of the non-medical healthcare professions' demonstrated a real recognition of the need for change. Patient and public groups were supportive of the proposals in the two reports, with some pressing for more radical changes. There was broad support for the concept of revalidation among most of the professions and their regulators, provided that its operation would be proportionate to the benefits that it was seeking to secure. While there were different views among the professionals about the extent to which the governance arrangements for the national professional regulators should be changed, there was a general acceptance of the need to adapt to a new environment. For doctors, there was a recognition that the gap between local employers and the professional regulator needs to be bridged for a fairer and more effective system, but there was debate about the most effective and cost-effective means of doing so.

Risk-based regulation

23. In responses to consultation, risk-based regulation was a common theme and it has been at the heart of the development of the proposals in this White Paper. Since 1997, there has been a growing focus in Government, led by the work of the Better Regulation Commission and its predecessor, the Better Regulation Taskforce, to ensure a more rigorous approach to the field of regulation. The core principles of proportionality, accountability, consistency, transparency and targeting are bringing a more common-sense approach to regulation. They recognise that, in many spheres of life, people are prepared to tolerate a level of risk and that any proposals to seek to protect against such risks need to be tested thoroughly to ensure they are not over-burdensome and that they do not unduly limit innovation and local and individual freedom of action.
24. Risk-based regulation applies as much to public sector services as it does to the private sector. The costs of professional time in meeting the requirements of regulation are opportunity costs for patients. Every hour that a highly-trained and costly health professional spends demonstrating objectively their continuing competence is an hour lost to patient care. The Government itself therefore has an in-built incentive to ensure that the expenditure of that time adds real value to patient care, providing the assurance and peace of mind that allows patients to take the quality of their care for granted, confident that they are being treated in a way that maximises their safety. In a health service facing demanding challenges to deliver for the public, these judgements are critical. The same concerns apply to those who employ health professionals in the private and independent sectors.
25. The Regulatory Impact Assessment that accompanies this White Paper sets out some of the risks and benefits that can be measured in the field of professional regulation. These in themselves are significant. However, it is fair to say that there are real challenges in constructing a rigorous, comprehensive and robust assessment which can put accurate costings on the risks and benefits that need to be weighed carefully in an ideal analysis of professional regulation.

26. Empirical information on the prevalence of death, injury, disability and mental distress caused by inadequate professional competence or malicious, discourteous or abusive conduct is not available. Even if it were, it would be difficult to cost. What price do we put on the benefits of patients' peace of mind and public confidence? How do we cost lives scarred by grief in families who have lost those they love? Can we measure the frustration and anxiety of health professionals enmeshed unnecessarily in national professional regulatory procedures? How do we measure the costs of a sense of having been unjustly treated? Would the costs and burdens of accurately collecting these data be justified?
27. These are not sentimental points, but ones that recognise the difficulties of capturing quantitatively the intangible dimensions of issues that sit at the heart of healthcare regulation. It is not a reason to side-step the need for rigorously costed and quantified scrutiny of the issues where that is practicable and proportionate, but it means that we are more dependent than we would wish to be on using judgement, based on the experiences and advice of all the stakeholders who have contributed to consultation and debated these issues over many years.
28. To an extent, we can measure components such as public and professional confidence, the costs of litigation, clinical accidents, addiction rates in health professionals, complaints or the number of referrals to regulators. The emerging and growing anxieties about these issues, combined with the cumulative evidence from the thorough and thoughtful public inquiries into cases of unacceptable professional practices and behaviour, create a compelling case that, on the balance of probabilities, change is needed.
29. Because of that information gap, for the proposals in this White Paper that are most costly in terms of taxpayers' money, registrants' fees and professional time, we are moving forward cautiously and testing implementation proportionately and through piloting. For example, for revalidation, the nature of the process itself will be proportionate to the risks to patient safety in each profession. Within medical revalidation, we will be piloting different approaches to recertification in different specialties in partnership with the relevant Royal Colleges. In seeking to introduce a more local regulatory presence in England, we are moving first to establish whether a model for General Medical Council Affiliates would operate best at regional rather than local organisational level, to ensure the most effective and cost-effective means of closing the regulatory gap for medical professionals. This will be piloted prior to decisions about how best to introduce the Affiliates arrangements.

Scotland, Wales and Northern Ireland

30. Concerns were expressed in the consultation that some of the proposals in the two reviews of professional regulation would need to be adapted in order to work well in Scotland, Wales and Northern Ireland. The Devolved Administrations are committed to regulation across the UK, including in the professions new to regulation. However, it is recognised throughout this White Paper that some of its proposals need to be considered by these Devolved Administrations, which take a different approach from England in terms of operational practicalities, due to their different structures and systems. These arrangements need to enable health professionals to move easily around the UK during their careers. In developing the more detailed aspects of implementation of these proposals, Scotland, Wales and Northern Ireland will be closely involved in order to ensure the implementation of systems and approaches that work across the UK.

Securing a lasting settlement

31. I am confident that the measures set out in this White Paper will help put an end to the arguments and controversies of recent decades and enable the regulators and the professionals whom they oversee to move forwards with a clear focus on patient safety and improvement of professional standards. Together, the measures will put in place the foundations of a lasting settlement which will enable the public to continue to have confidence in the health professionals who serve them and enable the health professionals to have confidence in their regulators.
32. This White Paper provides a framework through which the health professionals retain their independence. It ensures that the integrity of their professional judgement is preserved. It provides for fairer treatment of health professionals whose fitness to practise is called into question and more supportive measures for addressing those concerns where that is possible. There is no doubt that, for some, such important changes will feel uncomfortable and that they will want to examine the measures carefully. There is no doubt in my mind that, when implemented, the changes will provide for safer patient care in the UK and will enable the public and patients to be confident that the health professional who cares for them is practising to nationally agreed standards based on an ethos of high-quality care.

Liz Donaldson

Chapter 1: Assuring independence: the governance and accountability of the professional regulators

Introduction

- 1.1 All the bodies regulating health professionals are governed by councils that guide and oversee the administration of their policies and procedures. In some, council members still carry out operational roles, such as sitting on panels that decide on the fitness to practise of registrants whose conduct has been called into question. The councils operate within a wide variety of legal frameworks that have been agreed and amended by Parliament in different ways and at different times over the past 150 years.
- 1.2 The professional regulators have a number of core functions:
 - setting and promoting standards for admission to the register and for remaining on the register;
 - keeping a register of those who meet the standards and checking that registrants continue to meet those standards;
 - administering procedures for dealing with cases where a registrant's right to remain on the register has been called into question; and
 - ensuring high standards of education for the health professionals that they regulate.

Independence

- 1.3 To exercise these functions fairly and effectively, patients, the public and health professionals need to be able to take it for granted that the councils act dispassionately and without undue regard to any one particular interest, pressure or influence. This will ensure that the regulators are not only independent in their actions, but, just as critically, that they are *seen to be independent* in their actions. Doubts based on perceived partiality have threatened to undermine patient, public and professional trust in a number of the regulators over many decades.

- 1.4 Over recent years, most of the regulators have made changes to provide greater reassurance that they are even-handed in their deliberations and decisions, and independent in their actions, but their perceived dependence on, or attachment to, a particular interest has continued to weaken or threaten professional or public confidence in those actions. The Government believes it is no longer acceptable for doubt to be cast on the regulators because of a suspicion that they are 'looking after their own' or because some professionals suspect that they are being unduly harsh in their actions to counter that perception, or that they are pandering to media pressure to mete out draconian punishments.
- 1.5 To ensure professional and public confidence, all the stakeholders need stronger assurance of their independence:
- they must be separate from the Government, constitutionally insulated from day-to-day political pressures;
 - they must be independent of those who employ health professionals, whether in the NHS, the independent sector, or the voluntary sector, to ensure that employer interests are not perceived to weaken safeguards for the public or undermine the fair conduct of regulation; and
 - they must be independent of health professionals themselves, so that they are not thought to be beholden to a perceived natural *esprit de corps* with professional colleagues.
- 1.6 While all these stakeholders themselves share a commitment to the fair regulation of health professionals in the best interest of patients and the public, they do so from different viewpoints and perspectives. The ability of the regulators to sit outside those differences and day-to-day disagreements, and to be guided solely by the role that Parliament has agreed for them on behalf of society, is critical to their effectiveness. To be effective, regulators must be seen to be independent, transparent, accountable, ethical, dispassionate and just.
- 1.7 The constitutions of the regulators are central to those perceptions. First, some are seen to be partial to professionals because they form a majority on their councils. Second, some are seen to be partial because their councils are thought to be elected to represent the particular interests of health professionals.

Ensuring the independence of councils: the composition of councils

- 1.8 The current proportion of lay membership of the nine councils of the healthcare regulators is set out on the next page.

Health Professions Council	48%
Nursing and Midwifery Council	48%
General Medical Council	40%
General Dental Council	34%
Royal Pharmaceutical Society of Great Britain	33%
General Osteopathic Council	33%
General Optical Council	32%
General Chiropractic Council	30%
Pharmaceutical Society of Northern Ireland	0%

- 1.9 All the councils have a professional majority within their membership. In practice, most act and decide by consensus and rarely, if ever, take formal votes in which a professional majority would be the deciding factor. In reality, the proportion of members derived from different constituencies is also less significant because some professional members tend to be more sympathetic to lay perspectives and some lay members may have significant allegiances to the viewpoints of registrants. Councils rarely divide neatly between distinct professional and lay camps.
- 1.10 The composition of councils is none the less significant, because it influences the perception of their independence from particular interests. The existence of professional majorities undermines councils' independence, and their perceived independence, by allowing doubt to be expressed about the weight of opinion they carry in council discussions and decisions, and the perceived reluctance of some registrants to the ending of professional majorities. **The Government is convinced that in order to establish and sustain confidence in the independence of the regulators, all councils should be constituted to ensure that professionals do not form a majority.**
- 1.11 As a minimum, this would entail parity of membership between professional and lay members. In such circumstances, councils will need to consider what further measures are necessary to provide a clear assurance about their overriding commitment to patient and public interest and to guard against well-intentioned professional introspection that might fail to take account of wider social and cultural changes and expectations. Such measures could include:
- better systems for patient and public involvement panels within the regulatory bodies, with terms of reference to ensure that wider societal interests and concerns are taken into account in the conduct of councils' business and the shaping of their policies;
 - proactive programmes to engage more widely with public, patient and parliamentary opinion on issues where there are obvious tensions between patient and professional interests; and
 - greater openness in the conduct of the regulatory bodies' governance, with council papers published on their websites beforehand or available on request and council meetings open to the public, except in exceptional circumstances. Councils will wish to consider this approach, regardless of their composition.

- 1.12 **The Government will therefore seek to secure the legislative changes required to reconstitute councils with parity of membership as a minimum. For the General Chiropractic Council, which proposed a lay majority in its consultation response, the Government will put in place the necessary enabling legislation, subject to parliamentary approval.**
- 1.13 **For those regulators that adopt parity rather than lay majorities, the Government expects that they will put in place packages of measures to demonstrate to the public, patients and Parliament their commitment to conducting their responsibilities in a manner that commands public confidence and puts an end to accusations of partiality. Those that choose parity will be subject to review in 2011 to consider whether these changes have been sufficient to secure that aim.**
- 1.14 It is important that the issue of lay membership is addressed in the spirit in which it is intended. If lay members are perceived to be deliberately drawn from groups that might be naturally sympathetic to professional interests, such as retired members of the profession, they will risk undermining the critical perception of independence that they need in order to conduct their work well. In addition, drawing on a truly lay membership will enable councils better to reflect the society on whose behalf they operate. Where possible, both lay and professional membership should reflect greater diversity, but council membership will be able to draw on a much wider and diverse lay population across England, Scotland, Wales and Northern Ireland to take account properly of the wider views of society and of the overwhelming majority of health professionals who do not aspire to national office. As is the case already with the Nursing and Midwifery Council and the Health Professions Council, the Department of Health will consult with stakeholders to establish a clear definition of a lay member in legislation.

Ensuring the independence and accountability of council members – appointment of council members

- 1.15 One way in which better regulatory practice can be achieved is to put in place systems to help ensure that council members have the appropriate knowledge and skills for their roles. Many council members are currently elected by registrants and fulfil their roles effectively. Elections are the best means of ensuring that members are responsive to the interests of their electorate and responsive to their particular concerns.
- 1.16 For all health professionals, such interests will put patient welfare and the highest standards of professionalism at the top of the list of issues on which they would wish council members to exercise their authority. Nevertheless, for patients and the public, who do not participate in this democratic process, the perception will remain that their own interests are at risk of being given less weight. The perception of independence is undermined as a result and the effectiveness of the regulators is significantly diminished.

- 1.17 It is not practicable to hold elections to the governing councils of the regulators based on the broad and inclusive electorate that would be needed to ensure confidence in the independence of the regulators. Parliament already represents that balance of interests and opinion across society. **The Government will therefore put in place measures to ensure accountability on the part of the professional regulatory councils direct to the UK Parliament, with equivalent reporting arrangements to the Parliaments or Assemblies of the Devolved Administrations, for those councils regulating professionals whose regulation is a devolved matter.**
- 1.18 **In order to ensure the independence of all the national professional regulators, all members of all councils will be appointed independently by the Appointments Commission against clearly specified criteria and competencies.**

The size of the councils

- 1.19 In *Good doctors, safer patients*, Sir Liam Donaldson recommended that the General Medical Council (GMC) should become more board-like in its operations, holding the executive to account for the exercise of its core functions. **The Government supports this recommendation and believes that it applies equally to the other professional regulatory bodies.**
- 1.20 The intention is to ensure that councils focus on strategic rather than operational issues with the aim of assuring excellence in delivery in the long term. In order to do this, councils will need to be smaller to ensure effective strategic decision making and oversight of their executives, shifting away from the model of large representative bodies that seek to include all possible professional, clinical, trades union, lay, educational, employer and geographical interests. **The Government believes that all the councils should move to a more consistent and smaller size that enables them to function more effectively as boards for their organisations, with a statutory duty to ensure that the interests of all stakeholders are considered in their deliberations.**
- 1.21 It is important that those appointed to councils demonstrate that they have the time and commitment to attend assiduously and frequently to their responsibilities as council members. **The Government will therefore remove the provision for 'alternate' members of some of the councils, who act as stand-ins if the member they shadow cannot attend. While many alternates have made an excellent contribution to the councils on which they serve, more board-like arrangements require consistent attendance and a high level of commitment from council members.**
- 1.22 **In the case of the GMC, the Government believes that its proposals on a model of membership, drawing on lay, professional, educational and employer members from across the UK, are a significant step in this direction.**

- 1.23 **For the other professional regulators, a working group on governance will consider, with the relevant stakeholders including the Devolved Administrations, similar changes that will bring greater consistency of size and approach and enable more board-like oversight of their work. The Government will then seek the necessary changes to the relevant legislation. In keeping with this more board-like approach, councils will elect chairs rather than presidents. The Government will review, in 2011, in the light of the experience of working with wholly appointed councils, whether there would be any advantage in the independent appointment of chairs.** The Government would enable any council that wished to adopt this approach before 2011 to do so.

