



HM Government

Safer management of controlled drugs

The Government's response
to the Fourth Report of the
Shipman Inquiry



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**Presented to Parliament by
the Home Secretary and the Secretary of State for Health
by Command of Her Majesty**

December 2004

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Foreword by the Home Secretary and the Secretary of State for Health



The Shipman Inquiry was set up in January 2001, following the conviction of Harold Shipman for the murder of 15 of his patients. The Inquiry was tasked with investigating the extent of Shipman's unlawful activities, enquiring into the activities of the statutory authorities and other organisations involved, and making recommendations on the steps needed to protect patients for the future.

Five Inquiry reports have now been published. The first three addressed the extent of Shipman's criminal activities, the 1998 investigation by the Greater Manchester Police, and death certification and the coroner system. The Fourth Report, *The Regulation of Controlled Drugs in the Community* – the subject of this Government response – was published on 14 July 2004 and is concerned with the systems for ensuring the safe and appropriate use of controlled drugs. The Fifth Report, *Safeguarding Patients: Lessons from the Past – Proposals for the Future* addresses the arrangements for monitoring, assessing and disciplining GPs and arrangements for whistleblowing and handling complaints in the NHS.

Once again we would like to thank Dame Janet Smith and her team for their meticulous analysis of the weaknesses in existing systems which Shipman was able to exploit for his criminal purposes, and for the skill with which her recommendations balance the need to safeguard the legitimate use of controlled drugs for patient care and the need to protect the public from their misuse.

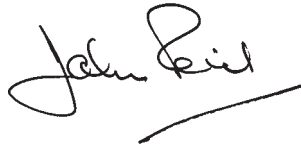
The Government fully accepts the need to strengthen current arrangements for the management of controlled drugs, and to do so in a way which does not hinder patients from accessing the treatment they need. We fully accept the great majority of the recommendations, and for the remainder we propose to achieve the same recommended ends by alternative action. We have also considered the implications of Dame Janet's recommendations for other healthcare sectors such as hospitals and care homes, and for the initial training and professional development of healthcare professionals. Our aim is to set the management of controlled drugs in the context of wider initiatives to create a culture of continuous quality improvement in the NHS.

In developing the Government's response we have been mindful of the far-reaching recommendations in the Inquiry's Fifth Report. We are still assessing the full implications of this report and will respond to it in detail in due course. However, we are confident that the action programme set out in this document is fully consistent with the broader picture.

As Dame Janet has acknowledged, no system for the regulation of controlled drugs can offer complete security against abuse from minds as devious as Shipman's. We believe however that the comprehensive programme of action which we are launching today will provide patients with robust safeguards against abuse, while still allowing controlled drugs to be used for their proper purposes in modern patient care.



David Blunkett



John Reid

Executive Summary

The Inquiry's recommendations

1. The Inquiry's Fourth Report, published on 14 July 2004, analyses the means by which Harold Shipman was able to obtain his lethal armoury of controlled drugs, and finds weaknesses both in current systems of control and in the ways in which those controls were operated. The report recommends strengthening current arrangements in four main areas:

- a new integrated, multiprofessional inspectorate to inspect the management of controlled drugs in NHS primary care to replace the existing uncoordinated arrangements for inspection;
- restrictions on the right of GPs to prescribe controlled drugs in certain circumstances, eg prescribing for oneself or one's immediate family or prescribing beyond the requirements of one's normal clinical practice;
- strengthened arrangements for auditing the prescribing of controlled drugs in primary care and the movement of supplies of controlled drugs in the community; and
- better information to patients on the special legal status of the controlled drugs which are prescribed for them.

2. These recommendations need to be considered in the context of the Inquiry's Fifth Report, *Safeguarding Patients: Lessons from the Past – Proposals for the Future*. This report recommends much greater support for people wishing to complain about healthcare treatment or raise concerns about the actions of healthcare professionals. It calls for improved monitoring of medical practitioners and improved access to information about them. It is broadly supportive of recent developments in the NHS and in particular recent moves to strengthen the arrangements for holding medical practitioners to account, both by NHS primary care organisations and by the General Medical Council. The report however considers that much more is needed to support these developments. The Government will carefully consider the Inquiry's conclusions and recommendations in detail and will respond in due course.

The Government's overall approach

3. The Government fully agrees that current systems of control for controlled drugs need strengthening, and that every reasonable effort should be made to minimise the risks to patient safety of the inappropriate use of controlled drugs. However, as the Inquiry itself recognised, controlled drugs are used in healthcare for a wide variety of clinical reasons – for instance, as strong painkillers in terminal care, and in the treatment of substance abusers – and systems of control should not be so onerous as to get in the way of good patient care.

4. In addition, as the Inquiry's Fifth Report recognises, the NHS in 2004 is very different from the NHS in the 1970s and 1980s, when Shipman began to practise. These changes, which were anticipated in 1998 in *A first class service: quality in the new NHS* and in *Learning from Bristol* (the Government's response to the Bristol Royal Infirmary Inquiry), include:

- a statutory duty of quality placed on the Chief Executive of every NHS organisation;
- explicit standards covering all care provided to patients whether in the NHS or in the private sector, including the quality of care;
- assessment of performance against these standards by the Healthcare Commission and Commission for Social Care Inspection;
- comparative data on the clinical practice and outcomes of healthcare organisations;
- local systems of clinical governance to ensure that all healthcare professionals regularly review their clinical practice and update their skills;
- improved disciplinary procedures in primary care, allowing primary care organisations to remove or suspend healthcare professionals if the safety of patients is at risk; and
- plans for a 5-yearly revalidation for all doctors, requiring them to provide evidence on the ways in which they are seeking to improve their clinical practice.

The Inquiry's Fifth Report recognises the potential significance of these changes while suggesting a number of ways in which they could be reinforced.

5. The Government accepts that there is a need for further strengthening of the processes which have been introduced to drive improvements in the quality of care. However, it considers that improvements in the systems for managing the use of controlled drugs should form an integral part of these developments, rather than be superimposed as something separate. In doing so, the emphasis should be on supporting healthcare professionals to do things right first time, rather than on catching them out and punishing them when they do things wrong. Better systems will not only help the vast majority of healthcare professionals who want to provide the best possible care for patients, but will also deter the small minority who may be tempted to abuse their professional position.

6. In this spirit, the Government believes that it is possible to achieve all the objectives underlying the Inquiry's recommendations, although in some cases the means of delivery may be rather different. The following paragraphs describe in more detail how this will be done. (The programme of action will apply in detail only to England. Scotland, Wales and Northern Ireland will respond separately, although in general any changes to Misuse of Drugs or Medicines legislation will apply throughout the UK).

Monitoring and inspection

7. As the Inquiry noted, there are already substantial resources involved in local monitoring and inspection of NHS clinical activities, in the inspections of community pharmacies carried out by the Royal Pharmaceutical Society of Great Britain and police Chemist Inspection Officers, and in the inspections of the private and voluntary sectors carried out by the Healthcare Commission and Commission for Social Care Inspection. But there is no systematic coordination of this work and no

clear lines of accountability; and in recent years there have been few or no inspections of the safekeeping of controlled drugs in GP practices.

8. The Government therefore intends to place on each healthcare organisation, both in the NHS and in the private sector, a statutory responsibility to nominate a “Proper Officer” of appropriate seniority, with responsibility for ensuring that the organisation has adequate arrangements for ensuring the appropriate management and use of controlled drugs. This would include:

- the analysis of routine prescribing and other audit data, as described more fully below, with further investigation of apparent anomalies; and, as back-up,
- ensuring that a sample of practices and pharmacies are subject to inspection each year, either by officers of the Primary Care Trust or through agencies; and
- regular developmental visits to GP practices and pharmacies at which the proper use of controlled drugs would be discussed in the context of improvements in clinical care more generally.

9. The Government will also place a corresponding duty of collaboration on other local and national agencies, including professional regulatory bodies, police forces, the National Patient Safety Agency, the Healthcare Commission and the Commission for Social Care Inspection. Essentially, the Proper Officer will act as the central point of a local intelligence network which will detect early signs of poor handling or deliberate misuse of controlled drugs and will agree on appropriate remedial action.

10. The Government will require the Healthcare Commission to assess the performance of NHS organisations in relation to these responsibilities and to ensure that local networks are working as intended.

11. There will be equivalent arrangements to cover the use of controlled drugs in NHS secondary care Trusts, in the private and voluntary sector, and in other clinical settings.

12. The Government believes that this combination of clear local responsibility for action, and national inspection of performance against the required standards, will give the best possible assurance against a future case like Shipman’s, and will achieve the objectives set out by the Inquiry.

Prescribing of controlled drugs

13. The Inquiry recommended that restrictions should be placed on the freedom of doctors to prescribe in circumstances in which there was no legitimate clinical rationale, or a risk of diversion or abuse, or where the quantities prescribed were excessive; in serious cases they suggested that infringing these restrictions should be a criminal offence. The Government agrees in principle with all these restrictions but considers that criminal sanctions are not an appropriate means of delivery. The boundary between appropriate and inappropriate prescribing is difficult to draw and is best defined through professional good practice guidance; clinical behaviour which clearly breaches this guidance should then be assessed, and sanctions imposed as required.

The Department of Health will work with the healthcare regulatory organisations (in this context principally the General Medical Council, General Dental Council, Royal Pharmaceutical Society of Great Britain and Nursing and Midwifery Council) to ensure

that they have clear and explicit guidance in this area and that there are effective means of enforcing it.

14. The Inquiry noted, without a formal recommendation, that authority to prescribe is being extended to professions other than doctors and dentists.

The Government believes that these new prescribers should be authorised to prescribe controlled drugs where it is clinically appropriate and safe for them to do so, and will legislate to enable this. New prescribers will be subject to similar arrangements for clinical governance and professional oversight to those for doctors.

The audit trail

15. The Inquiry pointed to major gaps in the information available to audit the prescribing and supply of controlled drugs, and recommended extending the information base to include private prescribing and requisitions of controlled drugs, and audit of the use of injectable opioids in patients' homes. The Government agrees in principle with the great majority of these recommendations. The Government believes that the key to practical implementation lies in moving as rapidly as practicable, towards electronic generation of prescriptions and electronic controlled drug registers.

The Government will amend controlled drug legislation as required to enable this change and will work through the National Programme for IT to make suitable software available for GP practices and pharmacies.

16. The Government agrees that information on private prescribing of controlled drugs, and on requisitions of controlled drugs for use within GP practices, should be captured and analysed to support clinical governance processes. In addition, the Government intends to capture information from wholesalers, pharmacists and practices on the movement of controlled drugs down the supply chain so that any apparent diversions can be identified and further investigated.

The Government will legislate to require wholesalers, pharmacists and prescribers (including private prescribers) to use standardised electronic or handwritten forms and to send this information to a central data repository for analysis. Any irregularities will be brought to the attention of local controlled drug leads for further investigation and action as needed.

17. The Government agrees in principle with the Inquiry's proposal for a patient drug record card to provide an audit trail for injectable Schedule 2 drugs (eg opiates) in the community.

However, because of concerns over how such a system would work in practice, the Government intends to pilot the proposal in order to assess the potential benefits and any additional workload on frontline clinicians.

Information for patients

18. The Inquiry recommended that pharmacists should give patients information about the nature of the controlled drugs they are prescribed and the specific legal requirements that relate to their use. The Government agrees that patients should have information about the nature of the treatments prescribed for them, if possible in the context of an informed discussion of treatment options. However, many of the issues about the safe handling of controlled drugs apply, to a greater or lesser extent, to all medicines.

The Government will therefore work with professional and patient organisations to deliver a sustained programme of communication activities on the safe handling and safe disposal of all medicines, and to encourage healthcare professionals to give appropriate information on the special legal status of controlled drugs as part of an informed dialogue with patients.

Education and training

19. Underpinning all the other specific actions outlined in this plan is the need to improve the quality of initial professional education and to promote continuing professional development in the safe management and use of controlled drugs.

The Government will work with professional regulatory organisations and education providers:

- **to review the curricula for undergraduate and postgraduate education so that all newly graduating healthcare professionals understand the legal requirements and have the knowledge and skills to use controlled drugs appropriately and safely as an integral part of high quality clinical care;**
- **to define the competencies required by those who will be involved in the processes of clinical governance and inspection; and**
- **to ensure that requirements for appraisal and revalidation promote the continuous updating of skills.**

Chapter 1

The context: controlled drugs in the modern NHS

The Shipman Inquiry

1.1 The Shipman Inquiry was set up on 31 January 2001 under the chairmanship of Dame Janet Smith DBE as an independent public inquiry into the issues arising from the case of Harold Shipman. The Inquiry was asked to enquire into the actions of the organisations involved in investigating the deaths of “those of Harold Shipman’s patients who died in unlawful or suspicious circumstances” and of the organisations responsible for “monitoring primary care provision and the use of controlled drugs”, and “to recommend what steps, if any, should be taken to protect patients in the future”. The full terms of reference are at Annex A.

1.2 The Inquiry’s first three reports deal with the number of patients who may have been murdered by Harold Shipman, the police investigation of March 1998, and the arrangements for death certification and investigation of deaths by coroners. The Government’s proposals for reforming the coroner and death certification service were published in a Position Paper on 12 March 2004 by Home Office Minister Paul Goggins. This draws on the work both of the Inquiry’s Third Report and of an independent Fundamental Review.

The Inquiry’s Fourth Report: controlled drugs

1.3 The Inquiry’s Fourth Report was published on 14 July 2004. It focuses on the methods used by Harold Shipman to divert large quantities of potentially lethal drugs to his own criminal purposes, and considers how it was possible for him to continue to do so for so long without detection.

1.4 Controlled drugs – as the name implies – are medicines which are subject to special legal controls because of their particular potential for harm if wrongly used. The legislation goes back to 1920 and the current legislation is the Misuse of Drugs Act 1971, though it has been marginally modified on at least 16 occasions since then. The legitimate use of controlled drugs is regulated by the Misuse of Drugs Regulations which have been revised in 1973, 1985 and 2001. The Regulations divide controlled drugs into five schedules of varying degrees of control – drugs in Schedule 1 are not used in clinical practice, and Schedules 2 to 5 provide reducing levels of control, depending on the perceived risk of addiction of the particular drug or preparation. Further details on the legislation are at Annex B, and figures for the number of prescription items dispensed in the NHS in England in each schedule for the most recent available year are given in Table 1 below.

Table 1: Prescription items dispensed in the NHS in England 2003-2004

Schedule	Number of prescription items	%
2	2,636,000	6
3	4,534,000	10
4	9,075,000	21
5	27,059,000	62
Total	43,303,000	100

Source: Prescription Pricing Authority

1.5 The drug used by Harold Shipman, diamorphine, is in Schedule 2 which means that it is subject to the following special controls:

- all prescriptions must be handwritten (not generated from the GP's computer) and conform to other special requirements;
- GP practices which keep a stock of diamorphine for use within the practice (ie for personal administration to patients) must maintain a controlled drug register showing each new supply of diamorphine and each administration to patients;
- community pharmacies must also maintain a controlled drug register showing each supply of diamorphine received from wholesalers or manufacturers, and each supply dispensed to patients, with the name of the patient and the name of the prescriber;
- stocks of diamorphine, whether in the GP practice or in the community pharmacy, must be kept securely in conformance with the detailed requirements for safe custody set out in regulations.

1.6 Shipman obtained his supplies of diamorphine illicitly, and did not maintain a controlled drug register. He obtained his illegal supplies by a variety of means, but mainly by collecting prescriptions on behalf of patients (but then diverting all or part for his own purposes) and by appropriating to himself the diamorphine left in patients' homes after their death. The controls that applied at the time did not identify these practices, although an unusual pattern of prescriptions for diamorphine in 1993 might have drawn attention to them. Had these clues given rise to concerns and enquiries initiated, Shipman's homicidal activities might have been detected earlier. Shipman was well regarded by his patients and by other healthcare professionals and, in the mindset that was common at the time, none of his colleagues were able to conceive that these unusual prescribing patterns were an indication of underlying criminal behaviour.

1.7 The Inquiry concluded that there were serious shortcomings both in the systems for regulating the use of controlled drugs such as diamorphine and in the way in which those systems were operated. The Inquiry's Fourth Report includes a comprehensive set of recommendations for strengthening the current controls and for ensuring that they are effectively implemented.

Controlled drugs in modern clinical care

1.8 Controlled drugs form an integral part of modern clinical care. They are used for a wide variety of indications, including the relief of pain, in obstetrics and anaesthetics, as tranquillisers and hypnotics, and in the treatment of hyperactivity (Attention Deficit Hyperactivity Disorder). Diamorphine (the drug used by Shipman) and the other opioids are important treatment options:

- for relief of severe acute pain, for instance immediately after a heart attack or fracture;
- for relief of severe chronic pain, for instance in patients with terminal cancer;
- for treatment of drug addiction; and
- in anaesthesia.

1.9 Each of these clinical contexts poses different challenges to healthcare professionals who are seeking to provide high quality patient care while minimising the risk of diversion of controlled drugs to illegal uses. For instance:

- in treating severe acute pain doctors, ambulance paramedics and others need instant access to a powerful injectable analgesic. Typically, they take supplies with them for personal administration to the patient;
- in the relief of severe chronic pain, it is more normal for the analgesic to be supplied to the patient through the conventional prescribing/dispensing route, ie the patient's GP or other prescriber writes a prescription for a reasonable period of supply which a community pharmacy (or dispensing assistant in a dispensing practice) then makes up and hands over to the patient or their representative. For injectable analgesics such as diamorphine the medicine would probably be administered in the patient's home as a slow infusion set up by a community nurse or other healthcare professional;
- some patients receive injectable controlled drugs for the treatment of drug dependence. So the patient receives only an amount judged suitable by the prescriber on any one day, these can be prescribed in daily instalments (instalment dispensing) for self-medication.

Control systems need to encompass all these different clinical contexts and all the healthcare professionals involved – the prescriber, the pharmacist or dispensing assistant, the nurse – while ensuring always that patients receive the care they need.

1.10 The last few years have seen major advances in the therapeutic use of controlled drugs; in particular, many patients have benefitted from the better pain control that can be achieved through the more finely adjusted use of opioids. The challenge is to introduce the stronger controls which the Inquiry rightly recommends without doing anything to jeopardise this recent progress.

Systems for improving clinical quality

1.11 The Inquiry's Fifth Report considers the arrangements for monitoring, assessing and disciplining GPs and arrangements for whistleblowing and handling complaints in the NHS. It recommends much greater support for people wishing to complain about healthcare treatment or raise concerns about the actions of healthcare professionals. It is broadly supportive of recent developments in the NHS and in particular recent moves to strengthen the arrangements for holding medical practitioners to account, both by NHS primary care organisations and by the

General Medical Council (GMC). However it considers that much more is needed to support these developments.

1.12 As the report recognises, the NHS in 2004 is very different from the NHS in which Harold Shipman first started out as a GP. In the 1970s and 1980s, the responsibility for ensuring a high quality of care was regarded as primarily a personal matter for the individual healthcare professional. Of course, professional bodies were active in supporting professionals in this responsibility; and taking action where they fell short. In particular, they were responsible for ensuring the quality of undergraduate and postgraduate education, for providing good practice guidance, and for dealing with gross failures to meet professional standards. Nevertheless, provided that clinicians' performance did not fall to unacceptable levels there was little day-to-day oversight of their clinical practice or of the extent to which they took part in clinical audit and educational activities.

1.13 In 2004, it is fully recognised that clinical quality is a corporate as well as an individual professional responsibility:

- Every Chief Executive in the NHS has a statutory duty of quality to work to improve the quality of healthcare delivered by his/her organisation;
- Each NHS organisation (including Primary Care Trusts (PCTs) in relation to GPs and other primary care practitioners) is responsible for operating local systems of clinical governance to support high standards of care and continuous quality improvement;
- New disciplinary arrangements have been introduced in NHS primary care which give PCTs powers to suspend or remove practitioners from their lists to protect the safety of patients;
- Doctors working in the NHS are subject to annual appraisal and, with effect from 2005, all doctors – including those working solely in private practice – will be subject to 5-yearly revalidation in which they have to provide evidence of the ways in which they are seeking to improve their practice. A similar system applies to the nursing profession;
- Comparative data on the clinical practice and outcomes of healthcare organisations and individual healthcare professionals is becoming increasingly sophisticated and is being used to a greater extent to identify and remedy poor practice;
- At national level, the Government has recently published a set of explicit standards covering all care provided to NHS patients to complement the earlier standards for the private and voluntary sector. Clinical governance requirements are now embedded within these standards;
- The Healthcare Commission – for NHS organisations and private and voluntary healthcare – and the Commission for Social Care Inspection (CSCI) – for private care homes – are tasked with providing assurance, based on a combination of routine data and inspections, that local systems are working effectively and that these standards are being achieved, including those relating to the duty of quality. This will involve a combination of analysis of routine data, self-assessment and inspections.

Clinical governance

The concept of clinical governance was introduced in *A first class service: quality in the new NHS* and is defined as:

“A framework through which NHS organisations 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.”

Detailed guidance was issued in March 1999 in *Clinical governance in the new NHS*.

1.14 Many of these improvements were already in train, but were given powerful impetus by the report of the Bristol Royal Infirmary Inquiry, *Learning from Bristol*. A key issue at the Bristol Royal Infirmary was clinical failings rather than deliberate criminal wrongdoing, but there are some common features, in particular the failure of corporate management to appreciate the significance of routinely available data which might have given clues to the problems underneath.

1.15 It would be misleading to imply that these major changes in the NHS over the last ten years or so would, in themselves, be sufficient to prevent another case like Shipman's. The Shipman Inquiry raises some very specific issues over the arrangements for management of controlled drugs which require appropriate specific solutions. Nevertheless, we need to ensure that changes to the regulation of controlled drugs work with the grain of the various initiatives described above to improve the quality of clinical care more generally, as well as taking account of the Inquiry's recommendations in its Fifth Report.

The Government's overall approach: controlled drugs in healthcare systems

1.16 The Government fully accepts the need to strengthen the controls on the use of controlled drugs in the NHS and in the private and voluntary healthcare sector. Following consultation with key stakeholders, involving the four Working Groups whose members are listed in Annex C and drawing on some very helpful work by a special sub-committee of the Advisory Council on the Misuse of Drugs (ACMD), the Government has accepted the spirit of all the Inquiry's recommendations. In a few cases, the Government proposes to take a rather different path to implementation but believes that the proposals set out in this paper will achieve the objective of each of the Inquiry's recommendations.

1.17 The Government's action programme is set out in more detail in the following sections. In summary, the Government proposes*:

- to make clear that responsibility for the proper management of controlled drugs is an integral part of the clinical governance responsibility of all NHS and private sector healthcare organisations;
- to ensure that arrangements for national inspection of controlled drugs strengthen, rather than detract from, this proper local responsibility, in line with the principles set out in the 2003 policy statement *The Government's policy on inspection of public services*;

* Legislation relating to controlled drugs, and to the status and use of medicines more generally, is UK-wide. In contrast, the arrangements for providing NHS care are now devolved and differ in detail between the four countries of the UK. The specific measures set out in this response relate in the first instance to practice in England. Actions which result in amendments to the Misuse of Drugs Act or Medicines Act legislation will in general apply equally to other parts of the United Kingdom; other aspects of the arrangements for Scotland, Wales and Northern Ireland are matters for the respective Devolved Administrations.

- to ensure that prescribing of controlled drugs – which in future will include prescribing by healthcare professionals other than doctors and dentists – takes place in the context of a general framework of good prescribing practice backed by clinical governance frameworks and appropriate professional regulatory sanctions;
- to capture information on all prescribing and requisitioning of controlled drugs, including private prescribing, and to provide analyses of prescribing patterns by prescriber and by patient for those operating the local controls;
- to set up information systems which will enable a full audit trail for the movement of controlled drugs in the community, including (for certain drugs – injectable Schedule 2 drugs like diamorphine – and subject to satisfactory piloting) the supply and administration of drugs to the patient and their recovery at the end of the course of treatment; and
- to ensure that patients receive appropriate information about controlled drugs in the context of an informed discussion with the healthcare professionals involved in their care, and against a background of information about the safe handling of prescription medicines more generally.

The Government believes that these proposals are entirely consistent with the thrust of the Inquiry's Fifth Report, and indeed that there could be synergy between the actions flowing from the two reports.

1.18 In the short term, there will clearly be a need to raise the profile of controlled drugs issues in the NHS, as well as implementing a number of specific improvements. This will among other things require a major initiative to develop suitable training packages and to promote their take-up, as described in more detail below. But in the longer term our aim should be to mainstream the management of controlled drugs, so that this becomes simply one aspect of the good clinical practice of all healthcare organisations.

Controlled drugs in settings other than human healthcare

1.19 Although the Shipman Inquiry made little reference to veterinary medicine, veterinary surgeons also use controlled drugs. Their use of these drugs differs from the use in human healthcare in that there is no veterinary equivalent to the NHS, and many veterinary medicines are dispensed directly by veterinary surgeries rather than by pharmacies. The Royal College of Veterinary Surgeons and the British Veterinary Association are engaging with the issues raised by the Inquiry's Fourth Report, and will be considering over the coming months the most appropriate ways of implementing the spirit of the Inquiry's recommendations in the field of veterinary medicine.

Chapter 2

Monitoring and inspection

The Inquiry's recommendations

2.1 The Inquiry found three major weaknesses in the system of monitoring and inspection of controlled drugs at the time of Shipman's crimes:

- there was no overall coordination – management of controlled drugs in community pharmacies was inspected by Chemist Inspection Officers (CIOs) from the local police force, other aspects of professional practice in community pharmacies were inspected by inspectors from the Royal Pharmaceutical Society of Great Britain (RPSGB), and prescribing of controlled drugs in GP practices was monitored by the prescribing advisors of the local health authority;
- CIOs did not have the professional training or experience to detect unusual clinical practice – this may be one of the reasons why the CIO in Shipman's case failed to pick up the very unusual pattern of prescribing which could have given him away in 1993; and
- routine inspections of the management of controlled drugs in GP practices had been discontinued when the Regional Medical Service (RMS) was abolished in 1991, and health authority prescribing advisors who had picked up most of the RMS' other functions had other priorities and were not authorised to inspect GP premises or controlled drug registers.

2.2 The Inquiry recommended replacing the current uncoordinated arrangements with a single, integrated, multiprofessional inspectorate. In detail, the Inquiry's recommendation is as follows:

Recommendation 1:

A controlled drugs inspectorate should be created, comprising small multidisciplinary inspection teams, operating regionally but co-ordinated nationally. Each team would include pharmacists, doctors, inspectors and investigators, at least some of whom would have a law enforcement background. The inspectorate would be responsible for inspecting the arrangements in pharmacies, dispensaries and surgeries, as to both the safe keeping of stocks of controlled drugs and the maintenance of controlled drugs registers and other records. It could be responsible for the supervised destruction of controlled drugs. The inspectorate would also be responsible for the monitoring of the prescribing of controlled drugs by means of examination of prescribing analysis and cost (PACT) data, which would include information derived from NHS and private prescriptions and requisitions. It might be responsible for the issue of special controlled drug prescription pads. If thought appropriate it might also assume many of the inspecting and other functions currently performed by Home Office drugs inspectors. Inspectors and investigators would require access to background information about a doctor or pharmacist under scrutiny. There must be the facility to investigate expertly any irregularities or unusual features discovered as the result of such inspection and monitoring.

Outline of proposed approach

2.3 The Government's general policy on inspection of public services was set out in a policy statement in July 2003, *The Government's policy on inspection of public services*. The statement reiterates the need for inspection of public services wherever this can provide assurance that standards are being met and contribute to their improvement and where the benefit of inspection outweighs the cost. It calls on Ministers and their departments to manage the overall landscape of inspection, avoiding any duplication of effort and minimising the potential burden on service providers. Inspection is broadly defined as an external review independent of the providers of services and reporting in public. The statement stresses that those managing service providers are responsible for delivering services in accordance with relevant policies and standards; the role of inspection is to assess whether the systems being operated by the service provider are delivering effective outcomes for the service user.

2.4 In this context, the Government fully accepts the need for a comprehensive, integrated system which will raise standards of handling of controlled drugs, detect and deter poor practice and deliberate wrongdoing, and protect the safety of patients. In particular, the Government recognises the need:

- to ensure that all healthcare professionals who work with controlled drugs in any way are subject to equivalent standards of monitoring and inspection irrespective of the setting in which they work; and
- to bring together the skills of healthcare professionals with those of professionals with an inspection or law enforcement background in order to maximise the opportunity for deterring or detecting abuse.

2.5 However, the Government is not persuaded that setting up a new controlled drug inspectorate, divorced from the other systems which have recently been introduced into the NHS and private healthcare sector, would be the right way forward. As the previous chapter argued, any new arrangements for improving the management of controlled drugs in the healthcare sector should work with the grain of the new initiatives for improving clinical standards more generally. More pragmatically, the chances of detecting a future Shipman will be maximised if information on unusual or poor practice in the prescribing of controlled drugs is combined with information on other aspects of poor clinical practice.

2.6 As the Inquiry recognised, there are already substantial resources devoted to the inspection of healthcare organisations including in many cases their use of controlled drugs. These include:

- regular inspections of pharmacies by CIOs and inspectors of the RPSGB;
- inspections of NHS and private hospitals by the Healthcare Commission;
- inspections of private care homes by CSCI; and
- routine visits by prescribing advisors to discuss prescribing patterns as well as a range of less formal monitoring and developmental activities both by professional organisations and by NHS management.

But this activity is not systematically coordinated and the available resources are not used to their fullest potential.

2.7 The Government therefore proposes, subject to consultation on the legislative changes needed, to strengthen current arrangements for the monitoring and inspection of the management of controlled drugs as follows:

- at local level, a new statutory responsibility should be placed on each PCT and NHS Trust, Foundation Trust and private healthcare organisation to nominate a specific individual of appropriate seniority – a Proper Officer – who would monitor the use of controlled drugs within the Trust’s sphere of responsibility;
- this would be complemented by a duty of collaboration on other local agencies, including the local police force, social services authorities, the National Patient Safety Agency (NPSA) and relevant inspectorates, to share information and intelligence relevant to the assessment of healthcare professionals working for the PCT or Trust;
- new audit tools (described in more detail in Chapter 4) would be made available to help PCTs and Trusts discharge these responsibilities;
- for organisations and individuals working purely in the private and voluntary sectors, the Healthcare Commission and CSCI would continue (as now) to be responsible for assessing the management of controlled drugs as part of their regular inspections and for taking appropriate action over any concerns, including de-registration where necessary;
- at national level, an explicit responsibility would be placed on a named individual in the Healthcare Commission for the external review of these arrangements. He/she would be responsible for ensuring that all NHS organisations had satisfactory arrangements in place for assuring the safe use of controlled drugs, for ensuring the satisfactory operation of the local networks, and for alerting Government to any failure by other partners to collaborate fully or to devote adequate resources to controlled drug issues.

This combination of clear local responsibility for action, and national inspection of performance against the required standards, is in line with current arrangements for improving the quality of clinical care in the NHS more generally. It allows for local flexibility to determine the most appropriate arrangements locally with accountability to a national body. The Government believes that this combination will give the best assurance possible against a future Shipman.