Changes to the Council for Healthcare Regulatory Excellence

- 1.24 The Council for Healthcare Regulatory Excellence (CHRE) was established in 2003 to:
- promote the interests of the public and patients in relation to the regulation of health professionals;
 - promote best practice in regulating health professionals;
 - develop principles for good regulation of health professionals; and
 - promote co-operation between regulators and other organisations.
- 1.25 The work of CHRE has had a significant impact on the conduct of fitness to practise cases and their adjudication, improving the work of the panels and committees responsible for fitness to practise matters. Some felt that this early focus on challenging individual decisions of the health professional regulators at times inhibited more strategic work focused on the development of common principles and consistent approaches across the regulatory bodies. In the future, the Government expects that the reforms to the regulators and to fitness to practise procedures set out in this White Paper will provide greater room for CHRE's council to balance its work on scrutiny with enhanced and extended work on best practice and common regulatory issues.
- 1.26 In doing so, it needs to be an authoritative independent voice for patients on the regulation of professionals, providing expert advice on policy. To do so, it also needs to be independent of the professional regulators themselves. The Government will discuss with the Devolved Administrations, the regulators, CHRE and other key stakeholders the detailed composition and size of the CHRE council, but the intention is that it will be smaller, independent and more strategic and will be required by statute to include the views of stakeholders from across the UK in its deliberations.
- 1.27 **The Government will therefore seek to make the necessary legislative changes to reform the membership of CHRE's council, with a smaller more board-like membership appointed by the Appointments Commission against a clear set of criteria. The national regulators will no longer nominate members of the CHRE council. The chair of CHRE will be appointed, rather than elected.**

Changes to the number of regulators

- 1.28 **The Government agrees with the recommendation of the review of regulatory arrangements for health professionals that there should be no mergers of professional regulators for the time being, although ministers will continue to consider the future of the Pharmaceutical Society of Northern Ireland (PSNI) and its relationship with the Royal Pharmaceutical Society of Great Britain (RPSGB). The Government will review these arrangements in 2011.**

Pharmacy

- 1.29 Pharmacists practise on the high street, in hospitals, health centres and GP surgeries, in universities, laboratories and in the pharmaceutical industry. Those practising in a healthcare environment are a source of safe and convenient healthcare advice and support that is trusted by the public. Pharmacists are also working in roles in industry that place them at the cutting edge of drug discovery, and the clinical, technological, financial and ethical dimensions of modern healthcare.
- 1.30 Unusually, the RPSGB is both the regulator for the pharmacy profession and is also the professional body responsible for leading the profession to ensure the highest standards of professional practice. In addition, it has an important role in inspecting pharmacy premises and the Government is currently in the process of putting in place legislation to enable it to take on the role of regulating pharmacy technicians.
- 1.31 The practice of pharmacy is currently undergoing a revolution in which the clinical expertise of the profession is being given greater freedom to harness itself to the needs of patients. Increasingly, pharmacists are no longer constrained by outmoded limits on their ability to prescribe independently to patients and the prescribing of a far wider range of effective medicines will become more commonplace in future. Pharmacy technicians, too, are working more closely with patients and hence are expected to be the subject of statutory registration when the new legislation is implemented. As a profession, pharmacists are entering a new era, in which they will have much greater scope to apply their high levels of expertise in direct patient care. With these changes comes the need to ensure that their regulatory arrangements are in keeping with their increasing levels of professional responsibility and the accompanying benefits and risks to patients that that entails. These changes also require strong and effective clinical leadership and support.

- 1.32 The RPSGB's responsibilities towards pharmacists for professional leadership are potentially in conflict with its role as an independent regulator for the profession itself. The RPSGB itself has recognised the need for much greater clarity about its regulatory and leadership functions. As the profession takes on an increasingly clinically important and professionally demanding role in the treatment of patients, whereby pharmacists have autonomy to prescribe potent drugs, the Government believes that this dual responsibility is no longer sustainable if the public are to be reassured that there is effective independent regulation of this role. The RPSGB needs to separate its regulatory system from its system of professional and clinical leadership, allowing each distinct function to focus solely on its core role.
- 1.33 **The Government will therefore seek legislative time to bring proposals to Parliament to enable it to establish a General Pharmaceutical Council (GPC) responsible for the regulation of pharmacists and pharmacy technicians, and for the registration of pharmacy premises. It will exercise the role of inspection of pharmacies currently carried out by the RPSGB.** The review entitled 'The regulation of the non-medical healthcare professions' called for closer working between the RPSGB and the PSNI and, in time, for the amalgamation of the two. In the light of these proposals, further consideration is being given to the future arrangements for pharmaceutical and professional regulation in Northern Ireland.
- 1.34 The Government recognises this is a historic decision for the profession of pharmacy. As the safe and effective prescribing and dispensing of medicines becomes more complex and greater clinical responsibilities are placed upon the profession, the science and practice of pharmacy must retain strong professional and clinical leadership to navigate an increasingly demanding, complex and rewarding role for the profession. The profession will need a strong and clear voice to assume the critical responsibility of a role akin to that of a Royal College. This should be a learned and authoritative organisation, supporting excellence, professionalism, and innovation in the science and practice of pharmacy. It should have an important role in revalidation arrangements and contribute its expertise to the new GPC which, as the regulator, will set objective measurable standards for the regulation of the profession.
- 1.35 It may be necessary for the RPSGB to seek amendments to the existing Royal Charter or the granting of new Royal Charter should it choose to redefine its professional leadership role.
- 1.36 **A short-term working party, including the Chief Pharmaceutical Officers for England, Scotland, Wales and Northern Ireland, will work collaboratively with the broader pharmacy profession, including the PSNI, and other key stakeholders, on agreed proposals for implementation. Its work will help inform future decisions about the regulation and leadership of pharmacy in Northern Ireland. The working party will report to ministers with recommendations by the end of March 2007.**

Chapter 2: Revalidation: ensuring continuous fitness to practise

Introduction

- 2.1 In the traditional system for regulating health professionals, once people had qualified and demonstrated that they were fit to practise with patients, their names were placed on their relevant professional register and remained there unless a definite reason came to light for their removal. It was taken on trust by the public and professional colleagues that they continued to be fit to practise throughout their careers.
- 2.2 The Health Professions Council and the Nursing and Midwifery Council require re-registration every two and three years respectively. They, and other regulators, have begun the process of linking registration with professional development. However, there has been long debate about whether the health professionals, and particularly doctors, should be required to demonstrate objectively that they have kept up to date with professional and clinical developments and that they continue to apply, through their practice, the values that they committed themselves to when their names were first placed on their professional register. Revalidation is a mechanism that allows health professionals to demonstrate that they remain up-to-date and fit to practise. For the large majority, revalidation will provide reassurance and reinforcement of their performance, and encourage continued improvement. For a very small minority, the scheme will provide a way of identifying problems and an opportunity to put things right.
- 2.3 Public and professional opinion has moved on in the course of this debate, from a position where trust alone was sufficient guarantee of fitness to practise, to one where that trust needs to be underpinned by objective assurance. Public opinion surveys suggest that people expect health professionals to participate in the revalidation of their registration and that many believe that this already takes place every year.

- 2.4 *Good doctors, safer patients* and the review, 'The regulation of the non-medical healthcare professions', set out proposals for a new system of revalidation. In consultation responses to these reports, there was a clear consensus among the substantial majority of respondents in favour of such a system. The disagreements were not about whether revalidation should take place, but about how it should be carried out and how frequently it should occur. The Government continues to support the principle of revalidation and this chapter sets out its proposals for implementing a system that will spread to encompass all health professionals over the next five years.

Revalidation for doctors

- 2.5 As the review of medical regulation observed, the Shipman Inquiry was critical of the way in which proposals for revalidation were apparently diluted in their rigour over time. The Inquiry had three principal reservations about the implementation of revalidation: that the standards to be applied were too low; that revalidation would be based primarily on taking part in an appraisal process designed for a different purpose; and that revalidation needed to be objective and based on clear standards and thresholds.
- 2.6 The Inquiry concluded by recommending that appraisal should be more robust if it is intended to be used as a tool for clinical governance (recommendation 25) and that the arrangements for revalidation should be amended so that they genuinely comprise an evaluation of an individual doctor's fitness to practise (recommendation 103).
- 2.7 The Government believes that the proposals set out in *Good doctors, safer patients* for medical revalidation address these concerns. **The Government endorses the Chief Medical Officer's (CMO's) recommendations on revalidation, believing that they meet the recommendations of Dame Janet Smith in relation to doctors, and will implement these proposals in partnership with the medical profession and patients.**

Relicensure

- 2.8 **Medical revalidation will have two core components: relicensure and specialist recertification. All doctors wishing to practise in the UK will require a licence to practise. As a first stage, the General Medical Council (GMC) will issue these licences to practise as soon as it is practicable to do so.** Those doctors who are retired, overseas or taking a long-term career break will be able to maintain registration with the GMC if they wish, but will have no legal right to practise in the UK. Individual doctors will need to discuss with the GMC whether they need a licence or will be able to meet the requirements of revalidation in order to retain it.

- 2.9 This licence to practise will be subject to renewal every five years by undertaking revalidation successfully. The relicensing process will generally be based on agreed generic standards of practice set by the GMC, a revised system of NHS appraisal for doctors and any concerns known to the doctor's medical director (or responsible officer) and the GMC Affiliate (see Chapter 3). The Department of Health will discuss with the GMC and others how these generic standards might be adapted to address the skills and competencies required for career grade doctors who specialise in particular fields of practice.
- 2.10 The nature of the appraisal arrangements that are in place for doctors in the NHS varies between England, Scotland, Wales and Northern Ireland, and between different types of providers, all of which means that the process will not be uniform. Arrangements will be put in place to ensure that the GMC has available to it the information it needs to assure itself of the validity of the relicensing, where necessary by enhanced information-gathering powers. The implementation arrangements will be discussed in detail with all the relevant stakeholders. It is envisaged that in England the necessary information will be collected by the medical director or responsible officer. After agreement with his or her board, the responsible officer will then submit a formal list of recommendations to the GMC Affiliate. Scotland, Wales and Northern Ireland will consider the best means of ensuring robust revalidation arrangements in those countries to assure all patients in the UK of the fitness to practise of doctors in the UK, taking into account that a limited number of doctors may practise in more than one country during the revalidation period.
- 2.11 In England, these recommendations will endorse the renewal of a doctor's licence to practise on the basis that the doctor has engaged in an annual appraisal satisfactorily (this will also apply to doctors in training although for them appraisal takes a different form and complements formal assessment of progress); the doctor has participated in an independent 360-degree feedback (also known as 'multi-source' feedback) exercise in the workplace; and that any issues concerning the doctor's conduct or practice have been resolved to the satisfaction of the medical director or responsible officer and the regional GMC Affiliate (see Chapter 3). Relicensure will therefore be based on a positive affirmation of the doctor's entitlement to practise, not simply on the absence of concerns. For doctors on the specialist and GP registers, the licence to practise will also depend on specialist recertification.
- 2.12 **The Department will consult with the GMC, the profession, the medical Royal Colleges, patient groups, NCAS and the Devolved Administrations, and develop proposals to commission and pilot appropriate national tools for 360-degree feedback to support this process.** The Department will consider with stakeholders whether a single generic national tool would be appropriate or whether elements will need to be tailored to the specific circumstances of different medical specialties and spheres of practice.
- 2.13 Given the critical importance that patients attach to the courtesy and respect they are shown by doctors, communication skills will be an important component of that feedback.

- 2.14 When a practitioner moves post during a relicensure cycle in England, the medical director or responsible officer will provide a standardised record outlining the practitioner's current position in relation to the elements contributing to relicensure to their opposite number in the new organisation and the GMC Affiliate. Prospective employers should ensure that this record has been received, as well as any other professional references sought as part of their normal recruitment processes, before an appointment starts.
- 2.15 **In order to bring objective assurance of continuing fitness to practise, the appraisal process will encompass both summative and formative components.** Summative assessment looks back to assess whether performance has met specific standards. Formative assessment looks forward to any changes that might need to be made.
- 2.16 The Government recognises that this is a significant change to the existing system of appraisal for doctors. It will impact on doctors and the organisations in which they work. Appraisal arrangements are highly effective in most parts of the country, but the picture is variable and, in a few organisations, doctors are being let down through a failure to ensure appropriate appraisal arrangements.
- 2.17 **The Department will discuss with stakeholders the most effective means for the introduction of an appraisal process with summative components. The quality of the process will be regularly assured by the GMC. The appraisal arrangements will need to take account of the large numbers of doctors who work outside the NHS as well as in NHS Trusts, Foundation Trusts and primary care.**

Specialist recertification

- 2.18 **The second stage of revalidation for doctors will apply only to doctors who are on the specialist or general practice registers, requiring them to demonstrate that they continue to meet the particular standards that apply to their medical specialty, including general practice.** Recertification, like relicensure, will be a positive affirmation of the doctor's entitlement to practise, not simply an absence of concerns. Recertification will be carried out at regular intervals of no more than five years. Where possible, it will coincide with relicensure.
- 2.19 The process will be carried out by the relevant medical Royal College, and renewal will be based upon a comprehensive assessment against the standards drawn up by that college. Recertification will be contingent upon the positive statement of assurance by that college to the GMC. The GMC would need to be satisfied that these processes were sufficient to provide assurance of the integrity of the register. In England, external independent scrutiny will be applied to these processes to ensure that they are cost-effective, proportionate and represent effective use of professional time away from patients. Doctors will not need to be members of the relevant Royal College in order to apply for recertification. The costs of recertification will be recovered either through a direct payment to the relevant Royal College or through fees to the GMC, depending on the circumstances, and the Government will discuss the detailed arrangements with the profession, the Royal Colleges and the GMC.

2.20 The evidence that provides the basis for specialist recertification will vary between specialties, and the frequency with which specialists need to recertify may also vary (although it would have to occur at least every five years to coincide, where possible, with the overall relicensing cycle). Evidence may be drawn from a range of sources and activities, including employer appraisal, clinical audit, simulator tests, knowledge tests, patients' feedback, continuing professional development or observation of practice. Some specialties, for example, cardiothoracic surgery and dermatology, are already developing proposals to support the recertification process. **The Department will provide development funding to the Academy of Medical Royal Colleges to support the development of recertification processes and the Department will ask the Academy, working closely with the GMC, to establish a UK working group to support co-ordination and piloting of these processes, including ensuring equivalence of standards between medical Royal Colleges.**

Setting standards

2.21 Both relicensure and recertification depend on an objective assessment of doctors against clear standards. **To support relicensure, the Department will ask the GMC to consult with its key constituencies to translate its recent update of *Good Medical Practice* into an effective framework against which individual doctors' practice can be appraised and objectively assessed. In addition, in England the Department will discuss with the profession, NHS employers and other stakeholders the best means of enshrining these standards in the contracts of those doctors who are directly employed and in the commissioning arrangements for those doctors who work within the terms of contracts with commissioners.** Implementation in primary care will need to consider the impact on the wider contracting arrangements between the provider and the commissioner, and any unintentional impact on GPs' partners. The Devolved Administrations will consider appropriate arrangements for doctors working in Scotland, Wales and Northern Ireland.