2.8 The Department of Health will issue guidance to the NHS as soon as possible on how these new arrangements will work. The remainder of this chapter sets out the key points.

Detailed proposals

General principles

2.9 All healthcare organisations will, in the first instance, be responsible, through their normal clinical governance arrangements, for monitoring all aspects of the use and management of controlled drugs by all healthcare professionals who they employ or with whom they contract. To reinforce this principle, the Government proposes to place a statutory responsibility (subject to consultation and Parliamentary approval of the legislative changes needed) on each healthcare organisation to nominate a specific individual – the Proper Officer – to undertake these functions on behalf of the organisation. The Proper Officer would be a senior executive officer of the organisation with appropriate professional standing, normally reporting either directly to the Chief Executive or to another executive director of the organisation; this might be for instance the Director of Public Health (for PCTs) or the Medical Director (for NHS or Foundation Trusts).

2.10 The Department of Health is in discussion with the RPSGB, the Healthcare Commission and CSCI with the aim of ensuring that where appropriate they include inspection of arrangements for management of controlled drugs in their respective areas of responsibility.

2.11 The Government will place a statutory duty of collaboration on healthcare organisations, police forces, social services authorities, NPSA and the relevant inspection bodies (RPSGB, Healthcare Commission and CSCI). This duty should require these organisations to share intelligence about potential controlled drug offences and to take remedial action, singly or jointly as required, within their proper spheres of responsibility.

2.12 Within each area covered by a PCT, the PCT's Proper Officer will be responsible for setting up and operating an intelligence network for the sharing of information between the PCT and neighbouring PCTs, NHS and Foundation Trusts, inspectors from the RPSGB, other healthcare regulatory bodies, Healthcare Commission and CSCI, and local police forces, with the aim of:

- identifying those individual healthcare professionals or organisations (including private healthcare organisations which operate within the PCT area) where there is serious cause for concern over the management of controlled drugs; and
- agreeing what remedial action is needed.

In serious individual cases the relevant parties might set up an "Incident Panel" to review the intelligence on a particular healthcare organisation or individual.

2.13 The arrangements described in paras 2.9 to 2.12 could be at the level of the individual PCT or of a grouping of PCTs, depending on local geography and on the alignment of NHS, local authority and police force boundaries. Northern Ireland already has an arrangement of this kind. PCTs will be encouraged, where possible, to pool resources in order to achieve a concentration of skills and experience in dealing with controlled drugs issues.

2.14 Proper Officers will be required to establish mechanisms to allow for very quick sharing of intelligence and joint action in cases of urgency (for instance where patients are clearly in danger or where there is a risk that evidence will be destroyed unless action is taken without delay). They will also need to ensure that there are clear and well signposted routes for any healthcare professional, patient or member of the general public to raise matters of concern in confidence.

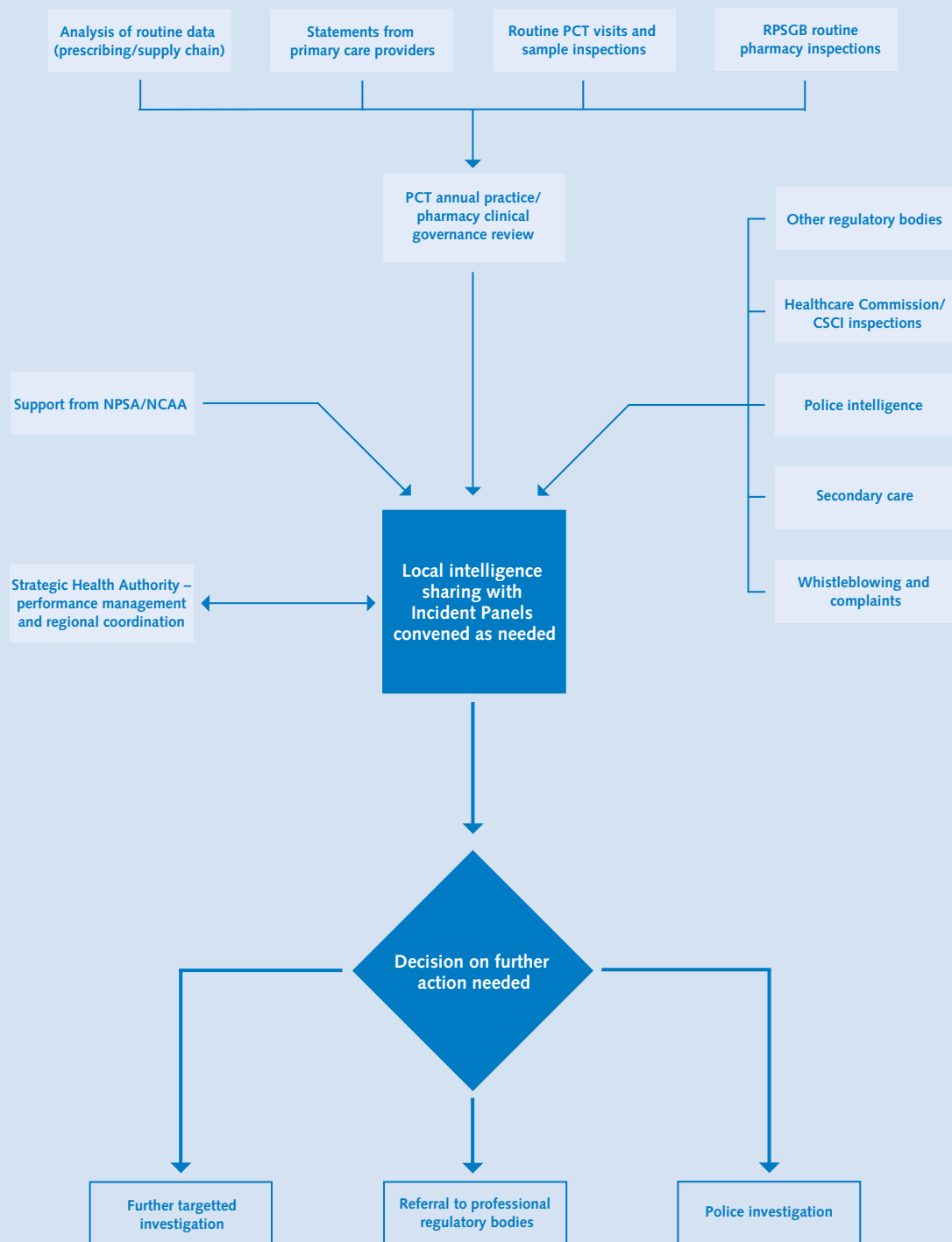
2.15 In the more serious cases – but not those requiring such urgent action – one option would be a formal inspection by a joint team consisting of an officer from the local police force with experience in controlled drug issues and a senior professional advisor from the relevant healthcare organisation, with other advisors as needed. This may be particularly relevant in the NHS primary care context. Following such an inspection the team should report back to the Proper Officer of the relevant healthcare organisation with recommendations for further action.

2.16 Remedial action could range from a developmental visit by the relevant clinical governance lead or his/her representative, through referral to the National Clinical Assessment Authority (NCAA)* or to the relevant professional or other regulatory body, to a request to the police to begin a formal investigation of potential criminal wrongdoing.

2.17 The proposed new arrangements are illustrated in Figure 1.

* From 1 April 2005 NCAA will be established as a separate division within NPSA.

Figure 1 : Proposed model for monitoring and inspection of controlled drugs



← information flows
 ← actions

Accountability

2.18 Where the cause for concern centres on a healthcare professional in relation to his/her NHS practice or on the performance of an NHS organisation, the relevant NHS Proper Officer will be responsible for determining what action is needed to protect public health, and for following through this action. They will be accountable for this responsibility, through the organisation's Chief Executive, to their Strategic Health Authority (SHA).

2.19 Where the concern centres on a Foundation Trust the responsibility for action will rest in the first instance with the organisation's management and ultimately with Monitor, the Independent Regulator of Foundation Trusts, acting on the advice of the Healthcare Commission. For private or voluntary healthcare or social care organisations, action will ultimately rest with the Healthcare Commission or with CSCI respectively. In this case, remedial action could, in extreme circumstances, result in withdrawal of registration.

2.20 Local police forces, in consultation with the Crown Prosecution Service as appropriate, retain the responsibility of determining whether the evidence for possible criminal behaviour is sufficiently strong to justify a criminal investigation with a view to subsequent prosecution.

2.21 In addition to these primary accountabilities, the PCT Proper Officer is responsible for ensuring that appropriate action is being taken, by one route or another, in each case brought to his/her attention.

2.22 SHAs would be accountable for ensuring that satisfactory local arrangements had been put in place, and for facilitating the exchange of intelligence information throughout the SHA's area. They would also performance manage PCTs and NHS Trusts (but not Foundation Trusts) for the discharge of their responsibilities.

Particular settings: NHS primary care

2.23 PCT Proper Officers will be responsible, through their normal clinical governance arrangements, including the work of prescribing advisors, for monitoring the prescribing and administration of controlled drugs by GP practices, community pharmacies and community nursing teams. They will be helped in carrying out this responsibility by the provision of a number of new or enhanced audit tools covering the prescribing of controlled drugs by all primary care prescribers (including private prescribing) and the movement of stocks of controlled drugs down the supply chain. Chapter 4 gives further details.

2.24 As part of this responsibility, PCTs will be asked to carry out a formal clinical governance review once a year of each primary care provider in contract with the PCT, based on a benchmark analysis derived from existing information, a statement from the organisation, and reports from routine visits by prescribing advisors and/or clinical governance leads. This review would include an assessment of the organisation's clinical standards in the prescribing, administration, storage and disposal of controlled drugs and an assurance that it was complying with the Misuse of Drugs Act and the associated regulations. The annual statement would include a formal declaration as to whether or not the organisation kept stocks of controlled drugs and would also provide the opportunity to draw attention to any special features (eg prescribing responsibility for a hospice or care home) which might explain unusual patterns of prescribing or supply.

2.25 Subject to further discussion with the RPSGB, their inspectors will be invited to include, as part of their routine inspections of community pharmacies, a check on the management of

controlled drugs, including examination of controlled drug registers and storage of controlled drugs. Routine inspections by CIOs will be discontinued, although police forces will be asked to consider inspecting a random sample of pharmacies and/or to taking part in joint inspections with RPSGB inspectors.

2.26 PCTs will also arrange for comparable inspection of the arrangements for handling controlled drugs at a random sample of dispensing practices and other practices at which stocks of controlled drugs are held, in addition to the visits from prescribing advisors or clinical governance leads to all GP practices.

NHS secondary care (including Ambulance Trusts)

2.27 Broadly similar principles will apply, with the responsibility resting on the Proper Officer of the NHS or Foundation Trust for monitoring the Trust's management of controlled drugs through normal clinical governance arrangements. The fullest possible use should be made of benchmarking and standard operating procedures.

2.28 The Healthcare Commission will be invited to report specifically on any points of concern as part of their routine assessment of Trusts' governance standards or compliance with healthcare standards. Trusts may also wish to consider arranging with similar Trusts for mutual audit of their management of controlled drugs, or inviting the RPSGB and/or local CIOs to carry out occasional inspections of their arrangements. For this purpose, the Government will legislate to give RPSGB inspectors the power (but not the duty) to inspect hospitals at the request of the Proper Officer or the hospital or of a relevant PCT, including as necessary down to ward or departmental level.

2.29 The Trust will be expected to play a full part in the local intelligence network and should in particular be involved in the discussion of any issue at the interface between primary and secondary care, for instance in community hospitals.

Private healthcare and care home sectors

2.30 All private and voluntary healthcare providers are required to register with the Healthcare Commission and are subject to periodic inspection as a condition of their continued registration. However there are persistent concerns over the extent to which some types of small-scale clinic, including some infertility and slimming clinics, are registering as required. The improvements in the audit trail described in Chapter 4 will help to throw light on this issue and will provide the means of enforcing the legal requirements.

2.31 CSCI already has a regular programme of inspections for care homes and other types of residential establishment such as special residential and boarding schools. Specialist pharmacy inspectors are available for follow-up visits if the generic inspection reveals any cause for concern.

2.32 In future, all private and voluntary healthcare and care home providers will be required to make an annual declaration stating whether they prescribe, administer or supply controlled drugs. Where such a declaration is in force, the Healthcare Commission/CSCI will, as part of their regular assessments – as is already their practice – include an assessment of the adequacy of arrangements for management of controlled drugs. If there are grounds for concern, the provider will be given a fixed period to remedy the concern under threat of losing its registration.

2.33 The Healthcare Commission and CSCI will play a full part in local intelligence networks, including attending Incident Panels as required, for discussion of any individual practitioners who

work in both the NHS and private sectors, including prescribers who prescribe for care homes. Any concerns relating to practitioners who work solely in the private sector will, as now, be taken up directly with the local police force concerned.

Standards and training

2.34 The new arrangements will require common standards for developmental and inspection visits and a competency framework for those involved in developmental visits, inspection and enforcement. Work is already underway to develop these standards, in collaboration with all organisations involved in the monitoring and inspection of the use of controlled drugs in healthcare.

2.35 Based on the competency framework, the Government will work with professional and educational organisations to ensure access to suitable initial and update training for all who will be involved in developmental, inspection or enforcement work. Where possible, such training will be multiprofessional.

2.36 All police forces will be asked to ensure that they have access to appropriate expertise in the management of controlled drugs in the NHS to enable them to fulfil the responsibilities set out above.

Central oversight and support

2.37 The Government has asked the Healthcare Commission to give specific responsibility to a senior officer for assessing the performance of NHS organisations in relation to their responsibilities for ensuring the safe and appropriate use of controlled drugs. Where the Healthcare Commission is not satisfied with the performance of a particular organisation it will be invited to report its concerns to the Secretary of State for Health and (where appropriate) the Home Secretary or to Monitor in respect of Foundation Trusts.

2.38 In the short term, PCTs and NHS or Foundation Trusts may need additional support in discharging their responsibilities in addition to access to training (see para 2.35 above). This might include:

- the further development of tools for the analysis of routine prescribing data, including prescribing in the private and voluntary sectors;
- application of the risk analysis tool developed by NPSA to help PCTs and Trusts with the handling of individual cases;
- support in individual cases from NCAA; and
- providing contacts for specialist skills such as expertise in detecting computer fraud; and
- networking arrangements to share examples of good practice.

The Government will consider further what additional help should be made available. However, PCTs/Trusts would remain responsible for decisions in individual cases.

Further work

2.39 Further work is needed to apply the general principles set out above to other healthcare settings in which controlled drugs are supplied or administered, including:

- dental services, both in the NHS and in the private sector;
- educational establishments;
- regulated children's services;
- prisons;
- military establishments;
- occupational health services;
- rescue services; and
- ships and other offshore settings.

The Government will issue further guidance as needed.

2.40 The Government will also commission a study of the best ways of sharing intelligence on controlled drug issues in healthcare organisations between police forces nationwide (including between the different parts of the UK). Information held by police forces would be made available, subject to stringent safeguards and a clear "need to know" principle, to healthcare regulatory bodies, local NHS organisations, and inspection bodies. Similarly information held by the regulatory bodies would be made available as appropriate to the law enforcement agencies. The principles underlying this reciprocal sharing of information would be set out in Memoranda of Understanding, as recommended (in the particular case of the GMC and police forces) by the Clifford Ayling Inquiry report. In carrying out this feasibility study, the Government will take into account the Inquiry's recommendation in its Fifth Report for a national database of information for NHS organisations on the employment and disciplinary history of healthcare professionals.