2.22 **Standards will be drawn up for each area of specialist recertification by the appropriate medical Royal Colleges and specialist associations. These standards will be tested against the needs of patients and healthcare providers and based on wide consultation with all relevant stakeholders. The standards will be agreed with the GMC to ensure that they are sufficient to meet the requirements for remaining on the appropriate part of the medical register. This work will be led by the Academy of Medical Royal Colleges.**

2.23 For some doctors working in other settings, such as the pharmaceutical industry, research, academic medicine, health service management, appeal tribunals or government, the particular context in which they are working may require the adaptation of specialist standards. There may also need to be additional training for those who wish to move back to clinical practice. **The Government will discuss with the Devolved Administrations, relevant stakeholders, the GMC and the Royal Colleges the best means of ensuring appropriate arrangements for doctors working in such contexts.**

Information to support revalidation

- 2.24 The information needed to support revalidation processes will evolve and develop over time. Ideally, recertification will be supported by information that shows how clinically effective each doctor's treatment of his or her patients has been. This will not be straightforward. More experienced doctors often take patients with more serious illness or multiple illnesses, so analysis of the outcomes of their treatment need to be adjusted to take account of this. Nevertheless, robust clinical audit, adjusted to take account of the health of the patients that doctors treat, will in time become an important component of recertification for most specialties.
- 2.25 In addition, as *Good doctors, safer patients* pointed out, valid up-to-date information on the quality of care is also vital for patient choice and identifying opportunities for service improvement. Local clinical audit, within the framework of clinical governance, needs to be revitalised. **The Government therefore agrees with the CMO that a wide and inclusive clinical audit advisory group should be established in England to drive the further development of local and national clinical audit programmes and to establish how best the 'Connecting for Health' programme can support this work. The work will yield publicly available information to accelerate improvement in practice and service delivery. The Department will make additional funding available to support this work in England and will discuss with the Devolved Administrations how they will take this work forward.**

Retired doctors

- 2.26 As doctors approach retirement, they should be invited to a review with their medical director or responsible officer to discuss whether continuation of their licence to practise beyond retirement would be desirable.
- 2.27 The Department will discuss with the Devolved Administrations, the British Medical Association (BMA), the GMC, patient groups and others the desirability of maintaining a register of retired doctors and the safety of allowing retired doctors to undertake occasional practice and to retain limited prescribing rights for a defined range of medicines. This consideration will take account of the need to ensure that practising doctors' knowledge is up-to-date, in order to ensure safe and effective treatment. GMC guidance already stresses that self-prescribing or prescribing to family members is to be discouraged. Any changes to these arrangements would need to be clear about the circumstances in which such prescribing took place.

Failure to revalidate

2.28 The high standards of medical practice and professionalism in the UK mean that the overwhelming majority of doctors will meet and exceed the standards required for revalidation. Where doctors who are working in clinical practice fail to satisfy the requirements of either element of revalidation, they should spend a period in supervised practice or out of practice, prior to assessment, in order that a tailored plan of remediation and rehabilitation may be put in place.

As part of the wider work set out in Chapter 4 to bring a more rehabilitative and supportive emphasis to professional regulation, the Department will work with the Devolved Administrations, the GMC, the BMA, the National Clinical Assessment Service, the medical Royal Colleges and others to agree appropriate arrangements and support mechanisms to facilitate this. In the majority of cases, remediation will result in revalidation and successful and safe return to practice.

Revalidation for the non-medical healthcare professions

2.29 ‘The regulation of the non-medical healthcare professions’ review endorsed the principle of revalidation for these professional groups as well. **The Government endorses the recommendations in this review.** Revalidation is necessary for all health professionals, but its intensity and frequency needs to be proportionate to the risks inherent in the work in which each practitioner is involved. **Working closely with the Devolved Administrations, the Department will discuss with each regulator the most appropriate arrangements that are proportionate to the risk that each profession may pose to patients.**

2.30 **The Government agrees that the regulatory body for each non-medical profession should be in charge of approving the standards which registrants will need to meet to maintain their registration on a regular basis. Where appropriate, common standards and systems should be developed across professional groups where this would benefit patient safety. The Department will ask the Council for Healthcare Regulatory Excellence (CHRE) to work with regulators, the professions and those working on European and international standards to support this work. This will encompass the development of standards for higher levels of practice, particularly for advanced practice in nursing, AHPs and healthcare scientists. The Department will discuss with the Nursing and Midwifery Council the outcome of their consultation on advanced nursing practice to agree next steps.**

2.31 There are some non-medical professional staff, such as clinical scientists, who undertake higher specialist training and practise for most of their careers at a specialist autonomous level. **The Department will work with the Devolved Administrations to establish a short-term working party to consider how regulation and revalidation should reflect this.**

Higher	Lower
High level of responsibility for patient safety inherent in scope of practice	Low level of responsibility for patient safety inherent in scope of practice.
Leaders of clinical teams	Team members
People who practise outside managed environments such as a hospital or clinic	People who practice within such environments
People whose working environment is not subject to NHS standards of clinical governance	People whose working environment is subject to NHS standards of clinical governance
Practitioners who are frequently alone with patients/clients (including in their homes)	Practitioners who always work in a team/do not work face to face with patients/clients
Unsupervised practitioners/post	Supervised practitioners/posts
People in their first few years of registration (and possibly also their last few, according to some evidence)	Registrants in mid (or late?) career
Recent adverse finding by a regulator	Clean regulatory record
Recent appraisals show concern about performance	Good performance record
People who are in current practice	People who are not practising (some regulators have proposed a scheme where non-practising registrants need not revalidate at all) Those who are not practising should not be required to revalidate as there is no risk to the public. This does however have implications for re-entry to the register.
People using invasive, high-risk interventions	People using lower-risk interventions

2.32 Professionals will fall broadly into one of three groups for revalidation in England:

- **for employees of an approved body, for example, nurses, dietitians or paramedics working in an NHS organisation or a licensed private or independent sector provider, evidence to support revalidation will be provided as part of the normal staff management and clinical governance systems, with employers providing recommendations to the professional regulators;**
- **for those, including self-employed contractors, performing services commissioned by NHS primary care organisations (such as dentists or optometrists), the revalidation processes will be carried out under the supervision of either the NHS commissioning organisation or, particularly where it is necessary to take an overview of both NHS and private work, the regulatory body, but in either case with appropriate collaboration between the two bodies; and**
- **for all others, for example, osteopaths, their regulatory bodies will develop direct revalidation arrangements.**

2.33 **The responsibility for revalidation arrangements for professionals directly employed by primary care contractors, for example practice nurses or dental hygienists, will be discussed with the relevant professions and regulators.**

2.34 **The Government agrees that the appraisal process within the NHS, which will be a central component of revalidation, should be both formative and summative, to ensure objectively that required standards are met. Information gathered under the Knowledge and Skills Framework should be used as far as possible as the basis of revalidation, with any additional requirements justified by risk analysis. As these measures will require the introduction of summative elements to assessment, the Department will discuss these proposals with the Devolved Administrations, the relevant regulators, NHS employers, trades unions and others with an interest to ensure this is proportionate, fair and appropriate.** As far as possible, the agreement of such arrangements should be professionally led, provided that they secure adequate objective assurance to patients and the public that they give appropriate safeguards to the maintenance of high professional and clinical standards. Scotland, Wales and Northern Ireland will consider how they wish to take this forward within their particular contexts.

Ensuring effective systems for revalidation

2.35 For all health professionals, including doctors, it will be important to ensure that the organisations, whether providers or commissioners, responsible for their revalidation are doing so in a sufficiently rigorous and fair manner to ensure patient safety and fair treatment of health professionals. **In England, the Department will include the capacity of organisations to carry out this role as a core component of the standards against which organisations are judged when they are granted their licence to operate by the new national system regulator.** As with the current arrangements, this is likely to be based on evidence-based self-assessment, validated through risk-based audit and investigation where concerns are identified. The Devolved Administrations will consider how to address this within their particular contexts.

Introducing revalidation

2.36 The Secretary of State commissioned CHRE to provide advice on the issues that needed to be considered in implementing revalidation arrangements for health professionals. Their main findings are that:

- there is general support for the concept of revalidation, and the most important issue is how to implement it;
- the Department needs to consider carefully the additional responsibilities placed on local organisations, to avoid overloading them; and
- the implementation of revalidation should be sufficiently flexible to take account of the diversity of employment environments across the UK.

2.37 The Department welcomes this advice. The introduction of a new appraisal and revalidation system covering all health professionals in the UK needs to be piloted thoroughly, managed carefully and phased in over time to ensure that it works well, that it works fairly and that it enables employers and commissioners to put in place the capacity and capability needed to make it work well. The setting of standards by the professions themselves will take time, thought, piloting and consultation. The Government is resolved that these changes should be introduced, but is equally determined that they should be introduced in a way that does not place unmanageable burdens on employers, staff or resources.

- 2.38 **The Government will discuss with the Devolved Administrations, and with public, private and voluntary sector employers the development of an affordable and manageable timetable for the effective implementation of revalidation.** This will reflect the state of readiness of each profession to deliver robust revalidation processes; the impact revalidation would have on diverting frontline staff from direct patient care; the capacity of regulators and employers for each professional group; the level of public concern about professional standards within each professional group; the risks inherent in the care provided by each professional group; the numbers of professionals working in each professional group, including the proportion of self-employed; the ability of practitioners taking career breaks, maternity leave and other absences from practice to engage with these processes; and the particular circumstances in Scotland, Wales and Northern Ireland.

Conclusion

- 2.39 The measures set out in this chapter will provide the objective assurance that the public now expect to underpin their trust in health professionals. The measures are framed in a way that is proportionate to the risk inherent in each professional group and designed to assure patient safety in relation to that risk. The Department believes that revalidation should be professionally led and proportionate and will work with the regulators for each profession to ensure that this is the case. It will be a complex undertaking to create workable and appropriate detailed arrangements for each profession involved and it will be important to develop and adapt these proposals to ensure effective implementation. **Therefore, a United Kingdom Revalidation Steering Group will be established to develop and co-ordinate this work.**

Chapter 3: Tackling concerns: the local role

Introduction

- 3.1 Health professionals in the United Kingdom work to, and meet, standards of conduct and clinical quality that put them in the front rank of professionalism internationally. In millions of interactions with patients every day – from a few simple words of advice to the most complex and technologically sophisticated procedures – they engage with patients with kindness, commitment, compassion and a clear focus on clinical excellence.
- 3.2 Such is the standard of care that patients receive routinely from health professionals, rare lapses from professionals are all the more stark and disturbing when they do occur. When concerns are raised about the behaviour or ability of health professionals, there are heightened levels of patient, public, professional and media scrutiny of the way in which the professions and their regulators respond. As a society, we are so used to having our high expectations of health professionals met that we take it all the more seriously when they are not. As the ability of modern healthcare to diagnose, treat and manage illness continues to accelerate, and as new investment in the NHS is rapidly expanding the capacity for health professionals to adopt these new interventions, public expectations of health professionals continue to rise.
- 3.3 So, while assessing and addressing concerns about health professionals is only one function of the UK's system of professional regulation, it is a function that acts as a focus for public, patient and professional concerns about that system. Confidence in the handling of fitness to practise cases is, therefore, fundamental to confidence in the system of professional regulation as a whole. As the medical profession continues to be central to public understanding of the healthcare system, the General Medical Council (GMC) has been the focus of particular scrutiny and controversy, but the need for a robust, fair and effective fitness to practise system is no less necessary for each of the professional regulators.

- 3.4 This chapter and the next set out proposals to ensure that patients, the public, health professionals and Parliament can be confident that when it is necessary to investigate a professional's fitness to practise, this will be done in a fair, honest and open way. They set out the changes needed to ensure a system that earns and sustains the confidence of all who encounter it. This means putting in place fitness to practise processes that not only provide assurance to patients that legitimate concerns will be dealt with effectively in order to safeguard them, but that also gain the respect of professionals by being consistent, fair and proportionate. The system for fitness to practise must be just and it must be seen to be just.

Local arrangements

- 3.5 The reviews of professional regulation *Good doctors, safer patients* and 'The regulation of the non-medical healthcare professions' highlighted the need for clarity about the respective responsibilities of local employers, local commissioners and professional regulators in ensuring high professional standards and addressing concerns about individual professional conduct or competence.
- 3.6 In consultation, for most health professionals there was generally a fair degree of confidence in the ability of local clinical management, contractors and employers to tackle effectively such concerns through line management, clinical governance and local disciplinary procedures. In England, while clearly there were still concerns in this context about other health professionals, for medical professionals in particular there were more significant concerns about the capacity of existing arrangements to deal promptly, fairly and effectively with complaints or concerns about their practice, conduct or health. In some clinical teams and in some organisations there has been the risk that problems are ignored or tolerated or only contained locally, with some doctors effectively 'quarantined' by their clinical colleagues from unsupervised patient care, leading to employers and commissioners failing to pass on concerns to the GMC or when the doctor takes a post elsewhere.
- 3.7 In others there has been the risk of managerial over-reaction. Good doctors working in difficult circumstances or in poor systems have made human errors and have been inappropriately referred to the national professional regulator, when what was needed was more effective local clinical, commissioner or organisational management. In addition, lack of clarity about what action had been taken or lack of confidence in local systems to deal with genuine concerns about a doctor mean that relatively low-key problems which might have been dealt with through local clinical management and disciplinary procedures are inappropriately referred to the GMC.

- 3.8 The reasons for these problems are complex and inter-related. For employers, the inheritance of a strong but diminishing historical ethos of self-regulation and clinical autonomy in medical professional culture means that there is at times a reluctance to engage with problems that have been seen as the responsibility of doctors to resolve between themselves. In some quarters, professional anxiety about taking the major step of referring a colleague to the GMC has discouraged some doctors from escalating concerns to the national professional regulator. A lack of mutual trust between clinicians, commissioners and managers has at times made it difficult for them to work together in the best interests of patients to tackle concerns. Shared clinical and managerial pride in the institutions or health economies that they work for, and a desire to preserve and enhance institutional reputations, mean that there is a risk of potential conflicts of interest in which it is seen to be damaging in the longer term directly and openly to address poor practice through referral to the regulator. In both the NHS and in the independent sector, the growth of patient choice in the provision of care will mean that organisations will seek to guard their public reputations all the more assiduously.
- 3.9 Greater public scrutiny, the implementation of clinical governance and clinical audit, a growing spirit of patient-centredness in medical professionalism, reforms initiated and implemented by the GMC itself, and increasing managerial, commissioner and organisational focus on the quality of clinical care have presented increasingly powerful countervailing forces to these drivers over the past decade. The NHS has worked hard to establish clinical governance structures and processes in primary, secondary and tertiary care settings, and this has delivered real improvements to the quality of patient care. However, much more needs to be done to support these positive trends and provide a framework through which they can facilitate fair and effective action to tackle concerns about medical practice at the local level. The measures set out in the Government's response to the recommendations of the Fifth Report of the Shipman Inquiry and the recommendations of the Ayling, Neale and Kerr/Haslam Inquiries, *Safeguarding Patients*, will further strengthen these trends. However, clear systems are not yet in place to support these positive trends through regulatory action and provide a framework for linking effective action at local and national levels.
- 3.10 These concerns and behaviours are not exclusive to the medical profession but are significantly more pronounced within it. Other regulators, particularly for those professions in which there are strong and long-standing professional cultures, do encounter similar issues. **The Government will continue to consult on whether similar measures are required for other professions, but, for now, will focus these additional local regulatory measures on the medical profession.**

- 3.11 **As part of the drive to ensure greater consistency of approach to the investigation of concerns about health professionals, the Government will ask the Council for Healthcare Regulatory Excellence (CHRE) to work with stakeholders to develop common protocols for investigation across all the regulators, with guidance to employers on when cases should be referred to the national professional regulator.** These protocols would apply not only to investigations by the regulators, but also to initial local investigations so that the findings of fact could then be relied upon by the regulators without having to duplicate the local investigation.