Summary of proposed action

2.41 Subject to further consultation and to Parliamentary approval of the legislative changes required, the Government will in England*:

- place a statutory requirement on all healthcare organisations to nominate a Proper Officer who will be responsible for all aspects of the management of controlled drugs within the organisation;
- place a statutory duty of collaboration on all healthcare organisations, police forces, social services authorities, and relevant inspection bodies, requiring them to share intelligence about potential controlled drug offences;
- require the Healthcare Commission to nominate a senior officer to assess the performance of healthcare organisations in relation to these responsibilities;

* Detailed arrangements will differ in other parts of the United Kingdom, although broadly similar principles will apply.

- invite the RPSGB, the Healthcare Commission and CSCI to include an assessment of the management of controlled drugs, where appropriate, in all the inspection visits or assessments which they carry out;
- require PCTs to arrange for the inspection of a random sample of dispensing practices and other GP practices at which stocks of controlled drugs are held;
- give further guidance on the application of these principles within the NHS, in the private and voluntary healthcare and care home sectors, and in other settings in which controlled drugs are regularly used;
- work with the organisations involved in developmental assessments or inspections to agree common standards for visits and a competency framework for those who will be involved in such work;
- work with professional and educational organisations to provide access to suitable training for inspectors and assessors;
- consider what additional support NHS organisations may need to help them discharge their responsibilities; and
- commission a study of the best ways of sharing police intelligence on controlled drug issues in healthcare organisations between police forces on a UK-wide basis.

Chapter 3

Prescribing of controlled drugs

The Inquiry's recommendations

3.1 Shipman was involved, at an early stage in his career, in the abuse of pethidine which he obtained by writing prescriptions in the name of patients who did not receive the drug. The high level of pethidine supplies to one community pharmacy during 1974/5 was noted by the Home Office Drugs Branch Inspectorate, and Shipman's prescribing identified. He was interviewed by the Inspectorate and West Yorkshire Police and admitted diverting the drug to his own use. He was convicted of offences under the Misuse of Drugs Act in 1976, and his case was subsequently considered by the GMC's Professional Conduct Committee. Despite this, no restrictions were placed on his professional practice and Shipman, like virtually all other registered doctors and dentists, continued to have the right to prescribe and to possess all drugs including controlled drugs.

3.2 The Inquiry therefore considered whether it would be sensible to impose some restrictions on what is at present the virtually total freedom of doctors to prescribe controlled drugs. It recommended restrictions in four main areas:

- prescribing by doctors who have no legitimate reason to prescribe controlled drugs as part of their normal clinical practice;
- prescribing controlled drugs for oneself or for one's immediate family;
- prescribing by doctors who have been convicted of a controlled drug offence or cautioned in relation to a potential offence; and
- restrictions on the total quantity that can be prescribed and the length of time for which the prescription remains valid.

Outline of proposed approach

3.3 The professional and patient groups consulted by the Government in Working Group 2 agreed that the restrictions recommended by the Inquiry were all highly desirable and should in due course be applied not only to doctors and dentists but also to other prescribers who may in future be authorised to prescribe controlled drugs (see paras 3.18 – 3.21 below). The only issue was how to implement them in a way which does not impede patient care and does not require disproportionately complex machinery. Taking the first point in para 3.2 as an example, it is relatively easy to recognise inappropriate prescribing of controlled drugs by doctors going outside their normal clinical practice but much more difficult to determine which doctors are unlikely ever to need to prescribe controlled drugs. Defining two categories of doctors – those who were allowed to prescribe controlled drugs, and those who were not – would either allow much inappropriate prescribing to take place or would risk putting barriers in the way of appropriate patient care.

3.4 The Government's preferred approach is to build on existing work by the GMC and other professional regulatory bodies* to define standards of good clinical practice, including good prescribing practice, and to rely on the systems for monitoring and inspection described in the previous chapter to detect instances of practice which fails to meet these standards. Where clearly inappropriate prescribing of controlled drugs is detected, NHS organisations and the professional regulatory bodies have powers to impose sanctions on prescribers and to safeguard public health. The Government fully agrees with the Inquiry that the performance of PCTs and of the GMC in using their available powers needs to be audited.

Detailed proposals**

Recommendation 2:

A medical practitioner should be entitled to prescribe or administer controlled drugs only if s/he needs to do so for the purposes of the actual clinical practice in which s/he is engaged. For the vast majority of doctors, the existence or otherwise of such a need will be obvious. A practitioner who wishes to prescribe controlled drugs may, where the need is not obvious, have to justify such need when applying for the issue of a special controlled drug prescription pad.

Recommendation 5:

The General Medical Council should make plain that it will be regarded as professional misconduct for a doctor to prescribe controlled drugs for anyone with whom s/he does not have a genuine professional relationship.

3.5 The Government agrees in principle with these recommendations. As a minimum, eligibility to prescribe controlled drugs (and all other medicines) will be dependent on the prescriber being accredited with a "licence to practise", or its equivalent, by the appropriate professional or registration body***.

3.6 Beyond this, ethical guidance from the GMC in *Good medical practice* and *Prescribing medicines – frequently asked questions* already makes clear the ethical basis on which doctors may treat patients, in particular that:

- treatment should be based on a thorough history taking and examination;
- there is a genuine clinical need for treatment;
- the doctor does not prescribe beyond his/her experience and competence; and

* In the context of this Chapter the principal bodies are the RPSGB, the Nursing and Midwifery Council (NMC) and the General Dental Council (GDC), though other regulatory bodies may also be relevant.

** In the Inquiry's report all recommendations are understood to apply to all controlled drugs (ie to controlled drugs in schedules 2-5) unless otherwise specified. The same convention is followed in this response. The Home Office is considering a review of the current schedules which could result in some recategorisation of some classes of drugs. If and when this occurs, the Government will review at the same time the schedules to which each of the controls described in this response should apply.

*** With effect from April 2005, all doctors registered with the GMC will in addition require a "licence to practise" to be allowed to treat patients. The licence to practise is subject to a 5-year revalidation which in turn depends on the doctor producing evidence that he/she has kept up his/her clinical skills. For example, doctors who have retired from active clinical practice may wish to keep their GMC registration but will not in future have a licence to practise and associated privileges.

- the doctor (if not the patient's normal GP) should seek to gain the patient's consent to inform the GP of the result of the consultation.

The Government will work with the professional regulatory bodies to build on and strengthen such guidance; to make clear that prescribing of controlled drugs not in accordance with these principles will be regarded as calling into question the prescriber's fitness to practise; and to ensure that there is equivalent guidance for each of the professions that will in future have the authority to prescribe.

Recommendation 3:

It should be a criminal offence for a doctor to prescribe a controlled drug for him/herself or to self-administer a controlled drug from his/her own or practice stock save in circumstances of emergency which circumstances should be covered by an appropriately worded statutory defence. The doctor should be required to declare the position on the prescription.

Recommendation 4:

When a general practitioner (GP) has members of his/her immediate family on his/her list (which should happen only very rarely) s/he should inform his/her local primary care trust (PCT) of the position. It should be unacceptable for a doctor to prescribe a controlled drug for an immediate family member who is not on his/her list save in circumstances of emergency. In all cases where a doctor prescribes a controlled drug for a member of his/her immediate family the doctor should be required to declare on the prescription his/her relationship to the patient and if it is the case that s/he is prescribing in an emergency.

3.7 The Government agrees that it is entirely inappropriate for a prescriber to prescribe a controlled drug for him/herself or to self-administer from practice stock except in genuine emergencies. However, the Government does not consider that this objective would be best achieved by making such behaviour a criminal offence. Such a sanction would be difficult to enforce (especially in the case of self-administering from stock) and would deter prescribers with an addiction problem from seeking professional help and rehabilitation. Instead, the Government will discuss with the professional regulatory organisations how current ethical guidance can be strengthened, in particular to define as clearly as possible what self-treatment is permissible in an emergency.

3.8 The Government also agrees that GPs and other primary care practitioners should not normally have members of their immediate family on their personal list, or to prescribe controlled drugs in Schedules 2-4 for a family member not on their list. The Department of Health will work with the Council for Healthcare Regulatory Excellence (CHRE) and with professional regulatory bodies to develop NHS and professional good practice guidance defining the (very limited) range of circumstances in which such treatment could be acceptable.

3.9 Where a GP is a member of a multi-partner practice, and wishes members of his/her immediate family to be treated by the practice, the GP will be required to explain the reasons to the PCT, setting out the circumstances (if any) in which he/she will personally treat the family member. The guidance will need to deal specifically with the issue of rural areas where such arrangements may be unavoidable.

Recommendation 6:

A medical practitioner convicted or cautioned in connection with a controlled drugs offence should be under a professional duty to report the conviction or caution to the GMC which should immediately consider what if any interim action should be taken and should report the facts and its own action to the practitioner's employer or PCT.

3.10 The Government agrees with this recommendation, and will work with the CHRE and with the professional regulatory bodies to implement it. The GMC has already issued guidance to this effect.

Recommendation 7:

The Government should commission an independent review and audit of the way in which the GMC and PCTs are using their powers to restrict the rights of medical practitioners involved in controlled drugs offences to prescribe and administer controlled drugs. Only if satisfied that these powers are being properly exercised for the protection of the public should the Government allow the provisions of section 12 of the Misuse of Drugs Act 1971 to remain in abeyance or to be repealed.

3.11 The Government accepts this recommendation in principle and agrees that it is reasonable to seek an assurance that PCTs and the GMC are using appropriately the powers given to them.

3.12 For its part, the Government will carry out a survey of a sample of those PCTs where a doctor has been involved in a controlled drug offence, seek independent audit of the validity of the decisions reached, and publish the results.

3.13 The GMC has already established a Determination Audit Sub-Group to audit the decisions made by its Fitness to Practise panels, and summary outcomes are published in the form of an annual report to Council. The decisions of the Fitness to Practise panels are also in effect subject to external audit by the CHRE. The Government will work with the CHRE and with the other professional regulatory bodies to ensure a similar degree of accountability and transparency, taking into account the Inquiry's further recommendations on this subject in its Fifth Report.

Recommendation 8:

Whenever a restriction is placed on a doctor's prescribing powers this information must promptly be made available (preferably by electronic means) to those who need to know it especially pharmacists who require access to such information at all times.

3.14 The Government accepts this recommendation. There are already established arrangements for cascading information about potential threats to public health which will in the short term be used to make such information available to pharmacists. In the longer term, when all community pharmacists are linked to the electronic transmission of prescriptions (ETP) service, the Government will consider whether such information could be held on a secure intranet site (the GMC have already agreed in principle that all current restrictions on doctors' clinical practice should be held on the online version of the GMC Register, and plans to implement this as soon as possible). Alternatively, prescriptions from unauthorised prescribers could be stopped at source through the GP prescribing system. In taking these ideas forward, the Government will also bear in mind the Inquiry's proposals for a comprehensive national database of information about doctors working in the NHS.

Recommendation 14:

The amount of a controlled drug that can be dispensed on a single prescription should be limited to a supply sufficient to last 28 days. This restriction would not apply to drugs in Schedule 5 to the Misuse of Drugs Regulations 2001.

Recommendation 15:

The duration of validity of a prescription for controlled drugs should be limited to 28 days. This restriction would not apply to drugs in Schedule 5 to the Misuse of Drugs Regulations 2001.

3.15 The Government agrees that a supply of 28 days should be sufficient in most clinical circumstances, but is persuaded that there may be legitimate exceptions – for instance, where a UK resident is intending to spend some time abroad and wishes to take a sufficient supply of pain-relieving drugs. The Government therefore proposes to work with the professional regulatory bodies to issue guidance making clear that single prescriptions for controlled drugs in Schedules 2-4 should normally be limited to a supply of 28/30 days*, unless there are genuine clinical reasons for a longer supply. Repeat dispensing might be helpful in order to limit the quantity of controlled drugs physically present in the patient's home at any one time. The Government will consult further on whether to amend the Misuse of Drugs Regulations 2001 to make this possible.

3.16 The Government agrees that the validity of a prescription for controlled drugs in Schedules 2-4 should normally be limited to 28/30 days and proposes to amend the Misuse of Drugs Regulations 2001 to that effect. The Government considers that there can be very exceptional circumstances in which a longer validity might be justified – for instance, certain recurrent conditions where the patient could experience severe pain without notice at a time when a prescriber is not available to issue a fresh prescription. The draft amendment will therefore propose that the prescriber may, where clinically necessary, endorse and sign the prescription to extend its validity to the current legal limit of 91 days.

3.17 For NHS prescribing, the Department of Health will consider issuing guidance requiring prescribers to notify the PCT (in NHS or Foundation Trusts, the Trust's Medical Director) on each occasion that they prescribe for an exceptional amount or length of validity.

* Prescribers and dispensers may need some flexibility to enable dispensers to dispense whole packs of medicines, which may contain supplies for 28 or 30 days depending on the manufacturer.

Extended prescribing

3.18 The Inquiry's report discusses, but does not reach a firm recommendation on, the desirability of allowing prescribers other than doctors (and dentists) to prescribe controlled drugs. Nurse prescribers with access to the extended nursing formulary can already prescribe a limited range of controlled drugs both in palliative care and in other settings. Following consultation in 2003 proposals to extend the range of controlled drugs which can be prescribed by nurse prescribers have recently been discussed by the Committee on Safety of Medicines (CSM) and by ACMD. In addition, the Home Office has consulted on a proposal to allow prescribing of controlled drugs by supplementary prescribers*.

3.19 The consensus from all these groups is that new prescribers should be entitled to prescribe controlled drugs where there is a genuine need and where patient safety can be assured. For instance, where a patient has been prescribed opioid drugs for pain relief in a terminal condition and the drugs are being supervised by a palliative care nurse specialist, it could be very convenient for the patient for subsequent prescriptions to be written by one of the nursing team rather than having to refer back to the original prescribing doctor. This would be an example of supplementary prescribing of controlled drugs.

3.20 The Government agrees with the consensus view and proposes to amend the Misuse of Drugs Regulations 2001 and the GMS contract regulations to allow prescribing of controlled drugs by supplementary prescribers, and in due course to extend the range of controlled drugs which independent prescribers may prescribe.

3.21 In agreeing to these proposals, the ACMD has stressed the importance of adequate training for new prescribers. Education and training for healthcare professionals dealing with controlled drugs are discussed further in Chapter 6.

Summary of proposed action

3.22 Subject to Parliamentary approval of the necessary legislative changes, the Government will in England:

- discuss with the CHRE and with the professional regulatory bodies the best way to strengthen professional and ethical guidance on:
 - prescribing beyond the limits of one's competence and experience;
 - prescribing for oneself;
 - providing treatment on a regular basis or prescribing for one's immediate family; and
 - prescribing outside a genuine professional relationship, making clear in each case their particular application to controlled drug prescribing;
- work with the CHRE to encourage the GDC, RPSGB and NMC, and other professional regulatory bodies where appropriate, to follow the GMC in placing prescribers under a professional obligation to notify them of any controlled drug-related convictions or cautions within a reasonable period of time;

* Broadly speaking, "supplementary prescribers" are not allowed to initiate courses of treatment but may extend or vary courses of treatment after initial diagnosis by a doctor or other independent prescriber. "Independent prescribers" have full prescribing rights within their area of professional competence.

- carry out and publish an audit of a sample of decisions by PCTs where a doctor has been involved in a controlled drug offence;
- work with the CHRE to encourage the GDC, RPSGB, NMC and other professional bodies to develop transparent arrangements for internal and external audit of the decisions taken by their fitness to practise committees;
- use established arrangements for cascading information about prescribers who have had restrictions placed on their prescribing of controlled drugs; and in the longer term consider placing such information on a secure intranet site accessible by all pharmacists with access to the NHSnet or its successors;
- work with the CHRE and with professional regulatory bodies to issue NHS and professional guidance to the effect that single prescriptions of controlled drugs should normally be limited to a supply of 28 or 30 days, and clearly defining the clinical reasons which might justify a longer supply;
- consult on the possibility of amending the Misuse of Drugs Regulations 2001 to allow repeat dispensing of controlled drugs where this could help to reduce the quantities present in the community at any one time; and
- amend the Misuse of Drugs Regulations 2001 to limit the validity of controlled drug prescriptions to 28/30 days, unless the prescriber has endorsed and signed the prescription to extend its validity to the current legal limit of 91 days.

Chapter 4

The audit trail

The Inquiry's recommendations

4.1 As already noted, Shipman appears to have obtained most of his lethal armoury of drugs in one of two ways: by collecting controlled drug prescriptions on behalf of patients and diverting part or all of the supply for his own purposes; or by removing the remaining quantities of controlled drugs left over on the death of a patient. Under current legal controls, there is no complete audit trail of the movement of controlled drugs from dispenser to patient to destruction of any unwanted drugs at the end of the course of treatment. As a result, diversions for inappropriate use can go undetected.

4.2 The Inquiry has devoted a large proportion of its recommendations to addressing this issue of completing the audit trail. As the Inquiry itself recognises, there is no way of devising a system so watertight as to guarantee that a future case similar to Shipman's could never occur. However, the change in the overall context in recent years and in particular the increasing emphasis on clinical audit (see Chapter 1) will make it less likely that a maverick clinician would be able to continue to practise without questions being asked. In addition, there are a number of obvious gaps in the current arrangements and the Inquiry's recommendations seek to address these, in particular:

- to extend current arrangements for analysing the prescribing of controlled drugs to cover:
 - private prescribers; and
 - use of controlled drugs in GP practices for personal administration to patients (ie without prescription)*;
- to ensure that GP practices and pharmacies maintain a running balance of the quantity of controlled drugs accounted for by supplies in and supplies out and that this is reconciled at regular intervals with the physical stock in the controlled drug cupboard;
- to capture information on the name and ID details of anyone presenting and collecting a controlled drug prescription on behalf of a patient;
- for the most potentially harmful controlled drugs used in the community – injectable Schedule 2 drugs such as diamorphine – to provide for a reconciliation between the quantities received from dispensers, the quantities administered to patients, and the quantities still remaining in the patient's home.

* NHS Regulations allow GPs and other primary care practitioners to give drugs to patients by personal administration, using drugs drawn from the practice's own stock, rather than to give the patient a prescription which must then be presented to a dispenser. This is particularly common in medical emergencies, where the need for urgent treatment overrides the usual safeguard of separating the prescribing from the dispensing of the drug.

Prescribing Support Unit study on information systems

4.3 Although some of the necessary safeguards could be implemented by fairly simple adaptation of existing systems, achieving a full reconciliation at all stages of the cycle of supply and usage of controlled drugs is likely to be possible – as the Inquiry fully recognised – only with the use of modern information technology.

4.4 The Government therefore commissioned the Prescribing Support Unit (PSU), an analytical team based in West Yorkshire SHA, to carry out a study on the information requirements for meeting the Inquiry's recommendations on the audit trail and to advise on the options for implementation, both short term and long term.

4.5 The PSU has analysed the processes involved in the supply and use of controlled drugs, and associated information flows, into three "cycles" which they call the supply cycle, the prescribing/dispensing cycle, and the patient cycle. This analysis:

- confirms the Inquiry's view that there are a number of key gaps in the information which is available for monitoring; and
- suggests that it should be feasible to fill these gaps at reasonable cost, either through adapting existing information systems at the Prescription Pricing Authority (PPA) or in due course through the National Programme for IT (NPfIT).

4.6 In addition, the PSU recommends that:

- the Government should amend the Misuse of Drugs Regulations 2001 to require all those involved in the supply chain (manufacturers, wholesalers, dispensers and GP practices) to supply information in standardised formats on the flow of controlled drugs down the supply chain; and
- this information should be centrally collated and analysed so that any apparent discrepancies/diversions of controlled drugs can be further investigated at local level.

Outline of proposed approach

4.7 The Government agrees the need to enhance the audit trail in all the ways proposed by the Inquiry. However, the Government believes that in many cases there are better technical solutions. In particular, the Government considers that an early move towards electronic generation of prescriptions and electronic controlled drug registers holds the key to the efficient capture and analysis of the information needed. The Government also agrees with the PSU's view that information should, in general, be analysed centrally and reports issued to local controlled drug leads for further investigation as needed.

4.8 Subject to further work on cost and technical feasibility the Government is minded to accept the PSU's recommendation for collecting information at various points in the supply chain, which would provide a further level of safeguard over and above those recommended by the Inquiry. The Government will consult relevant stakeholders in the light of the results of these studies before final decisions are taken.

4.9 Professional organisations have however raised concerns over the practicality of the proposal for a “patient drugs record card” (PDRC) which would accompany the issue of injectable Schedule 2 controlled drugs in the community (see paras 4.21 – 4.25 below). The Government will therefore pilot this proposal before deciding whether to roll it out more widely.

Detailed proposals

Controlled drug prescriptions

Recommendations 9-16:

The Inquiry recommended that all prescriptions for controlled drugs – including private prescriptions – should be written on a special, distinct pad; that the form should indicate uniquely the identity of the prescriber and of the patient; and that, subject to patient consent, information about the patient’s condition should be included on the face of the prescription.

4.10 The Government accepts the spirit of these recommendations but believes that there are better ways of implementing them. Separate pads for different purposes would impede efficient patient care and would encourage the borrowing of pads from one prescriber to another, thus negating the intention of linking the prescription unambiguously to the prescriber. Also the detailed proposals below for completing the loop of the audit trail rely on, or would at least be made much more effective with, electronic generation and ultimately electronic transmission of prescriptions. Electronic prescribing is also the key to transfer of information, subject to patient consent, between prescriber and dispenser.

4.11 The Government is therefore persuaded that it should move as swiftly as possible to enable the electronic generation of prescriptions, subject to assurance that adequate security measures are in place. The special status of prescriptions of controlled drugs could be indicated in other ways – for instance, through overprinting on standard prescription stationery – and additional information such as a unique ID number for the prescriber, or the patient’s NHS number, could be added relatively easily.

4.12 The Government agrees that data from private prescribers should be captured. Subject to Parliamentary approval, the Government will amend the Misuse of Drugs Regulations 2001 to require private prescribers to use a standard form similar to (but distinguishable from) the NHS prescription form, and pharmacies dispensing such prescriptions to send them to a central data repository for analysis. The Government will consult on the proposal that private prescriptions should bear the patient’s NHS number, so that the quantity of controlled drug prescribing can be analysed by patient as well as by prescriber.

4.13 The Government does not believe that it would be acceptable to include information on the patient’s condition on the face of the prescription and suggests that sharing of information between prescriber and dispenser will need to wait for role-based access to the electronic patient record, as already envisaged in the NPfIT. The Government agrees that prescribers should be encouraged, through professional good practice guidance, to explain to patients the advantages of sharing information about their condition within the clinical team. However, patients’ wishes not to allow such sharing of information should be respected.

Safe custody and record-keeping in GP practices

Recommendations 17-19:

The Inquiry recommended that existing controls should be strengthened in two major areas. Firstly, GP practices should be required to use a standard form when requisitioning stocks of controlled drugs for use in the practice, and should send a copy to the Prescription Pricing Authority for analysis. Secondly, practices should maintain a running balance of stock levels in their controlled drug register, which could in future be in electronic form, and should carry out periodic reconciliations at a frequency which would be set out in standard operating procedures agreed with the PCT or the new national controlled drugs inspectorate.

4.14 The Government accepts these recommendations, and agrees with the Inquiry that an early move to electronic controlled drug registers will help to improve controls. The Government will therefore amend the Misuse of Drugs Regulations 2001:

- to require GP practices to use a standard form for requisitions of controlled drugs for practice use;
- to require pharmacists and wholesalers, when filling such orders, to send a copy of the requisition to the PPA for data capture and analysis; and
- to allow controlled drug registers (both in GP practices and in pharmacies – see below) to be held in electronic form.

4.15 In addition, and subject to further assessment of cost and feasibility, the Government will legislate to require practices to send or transmit information from the practice's controlled drug register to a central data repository (eg the PPA) for reconciliation with information from suppliers. The PPA would send reports of any discrepancies to the PCT which would investigate further as needed. This would act as a further disincentive to fraudulent manipulation of the practice controlled drug register. More generally PCTs will be responsible, through normal clinical and corporate governance arrangements, for educating GP practices, agreeing standard operating procedures and assessing compliance.

4.16 These principles will be extended to all other providers of primary healthcare services where stocks of controlled drugs are held, in particular to providers of out-of-hours services and to community midwifery services.

Controlled drugs in the pharmacy

Recommendations 20-27:

As already noted, one of the main loopholes which Shipman exploited was through collecting controlled drugs on behalf of the patient for which he had prescribed and then diverting the drugs to his own use. The Inquiry therefore recommended, as an additional check, that pharmacists should seek to establish the identity of anyone claiming to be collecting controlled drugs on behalf of patients, and record this information in the pharmacy's controlled drugs register. They also recommended that controlled drug registers could be kept in electronic form, should maintain a running balance which would be regularly reconciled against stock level, and should be stored for up to 10 years. Finally, the Inquiry recommended that pharmacists should have discretion to correct technical errors in the prescription where the prescriber's intention was clear.

4.17 The Government accepts all these proposals, and considers that the move to electronic controlled drug registers should take place as soon as possible since this is seen as an essential precursor to implementing other parts of the audit trail. The Government will therefore amend the Misuse of Drugs Regulations 2001:

- to allow controlled drug registers for pharmacies and dispensing practices to be held in electronic form;
- to allow running balances;

and will work with pharmacy professional organisations to promote their use.

4.18 In addition, once electronic controlled drug registers are in common use, the Government will:

- make the use of electronic controlled drug registers mandatory;
- require pharmacies and dispensing practices to keep secure copies for up to 11 years; and
- require all pharmacists and dispensing practices to transmit or copy information in their controlled drug registers to a central data repository for reconciliation with records from suppliers, as an external audit of their accuracy and completeness; this information would also be used to identify any prescribers regularly collecting large volumes of controlled drugs on behalf of their patients.

4.19 The Government agrees that pharmacists or qualified dispensers should have discretion to amend a controlled drug prescription where there is a technical error and where the prescriber's intention is clear, in the light of all the information available at the time of dispensing, and will amend the Misuse of Drugs Regulations 2001 to allow this.

4.20 NHS and professional organisations in Working Group 3 suggested that the principle should if possible be extended to cover cases in which the intention is not fully clear but the pharmacist can make a supply which in his/her judgement is safe and consistent with the underlying therapeutic intention. The group recognised that it might be difficult to express this in amendment

to the Regulations. The Government agrees that every effort should be made to enable patients to get access to the medicines they need provided this does not put their safety at risk, and will explore this suggestion further in discussion with relevant stakeholders.

Controlled drugs in the community

Recommendations 29-33:

The Inquiry was concerned to close the final loophole in the audit trail by establishing a reconciliation between the quantities of controlled drugs dispensed to patients with the quantities actually used and the quantities returned for destruction. They recognised that this was feasible (and necessary) only for Schedule 2 injectable drugs such as diamorphine the drug used by Shipman. They proposed the use of a patient drug record card (PDRC) which would be prepared by the pharmacy or dispensing practice dispensing the supply of drugs and annotated by the healthcare professional responsible for each administration of the drug. At the end of the course of treatment (or on the death of the patient) the responsible healthcare professional should either destroy the remaining drugs or return them to a pharmacy for destruction and the destruction or removal should be witnessed and entered on the card. The Inquiry suggested that removal of controlled drugs might be easier if ownership of controlled drugs reverted to the Crown on the death of the patient. Finally the PCT should inspect the PDRC and ensure that all quantities were accounted for.

4.21 The Government is sympathetic to the objective underlying these recommendations. However, serious concerns have been expressed over the feasibility of the proposed system of PDRCs and in particular the difficulty of ensuring that the completed PDRCs are returned for analysis. The Government therefore intends to pilot the proposals, and to assess the likely costs and benefits, before deciding whether to implement them more generally.

4.22 Subject to the results of this pilot, the Government considers that it would be more efficient for the completed PDRCs to be sent to a central data repository such as the PPA for audit and for reconciliation against pharmacy controlled drug registers, rather than analysed locally. This would provide another check against fraudulent alteration of the PDRC, and would cope more easily with the movement of patients (and their controlled drugs) between home and secondary care settings or between one PCT and another. The Government also believes that it is likely to be more practicable to complete the PDRC for each separate supply of controlled drugs rather than to copy the information into a master PDRC as recommended by the Inquiry.

4.23 The Government is not persuaded that changing the current law is either necessary or would (as the Inquiry intended) make it easier for healthcare professionals to remove or destroy unwanted controlled drugs after the death of a patient. Under current legislation, no patient or carer is entitled to possess a controlled drug once there is no longer a clinical need. It would seem more sensitive to rely on this argument than to attempt to persuade a grieving relative that they no longer owned the medicines in question – this might be particularly difficult in the case of a privately dispensed controlled drug.

4.24 The Government agrees that PCTs should be responsible for agreeing local arrangements for the recovery and disposal of unwanted controlled drugs. The Government considers that, as a general rule, the healthcare professional responsible for the patient's care should also take responsibility for retrieving any unwanted controlled drugs (and the related PDRC) at the end of

a course of treatment or on the death of the patient. The Government agrees with the advice from Working Group 3 that unwanted controlled drugs should normally be returned to a pharmacy or dispensary for audit and destruction, rather than destroyed on the spot; there may be other appropriate local solutions.

4.25 For the private sector, the Government will amend the Misuse of Drugs Regulations 2001 to make clear that the Registered Manager of each private healthcare or social care establishment is responsible for ensuring the safe recovery and disposal of any controlled drugs unwanted at the end of a treatment or on the patient's death, and for recovering any associated PDRCs and returning them to the central data repository. The Government will ask the Healthcare Commission or CSCI, as appropriate, to enforce this requirement.

Further work

4.26 The Government has commissioned research by the Sheffield School of Health and Related Research (SchARR) on current best practice in the disposal of unwanted controlled drugs. When the results of this research are available, the Government will draw on it in developing good practice guidance for the NHS and in designing the pilot studies of the PDRC proposal.

Summary of proposed action

4.27 Subject to Parliamentary approval of the required legislative changes, and to the results of the pilot studies referred to above, the Government will in England:

Prescriptions

- redesign the standard NHS prescription form to take the additional information recommended by the Inquiry (the patient's ID and a marker that the prescription is for a controlled drug);
- discuss with computer suppliers the feasibility of overprinting a controlled drug "watermark" on computer-generated prescriptions;
- amend the Misuse of Drugs Regulations 2001 to require private prescribers to use a standard form for controlled drug prescriptions (similar to but distinct from that used in the NHS), and to obtain forms from the PPA with identification numbers pre-printed; and to require pharmacists dispensing such prescriptions to send a copy to the PPA for data capture and analysis;
- amend the Misuse of Drugs Regulations 2001 to allow computer generated prescriptions for controlled drugs and to require prescribers to endorse separately each controlled drug (on a prescription containing several items);
- amend the Misuse of Drugs Regulations 2001 to require all prescriptions for controlled drugs to carry the prescriber's unique ID number (in future, the 12-digit practitioner code);
- discuss with pharmacy organisations the feasibility of a check that, for handwritten prescriptions, the prescriber ID number matches the signature;
- consult on a proposal that private prescriptions should carry the patient's NHS number;
- ensure that software for electronic transmission of prescriptions captures both the time of issue of a prescription and the time at which the prescription is handed over to the patient; and

- develop, in collaboration with professional organisations, good practice guidance encouraging prescribers to explain to patients the benefits of allowing information on their condition to be shared with other members of the care team.