National solutions: changes to the GMC

- 3.12 This White Paper sets out measures that will begin to tackle these issues through changes to the professional regulators (Chapter 1) and the way in which fitness to practise cases are administered centrally (Chapter 4). Through measures that provide the GMC with full independence and through reforms to its fitness to practise procedures which provide further assurance of fair treatment and provide for effective remediation and rehabilitation, the barriers to appropriate referral of doctors to the GMC will be reduced. Growing professional confidence in the independence and even-handedness of the GMC, combined with the knowledge that colleagues will be fairly treated and properly supported with mentoring, retraining and rehabilitation if that is possible, should mean that both clinicians and employers will be more willing to refer cases to the professional regulator when that is appropriate. The Government's response to the Shipman Inquiry and other inquiries also sets out measures for further clarification of regulatory standards which should help to support a greater willingness to take appropriate regulatory action. The new guidance for referral to the national regulators that will be drawn up by CHRE (see Chapter 4) will also support these changes.

Local solutions: recent developments

- 3.13 In 1999, in *Supporting doctors, protecting patients: a consultation paper*, the Chief Medical Officer (CMO) for England stated that one of the key barriers to effective action being taken at a local level was the lack of a national approach to the local handling of doctors and dentists. The National Clinical Assessment Authority (now the National Clinical Assessment Service, NCAS, a part of the National Patient Safety Agency in England) was created in 2001 as a result and quickly made a sustained impact, whether advising on the early management of a case where suspension by the employer was being considered, or working closely with the NHS body on the handling of a complex case, or providing a thorough assessment of a doctor's performance and facilitating a practical approach to resolution.

- 3.14 The review of its first four years of operation shows that NCAS has increasingly gained the confidence of the NHS in England and referrals are rising steadily. The next barrier to be surmounted is the perception that, even if the performance problems can be correctly analysed and a remedial prescription agreed, there are still difficulties in delivering the remedial action and getting the doctor back to work. The recent work by NCAS, published in October 2006 as *Back on Track*, has signposted the practical steps that employers and commissioners can take to help doctors and dentists to return to safe practice following local or national performance procedures. It is also applicable to doctors who have taken a career break or worked for a time abroad.
- 3.15 In 2005 the Government replaced the much criticised HC(90)9 disciplinary arrangements in the NHS in England with the new disciplinary processes set out in *Maintaining high professional standards in the modern NHS*. This framework removed the distinction between personal and professional misconduct that had previously led to different disciplinary procedures depending on the nature of the allegation. All doctors and dentists employed in the NHS in England are now disciplined for misconduct under the same locally-based procedures as any other member of staff; provision is made for restricting the use of exclusion from work in cases where, previously, doctors had been suspended for long periods; advice from NCAS must be obtained; NHS employers are bound by the Employment Acts and Acas good practice. The new procedures for England were agreed with the British Medical Association (BMA) and NHS employers and include handling capability and health issues.
- 3.16 Arrangements for primary care are covered by the Performers List system. Primary care trusts (PCTs) in England have a range of disciplinary powers available to them to protect patients in cases where the competence or behaviour of individual contractors could put them at risk. These were introduced in 2001 in response to a series of high-profile cases which drew attention to the inadequacy of the existing procedures under the NHS tribunal system in England. In developing the new procedures, the Department of Health sought to ensure that:
- all doctors providing primary care services are featured on a list of practitioners held by the PCT;
 - PCTs could suspend doctors from the list promptly while investigating concerns about their practice; and
 - PCTs could remove doctors from their list.
- 3.17 These powers enable PCTs in England to act swiftly and decisively to avert harm to patients, while being fair to the doctor whose livelihood could be at stake. The procedures are less formal than previous arrangements. There is a right of appeal to the Family Health Services Appeal Authority in England. Dame Janet Smith, in her fifth report of the Shipman Inquiry, questioned whether PCTs were using their new powers effectively. **The Government will be reviewing the current Performers List arrangements in England to consider whether or not they are being used effectively. In particular, following the GMC's introduction of the GP register in April 2006, the Government will consider the regulatory burden of separate lists being held by each PCT.**

Local and regional solutions: GMC Affiliates and medical directors

3.18 The changes that have already taken place are, on their own, insufficient:

- Patients, doctors, commissioners and employers need clearer and more effective mechanisms to allow problems to be resolved locally if possible. Medical directors, clinical directors and NCAS already have important roles to play in the local management of doctors about whom there are concerns, but responsibilities are too often unclear and there is a risk that difficult cases are not promptly or effectively addressed as a result.
- Locally, commissioners, employers and medical directors may feel isolated and ill-equipped to tackle more complex and unusual concerns and are given little option but to refer these to the GMC.
- Patient, doctors, commissioners and employers need to feel confident that local arrangements are in place which are independent both of the institutional interest of the organisation concerned and the normally desirable and valuable professional loyalties within clinical teams.
- The long delays involved in the referral of a doctor to the GMC mean that one-off or relatively low-level concerns take too long to address, causing unnecessary delays for patients seeking explanations and apologies, unwarrantedly lengthy periods of anguish and anxiety for the doctor concerned and duplication of investigations by the GMC which have already been carried out locally.
- There is currently no mechanism by which a complainant can meet with the doctor concerned to seek a prompt local explanation or resolution of concerns following local investigation.
- Mechanisms for sharing information about doctors whose practice has been found wanting or raised concerns are not in place, so patterns across time and different localities are not picked up. *Good doctors, safer patients* proposed the introduction of a system of 'recorded concerns' which would address this issue. The recorded concern would be a written agreement with the doctor setting out the agreed understanding of the nature of any incidents that had occurred and the nature of the concern in terms of any future restrictions on the doctor's practice or conduct, and any actions that it is agreed the parties should take to remove the cause of the concern and to prevent recurrences. (Recorded concerns are discussed in greater depth at paragraphs 3.40 to 3.46 below.)

- 3.19 One key strand of action to address these issues is continued work to strengthen clinical governance, and the Government's response to the recommendations of the Fifth Report of the Shipman Inquiry and the recommendations of the Ayling, Neale and Kerr/Haslam Inquiries, *Safeguarding Patients*, sets out a programme of action to do so. This includes a range of measures to strengthen the systems for the prevention, identification and management of those rare cases in which malice in individual health professionals betrays patient trust and lets down fellow professionals. The core purpose is to build on and strengthen the existing clinical governance processes in healthcare organisations, in particular by:
- supporting those who want to register complaints or concerns and ensuring that these are taken seriously, with further investigation whenever the safety of patients or the public is potentially at risk;
 - making more systematic use of the clinical outcomes data relating to individual teams or practitioners;
 - ensuring that information from different sources is brought together and, where appropriate and subject to strict safeguards, shared between healthcare organisations and with the GMC Affiliate (see para 3.20 below); and
 - requiring all primary care organisations to adopt best practice in separating the investigation of potential abuse or poor performance from the formal decision-making processes to determine the steps needed to protect patients.
- 3.20 *Good doctors, safer patients* set out proposals for bridging the gap between the local and national regulation of doctors through a network of GMC Affiliates. This was envisaged as a role whereby practising doctors, employed, trained and accredited by the GMC, would act on behalf of the national professional regulator, and with local employers and commissioners, from within local organisations. In the CMO's original proposals, they would be partnered with lay associates to ensure a robust patient perspective; they would have strong links to local intelligence about the practice of their colleagues; expertise in the prompt local investigation and resolution of complaints; the ability to share information appropriately across organisational boundaries; the responsibility to meet directly with patients who had concerns; accountability independent of the local organisations; and an important role in assuring the ongoing fitness to practise of the medical employees and contractors with whom they worked.
- 3.21 The Government agrees with the underlying philosophy and the key aims and objectives of the model proposed in *Good doctors, safer patients*. The CMO for England set out a compelling diagnosis of the problems of local regulation and the types of responses needed to address them. As he pointed out in his report, the evidence base for local regulation is underdeveloped, both domestically and internationally, and there are few tried and tested models, so his proposals would need to be refined further and adapted through discussion with stakeholders and through piloting of implementation.

- 3.22 The key issues raised in consultation were, first, the logistical limits on the pace and scale of implementation; second, whether the scale of investment implied by the proposals was proportionate to the benefits they would secure; and, third, whether the proposed model could be applied appropriately to Scotland, Wales and Northern Ireland.
- 3.23 Further work on modelling the costs of the Affiliate role was carried out during the consultation period. Under the proposals initially set out by the CMO, a national network of about 450 medically qualified Affiliates, working full time with support from lay Affiliates, would be likely to cost in the region of £43 million a year in England. If the affiliate role were to be performed in three sessions each week, the costs would fall proportionately to approximately £13 million. While large institutions were confident that there were practitioners of sufficient standing and experience to fulfil the role, concerns were expressed by primary care organisations, smaller institutions and the independent sector about their ability to do so. Many expressed a preference for the medical director, perhaps with wider support and enhanced accountabilities, to take on many of the roles envisaged for the GMC Affiliate.
- 3.24 Based on figures from the GMC on the number of cases referred to them, NCAS's annual referral rate of 600 doctors each year and the international estimates of a 5% prevalence of hospital doctors with significant performance or conduct problems over five years, this would mean that each year there would be a potential caseload across England of perhaps 4,000 doctors for whom early intervention without further action was sufficient to address concerns, 1,200 doctors for whom a recorded concern might be appropriate and 380 doctors who might need to be referred to the GMC. In England, at SHA level the equivalent would be 400, 120 and 38 respectively. At PCT level, the figures would be 25, 7 and 2.
- 3.25 In Scotland, Wales and Northern Ireland, smaller populations mean that the numbers are proportionately smaller. For example, in Scotland in 2005, around 300 complaints about doctors were received. In the consultation, respondents in Scotland, Wales and Northern Ireland expressed concerns about whether the arrangements proposed would work effectively within the different healthcare arrangements in different parts of the United Kingdom. Others expressed concerns that the role of the GMC Affiliate may sit uneasily locally alongside established systems of local clinical governance and employers' existing disciplinary powers.

Organisation of GMC Affiliates system

- 3.26 While the Department accepts some of these concerns, there remains the need to ensure that:
- there are prompt and direct local responses to patient concerns and complaints;

- there are local powers under GMC auspices for a system of recorded concerns to provide alternatives to national fitness to practise procedures, ensure tracking of patterns of behaviour across time and organisations and to enable more proportionate responses to lower-level concerns about a doctor's conduct or practice;
- there is greater independence from local institutional and professional interests so that both patients and doctors can be confident of the fairness of any investigation or disciplinary actions;
- an independent and impartial decision can be made on whether further action should be taken on local 'soft' information and intelligence about professional and patient concerns and complaints about doctors;
- there is a more local resource providing expertise and advice for local employers and medical directors when dealing with difficult and complex cases; and
- there is a more direct connection between local employers and the national professional regulator to ensure that concerns about doctors are addressed effectively in the right place and at the right time. The work led by CHRE on common protocols for investigation and on guidelines as to when cases should be referred to national regulators will assist in this process.

3.27 The Government believes the model set out in *Good doctors, safer patients* would effectively deliver these aims in the NHS in England, but accepts that the level of investment needed to establish such a system is significant, and that the practicalities of the approach need to be piloted first to learn the most effective means of delivering the aims of the GMC Affiliate model.

3.28 This change is intended to complement, rather than remove, the responsibility of employers for the discipline of their staff. Discipline in this context covers all the arrangements for ensuring that staff are fit for purpose and trained to do the job for which they are employed; not just the imposition of sanctions or termination of contracts. Similarly, the Government does not wish to weaken the responsibilities given to primary care organisations under the Performers List system.

3.29 There are, however, enduring weaknesses in the current local arrangements for addressing significant concerns about doctors. The key personnel involved in these matters in the hospital setting are the medical director and clinical directors. Under *Maintaining high professional standards in the modern NHS*, separate roles have been allotted to case management and investigation, and the framework stresses the importance of properly training people for the roles they are expected to play. However, there is no standard against which to judge whether people have reached the right level of competence in a role that they are unlikely to exercise frequently.

- 3.30 The GMC and other professional regulators increasingly rely on the investigatory work of employers when making decisions about the fitness to practise of individuals whose cases have been referred to them. It is therefore important that the investigations carried out by the employer and by the regulator are undertaken to the same high standard, not only in the interests of fairness to the practitioner but also to the individual complainant, especially when this is a patient or a patient's relative.
- 3.31 **As a first stage, the Government will seek parliamentary approval to establish a UK network of GMC Affiliates at regional level in England and at a national level in Scotland, Wales and Northern Ireland. In England, the Affiliates will cover areas that are coterminous with strategic health authority (SHA) boundaries. The Government will pilot these approaches at different levels of engagement within this prior to full-scale rollout. The Government will seek parliamentary approval at the earliest opportunity to enable the implementation of a system of GMC Affiliates, informed by piloting and local or national considerations.** The proposals will be piloted in England prior to consideration of their introduction in Scotland, Wales and Northern Ireland.
- 3.32 Appointed by, and accountable to, the GMC, the GMC Affiliates will lead and establish devolved GMC offices in England and work within existing structures in Scotland, Wales and Northern Ireland. In England, they will lead regional medical regulation support teams, including the SHA director of public health, the SHA clinical governance lead and workforce director, the NCAS, the Healthcare Commission (or its successor), the GMC's postgraduate dean, provider representation and four lay GMC Affiliates. In Scotland, Wales and Northern Ireland, the arrangements will be considered in the light of piloting in England.
- 3.33 Advised and assisted by the regional medical regulation support teams, in England the GMC Affiliates would carry out the following roles:
- providing advice, support and guidance to local employers, NHS organisations and medical directors (or equivalent roles) on local investigations and action to address concerns about doctors;
 - monitoring the investigatory work of healthcare organisations and assuring the quality of those who take part in case management, investigation and decision making at local level;
 - in England, leading a regional network of medical directors and their equivalents;
 - working with a small team of lay GMC Affiliates who would assist and advise clusters of employers within the region, ensuring that local investigation, disciplinary and regulatory actions are carried out in a way that is independent of any conflicting institutional or professional interests;

- assisting employers, commissioners and medical directors and other relevant individuals and organisations in agreeing, developing and delivering packages of assessment, treatment, rehabilitation, remediation, retraining or supervised practice for doctors who either need assistance in preventing emerging difficulties from becoming regulatory matters or who need support or rehabilitation to assist a possible return to practice following regulatory intervention, involving the NCAS where appropriate;
- assisting employers and medical directors in identifying individuals outside their organisation who are capable of carrying out independent investigations, by drawing on their regional network, with oversight from the lay Affiliates;
- issuing recorded concerns about doctors, based on local investigations and taking into account the recommendations of the local medical director and the relevant lay Affiliate;
- in England, through proportionate risk-based and random sampling of local relicensing procedures, providing independent assurance that these are fit for purpose; and
- through the production of an annual report, ensuring that organisational and individual lessons are learned from local cases and disseminated throughout the healthcare system and between regional networks.

3.34 NCAS has already developed significant expertise in supporting local employers in handling such issues and will need to be closely involved in the design and delivery of the Affiliate role in England. The Department will discuss with NCAS, the GMC and other stakeholders arrangements that avoid duplication of effort and provide integrated support to employers.

The role of medical directors

3.35 **These changes mean that medical directors, and others in similar roles, will generally take on the roles originally envisaged for more local GMC Affiliates in *Good doctors, safer patients*.** In England, all practising doctors on the medical register **will relate formally to a responsible officer who will either be the organisation’s medical director or a responsible officer designated by the organisation for which they work or provide services. In other cases the GMC Affiliate will assign a responsible officer in the region to carry out the role for doctors.**

3.36 For those who take on this new role for medical directors and their equivalents in other organisations, this is a significant extension of their authority, responsibility and workload. In addition to managing the interface between employers and the regulator in addressing concerns about doctors, it is envisaged that they will oversee local revalidation processes and be a clearer and more effective focal point for holding and sharing information on complaints and concerns about doctors. The medical director would also need to work closely with the accountable officer for controlled drugs. This interface will be agreed in discussion with stakeholders to ensure that it is appropriate to different health service structures within England, Scotland, Wales and Northern Ireland and to ensure that it is compatible with the circumstances of those who work outside the NHS.

- 3.37 The Devolved Administrations will consider arrangements to ensure that there are appropriate roles and accountabilities in keeping with their healthcare systems. In England, for this new approach to function with public confidence, there is a need to clarify the personal accountability of medical directors for the standards of performance of the medical staff working in or contracted with their organisations. **The Department will lead a project to establish more explicit competencies for the role of medical directors in England as well as measures to enhance their direct accountability to boards for actions that relate to their new responsibilities and powers for regulation and revalidation. This will include consideration of whether responsible officers should have a personal statutory accountability for handling performance issues. It is envisaged that in order to be approved as the responsible officer by the regional GMC Affiliate, they will need to demonstrate that they are able to meet a set of agreed competencies; are registered doctors; are properly resourced to carry out their functions; and have appropriate accountability to their boards for the exercise of their regulatory responsibilities. Responsible officers, including those who are medical directors, will be able to require doctors to attend meetings to resolve patient complaints.**
- 3.38 In England, while the role of medical director is well established in both NHS and independent sector secondary care organisations, the picture is more varied in primary care. In Scotland, each NHS board has a medical director who sits on the board, and in Wales there are medical directors on local health boards. **In future, in England, all PCTs will be expected to have in place, at board level, a responsible officer who meets the criteria set out above.** The Department will discuss this further with stakeholders in the NHS and elsewhere.
- 3.39 Doctors practise in a wide variety of settings outside hospital and primary care settings. Some are engaged in wholly independent private practice. Others are employed by research and pharmaceutical companies. Many spend some time in their careers engaged in humanitarian work overseas. In order for them to be able to participate fully in revalidation and in order for there to be a proper framework of regulatory oversight and assistance for their practice, even if they have no clinical responsibilities, it is important that systems are in place which enable them to relate formally to a responsible officer. Where organisations are unable to meet the criteria for designating their own responsible officer or medical director, the relevant GMC Affiliate will assign an appropriate responsible officer from the regional network of medical directors and responsible officers. Generally, this will be the responsible officer for the primary care organisation in whose area the doctor lives or works, whichever is more appropriate.

Recorded concerns

- 3.40 *Good doctors, safer patients* proposed a new measure, recorded concerns, for the local regulation of concerns about doctors' conduct or practice. The measure serves a number of important functions in the English healthcare context. In developing this proposal further, the Department will discuss with the Devolved Administrations how this approach could be adapted for their health economies. This will be considered in the light of English experiences with the piloting of GMC Affiliates.
- 3.41 In England, recorded concerns could serve a number of important functions. They would enable:
- proportionate action to address concerns about doctors;
 - more responsive and timely resolution of issues closer to the workplace;
 - any regulatory action to be allied with that of an employer or contracting organisation;
 - significant incidents in a doctor's career to be tracked over time and across different institutions to identify patterns of behaviour that may require further investigation;
 - patients who complain about significant issues that do not merit statutory UK professional regulatory action at a central level to see that the problem has been taken seriously and that the doctor has not simply been 'let off'; and
 - commissioners and local employers in England, working with the GMC Affiliate, to agree a clear and formal signal to doctors that there are significant issues about their practice or behaviour, allowing lower-level problems to be addressed early before they can develop into behaviour or practice that might later require full regulatory action at a national level.
- 3.42 The CMO proposed that the GMC would have a committee that met regularly to review recorded concerns, first to establish whether these demonstrate patterns of behaviour requiring further investigation and second to ensure, through sampling, that the issuing of recorded concerns has been proportionate to the results of local investigations and that doctors have not been dealt with unduly leniently.
- 3.43 Arrangements would be put in place for recorded concerns to be removed from a doctor's GMC records in appropriate circumstances; for example, where an issue of professional performance has been addressed and the doctor is now fully capable of meeting a competency that he/she previously lacked. The Department will discuss with key stakeholders what might be the appropriate method for publication of recorded concerns that remain current.

- 3.44 Doctors would be able to block the issue of a recorded concern by indicating that they would prefer their case to be taken to the GMC for further investigation. If they do so, they will open themselves up, potentially, to the sanctions that can be imposed centrally, which include formal warnings, conditional registration and suspension, so arrangements will be put in place to ensure that central referral is not undertaken inappropriately, even in cases where the issue of a recorded concern is in dispute. To operate fairly for both doctors and patients, there will need to be clear procedures for the administration of recorded concerns, specifying the circumstances in which they are appropriate and those in which referral to the national professional regulatory processes would be more appropriate. Recorded concerns would be issued only after proper and independent investigation under the common protocols that are to be developed by CHRE and under the authority of the GMC Affiliate.
- 3.45 **The Department agrees with the proposals set out in *Good doctors, safer patients for recorded concerns*.** There are important legal issues to be addressed to ensure that they work effectively and fairly and further discussion will be needed to ensure that they mesh appropriately with employers' existing disciplinary arrangements.
- 3.46 **The Department will discuss with key stakeholders from across the UK how to frame detailed proposals on the practical implementation of the new system of GMC Affiliates and recorded concerns, through a piloted approach in England, with Devolved Administrations considering local arrangements in the light of learning from these pilots.** The Department will invite stakeholders covering appropriate UK interests to participate in these discussions, agreeing membership in consultation with Scotland, Wales and Northern Ireland.

Locums

- 3.47 *Good doctors, safer patients* proposed a number of measures to provide greater assurance of the quality of medical locums. Locum doctors and other health professionals provided by agencies perform an invaluable role in both the NHS and the independent sector. The agencies that provide these staff often have processes in place to ensure that they are recruiting good quality staff; that their performance is monitored and reviewed; and that they have an appropriate level of support. However, this is not always the case and healthcare providers and patients have the right to expect agencies, and the staff they supply, to meet certain standards. Agencies, like any other employer, also have the duty to address any poor performance exhibited by their employees and to take steps to address such performance, including, where necessary, raising this with the relevant regulatory body.

3.48 Nursing agencies are already registered and inspected by the Commission for Social Care Inspection, which ensures that an agency is run by a fit person and has appropriate checks and processes in place. In addition, agencies that supply health professionals to the NHS under the NHS Purchasing and Supplies Agency framework agreements are regularly audited. These audits cover areas such as employment procedures and training. On the basis of these existing safeguards, **the Department will consider, with stakeholders, the regulatory and other impacts of developing a more effective system of registration and inspection for agencies providing health professionals. This work will include a review of the practicalities of the CMO's recommendation that local services should provide simple exit reports for medical locums, and whether these arrangements are appropriate to other health professionals who work as locums. The Devolved Administrations will consider these issues in the context of their own regulatory frameworks.**

Chapter 4: Tackling concerns: the national role

Introduction

- 4.1 Chapter 3 set out proposals for improving the investigation of concerns about health professionals at local level and additional arrangements for assuring confidence in medical practice in particular. This chapter sets out proposals for improving the way concerns about health professionals are managed nationally.
- 4.2 There are three key components to these proposals:
- first, a move to a common standard of proof across all professions;
 - second, extending the range of actions available to regulators when they have identified concerns, so that, where appropriate, the options of rehabilitation, remediation and retraining are more readily available; and
 - third, changes to the way in which judgements are made about a health professional's fitness to practise, often referred to as 'adjudication'.

The standard of proof

- 4.3 One of the key recommendations made by the Chief Medical Officer (CMO) in *Good doctors, safer patients* was that in adjudicating on concerns about a doctor's performance, health or conduct, panels should use the civil rather than the criminal standard of proof. 'The regulation of the non-medical healthcare professions' recommended that a common standard of proof should apply consistently across all the health professions.
- 4.4 The difference between the two standards of proof is not always well understood. The standard of proof itself refers to the level of certainty that must be achieved in order to prove disputed facts and is applied only in determining whether or not alleged facts are found proven. In law, the standard of proof has two forms, the criminal and the civil.
- 4.5 The **criminal standard** of proof requires that panels assessing facts about health professionals must be wholly convinced that the facts are fully proven, beyond any reasonable doubt, or they must find in favour of the health professional.

- 4.6 The **civil standard** of proof, in contrast to the criminal standard, is not, in this context, a single inflexible standard to be applied in all cases. Generally, the civil standard requires that the facts are judged more likely than not to be true (known as ‘the balance of probabilities’). However, the civil standard of proof can be flexibly applied to take into account the circumstances and gravity of individual cases, with more serious matters requiring a greater degree of probability of the evidence being true. There is clear legal authority that, in cases of sufficient gravity, the flexibly applied civil standard, sometimes referred to as the sliding civil standard, is virtually indistinguishable from the criminal standard. This is most likely to be applied to cases that are of sufficient gravity that a health professional might lose his or her livelihood.

Table 4.1: The standard of proof used by the professional regulators

Regulatory body	Standard of proof used
General Medical Council	Criminal
General Optical Council	Criminal
Nursing and Midwifery Council	Criminal
General Chiropractic Council	Civil
General Dental Council	Civil
General Osteopathic Council	Civil
Health Professions Council	Civil
Royal Pharmaceutical Society of Great Britain	Civil
Pharmaceutical Society of Northern Ireland	Civil

- 4.7 The sliding civil scale is already used by the substantial majority of health regulators. It ensures that appropriate weight can be given to the serious implications for health professionals involved in fitness to practise proceedings, which could in some cases result in erasure from a professional register and consequent loss of livelihood in that particular sphere of employment. The sliding civil scale is the standard of proof adopted during child protection cases where decisions are taken about permanently removing children from their parents for protection, and is the standard adopted by employment tribunals where decisions in respect of employees’ jobs and livelihoods are reviewed. The Nursing and Midwifery Council have supported the adoption of the sliding civil standard in their consultation response.
- 4.8 **The Government agrees with Dame Janet Smith and the CMO that the civil standard of proof, with its sliding scale, should be the common standard of proof for all the regulatory bodies in fitness to practise proceedings.**

- 4.9 Professional regulation is a protective jurisdiction which must put patient safety first. There is currently a perception, particularly in cases relating to doctors' fitness to practise, that the criminal standard of proof adopted by the General Medical Council's (GMC's) fitness to practise proceedings acts as a bar or an impediment to the referral of complaints to the GMC. It is considered that this results in a culture of hesitancy and reluctance to refer cases to the GMC, which currently gives rise to delay and inaction in dealing with cases where doctors are causing concern. The perception that it is not worth taking action due to the perceived difficulties in proving allegations to the required standard of proof potentially weakens public confidence in the health regulators and threatens public health safety.
- 4.10 It is intended that the use of the sliding civil scale will go some way towards removing this perceived bar or impediment, thus encouraging the earlier referral of complaints and concerns to the regulator, which should result in earlier intervention for the health professional concerned and in increased patient safety.
- 4.11 This reform will reinforce the Government's policy of supporting health professionals where necessary with remedial and rehabilitative action at the earliest possible stage, following the identification of problems or the raising of concerns.
- 4.12 Some responses to consultation have suggested that this change would force health professionals to practise more defensively, erring on the side of caution when faced with difficult judgements, through fear of being unfairly struck off as a result. This argument rests on the misapprehension that, under the criminal standard, professionals might choose more risky, but potentially more effective, clinical interventions. The Government does not believe that health professionals will behave in this manner as a result of this change and has confidence that their high professional standards and commitment to their patients would guard against such a risk. Where there is doubt, uncertainty or significant risk in making such judgements, health professionals, usually working within a team of other professionals, would generally make such decisions in consultation with their colleagues to ensure a consensus of expert opinion and agreement. In addition, where significant doubt or concerns remain about a procedure, intervention or prescription, clinicians are professionally obliged to obtain informed consent from their patients, after properly explaining the potential risks, benefits and uncertainty about their proposed course of action.
- 4.13 In emergencies, such an approach may not be possible and the judgement of the individual clinician in such a situation will be paramount. Even so, health professionals should remain, through continued professional education and revalidation, competent to make good clinical judgements under the pressure of emergency circumstances. In circumstances where health professionals are unable to secure consent or consult with colleagues, regulators and panels would take this into account in considering whether the conduct of the health professional was appropriate in that context.