Safe custody and record keeping in GP practices

- amend the Misuse of Drugs Regulations 2001 to require GP practices (and other primary care organisations such as out of hours providers) to use a standardised form in requisitioning supplies of controlled drugs, and pharmacists/wholesalers supplying against such requisitions to supply a copy of the form to the PPA;
- amend the Misuse of Drugs Regulations 2001 to allow controlled drug registers to be kept in electronic form and to require them to maintain running balances of each drug stocked;
- work with professional organisations to promote the use of electronic controlled drug registers;
- amend NHS contract regulations to require all NHS primary care organisations to comply with a standard operating procedure agreed with the PCT; and
- work with the Healthcare Commission to issue good practice guidance and model standard operating procedures based on best current practice, for use both in the NHS (including out of hours providers) and in the private sector.

Controlled drugs in the pharmacy

- amend the Misuse of Drugs Regulations 2001 to allow the pharmacist or qualified dispenser to amend the prescription where there is a technical error and where the prescriber's intention is clear;
- discuss with patient and professional organisations whether this principle could be extended to circumstances in which the prescriber's intention is not fully clear but the pharmacist/ dispensing assistant is able to make a safe supply in line with the prescriber's underlying therapeutic intentions;
- amend the Misuse of Drugs Regulations 2001 to require the pharmacist or dispensing assistant to seek and record information about the name and ID of any person, including healthcare professionals, collecting a Schedule 2 controlled drug on behalf of a patient; and to require a person collecting Schedule 3 or 4 controlled drugs to sign the back of the prescription form;
- amend the Misuse of Drugs Regulations 2001 to allow pharmacy controlled drug registers to be kept in electronic form;
- amend or clarify the Misuse of Drugs Regulations 2001 to make clear that controlled drug registers may include a running balance and the name/professional ID number of the pharmacist dispensing a controlled drug prescription, and work with pharmacy organisations to promote the recording of such information; and
- amend the Misuse of Drugs Regulations 2001 to require controlled drug registers to be kept for 11 years.

Controlled drugs in the community

- amend the Misuse of Drugs Regulations 2001 to require pharmacists, dispensing practices, and secondary care providers to prepare a PDRC to accompany each supply of injectable Schedule 2 controlled drugs dispensed into the community;
- amend the Misuse of Drugs Regulations 2001 to require healthcare professionals to make an appropriate record when administering injectable Schedule 2 controlled drugs or when removing or destroying any such controlled drugs;
- work with professional organisations to issue professional good practice guidance on these procedures;
- review the classes of person entitled to undertake or witness destruction of controlled drugs;
- issue NHS guidance to make PCTs responsible for the recovery and safe disposal of any unwanted controlled drugs (and associated PDRCs) after a patient's death or at the end of a course of treatment, and on possible models for discharging this responsibility; and
- amend the Misuse of Drugs Regulations 2001 to place a similar responsibility on the Registered Manager of each private healthcare or social care organisation.

4.28 In the longer term, when electronic generation and transmission of prescriptions and electronic controlled drug registers are in common use, the Government will further amend the Misuse of Drugs Regulations 2001 (subject to further consultation at the time and Parliamentary approval):

- to require prescribers to keep an electronic record of the controlled drug prescriptions they have written and to make it available for audit as required;
- to make electronic controlled drug registers mandatory, both for GP practices and for pharmacies;
- to require the pharmacy controlled drug register to capture information on the name and professional registration number of the prescriber and the name of the pharmacist dispensing the controlled drugs; and
- to require wholesalers to send information on the controlled drug orders they supply, and GP practices and pharmacists to send information on movements of stock into and out of their controlled drug registers, to a central data repository.

Chapter 5

Information for patients

The Inquiry's recommendations

5.1 The Inquiry recommended that patients receiving controlled drugs should have sufficient information to understand the special legal status of the drugs they were receiving. The recommendation is as follows:

Recommendation 28:

The RPSGB should provide guidance to its members as to the information and advice to be given to patients and their representatives when receiving a supply of a controlled drug. This should usually comprise an accurate description of the controlled drug prescribed and advice about the need to keep the drug safe because of the risk of diversion. Patients and their representatives should be advised to return unused drugs to the pharmacy. This information and advice should be given both orally and in writing.

Outline of proposed approach

5.2 The Government fully accepts the need to provide patients with accurate and objective information about any medication prescribed for them. At the same time, it has received strong representations both from the professional and from the patient organisations represented on Working Group 4 that this information should be sensitively conveyed, ideally in the context of an informed discussion in which the patient and the prescriber jointly review the options for treatment and jointly decide on the treatment to be prescribed. Working Group 4 also advised strongly that most of the key messages about controlled drugs – safe storage in the home, risk of harm if given to anyone other than the patient for whom they were prescribed, safe return of any unwanted medicines to a pharmacy or dispensary – were in fact equally applicable to all medicines.

5.3 The Government agrees that what is needed is a sustained programme of communications, backed up by information and training to healthcare professionals, to convey to patients these generic messages about the safe handling of (all) medicines. Specific information about the special legal status of controlled drugs should be conveyed in the context of a discussion with the prescriber or dispenser, backed up by access to factual information either about controlled drugs in general or about particular drugs.

Detailed proposals

5.4 Many of the proposals listed below will require concerted action between the Department of Health, patient organisations, professional organisations and the pharmaceutical industry. Where action does not solely fall to Government, the Department of Health will discuss further with the relevant partner organisations how each proposal should best be progressed.

General information for patients

5.5 The Government, working in cooperation with professional and patient organisations, will deliver a sustained communications programme to advise patients and carers of the need for safe storage of all medicines and for the return of unwanted medicines to community pharmacies for safe destruction (see Annex D for more detailed proposals on the messages to be conveyed and intended outcomes).

5.6 The opportunity will be taken to work with existing initiatives, such as the *Ask about Medicines Week* (part of the *Get the Right Treatment* campaign) and others, to promote this information.

5.7 The Government will consider how far NHS Direct and NHS Direct Online could be used more actively as a mechanism for reinforcing the messages to the public about safe storage, possession and return of unwanted medicines to the pharmacy.

5.8 Material will be produced in a way that is inclusive of all communities and groups in the UK.

Shared decision taking and specific information about controlled drugs

5.9 Healthcare professionals involved in prescribing, dispensing, supplying and administering controlled drugs to patients should convey any specific information about the legal status of controlled drugs, where appropriate, in the course of their clinical contact with these patients. The Department of Health will work with professional organisations to explore the best way of promoting and reinforcing this approach, including the use of professional and ethical codes of conduct.

5.10 In discussing treatment options with patients, prescribers should where appropriate refer to the special legal status of any controlled drugs under consideration, and should discuss sensitively any concerns expressed by patients.

5.11 Information about controlled drugs should be reinforced, where considered appropriate, by the provision of a suitable generic factual leaflet. The Government will discuss with relevant stakeholders how such a leaflet should be authored and disseminated. One possible starting point would be the material for professionals in the National Electronic Library for Health (NeLH), although this would need to be reworked in terms suitable for a lay audience. This material could also be held in the NHS Content Bank (managed by NHS Direct Online) and in the NeLH in a format that could be easily downloaded and printed off by patients and healthcare professionals. This would be a particularly suitable and cost effective mechanism for making local versions of the information about controlled drugs, including translations, available whenever and wherever it is needed.

5.12 The Government will work with its partner organisations in the *Medicines Guides* programme to give priority to those controlled drugs most commonly used in clinical practice. Information in the guides should make clear the special legal status of controlled drugs but should also emphasise their value in treating patients, in particular in areas such as pain relief.

5.13 Prescribers should explain to patients the advantages of sharing information about their condition with other members of the clinical team, including those responsible for dispensing, supply and administering medicines. Subject to patient consent, NHS IT systems should facilitate the sharing of appropriate information.

Education and continuing professional development

5.14 Initial and continuing education and continuing professional development (CPD) for healthcare professionals should include appropriate material on the need for safe storage, possession and return of all medicines, and on the legal status of controlled drugs (see chapter 6 for further details). The Government will work with professional bodies and educational providers to see how far existing curricula and arrangements for CPD need to be enhanced to achieve this aim.

5.15 The Government will invite the Healthcare Commission and CSCI to review the ways in which they can promote the safe handling of medicines both by healthcare professionals and by patients and their carers.

Information for the general public

5.16 The Department of Health will work with the Department for Education and Skills to review the opportunities in school and adult education to convey messages about the safe storage and safe return of medicines. The National Curriculum pilot programme *Making sense of health* might be one possible vehicle.

Further work

5.17 Further work is needed, in collaboration with patient and professional groups, to develop and pilot the key messages described above and to explore the possible vehicles by which they can best be communicated.

Summary of proposed action

5.18 In collaboration with patient, professional and educational organisations the Government will in England:

- deliver a sustained programme of communications to advise patients and carers of the need for safe storage of all medicines and for the return of unwanted medicines to pharmacies/dispensing surgeries for destruction;
- promote a climate in which prescribers and pharmacists/dispensing assistants convey specific information about the special legal status of controlled drugs in the context of shared decision taking and discussion of the appropriate use of medicines;
- ensure that NHS IT systems facilitate the sharing of appropriate information between members of the clinical team, and encourage prescribers to explain to patients the advantages of such sharing;

-
- support these initiatives by provision of suitable leaflets and internet material, including giving early priority to the most frequently used controlled drugs in the *Medicines Guides* programme;
 - consider how far existing curricula for initial and continuing education, and arrangements for continuing professional development, need to be enhanced to support the approach described in this chapter; and
 - review the opportunities in school and adult education to promote messages about the safe storage and safe return of medicines.

Chapter 6

Training and professional development

6.1 This chapter, which builds on recommendations from the ACMD's Shipman Committee (see para 1.16 above) and from Working Group 4, brings together the implications of many of the previous sections for professional education, training and professional development.

Healthcare professionals

Undergraduate education

6.2 The undergraduate education for healthcare professionals who prescribe, dispense or administer controlled drugs needs to cover:

- the legal basis for prescribing, dispensing or administering controlled drugs;
- the legal classification of controlled drugs;
- the law as it relates to clinical practice, including the requirements for safe storage, possession, record keeping and disposal of controlled drugs;
- the need for careful record keeping in relation to all uses of controlled drugs including (in the future, if implemented) PDRCs for injectable Schedule 2 controlled drugs;
- ethical guidance from the professional regulatory organisations;
- training in substance misuse and addictive behaviour; and
- training in the various clinical applications of controlled drugs.

6.3 Training should incorporate the requirements of the Misuse of Drugs Act 1971 and its associated Regulations and the responsibilities of the different healthcare professionals. This element of the curriculum should not be covered at too early a stage, so that it appears divorced from real clinical practice, and should be reinforced in clinical and early postgraduate training. Training should emphasise the appropriate use of controlled drugs in clinical care and in particular should not discourage the use of opiates in pain relief.

6.4 Undergraduate education of all healthcare professionals should emphasise the key importance of communications skills, both between members of the healthcare team and between the healthcare professional and the patient. This is particularly crucial in ensuring that information to patients on the special legal status of controlled drugs is sensitively conveyed in the context of a more general discussion of their therapeutic value (see Chapter 5).

6.5 The Government will open up discussions with professional regulatory bodies and education providers in order to review how far existing undergraduate curricula need to be enhanced to meet these needs.

Postgraduate education

6.6 A significant amount of formal professional education and training is delivered at the postgraduate level. In parallel with discussions on undergraduate education, the Department of Health will seek to work with the regulatory bodies and competent authorities to ensure that postgraduate curricula similarly reflect the need to reinforce and develop the appropriate and safe use of controlled drugs.

Continuing Professional Development

6.7 The Government will work with professional regulatory bodies and with education providers to ensure that healthcare professionals who prescribe, dispense or administer controlled drugs have access to update training programmes as needed on the legal requirements and on the safe storage, custody and disposal of controlled drugs. Where possible, training should be multiprofessional.

6.8 In the Government's view all healthcare professionals who prescribe, dispense or administer controlled drugs should be required to demonstrate, in meeting their CPD requirements, that they keep up to date on all aspects of controlled drug management including safe custody, safe storage, record keeping, supply and disposal of controlled drugs and the legal requirements of controlled drugs. They should have at least an annual appraisal to identify gaps in knowledge and skills in discussion with their employer, resulting in an agreed personal development plan and access to development mechanisms that will meet the agreed needs. For those professions that have formal revalidation processes, this appraisal should form an integral part of revalidation. The Government will work with the professional regulatory bodies, and with the clinical governance leads in NHS organisations, to achieve these ends.

Primary Care Trusts and primary healthcare providers

6.9 The Government fully recognises the importance of raising awareness in PCTs and primary care providers to the importance of controlled drug issues and in providing access to the knowledge and experience needed to ensure good practice in all primary care organisations. In 2003 the Department of Health commissioned the National Prescribing Centre (NPC) to develop management guidance covering both the legal requirements and further good practice guidance in relation to the use of controlled drugs in primary care, and a "preview edition" was published on the NPC's website in May 2004.

6.10 The NPC is now updating its guidance in the light of the Inquiry's recommendations and this response. The final version is expected to be published in 2005 and the NPC will reinforce this guidance through a series of presentations to NHS audiences. Once this programme has been rolled out, PCTs and Trusts will be expected to include training on controlled drug issues as a mandatory part of induction training for all new healthcare workers.

6.11 As already noted, guidance shortly to be issued on the new arrangements for provision of out-of-hours services will include specific reference to the management of controlled drugs. Out-of-hours providers will be asked to give assurances that all their staff are familiar with these requirements.

Secondary care providers

6.12 Good practice in the management of medicines in secondary care, including controlled drugs, was set out in the *NHS Executive Guidelines for the safe handling of medicines* (the Duthie Report). The Department of Health has asked the RPSGB to update the Duthie Report and the revised version will be published in January 2005. The Department will bring the revised guidance to the attention of NHS secondary care providers and ask them to ensure that all staff involved in the prescribing, supply or administration of medicines are familiar with its contents. The Department will also discuss with the Healthcare Commission the implications for its inspection of private providers.

Staff involved in monitoring and inspection

6.13 The new regime for monitoring and inspection outlined in Chapter 2 above will place new demands on staff in PCTs, professional inspectorates and police forces. Mention has already been made (para 2.16) of working to develop in more detail the content and standards for developmental visits and inspections relating to the management of controlled drugs. As part of this work, the Department of Health intends to commission a project to develop a competency framework for staff who will be involved in controlled drug monitoring and inspection work. This will in turn form the basis for commissioning suitable packages of initial and update training.

Summary of proposed action

6.14 The Government will, in consultation with professional regulatory bodies and education providers as appropriate, in England:

- review the extent to which the undergraduate and postgraduate curricula for healthcare professionals meets the need for training in the basic principles of the safe use and handling of controlled drugs;
- promote access to suitable update training to form part of healthcare professionals' continuing professional development;
- seek to ensure that all healthcare professionals who prescribe or use controlled drugs have a regular appraisal of the extent to which they have kept up to date with clinical or regulatory changes, and use this to identify training or development needs;
- promote the uptake in the NHS of the NPC guidance for PCT staff;
- promote the uptake in the secondary sector (both NHS and private) of the revised Duthie guidance on medicines management in hospitals; and
- ensure that suitable training packages are available for staff who will be involved in the monitoring and inspection of controlled drug arrangements.

Chapter 7 Implementation

7.1 This document outlines a challenging programme of action in response to the recommendations of the Shipman Inquiry's Fourth Report. The Government believes that this programme represents a proportionate and necessary response to the issues raised by the Harold Shipman case, and that the safety of patients in the UK's healthcare institutions deserves no less.