Initial proceedings

- 4.14 The Shipman Inquiry expressed concerns that, in initial investigation and screening of complaints and referrals, the GMC's current processes might result in some cases being abandoned, even where there was genuine cause for concern, rather than being taken forward to adjudication. **The Government will consult with the professional regulators with a view to ensuring the recommendations of the inquiry are fully reflected in their processes, protecting the interests of patients and the public.** In addition, *Good doctors, safer patients* proposed that the Healthcare Commission and the Parliamentary and Health Service Ombudsman should have powers, in exceptional circumstances, to conduct their own prosecutions of cases involving doctors. In consultation, responses focused on:
- the need to preserve the integrity and consistency of a single prosecutor;
 - concerns about adding another resource-intensive function to the Healthcare Commission and the Parliamentary and Health Service Ombudsman, which might distract from their core missions;
 - the need to ensure that all cases were prosecuted by an organisation with sufficient caseload and experience to bring forward cases successfully;
 - the desirability of a consistent approach across all the regulatory bodies; and
 - the desire for as light-touch regulation as possible.
- 4.15 The GMC has recently agreed a memorandum of understanding with the Healthcare Commission on such cases. **The Government will discuss with the Devolved Administrations, the Parliamentary and Health Service Ombudsman, the Healthcare Commission and the Council for Healthcare Regulatory Excellence (CHRE) what further arrangements would be appropriate to provide additional safeguards.** This will include consideration of whether a common memorandum of understanding covering all the healthcare professions would be desirable and whether this should apply across the United Kingdom. The Government will discuss with the Devolved Administrations whether these arrangements should include those professions for whom professional regulation is a devolved matter.
- 4.16 **In addition, for all the professional regulators, the Government will ask CHRE to review a sample of cases that the regulators have not taken to full fitness to practise panels. The Government will consider whether CHRE has the necessary powers to review the different fitness to practise cases, both their processes and application. CHRE will report annually to Parliament on whether patient safety interests have been properly considered in the decisions and operations of the regulators on fitness to practise cases.** These reviews will be informed by the more explicit standards for continuing fitness to practise that will be developed to support revalidation (see Chapter 2).

- 4.17 **To ensure greater consistency of approach to the investigation of concerns about health professionals, the Government will ask CHRE to work with stakeholders to develop common protocols for investigation across all the regulators and provide guidance to employers on when cases should be referred to the national professional regulator.** This will help to ensure that investigations at local level are conducted to a standard that avoids multiple investigations at local and national level.

Clinical assessment

- 4.18 **For doctors and dentists in England, where the GMC or the General Dental Council (GDC) is assessing a practitioner whose fitness to practise has been called into question, the Government agrees that they should make full appropriate use of the expertise of the National Clinical Assessment Service (NCAS). The Department of Health will work with the GMC, GDC, NCAS and others to agree criteria for identifying where such referrals would be appropriate and where existing reports should be relied upon.** This will enable the GMC and the GDC, as well as employers and contracting organisations, to make maximum use of the skills offered by NCAS, rather than duplicating particular aspects.
- 4.19 In consultation, some respondents argued for a more consistent approach to clinical assessment services for all health professionals, not just for doctors and dentists. While the Government believes that, for some health professionals, the substantial majority of such assessments are already successfully carried out by employers through existing professional and clinical management arrangements, it agrees that for other health professionals with advanced levels of practice, further support to employers and regulators is needed in conducting fair and thorough assessments of individual clinicians. NCAS is currently discussing with the Royal Pharmaceutical Society of Great Britain (RPSGB) whether similar arrangements would be cost-effective and proportionate for the assessment of pharmacists. **The Department will work with NCAS and with stakeholders to review the cost-effectiveness of extending its scope to other health professionals, as suggested by the Public Accounts Committee.**
- 4.20 In the meantime, a multi-agency working group set up by the Chief Nursing Officer in collaboration with NCAS and employers has developed a set of principles for handling concerns about professional performance. This document, published in September 2006, is intended for use in all healthcare settings and for all practitioners, and will help generate consistency and fairness for staff while maintaining patient safety.

Support and rehabilitation

- 4.21 Patient safety and the protection of the public must always be the paramount consideration of professional regulation. But for all health professionals, it is important that regulatory processes not only protect patients, but also have built-in mechanisms to help health professionals retain or regain their fitness to practise, when that is an appropriate and proportionate course of action. Processes need to be able to establish and help to tackle the root cause of poor performance, whether by identifying the need for professional training, or the need for medical help for mental ill health or addiction problems. In this way, fitness to practise investigations should act as a gateway to rehabilitation, where this is possible and realistic. The recent NCAS publication, *Back on Track*, sets out an important analysis of how doctors and dentists can be supported back into safe professional practice where appropriate.
- 4.22 **For doctors, the Government will ensure that the GMC can deliver this new emphasis on support and rehabilitation for doctors by requiring NCAS and the GMC to work together with employers to agree specific packages of rehabilitation and conditions on practice, following a comprehensive assessment, where fitness to practise has been called into question.** This may take place during the investigation stage, where agreement is reached between the GMC and the doctor concerned as part of 'consensual disposal', or following the determination of a fitness to practise hearing. In both cases, a comprehensive assessment of the practitioner will be required. In cases of consensual disposal, doctors will be referred to a fitness to practise panel where they are unco-operative or do not comply with the agreed conditions on practice.
- 4.23 One of the reasons why the focus of medical regulation has at times been perceived to be overly punitive and insufficiently rehabilitative in its approach is the reluctance of employers to allow doctors to return to work when they have referred them to the GMC, even when the GMC has judged that it is safe and appropriate for them to do so. It is important that there is a move away from a culture in which employers seek to shift to the GMC responsibility for doctors who cause concern. Employers will be expected to work more closely with the GMC and others to ensure that employees of low-level concern are given the help and support they need to get back on track through tailored rehabilitation that assures patient safety.
- 4.24 The Government's 2002 reforms gave the Investigation Committee of the GMC powers to agree actions with the doctor that would protect the public, and these powers have recently been augmented by the provisions of a 2006 Order which will come into force later this year. These sanctions include undertakings to comply with a wider range of practice conditions, rehabilitation and training programmes. Interim suspension will remain for the most urgent cases. Once these systems are established and used to full effect, it is anticipated that the number of cases reaching formal adjudication will fall. Serious impairment of fitness to practise that directly threatens patient safety would not fall within this approach and the Investigation Committee would still refer these to a fitness to practise panel hearing.

4.25 In general, where a doctor is employed, the expectation would be that the registrant would pay for any services or training that fell outside the normal healthcare, occupational health or training programmes provided by the NHS or other employer organisations, but employers would be expected to assist in identifying suitable placements and referrals. The Government will discuss the detailed arrangements with the GMC, NCAS, the profession and employers and will also examine whether professional indemnity insurance might be extended to address the costs of such packages.

Ill health

4.26 All employees, including health professionals, deserve sympathy and support if their personal health problems affect their performance or conduct. For health professionals in particular, additional levels of support are sometimes needed to ensure that they seek and receive the care that they require. This is for a number of reasons:

- they may be reluctant to use local services where they might come into contact with their patients or their work colleagues;
- there is, even among health professionals, significant stigma attached to some conditions such as problems of addiction, mental health or sexual ill-health – this can create barriers to seeking help, unless individuals are sure that their medical information will be kept confidential; and
- there may be a sense among some health professionals, particularly doctors, that they should not ‘let down’ their colleagues or patients by being unwell themselves.

4.27 The Government believes that, to ensure good employment practice and to help safeguard patients, further measures should be put in place to provide effective arrangements to support health professionals in maintaining their own health and in seeking confidential advice and treatment if they need it. To ensure the highest quality of care possible for patients, employers need to ensure that patients are treated by health professionals who are in good health themselves.

4.28 **To ensure an integrated, affordable and cost-effective approach to the health of health professionals, the Department will establish a wide-ranging and inclusive national advisory group to inform the development of a national strategy for health covering all health professionals.** Including a wide range of UK stakeholders, the group will advise on measures to ensure appropriate prevention and early intervention for health professionals; the role of health in revalidation arrangements; enabling easier and confidential uptake services; the roles and responsibilities of employers, regulators, professionals themselves and others in ensuring the health of professionals; and more effective arrangements for the rehabilitation of health professionals whose actions have led to regulatory involvement.

- 4.29 The advisory group will consider the piloting of referral services and the extent to which mainstream healthcare provision needs to be supplemented with specialised services for health professionals. The National Clinical Assessment Service will work with stakeholders to define a specification for a pilot service for practitioners with mental health or addiction problems which builds on existing good practice in the UK and abroad. This will be used to inform the work of the national advisory group. In developing the strategy, the Department of Health will work with the British Medical Association to develop specific proposals for addressing the particular health service needs of doctors.
- 4.30 The Government recognises the need to make local and national mental health and addiction services in particular more visible and to increase awareness of the availability of these services. The National Clinical Director for Mental Health will be publishing shortly a report with recommendations on these issues, *Mental Health and Illness in Doctors*. These recommendations will be considered as part of the work of the national advisory group.
- 4.31 The Devolved Administrations will consider whether they wish to participate in a UK-wide strategy or whether to develop approaches tailored to the circumstances of Scotland, Wales and Northern Ireland.

Adjudication

- 4.32 The separation of investigation, prosecution and adjudication is a fundamental principle of modern legal and judicial practice. The current arrangements for adjudication for the regulators of health professionals have been called into question in respect of this, particularly in the case of the medical profession. Dame Janet Smith's fifth report of the Shipman Inquiry recommended clearer separation of adjudication from the GMC's other functions.
- 4.33 The independence and impartiality of those who pass judgement on health professionals in fitness to practise proceedings is central to public and professional confidence in their findings and the sanctions that they impose. In the future, there must be no room for doubt that adjudication panels are compromised by partiality to the profession over which they pass judgement or that they are swayed by hostile media scrutiny.
- 4.34 A number of councils have already made changes that go some way to address these concerns, or are planning to do so. Since 2004, for example, GMC council members have not been allowed to sit on fitness to practise panels, in order to demonstrate the panel's independence. The Health Professions Council has taken similar action and the Nursing and Midwifery Council is currently working towards these changes as a public signal of the independence of their proceedings. **The Government believes that this principle should extend consistently across fitness to practise panels for all health professionals. Council members' sole function should be to act as strategic board members and they should not be engaged in operational matters where impartiality and independence are paramount.**

- 4.35 The Government has considered carefully the argument that all the professional regulatory bodies should have completely independent and separate adjudication arrangements through the establishment of an independent body. For doctors, the GMC has made significant changes to these procedures in recent years and fewer and fewer decisions are challenged successfully but, however fairly they operate in practice, it is critical that they are also perceived by all to be doing so fairly, and the constant scrutiny of the GMC on these issues risks undermining their progressive and patient-centred approach to their work elsewhere.
- 4.36 **For doctors, the Government agrees with Dame Janet Smith and with the CMO that the separation of investigation and prosecution from adjudication is essential to ensure complete public and professional confidence in the independence of the decisions made by the adjudicator. Working closely with the GMC, the Government will seek legislative agreement to establish an independent body to adjudicate on fitness to practise cases involving the medical profession. Doctors and the GMC (which is responsible for the integrity of the Register) will have the right of appeal against the decision of the independent body to the High Court or the Court of Session.** As part of its scrutiny function, CHRE will review the application of this new GMC right of appeal, reporting to Parliament on an annual basis.
- 4.37 **For all the other regulators, the Government will charge the new independent body with establishing a central list of vetted and approved potential panellists for all adjudication panels, chosen by the Appointments Commission for their expertise and specifically trained to undertake these duties in a fair and impartial manner. Regulatory bodies will be able to draw on this list in order to conduct independent adjudication panels within their own organisations.** Panels would need to include appropriate representation from the relevant profession to ensure the full professional context is available to panel members. **Over time, and in the light of the experiences of fully independent adjudication for the medical profession, other regulators may wish to adopt the independent body to provide further assurance of independence to the public.**

Fairness in fitness to practise – equality and diversity

4.38 In a diverse society in which healthcare is provided by professionals from a rich and invaluable mix of national, ethnic and religious backgrounds, it is critical that the regulation of health professionals is conducted in a manner that is fair, respectful, sensitive to diversity issues and free from discrimination. It is vital that fitness to practise proceedings are seen to be fair and impartial to all registrants. The forthcoming report from the CMO on race equality in the medical profession explores many of these issues in greater depth, but its principles extend to all health professionals. **As part of the accountability arrangements to Parliament, each regulator will be required, as part of its report to Parliament, to provide information on equality issues relevant to regulation within its profession; analyses of any trends in ethnicity in its fitness to practise proceedings; and an account of action taken to ensure fairness in the way that regulatory action is conducted.**

Chapter 5: Education: the role of the regulatory bodies

Introduction

- 5.1 Excellence in education is the foundation of professional excellence in healthcare. The educational process takes individual potential and an individual sense of vocation and, through learning, practice, reflection, supervision, mentoring and examination, builds expertise, confidence and capability, and imbues students and trainees with a set of professional values and standards that they are expected to meet or exceed throughout their careers. Education for health professionals in the United Kingdom is demanding and its exacting standards have been crucial in ensuring continuing high levels of public and patient confidence in the clinical practice of those who care for them.
- 5.2 The standards of conduct, ethics and clinical excellence set by the curricula for health professionals are therefore central to the regulation of health professionals. Only those who meet these standards can be registered with their regulator and, if the conduct or competence of professionals is called into question, their continuing fitness to practise is judged against those standards.
- 5.3 **The Government therefore agrees with the principle set out in ‘The regulation of the non-medical healthcare professions’ that the professional regulatory bodies should continue to be responsible for the assurance of educational standards in those professions. In doing so, the Government expects that the professional regulators will work collaboratively with the Sector Skills Council for Health.**

Medical education

- 5.4 *Good doctors, safer patients* questioned whether this principle should apply to the medical profession. Unlike the other health professions, medical education has been historically fragmented, with undergraduate education and continuing professional development currently overseen by the General Medical Council (GMC) and postgraduate education overseen by the Postgraduate Medical Education and Training Board (PMETB).

- 5.5 The Medical Act of 1983 makes clear that the Education Committee of the GMC has the general function of promoting high standards of medical education and co-ordinating all stages of medical education in the UK. The Order establishing the PMETB made clear that its functions were without prejudice to the responsibilities of the GMC.
- 5.6 Both the GMC and the PMETB have sought to work closely together on these issues, with reciprocal membership on their boards. The Government agrees that there are benefits to be secured through a more seamless and consistent approach to educational standards throughout doctors' careers. A single point of responsibility for medical education from admission to medical school through to postgraduate education and continuous learning until retirement would help to ensure consistency of expectations and uniformity of standards throughout doctors' working lives and provide a clearer and less complex framework for the relationship between individual doctors and the regulator. Increasingly, the acquisition of new skills and competencies will be a career-long responsibility that requires a seamless approach.
- 5.7 *Good doctors, safer patients* went on to recommend that this single point of responsibility should sit with the PMETB. In consultation, while there was support from respondents for a seamless oversight of medical education, doubts were expressed about the capacity of PMETB to take on these additional responsibilities and concerns were expressed about the need for the GMC to retain or strengthen its existing responsibilities on standard setting in order to ensure appropriate education of new registrants.
- 5.8 **The Government recognises the gains to be secured from single oversight of education, but believes that change should be introduced in such a way as to preserve the expertise and experience of the present organisations that undertake this role.** First, the wide-ranging reforms to the GMC set out in this White Paper in themselves will be a significant challenge for the regulator to manage while continuing to exercise its core functions. Second, PMETB is a relatively new organisation which, after a difficult start, is beginning to consolidate its performance. With PMETB engaged in a major programme of work – Modernising Medical Careers – it is important too that it also has a period of relative stability to enable it to focus on its core tasks.
- 5.9 **The Government agrees with the proposal, set out in the GMC's response to consultation, for a three-board model covering undergraduate education, postgraduate education and continuing professional development. The Department of Health will work with the GMC to establish an undergraduate board and a continuing professional development board in the GMC. The PMETB will continue as a separate legal entity, fulfilling the role of the postgraduate board within this three-board approach. Both organisations will continue to have a duty of co-operation.**

- 5.10 **The composition of the GMC Education Committee and the new boards will be reviewed to ensure the membership complements the new arrangements proposed for the GMC itself.** Given the interlocking nature of the GMC's four core functions, the council itself will assume statutory responsibility for the oversight of education. The Department will discuss detailed arrangements with the GMC, PMETB and other key stakeholders.
- 5.11 **The Government will review the effectiveness of these new arrangements in 2011 to establish whether any further integration of postgraduate medical education would be desirable.**
- 5.12 Concern was expressed during consultation about whether sufficient attention had been paid to continuing professional development. This White Paper sets out proposals (see Chapter 2) for the introduction of a new system of revalidation, whereby doctors and all health professionals will be required to demonstrate periodically that they continue to meet the standards expected by their patients and their professional colleagues. This will require a more rigorous approach to continuing professional development to support doctors in keeping their skills up to date and demonstrating objectively that they have done so. **In establishing the new board on continuing professional development, the Government will therefore ask the GMC to lead a consultation with key constituencies and stakeholders, including patients and the public, to consider what reforms are needed to the oversight of continuing professional development to support doctors in meeting the requirements of revalidation, and to make recommendations accordingly.**
- 5.13 Under these arrangements, the GMC will retain responsibility for the Professional Linguistics Assessment Board examination.

Effective regulation in a global economy

- 5.14 There are two critical elements to effective professional practice in healthcare. First, health professionals need to be able to meet and deliver every day the standards of conduct, ethics and clinical excellence that their professional education, personal vocation and clinical expertise demand. Second, as patients and their families repeat consistently, they need to be able to communicate effectively, clearly and sympathetically with the patients they care for, showing empathy and understanding, listening carefully and responding sensitively. In consultation, both healthcare professionals and patients have expressed significant concerns about the ability of some professionals, for whom English is a second language, and whether their linguistic ability with their patients and their colleagues is sufficiently strong to provide patient, public and professional assurance that they are delivering care to the standard that they themselves, their patients and their colleagues would wish.

- 5.15 From the perspective of patient safety and clinical effectiveness, it is imperative that health professionals working together in highly complex, specialised and pressurised environments understand each other clearly and quickly on issues such as diagnoses, drug names and drug doses. Even within clinical teams where there are very effective spoken and written communications, misunderstandings about these issues have led to avoidable death and disability for some patients and ‘near misses’ for others. This is not a concern solely about European Union (EU) nationals practising in the UK. Equally, the UK is keen to ensure, as the European Commission will wish to ensure, that doctors registered in the UK who seek employment in other member states do not put patients in those states at risk through misinterpretations and misunderstandings based on inadequate communication skills in the country and language in which they are practising. The emerging use of international telemedicine also requires careful consideration of possible misunderstandings or mistranslations that may endanger patient safety.
- 5.16 Just as importantly, professional practice in healthcare is not simply about technical, scientific and clinical competence, but about a relationship between the health professional and the patient in which mutual understanding and trust provide the foundation for effective healthcare. Healthcare is a relationship, dependent on good communications, not simply on the delivery of a procedure or a prescription to a passive recipient. It depends on patient consent to effective treatment based on a proper understanding of the clinical options. Those clinical options themselves depend on a proper understanding of the circumstances, aspirations and expectations of the patient.
- 5.17 Under current European law, the recognition of professional qualifications for the purposes of registration does not depend on other factors such as language or communication skills (except in relation to the language used to teach undergraduates). The European Commission accepts that people benefiting from recognition of their professional qualifications should have a knowledge of the languages necessary for practising the relevant profession in the member state to which they are moving, but not that these skills should be a prerequisite for registration. They argue it is the professional qualification that is registrable, not the practitioner’s linguistic knowledge. If that linguistic knowledge is to be assessed, it should be done after recognition of the qualification is granted. It would therefore be illegal to introduce a language test for EU nationals prior to registration to practise in the UK.
- 5.18 Language testing conducted after registration but prior to employment is permissible but has to be proportionate. The level of competence required would depend on the nature of the tasks to be performed. It would probably also be disproportionate to require people who have received all or part of their professional education in English to provide further evidence of linguistic competence, ruling out systematic testing of all applicants.

- 5.19 All employers must assure themselves that their professional employees have sufficient English-language skills for safe and effective care. **Given this context, the Department will ask the UK regulatory bodies to work with NHS employers to develop arrangements for selective language testing for applicants to posts, where appropriate.** The intention is for employers to have access to simple, standardised tests that can, if necessary, be customised to suit the local clinical context. In the case of European applicants, this would apply only where there are reasonable grounds for doubting language competence, for example because the applicant:
- has not qualified in an English-speaking environment;
 - has not previously practised professionally in the United Kingdom; or
 - has not demonstrated language competence in a written application or interview.
- 5.20 The Department will request that independent providers of healthcare in England conduct similar selective and proportionate testing of potential employees. The Devolved Administrations in Scotland, Wales and Northern Ireland will consider taking similar action to suit their requirements.

National examinations

- 5.21 *Good doctors, safer patients* raised the possibility of the introduction of a national examination prior to the initial registration of doctors with the GMC, while acknowledging that European law would prevent this being introduced in the case of European applicants. The Government will discuss this further with the GMC, who are considering a range of options.

Chapter 6: Information about health professionals

Introduction

- 6.1 The early professional registers were handwritten lists of names in leather-bound volumes. They were difficult to access, so it was hard for people to establish the professional credentials of the health professionals they encountered. Today, all the professional regulators have begun to exploit the power of modern communications and information technology to provide better and more easily accessible information to patients, the public, professionals and employers. This chapter sets out proposals for ensuring that the opportunities provided by these changes are maximised.
- 6.2 It also sets out proposals for ensuring that entry to the register is managed appropriately for patient safety and that the registers themselves provide information, with appropriate safeguards, to enhance patient safety.

Entry to and exit from the register

- 6.3 **Entry to the professional register depends ultimately on demonstrating fitness to practise by securing the educational qualifications and, in some cases, levels of competence, recognised by the relevant regulatory body. As ‘The regulation of the non-medical healthcare professions’ noted, however, the different regulatory bodies have similar, though not identical, requirements of people seeking new registration.** They require evidence that a new registrant is fit to practise, mostly in terms of health, character and training. In response to a government initiative, indemnity insurance is also becoming a requirement. The Government agrees that what is needed now is a further effort to identify a common approach to ‘good character’. **The Government will ask the Council for Healthcare Regulatory Excellence (CHRE) to recommend a single standard definition of good character, working with the regulatory bodies and encompassing wider work within Europe to promote information sharing on the good character of professionals who cross national borders.**

- 6.4 **The Government will also take forward the recommendation to ensure closer co-operation and co-ordination between regulators and employers when a health professional enters employment for the first time.** The differing but overlapping requirements of each can present a new entrant to the profession with a daunting and complex set of requirements; these need to be simplified and harmonised as far as possible. As 'The regulation of the non-medical healthcare professions' noted, the complexity stems in part from legal requirements on the regulators to collect information, and simplifying these arrangements represents a significant programme of work.
- 6.5 **The Department of Health will ask CHRE to lead a programme of work with regulators and employers from across the UK to investigate the feasibility and practicability of these proposals, reporting to ministers by April 2008.** This work should encompass recommendations on recording essential data about staff and ensuring that their registration, qualifications and other relevant issues are easily accessed by those with a legitimate interest in that information. As part of this work, CHRE will need to explore with the NHS 'Connecting for Health' programme, and equivalents in the Devolved Administrations, the potential for such a system to be encompassed within the electronic staff record for the NHS in England and the equivalents in the Devolved Administrations.

Student registration

- 6.6 **Both *Good doctors, safer patients* and 'The regulation of the non-medical healthcare professions' raised the issue of whether students and trainees should have closer relationships with their future regulators prior to qualification.** There was a range of views in consultation on this issue and there is no clear uniform solution across all professions. While many agreed that student registration would help to instil a clear sense of professional responsibilities at an early stage in practitioners' careers, there were mixed views on whether this would be proportionate for all professions. There may be other ways for students to achieve a greater understanding of the purpose of regulation, the procedures of the regulators and the role this will play in their professional careers. One option could be to require teaching on these issues in all pre-registration professional education and training.
- 6.7 **The Government believes that each regulator should consider this issue on the basis of the risk presented to patients by trainees and students in particular professions. The Department will ask the regulators to report back with proposals by January 2008.**

Information held on the medical register

6.8 The Shipman Inquiry proposed the establishment of a central database containing information about every doctor working in the UK. This would include information about the doctor's registration status, any disciplinary action taken by employers, adverse reports following complaints, and any findings of clinical negligence. The information would be accessible to offices of NHS bodies, accredited private employers and regulators. **The Government agrees with the Shipman Inquiry and the Chief Medical Officer (CMO) for England's key proposals for changes to the medical register. The medical register should be the key national list of doctors entitled to practise in the UK** and should fulfil the overarching functions proposed by Dame Janet Smith in the Shipman Inquiry. The GMC now publishes a List of Registered Medical Practitioners, which is available on the GMC's website or accessible by telephone or written enquiry by any member of the public. The publicly available list gives details of:

- a doctor's reference number, name, any former name, and sex;
- the year and place of their primary medical degree;
- their registration status – full or provisional, suspensions, warning or conditions imposed;
- the date of registration;
- whether they are on the general practice or specialist register; and
- all publicly available fitness to practise history since 20 October 2005.

6.9 The GMC makes further information available to prospective employers and primary care organisations to enable them to make pre-employment checks. The dedicated employer enquiry point allows the following questions to be answered:

- Is the doctor registered to practise in the United Kingdom?
- Has the GMC placed any restrictions or conditions on the doctor's practice?
- Does the doctor's reference tally with the information the applicant has provided?
- Can the employer can be confident of the doctor's identity?
- Is the doctor on the appropriate specialist or general practice register for the post to which they are applying?

- 6.10 **The Department will discuss with the GMC and stakeholders, including employers and the British Medical Association (BMA), how the register will be further developed to become the single authoritative source of information on doctors, including disciplinary action by employers and alert notices.** As part of the review of the Performers List system in England, the Department will consider what information about GPs and the primary organisation in which they practise could be held centrally. This will seek to simplify the checking processes that employers must undertake before doctors are employed or authorised to provide primary care in the NHS. It will also seek to ensure that the maximum amount of information about registered doctors that is reasonable and consistent with the fair treatment of professionals is made available to the public. The Government supports the concept of a tiered approach, with appropriate levels of access to the public, professionals and employers, as recommended by the CMO and Dame Janet Smith, and this will be discussed with stakeholders, building on the work already initiated by the GMC. The database will use the unique seven-digit reference number identifier for each doctor registered with the GMC. Subject to the requirements of human rights law, this will seek to include full demographic information, information on current recorded concerns and other significant information on each doctor's sphere of practice.
- 6.11 Other professional regulators will wish to consider whether similar arrangements would be appropriate and proportionate and provide better information to the public. **The Government agrees with the recommendation in 'The regulation of the non-medical healthcare professions' that, for the non-medical health professions, post-registration qualifications should be recorded in the register where these are relevant to patient care, risk management and are at a level substantially beyond the requirements for basic registration. In reviewing such arrangements, the Department of Health will ask the regulators what other changes could be made to provide better information for patients, the public and employers.**
- 6.12 Post-registration qualifications may fall into a number of categories:
- additional training resulting in a further award that adds to an individual's professional practice, experience and career development: these qualifications may be taken as part of continuing professional development (sometimes encouraged by the professional bodies), at the behest of the employer or through the personal choice of the individual. These can be seen as part of normal career enhancement and may not always directly change the scope of practice, but simply widen the knowledge and skill that a professional will bring to their role;
 - those that can currently be recorded by the Health Professions Council and the Nursing and Midwifery Council as marks on the register, such as supplementary prescribing. These identify that an individual has obtained a further qualification currently approved by the regulator, which may be referred to in legislation as a requirement prior to undertaking a specific activity; and

- existing specialist qualifications undertaken by a variety of professionals, and directly related to the ability to practise at a significant level. This is usually identified at level 9 on the Skills for Health Career Framework, although sometimes at level 8. Currently, not all regulators record this award.

Soft intelligence and hard information

- 6.13 While the proposed changes to the professional registers set out in this chapter will provide better information to the public and to employers about health professionals registered in the UK, there remains a dilemma about the extent to which information about health professionals held at local level should be shared at a national level. Issues of fairness and confidentiality need to be balanced against the need for proper safeguards of patient safety, allowing appropriate action to be taken.
- 6.14 No one believes that professional livelihoods should be threatened by malicious local gossip. Equally, everyone is concerned when it emerges that problems with a health professional were local common knowledge and no one took action. Recent inquiries have demonstrated too often how local concerns were not pursued with proportionate action.
- 6.15 Furthermore, when a health professional whose practice has been called into question moves elsewhere while investigation is still under way, perhaps to avoid that investigation, it is important for patient safety that potential employers elsewhere are aware that this is the case. The management of such information through the alert notice system in England and its relationship to the Performers Lists and the professional registers is complex, but it is clear that employers, NHS organisations and regulators need better systems for sharing information in ways that respect the reputations of individual professionals while, above all, protecting patients. **The Department will work with the Devolved Administrations, CHRE, the regulators, the professions, employers, the National Clinical Assessment Service, the public and patients to draw up protocols and systems for managing this information effectively, taking into account recommendation 35 of the Shipman Inquiry on the handling of such information.** This is discussed in greater depth in Chapter 8 of the Government's response to the recommendations of the Fifth Report of the Shipman Inquiry, and the recommendations of the Ayling, Neale and Kerr/Haslam Inquiries, *Safeguarding Patients*.

Chapter 7: New roles and emerging professions

Introduction

- 7.1 Previous chapters reviewed the existing systems of professional regulation and set out plans for a fair, robust and effective system for the future. It is important that the scope of statutory regulation itself is considered. Some existing professionals who are not statutorily regulated have been in practice with patients for many years; practice that carries at least the same potential risk to people who use their services as that of the statutorily regulated professions. **The Government believes that these professionals should also be subject to a system of regulation that is proportionate to the risks and benefits entailed.**

Existing professions

- 7.2 **The Government is planning to introduce statutory regulation for applied psychologists, healthcare scientists, psychotherapists and counsellors and other psychological therapists. These are the priorities for the introduction of statutory regulation,** because their practice is well established and widespread in the delivery of services, and what they do carries significant risk to patients and the public if poorly done. Further work is needed on these areas and the Government intends to continue with it.
- 7.3 There are other professions, currently unregulated, that aspire to statutory regulation. Some have developed over time but have not yet been regulated, such as play therapists; others have been recently established in response to developing Government policy, such as health trainers. We have established a working group chaired by Professor Mike Pittilo to look at the practicalities of regulation of acupuncturists, herbal medicine practitioners and traditional Chinese medicine practitioners. We are awaiting the working group's report and in the light of that we will consider next steps for the way forward.
- 7.4 In Scotland, the regulation of these new professions is a matter for the Devolved Administration.