7.2 Nevertheless, it will be important in implementing this action programme to ensure that we do not lose sight of the reasons for using controlled drugs in healthcare in the first instance – the promotion of health, the treatment of disease and the relief of pain. The Government therefore intends to continue to work closely with patient organisations, partner organisations in the NHS, and the professions to ensure that implementation of these necessary safeguards is not at the expense of patient care.

7.3 This chapter outlines the Government's broad approach to implementation in England. A more detailed implementation plan, covering actions in response to the Shipman Inquiry as a whole will be prepared in due course in coordination with the Government's response to the Inquiry's Fifth Report.

Phase 1 (January to August 2005)

7.4 The immediate priorities will be the setting up of the new inspection arrangements (Chapter 2) and promoting the move towards electronic generation of prescriptions and electronic controlled drug registers (Chapter 4). By July 2005 the Government intends:

- to draft legislation to impose a statutory duty on healthcare organisations and a statutory duty of collaboration on healthcare and partner organisations (paras 2.7 and 2.11);
- to issue guidance on the new inspection arrangements to the NHS and to police forces and other partners (para 2.8);
- to have reached agreement with the RPSGB over the inclusion of controlled drug aspects in their routine inspections of community pharmacies (para 2.10 and 2.25);
- to have set up arrangements for the training of inspectors and for support to PCTs (paras 2.34 – 2.36);
- to amend legislation to allow computer-generated prescriptions and electronic controlled drug registers (paras 4.14 and 4.17); and
- to have made good progress on many of the actions listed under phase 2.

Phase 2 (September 2005 to March 2006)

7.5 During phase 2 the Government intends to complete the remaining early legislative changes needed to implement the action programme and much of the preparatory work for the enhancements to the audit trail (Chapter 4); and will be looking to professional organisations to issue good practice guidance covering the restrictions on controlled drug prescribing (Chapter 3). The information campaign on safe handling of controlled drugs (Chapter 5) should be well underway, as will improvements in education and training (Chapter 6). Specifically the following actions should be completed during this phase:

- the legislative changes to impose a statutory duty on healthcare organisations and a statutory duty of collaboration on healthcare and partner organisations (para 2.7 and 2.11);
- a feasibility study of the proposed national controlled drug intelligence database (para 2.40);
- regulation of the normal maximum validity of controlled drug prescriptions (para 3.16);
- professional guidance on restrictions on the prescribing of controlled drugs, including guidance on the normal maximum amount to be prescribed (para 3.15);
- regulations on the mandatory use of standard forms for private prescribing of controlled drugs and GP requisitions for controlled drugs (paras 4.12 and 4.14);
- regulations requiring GP practices to follow agreed standard operating procedures (para 4.15);
- guidance on the role of PCTs and the content of standard operating procedures (paras 4.15 and 4.24);
- regulations to allow pharmacists to correct technical errors in controlled drug prescriptions (para 4.19);
- guidance, in collaboration with professional organisations, to promote the use of electronic controlled drug registers and running balances (para 4.17);
- an evaluated pilot study of the possible use of PDRCs for Schedule 2 injectable controlled drugs (paras 4.21 – 4.22);
- guidance to PCTs on the recovery and safe disposal of unwanted controlled drugs (para 4.24);
- the beginnings of the sustained programme of information to patients about the safe storage of all medicines and the return of unwanted medicines to pharmacies (paras 4.25, 5.5, 5.17 and 5.18); and
- a review of the arrangements for initial and continuing education of healthcare professionals in controlled drug issues (para 5.14).

Phase 3 (April 2006 to March 2007)

7.6 During this period, subject to the outcomes of the feasibility study on the PDRC proposal, the Government will:

- legislate to require pharmacists and dispensing practices to prepare PDRCs for each issue of Schedule 2 injectable controlled drugs (paras 4.21 – 4.22);
- set up systems to capture (and subsequently to analyse) the data from private prescribing, GP requisitions, and PDRCs (paras 4.12, 4.15 and 4.18);
- issue good practice guidance about the use of PDRCs (para 4.26).

Phase 4 (April 2007 onwards)

7.7 In the final phase of implementation the Government will seek to complete those actions which depend on the widespread use of electronic generation of prescriptions, electronic controlled drug registers and other developments in IT. In this period the Government intends (subject to consultation nearer the time):

- to consider the feasibility of setting up a secure intranet site listing those prescribers whose prescribing of controlled drugs is restricted (para 3.14);
- to require wholesalers to send information on their supplies of controlled drugs, and GP practices and pharmacies to send information from their controlled drug registers (para 4.14);
- to set up systems for the collation and analysis of these data (para 4.18); and
- to make mandatory enhancements to the pharmacy controlled drug register such as running balances and the name of the pharmacist dispensing prescriptions (para 4.17).

Annex A: The Shipman Inquiry's terms of reference

The Shipman Inquiry has been established under the Tribunals of Inquiry (Evidence) Act 1921. Its terms of reference are as follows:

- (a) after receiving the existing evidence and hearing such further evidence as necessary, to consider the extent of Harold Shipman's unlawful activities;
- (b) to enquire into the actions of the statutory bodies, authorities, other organisations and responsible individuals concerned in the procedures and investigations which followed the deaths of those of Harold Shipman's patients who died in unlawful or suspicious circumstances;
- (c) by reference to the case of Harold Shipman to enquire into the performance of the functions of those statutory bodies, authorities, other organisations and individuals with responsibility for monitoring primary care provision and the use of controlled drugs; and
- (d) following those enquiries, to recommend what steps, if any, should be taken to protect patients in the future, and to report its findings to the Secretary of State for the Home Department and to the Secretary of State for Health.

Annex B:

The Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001

The Misuse of Drugs Act 1971 (the Act) and the Misuse of Drugs Regulations 2001 (the Regulations) restrict the possession, supply, administration and disposal of controlled drugs.

Controlled drugs are categorised into three classes as specified under Schedule 2 of the Act. This classification is designed to enable the control of particular drugs according to their comparative harmfulness, either to individuals or to society at large, when they are misused. The classes determine the level of penalties (fine and/or imprisonment) applicable to offences (as defined in the Act) involving the different drugs in a descending order of severity, from A to C.

Class A (the most harmful) includes morphine, diamorphine (heroin), cocaine, LSD.

Class B (an intermediate category) includes amphetamines and barbiturates.

Class C (the least harmful) includes anabolic steroids, benzodiazepines, growth hormones, cannabis and cannabis resin.

Controlled drugs are also categorised into five schedules by the Regulations, corresponding to their therapeutic usefulness and misuse potential. The drugs listed in Schedule 1 have no recognised medicinal use and may only be lawfully possessed under licence from the Home Office. For the purposes of medicinal use, reference is restricted to Schedules 2–5.

Schedule 2

Schedule 2 controlled drugs include the opiate based drugs used in acute and palliative care. They are subject to regulations determining their supply and storage.

Supply: Supply is restricted to licensed wholesalers, practitioners, hospitals and registered pharmacies. Wholesalers are permitted to supply only to a person authorised to possess. Practitioners are restricted to supplying their patients. Hospitals (in so far as it represents the business of the hospital) may supply patients, wards and practitioners. Pharmacies may supply on receipt of a valid prescription or signed order. Additional prescription writing requirements exist.

Record: A record of all Schedule 2 controlled drugs obtained and supplied must be kept in a register, the form of which must comply with the relevant regulations.

Storage: Schedule 2 controlled drugs are subject to safe custody requirements.* They must be stored in a locked receptacle, usually in an appropriate controlled drug cabinet or approved safe, which can be opened by a person in possession of the controlled drug or a person authorised by that person.

* The Misuse of Drugs (Safe Custody) Regulations 1973

Destruction: The destruction of Schedule 2 controlled drugs must be appropriately authorised and the person witnessing the destruction must be authorised to do so.*

Schedule 3

Schedule 3 contains a number of substances that are perceived as being open to abuse, but less likely to be so than Schedule 2 controlled drugs. It includes a number of synthetic opioids together with other substances.

Supply: The regulations concerning supply (and the additional prescription writing requirements) are similar to Schedule 2 controlled drugs.

Record: There is no statutory requirement to record the supply of Schedule 3 controlled drugs.

Storage: The majority of Schedule 3 controlled drugs are exempt from safe custody requirements and can be stored on the open dispensary shelf. Certain Schedule 3 controlled drugs are exceptions to this exemption.**

Destruction: The requirements relating to destruction do not apply to Schedule 3 controlled drugs (unless the controlled drugs are manufactured by the individual).

Schedule 4

All Schedule 4 controlled drugs are Prescription Only Medicines (POMs) and are divided into two parts. Part 1 contains most benzodiazepines and zolpidem. Part 2 contains most of the anabolic steroids.

Supply: Supply is restricted to supplies against practitioners' prescriptions or in accordance with Patient Group Directions (PGDs) but there are no additional requirements as to the form of prescription other than those that apply to all POMs.

Record: There is no statutory requirement to record the supply of Schedule 4 controlled drugs.

Storage: Schedule 4 controlled drugs are exempt from safe custody requirements and can be stored on the open dispensary shelf.

Destruction: The requirements relating to destruction do not apply to Schedule 4 controlled drugs (unless the controlled drugs are manufactured by the individual).

Schedule 5

Schedule 5 controlled drugs, which include POMs and over the counter medicines, contains preparations of certain controlled drugs such as codeine, pholcodeine, cocaine and morphine which are exempt from full control when present in medicinal products of low strength. They are excepted from the prohibitions on importation, exportation and possession.

Supply: Some of the controlled drugs in Schedule 5 are available for over the counter sale in registered pharmacies. It is for the pharmacist to use their professional judgement to determine the appropriateness of any supply and be alert to potential abuse of products.

* Regulation 27 (1) of the Misuse of Drugs Regulations 2001

** A small number of Schedule 3 controlled drugs are subject to safe custody requirements by virtue of the Misuse of Drugs (Safe Custody) Regulations 1973.

The Schedule 5 controlled drugs that are prescription only medicines (including codeine, dextropropoxephine and dihydrocodeine tablets) can only be supplied in accordance with a valid prescription or PGD.

Record: There is no statutory requirement to record the supply of Schedule 5 drugs.

Storage: Schedule 5 controlled drugs are exempt from safe custody requirements and can be stored on the open dispensary shelf.

Destruction: The requirements relating to destruction do not apply to Schedule 5 controlled drugs.

Annex C: Membership of the working groups and the Shipman sub-committee of the ACMD

Working Group 1

Name	Department/Organisation
Felicity Harvey	Department of Health (chair)
Susan Aitkenhead	Nursing and Midwifery Council
David Baker	Dispensing Doctors Association
Lynsey Balmer	Royal Pharmaceutical Society of Great Britain
Margaret Birtwistle	Advisory Council on the Misuse of Drugs
Elizabeth Dimond	Healthcare Commission
David Francis	Association of Chief Police Officers
Joe Gault	Department of Health, Social Services and Public Safety, Northern Ireland
Clare Gerada	Royal College of General Practitioners National Clinical Governance Support Team
David Glover	Department of Health
Stuart Harwood	ACMD Secretariat, Home Office
Christine Hastie	Commission for Social Care Inspection
Diane Heath	Guild of Healthcare Pharmacists
Carwen Wynne Howells	Welsh Assembly Government
Raymond Humphries	National Association of Chemist Inspection Officers
Sian James	Welsh Assembly Government
Una Lane	General Medical Council
Mandie Lavin	Royal Pharmaceutical Society of Great Britain
Michael Mawhinney	Department of Health, Social Services and Public Safety, Northern Ireland
Mike Mitchell	Welsh Assembly Government
Paul Philip	General Medical Council
Kay Roberts	Advisory Council on the Misuse of Drugs
Alaster Rutherford	NHS Confederation
Jim Smith	Department of Health
Hazel Sommerville	Commission for Social Care Inspection
Alan Stears	Consultant (retired Home Office Inspector)
Malcolm Ward	Dispensing Doctors Association
Pamela Warrington	Scottish Executive
Duncan White	National Association of Chemist Inspection Officers
Heidi Wright	National Prescribing Centre

Secretariat

Name	Department/Organisation
Charles Dobson	Department of Health
Margaret Jackson-Roberts	Department of Health
Tony Hill	Department of Health

Working Group 2

Name	Department/Organisation
Philip Leech	Department of Health (chair)
Susan Aitkenhead	Nursing and Midwifery Council
David Baker	Dispensing Doctors Association
Lynsey Balmer	Royal Pharmaceutical Society of Great Britain
Nigel Barns	Prescribing Advisers Group
Terry Bowley	Macmillan Cancer Relief
Chris Edwards	Home Office
Llora Finley	ACMD Shipman Sub-Committee
Sonia Garner	National Pharmaceutical Association
Brian Gennery	Joint Consultants Committee
David Glover	Department of Health
John Grenville	BMA General Practices Committee
Matt Griffiths	Royal College of Nursing
Jim Kennedy	Royal College of General Practitioners
Ian McMaster	Northern Ireland Office
Padmini Mishra	Scottish Executive
Mike Mitchell	Welsh Assembly Government
Christine Payne	General Medical Council
David Pruce	Royal Pharmaceutical Society of Great Britain
Kay Roberts	Advisory Council on the Misuse of Drugs
David Sleator	Department of Health
Lynn Smith	Nursing and Midwifery Council
Cathy Stannard	British Pain Society
Beth Taylor	Primary and Community Care Network
Amanda Watson	General Medical Council

Secretariat

Colin Pearson	Department of Health
Charles Dobson	Department of Health
Collette Young-Breeze	Department of Health

Working Group 3

Name	Department/Organisation
Barbara Hakin	Bradford South & West PCT (chair)
Susan Aitkenhead	Nursing and Midwifery Council
David Baker	Dispensing Doctors Association
Lynsey Balmer	Royal Pharmaceutical Society of Great Britain
Carol Bates	Royal College of Midwives
Chris Brooker	British Association of Pharmaceutical Wholesalers
Sue Carter	Guild of Healthcare Pharmacists
Paul Evans	Macmillan Cancer Relief
Tony Garlick	British Association of Pharmaceutical Wholesalers
Joe Gault	Department of Health, Social Services and Public Safety, Northern Ireland
Clare Gerada	Royal College of General Practitioners
David Glover	Department of Health
John Grenville	BMA General Practices Committee
Matt Griffiths	Royal College of Nursing
Mark Jones	Community Practitioners' and Health Visitors' Association/Amicus
Jim Kennedy	Royal College of General Practitioners
Tina Kenny	NHS Confederation/Milton Keynes PCT
Sadru Kheraj	South East London Strategic Health Authority
Stephen Lutener	Pharmaceutical Services Negotiating Committee
Colette McCreedy	National Pharmaceutical Association
Mike Mitchell	Welsh Assembly Government
Andrea Oz	National Conference of Cancer Self Help Groups
Jennie Potter	Community and District Nursing Association
David Pruce	Royal Pharmaceutical Society of Great Britain
Dave Roberts	Prescribing Support Unit
Ellie Scrivens	Keele University, Controls Assurance (HCSU)
Neil Slater	Company Chemists' Association
Lynn Smith	Nursing & Midwifery Council ACMD Shipman Sub-Committee
Tony Smith	Prescribing Support Unit
Alan Stears	Consultant (retired Home Office Inspector) ACMD Shipman Sub-Committee
Michelle Styles	National Pharmaceutical Association
Theresa Tate	National Council for Hospice and Specialist Palliative Care
Duncan White	National Association of Chemist Inspection Officers
Heidi Wright	National Prescribing Centre ACMD Shipman Sub-Committee
Lynn Young	Royal College of Nursing