Emerging professions

- 7.5 The healthcare professions continue to change and evolve as new clinical capabilities develop and as new ways of providing healthcare change the settings in which it is delivered and the professions which deliver it. There are emerging professions which may develop out of a function carried out by a number of existing professionals, such as sonographers or genetic counsellors. In these cases a decision has to be made as to whether these should be stand-alone professions attracting direct entrants with no previous healthcare professional background. If so, statutory regulation may be necessary.
- 7.6 On the other hand, it may be that demand for these functions will be met primarily through post-registration training for members of existing professions. If so, the Department of Health will discuss with stakeholders in England whether collaborative working between regulators could ensure that all staff engaged in this work do so to the same standard, regardless of professional background, and who should regulate them. Any such standard might be recognised by recording a common post-registration qualification. This would fall into the second category of the specialist post-registration qualifications mentioned in Chapter 6.
- 7.7 There are also new roles being developed and piloted with a view to enriching the skills mix and reinforcing the capacity of the workforce to deliver timely, high-quality services. In England, these include those staff using the working titles of anaesthesia practitioner, surgical care practitioner and other similar roles. The nature of the work undertaken in these roles and the level at which it is undertaken are identical to that done by existing regulated professionals, so it would be hard to argue that the eventual agreed role or roles should not be subject to statutory regulation as a new profession or professions in their own right. The Government will consider extending statutory regulation to these roles when they are agreed as fit for purpose. This will include an assessment of whether they can or should be merged to form more generic roles, and whether there is sufficient demand for them from service users, providers and commissioners.
- 7.8 In reforming the system of regulation it is important that it is able to adapt to reflect these changes in a way that ensures patient safety but does not stifle beneficial innovative practice or frustrate safe and legitimate professional development into new spheres of practice. 'The regulation of the non-medical healthcare professions' made a number of proposals to address the regulation of new professional roles and emerging professions.
- 7.9 **For emerging professions, the Department will establish a United Kingdom working party to develop criteria to determine which roles should be statutorily regulated.** These criteria are likely to include:
- whether a new role is sufficiently different from others to be regulated as a profession in its own right;
 - whether it attracts recruits from a variety of backgrounds, including other healthcare professions and occupations, and also from other sectors;

- whether it will contribute to workforce development so as to enable service delivery to support Government policy and user choice;
- whether there is evidence for the efficacy of the role's practice;
- whether agreed training standards are in place for all practitioners in all employment sectors, including self-employment;
- the level of risk and impact on public safety, so that the relative restriction of statutory regulation is used only where it is proportional to the risk involved. For instance, regulation could be restricted, as the Health Professions Council currently recommends, only to groups involved in invasive procedures, clinical interventions with the potential for harm, or unsupervised exercise of judgement with a substantial impact on patient health or welfare; and
- the level of demand across healthcare as a whole for a nationally-transferable qualification, standard and scope of practice.

7.10 The Department will discuss with the Devolved Administrations and key stakeholders whether a formal mechanism should be devised to consider the national need for new roles and the regulation of new roles.

7.11 Having reached UK-wide agreement to regulate a new role across the UK, it will also be necessary to assess that role's state of readiness for regulation against agreed criteria, such as those used by the Health Professions Council. These would need to be adapted, but would include the following:

- the role should be a discrete and homogeneous area of activity;
- the role should encompass a defined body of knowledge;
- the role should carry out evidence-based practice;
- there should be an established professional body;
- there should be a voluntary register or list of eligible practitioners;
- there should be defined entry routes into the role;
- there should be independently assessed entry qualifications;
- the role should be governed by standards of conduct, performance and ethics;
- there should be disciplinary procedures to enforce those standards; and
- there should be a commitment to continuing professional development.

- 7.12 Before legislation can be introduced to regulate a profession, there must be agreement on the identity of the profession; its scope of practice; what its members need to know and do; what aptitudes are needed for the safe and effective practice of the profession; and what training is needed to produce competent practitioners. To meet the requirements of statutory regulation, the education and training of professionals has to exist within a robust quality assurance framework to ensure that the training itself is of good quality, consistent and fit for purpose. To enable statutory regulation to take place as soon as the legislation is passed, there needs to be a voluntary register of competent practitioners who are fit to practise in all respects. This means that prior to regulation by the statutory regulator, those practitioners should be assessed for competence, good character and good health; and that they should be bound by a voluntary code of conduct and ethics. There should also be a mechanism for investigating and resolving allegations of unfit practice so that the voluntary register that is transferred to the statutory regulator contains only those practitioners who are fit to practise. This is important on the grounds of public safety.
- 7.13 The statutory regulator of a new profession needs to be able to work with a wide range of stakeholders to ensure that the threshold standards of professional practice (the 'Standards of Proficiency') that the regulator sets are relevant to the competencies needed for safe and effective practice at the point of entry to the professional register. The standards should be sufficiently comprehensive to cover the profession's scope of practice, specific enough to provide meaningful quality and safety safeguards, and achievable by the majority of current practitioners within that sphere of professional practice. The distinction is to be made between the role of the regulator in setting threshold standards that reflect contemporary practice, and the role of the professional body, where one exists, in developing standards for the future based on advances in practice as part of its leadership function for the profession.
- 7.14 These standards will be aspirational for some time until they become adopted by a given profession as a whole, at which point they will inform the regulator's revision of its threshold standards. The regulator needs to take account of a wide range of factors in setting standards: the needs of employers and service providers, the needs of service users and their families and carers and the general public; the ability of education providers to provide high-quality integrated theoretical and practical training; and the cost of funding such training. In doing so the regulator needs to demonstrate transparency in the rationale for the identification of specific standards, accountability to its stakeholders for carrying out its functions efficiently, and compliance with the wider legal context in which statutory regulation takes place, including domestic and European law.
- 7.15 **The Government has decided that the regulation of existing and emerging professions should be managed by the existing statutory regulatory bodies and the proposed new General Pharmaceutical Council. This is for the following reasons:**
- It will help to foster consistency where appropriate and the application of best regulatory practice across all regulated professions to stop members of some professions being treated more leniently or harshly than others.

- It will meet specific professions' educational, practice and conduct needs within a common framework, by engaging as much professional input as is necessary to inform the regulator's work without needing to reinvent and build up expertise in identical regulatory processes for new regulators.
- It will also promote multidisciplinary working to support integrated services to meet service users' needs, since regulators with a number of professions are more aware of the interface between different professions' practice, and are more likely to concentrate on general regulatory principles than on profession-specific issues. This includes taking account of all stakeholder needs (service users and providers as well as professions) in setting regulatory standards for practitioners to support service providers' workforce development in a variety of sectors and settings.

7.16 The Government's view is that most new professions should be regulated by the Health Professions Council which was designed for this purpose and has the most expertise in bringing new professions into statutory regulation and also in regulating a wide range of professions within a common system. Exceptionally, a particular profession may be considered for regulation by another existing statutory regulator, but this will be considered on a case-by-case basis where a particular advantage, outweighing those described above, can be demonstrated. **With the exception of the new arrangements for the regulation of pharmacy, the Government will not establish any new statutory regulators. Psychologists, psychotherapists and counsellors will be regulated by the Health Professions Council, following that Council's rigorous process of assessing their regulatory needs and ensuring that its system is capable of accommodating them. This will be the first priority for future regulation.**

7.17 **The Government will consider areas in which regulatory practice and legislative provisions should be harmonised across the regulators so that they all have the most up-to-date and comprehensive duties and powers.** The Government recognises that setting professional practice and conduct standards is at the heart of each regulator's activity, but is also aware that there are substantial areas in which common standards would be desirable. For example, standards of professional conduct and of professional practice relating to areas of practice undertaken by members of many different professions need greater harmonisation. While it is not the intention that one size should fit all and recognising that there needs to be appropriate flexibility to reflect relevant differences between professions, the Government believes that all professionals undertaking the same activity should be subject to the same standards of training and practice so that those who use their services can be assured that there is no difference in quality.

Distributed regulation

- 7.18 **Where a health professional joins a new regulated profession from within an existing regulated profession, it might be possible for them to remain registered with their existing regulator, in a system of distributed regulation, to avoid costly dual regulation.** Dual registration means that the same person has to be registered with two different regulators to perform one and the same role. (Any new or emerging profession will not require regulation by more than one regulator.) However, the Government recognises that many professionals feel a degree of loyalty to the profession in which they were first regulated. **The Government will therefore explore the practicality of a system of distributed regulation, including its relationship to revalidation, in which a lead regulator will regulate a new profession and register most of its practitioners, including direct entrants.**
- 7.19 Entrants from an existing regulated profession who want to retain registration with their original regulator, and have their new professional registration annotated on their original register along with their existing registration, will need to meet the relevant standards for both their new and their original professions, but this will be a matter of personal choice. **The Government will consider further the legal and operational practicalities of ensuring that these practitioners meet the same standards as everyone else in the new profession while continuing to meet the requirements of their original regulator.** It should be noted, though, that dual registration is currently necessary for any professional who is qualified in two different professions and wishes to retain the option of practising in both. However, the new demands for undertaking continuing professional development and meeting revalidation requirements for two professions may make this, and also distributed regulation, a less practical option in future.

Support workers

- 7.20 'The regulation of the non-medical healthcare professions' drew attention to the Scottish pilot of employer-led regulation of healthcare support workers (HCSWs) where arrangements for those who have met agreed national standards will be tested. In the Scottish model, standards relate to safe recruitment practice, induction and support of the continuing development of this group of workers. An independent evaluation has been commissioned and this will provide evidence about whether this route should be adopted across Scotland and whether this employer-led approach might be extended to cover the whole of the UK. The Scottish model is that induction standards focus on generic public protection concepts such as confidentiality, dignity, advocacy, and similar core concepts and values apply to all HCSWs employed in the NHS, regardless of their role. **The Government in England will evaluate the results of the Scottish pilot study and consider the way forward with stakeholders.**
- 7.20 **The Government will consider whether there is sufficient demand for the introduction of statutory regulation for any assistant practitioner roles at levels 3 and 4 on the Skills for Health Career Framework. This will be subject to the same mechanisms for determining need, suitability and readiness as for the other emerging professions described above.**

Chapter 8: Implementation

Introduction

- 8.1 The regulation of health professionals is complex in its diversity and wide-ranging in its scope, affecting patients, health professionals, the public, taxpayers, employers, the NHS, the independent sector, educators, regulators, trades unions and many others across the United Kingdom. This White Paper sets out a clear way forward that will sustain and enhance public and professional trust and improve patient safety.
- 8.2 Translating this programme of reform into action will require detailed consultation with each profession affected. The close involvement of a wide range of stakeholders across the UK will be essential to ensure that it is delivered well and in a way that acknowledges the capacity of employers, regulators and other key stakeholders to manage a substantial, resource-intensive and sometimes intricate programme of reform. As far as possible, within the direction of travel set out in this White Paper, the process of implementing reform should be led by the professions themselves, in partnership with patients, the public and all the stakeholders involved in health and healthcare.
- 8.3 This chapter sets out a summary of the key implementation issues. **The Government will publish a detailed implementation programme that encompasses both this White Paper and the Government's response to the recommendations of the Fifth Report of the Shipman Inquiry and the recommendations of the Ayling, Neale and Kerr/Haslam Inquiries, *Safeguarding Patients*.**

England, Scotland, Wales and Northern Ireland

- 8.4 Many aspects of the regulation of health professionals are reserved matters for the UK Parliament. Close consultation and discussion between the UK Government and the Devolved Administrations will be critical to ensuring effective and appropriate processes and delivery timetables across the UK. The Department of Health will ensure that the Devolved Administrations have appropriate representation on all the working groups and governance structures set out in this White Paper and will develop timetables and frameworks for delivery that reflect the circumstances of all parts of the UK.

Legislation

- 8.5 **Many of the reforms set out in this White Paper will require primary legislation.** Primary legislation is likely to be required for: enabling regulators to adopt lay majorities for their councils; changes to the Council for Healthcare Regulatory Excellence; changes to the regulation of pharmacy; changes to enhance the independence of adjudication; the delivery of revalidation; the establishment of GMC Affiliates; and changes to the powers and responsibilities of medical directors and their equivalents.
- 8.6 Other measures need to be enabled by seeking parliamentary approval for secondary legislation. These include changes to the composition of councils; the appointment of council members; changes to the size of councils; moving, in some cases, from the criminal to the civil standard of proof; prohibition of council members' participation in fitness to practise proceedings; a single standard definition of good character; changes to information held and made available on the regulators' professional registers; and changes to the regulation of existing and emerging professions.
- 8.7 **On specific matters where there is clear public, professional and parliamentary agreement on the need for change, the Department will consider with stakeholders whether it would be appropriate to seek Parliament's agreement in primary legislation to enable these issues to be addressed through secondary legislation.** On matters where there is significant disagreement, the Government will ensure that these are fully considered through full discussion of primary legislation.
- 8.8 **These legislative proposals will be developed in close consultation with the Devolved Administrations to ensure that they are appropriate to the whole of the UK.** The Devolved Administrations will give detailed consideration to the proposals affecting matters that are devolved to them. The legislative proposals and timetable will need to take full account of the timetable for elections to the legislatures in Scotland and Wales to ensure that ministers and elected members have appropriate opportunities to scrutinise and approve the proposals.

Participative delivery

- 8.9 **This White Paper sets out the key principles for a lasting settlement for professional regulation, but putting those principles into practice effectively will require the advice and participation of a wide range of stakeholders to ensure effective delivery.**

8.10 On a range of key issues addressed in the White Paper, the Department has committed itself to establishing groups to provide leadership, advice and support on detailed implementation, so that the practical delivery of reformed professional regulation is guided by the expertise, knowledge, aspirations and concerns of all those who have an interest. The Government is clear that the best arrangements for professional regulation are to be secured through a consultative spirit of social partnership guided by patient interests rather than vested interests. A range of working groups and steering groups are set out in this White Paper. They include groups working on revalidation; the health of healthcare professionals; the regulation of emerging professions; and the oversight of national clinical audit. **In addition, the Government will establish an inclusive national advisory group on professional regulation to advise the Department and the Devolved Administrations on the detailed implementation of the White Paper and the Government's response to the recommendations of the Fifth Report of the Shipman Inquiry and the recommendations of the Ayling, Neale and Kerr/Haslam Inquiries, *Safeguarding Patients*.** Detailed terms of reference and membership for all the working groups will be agreed through consultation with all relevant stakeholders and published in the integrated implementation plan for the White Paper and the Governments response to the Shipman Inquiry and related inquiries.



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