Secretariat

Charles Dobson	Department of Health
Gul Root	Department of Health
Margaret Jackson-Roberts	Department of Health
Tony Hill	Department of Health

Working Group 4

Name	Department/Organisation
Flora Goldhill	Department of Health (chair)
David Baker	Dispensing Doctors Association
Lynsey Balmer	Royal Pharmaceutical Society of Great Britain
Yael Bradley-Birrell	General Medical Council
Brian Gennery	Joint Consultants Committee
John Grenville	BMA General Practices Committee: Prescribing sub-committee
Matt Griffiths	Royal College of Nursing
Alice Holmes	Department of Health
Sian James	Welsh Assembly Government
Peter Jones	Prescribing Advisors Group
Jim Kennedy	Royal College of General Practitioners
Stephen Lutener	Pharmaceutical Services Negotiating Committee
Gopa Mitra	Doctor Patient Partnership
Michelle Moran	NHS Confederation
Andrea Oz	National Conference of Cancer Self Help Groups
David Pruce	Royal Pharmaceutical Society of Great Britain
Kay Roberts	Advisory Council on the Misuse of Drugs
Theresa Rutter	Primary and Community Care Pharmacy Network
Joanne Shaw	Medicines Partnership
Neil Slater	Company Chemists' Association
Cathy Stannard	British Pain Society
Michelle Styles	National Pharmaceutical Association
Malcolm Ward	Dispensing Doctors Association
Vicky Wyatt	Department of Health
Secretariat	
Charles Dobson	Department of Health
Gul Root	Department of Health
Margaret Jackson-Roberts	Department of Health

Advisory Council on the Misuse of Drugs (ACMD)

Chair Professor Sir Michael Rawlins

Shipman sub-committee members

Roy Robertson (ACMD member)	Chair of the Sub-Committee GP (Edinburgh) Community Health Sciences, Edinburgh University
Margaret Birtwistle (ACMD member)	Specialist GP (Substance Misuse) Education and Training Unit, St George's Hospital, Medical School, London
Kay Roberts (ACMD member)	Royal College of General Practitioners Greater Glasgow Pharmacy Needle Exchange Scheme
Lynsey Balmer	Royal Pharmaceutical Society of Great Britain
Richard Dempster	Medical Protection Society
Linda Donaldson	Women and Childrens Unit, Forth Valley NHS
Stewart M Drage	General Practitioners Committee, British Medical Association
Clare Gerada	GP RCGP's National Expert Advisory Group on Drug Misuse
Tony Garlick	British Association of Pharmaceutical Wholesalers
Baroness Finlay of Llandaff	Cardiff University and Velindre NHS Trust
Alan W Hunter	Association of the British Pharmaceutical Industry
Clive Jackson	National Prescribing Centre
Maria Johnson	Association of Chief Police Officers
Sally Knight	Community Practice (Surrey)
Mandie Lavin	Royal Pharmaceutical Society of Great Britain
Gordon Lindsay	General Medical Council
Ian Power	University of Edinburgh
Sarah Shepherd	District Nursing (Edinburgh)
Lynn Smith	Nursing and Midwifery Council
Alan Stears	Consultant (retired Home Office Inspector)
Heidi Wright	National Prescribing Centre

Annex D:
**Information for patients – the proposed
communications campaign**

Message	Intended outcomes	Audience	Conveyed by	Medium	“Allies”
A. Generic messages					
A1. All medicines have the potential to cause harm if not used appropriately or if used other than by the patient for whom they are intended. All medicines should therefore be stored safely and securely. All unwanted medicines should be returned to a community pharmacy or the dispensing doctor’s surgery for safe disposal. Medicines disposed of at home could result in harm to the environment.	To raise awareness in general public of the importance of safe storage and possession of medicines in the home; to reduce the number of incidents causing adverse outcomes because of inappropriate storage. To ensure that all unwanted medicines are returned to a pharmacy for disposal; to reduce risks to public health and to the environment resulting from inappropriate disposal in the home.	General public	DH & RPSGB, <i>Ask About Medicines Week</i> (AAMW)	Posters, magazines, leaflets, stories in national papers, professional press, guidance to pharmacists	Major pharmacy chains, other pharmacy organisations, medical and nursing organisations
A2. As above	As above	General public (local campaigns)	Government Offices for the Regions, SHAs, PCTs	As above plus local media	GPs, pharmacies, local medical and pharmacy organisations
A3. This is your medicine and it is for you and you only. Please do not let anyone else take this medicine, even if they suffer from similar symptoms because it could cause them harm. Your doctor, nurse or pharmacist can advise you.	To raise awareness of the dangers of sharing medicines and to reduce the number of incidents from inappropriate use of medicines.	Individual patient	Prescriber, nurse, other healthcare professional	Consultation or in the home, possibly backed up by information leaflet about the condition in general (eg generated by decision support)	RPSGB, British Medical Association, national pharmacy, nursing and medical organisations

Message	Intended outcomes	Audience	Conveyed by	Medium	“Allies”
<p>A4. This is your medicine and it is for you and you only. Please do not let anyone else take this medicine, even if they suffer from similar symptoms because it could cause them harm. Your doctor, nurse or pharmacist can advise you. [Specific information on benefits and side effects if appropriate and if pharmacist has sufficient information about reasons for prescription.] Keep it safe and locked away from children. Return it to the pharmacy or dispensing doctor’s surgery when no longer needed. Please do not attempt to dispose of it in the home – this could result in harm to the environment or to other people.</p>	As above	Individual patient	Dispenser	Orally at time of dispensing, backed up by generic leaflets (or condition-specific leaflets if available and if the dispenser has sufficient information about the reasons for the prescription).	RPSGB, Dispensing Doctors Association, national pharmacy organisations
<p>B. Specific messages on controlled drugs</p> <p>B2. All medicines have the potential to cause harm if used inappropriately but some medicines, which are called controlled drugs, are subject to special legal restrictions. However, my advice is that this is the most appropriate medicine for you and your symptoms. [Discussion of alternatives if patient is concerned.] Please store this medicine safely and securely and return any unwanted medicines to your pharmacy or dispensing doctor’s surgery for safe disposal. Please do not let anyone else use this medicine even if they have similar symptoms.</p>	<p>To raise the level of knowledge of patients taking controlled drugs about the special legal requirements, without deterring patients from taking the medicines they need; to reduce the number of incidents that result in adverse outcomes.</p>	Individual patient	Prescriber	Verbally during the consultation, possibly backed up by leaflet (either about controlled drugs in general or on drugs for the particular condition eg pain relief)	RPSGB, BMA, national pharmacy nursing and medical organisations

Message	Intended outcomes	Audience	Conveyed by	Medium	“Allies”
<p>B3. All medicines have the potential to cause harm if used inappropriately but some medicines, which are called controlled drugs, are subject to special legal restrictions. However, please do not be put off taking this medicine, as it has been prescribed specifically for you and your symptoms. Please store it safely and securely and return any unwanted medicines to your pharmacy or dispensing doctor’s surgery for safe disposal. Please do not let anyone else use this medicine even if they have similar symptoms as it could cause them harm.</p>	<p>To ensure the patient’s understanding of what a controlled drug is and to reinforce the message given by the prescriber</p>	<p>Individual patient</p>	<p>Dispenser or healthcare professional</p>	<p>Orally at time of dispensing administration, possibly backed up by leaflet (either about controlled drugs in general or on drugs for the particular condition eg pain relief)</p>	<p>National professional organisations, single-issue patient and voluntary organisations</p>

Message	Intended outcomes	Audience	Conveyed by	Medium	“Allies”
C. Messages to other information providers					
C1. The involvement of patients in the decisions about the medicines prescribed for them is much more likely to result in them taking their medicines appropriately. For controlled drugs, patients need to be aware that these medicines are subject to special legal controls and could be dangerous in the wrong hands. Patients may in the course of discussion ask about possible alternatives not involving controlled drugs. Provided patients have been given all the necessary information then they can make an informed decision as to whether they want a prescription for a controlled drug or not.	To raise awareness of the importance of shared decision-making and to promote changes in professional behaviour which result in sharing of appropriate information and shared decisions.	Healthcare professionals	Professional bodies (BMA, Colleges, RPSGB, RCN)	Good practice guidance and education	Medicines Partnership Taskforce, patient organisations
C2. The involvement of patients in the decisions about the medicines prescribed for them is much more likely to result in them taking their medicines appropriately. For controlled drugs, patients need to be aware that these medicines are subject to special legal controls and could be dangerous in the wrong hands (eg an opioid medicine for someone not having ever had an opioid before). Manufacturers are encouraged to ensure that patient information leaflets convey these messages in language which will inform but not alarm the patient. They should also underline the need for safe storage of all medicines and for returning unwanted medicines to a pharmacy or dispensing doctor’s surgery for safe disposal.	To ensure that manufacturers, when developing their Product Information Leaflets give factual information about the status of controlled drugs in language that does not deter patients from using their medicines appropriately.	Manufacturers	Medicines and Healthcare Products Regulatory Agency	Guidance	Medicines Partnership Taskforce, patient organisations

Annex E: Summary of the Inquiry's recommendations and proposed action

Inquiry recommendation	Proposed action
<p>1 A controlled drugs inspectorate should be created, comprising small multidisciplinary inspection teams, operating regionally but co-ordinated nationally. Each team would include pharmacists, doctors, inspectors and investigators, at least some of whom would have a law enforcement background.</p> <p>The inspectorate would be responsible for inspecting the arrangements in pharmacies, dispensaries and surgeries, as to both the safe keeping of stocks of controlled drugs and the maintenance of controlled drugs registers (CDRs) and other records.</p> <p>It could be responsible for the supervised destruction of controlled drugs.</p> <p>The inspectorate would also be responsible for the monitoring of the prescribing of controlled drugs by means of examination of prescribing analysis and cost (PACT) data, which would include information derived from NHS and private prescriptions and requisitions.</p> <p>It might be responsible for the issue of special controlled drug prescription pads.</p> <p>If thought appropriate it might also assume many of the inspecting and other functions currently performed by Home Office drugs inspectors.</p> <p>Inspectors and investigators would require access to background information about a doctor or pharmacist under scrutiny. There must be the facility to investigate expertly any irregularities or unusual features discovered as the result of such inspection and monitoring.</p>	<p>We agree in principle. The Government proposes to strengthen and coordinate existing arrangements for monitoring and inspection through local networks centred on a named officer in each PCT. There would be a corresponding duty of collaboration on other local agencies. Staff who would be involved in this work would include PCT prescribing advisors and clinical governance leads, RPSGB inspectors, inspectors from the Healthcare Commission and CSCI, and police officers with appropriate skills (see Chapter 2).</p> <p>We agree in principle. The new monitoring and inspection regime would cover all these sectors (and also the hospital and private healthcare sectors and care homes). The intensity of inspection will depend on assessment of relative risk.</p> <p>We agree in principle. Local NHS organisations (PCTs and NHS or Foundation Trusts) would be responsible for ensuring that all destructions of controlled drugs were appropriately witnessed and recorded (see Recommendation 32).</p> <p>We agree in principle. Audit tools would be devised centrally but applied locally by PCT or hospital clinical governance leads. They would draw on information on both NHS and private prescriptions and requisitions and also on movement on stock movements (see Chapter 4 for details).</p> <p>We disagree. This will not be needed (see Recommendation 9).</p> <p>We disagree. The Home Office Drugs Inspectorate will continue to issue licences and inspect manufacturers and wholesalers, sharing information as appropriate with the local networks.</p> <p>We agree. Partners in local networks will agree protocols for sharing of intelligence and for access to information needed for investigations.</p>

Inquiry recommendation	Proposed action
<p>2 A medical practitioner should be entitled to prescribe or administer controlled drugs only if s/he needs to do so for the purposes of the 'actual clinical practice' in which s/he is engaged. For the vast majority of doctors, the existence or otherwise of such a need will be obvious. A practitioner who wishes to prescribe controlled drugs may, where the need is not obvious, have to justify such need when applying for the issue of a special controlled drug prescription pad.</p>	<p>We agree in principle. As a minimum, eligibility to prescribe controlled drugs (and all other medicines) should be dependent on the prescriber being accredited with a "licence to practise", or its equivalent, by the appropriate professional or registration body. Beyond this, good practice guidance will be strengthened to make clear prescribers should not prescribe beyond the limits of their competence and experience, and that disregard of this principle will result in fitness to practise procedures.</p>
<p>3 It should be a criminal offence for a doctor to prescribe a controlled drug for him/herself, or to self-administer a controlled drug from his/her own or practice stock save in circumstances of emergency, which circumstances should be covered by an appropriately worded statutory defence. The doctor should be required to declare the position on the prescription.</p>	<p>We agree in part. We agree that self-prescribing of controlled drugs except in emergency is inappropriate and will look to professional bodies to enforce through professional guidance and sanctions.</p>
<p>4 When a general practitioner (GP) has members of his/her immediate family on his/her list (which should happen only very rarely), s/he should inform his/her local primary care trust (PCT) of the position. It should be unacceptable for a doctor to prescribe a controlled drug for an immediate family member who is not on his/her list, save in circumstances of emergency. In all cases where a doctor prescribes a controlled drug for a member of his/her immediate family, the doctor should be required to declare on the prescription his/her relationship to the patient and, if it is the case, that s/he is prescribing in an emergency.</p>	<p>We agree in part. The Government will work with professional bodies to strengthen and clarify existing professional guidance</p>
<p>5 The General Medical Council (GMC) should make plain that it will be regarded as professional misconduct for a doctor to prescribe controlled drugs for anyone with whom s/he does not have a genuine professional relationship.</p>	<p>We agree in principle. The Government will ask professional bodies to strengthen current ethical guidance, defining what constitutes a "genuine professional relationship" and setting out the appropriate clinical behaviours which underpin good practice.</p>
<p>6 A medical practitioner convicted or cautioned in connection with a controlled drugs offence should be under a professional duty to report the conviction or caution to the GMC, which should immediately consider what, if any, interim action should be taken and should report the facts and its own action to the practitioner's employer or PCT.</p>	<p>We agree. The GMC has already issued guidance to this effect.</p>

Inquiry recommendation	Proposed action
<p>7 The Government should commission an independent review and audit of the way in which the GMC and PCTs are using their powers to restrict the rights of medical practitioners involved in controlled drugs offences to prescribe and administer controlled drugs. Only if satisfied that these powers are being properly exercised for the protection of the public should the Government allow the provisions of section 12 of the Misuse of Drugs Act 1971 to remain in abeyance or to be repealed.</p>	<p>We agree in principle. The Government has commissioned an independent review of PCT decisions. The GMC already has transparent arrangements for both internal and external audit of its fitness to practise decisions. The Government proposes to take legislative powers to repeal section 12 of the Misuse of Drugs Act 1971 but will not apply them until assessment of the available information confirms that this is appropriate.</p>
<p>8 Whenever a restriction is placed on a doctor's prescribing powers, this information must promptly be made available (preferably by electronic means) to those who need to know it, especially pharmacists who require access to such information at all times.</p>	<p>We agree. In the short term, this can be achieved by current arrangements for cascading alerts (grey letters). In future, it may be possible to make the information available on a secure intranet site, or to prevent unauthorised prescribing via the GP prescribing system.</p>
<p>9 A special printed form should be introduced for use when prescribing a controlled drug, whether within the NHS or on a private basis.</p> <p>Pads of such forms should be supplied only to doctors who need to prescribe such drugs in the course of their clinical practice.</p> <p>For the time being, these forms should be completed by hand, to the extent required by the Misuse of Drugs Regulations 2001 (MDR 2001).</p> <p>However, prescribers should be encouraged, where practicable, to print the prescribing information on the prescription form using a computer and to copy the information by hand.</p> <p>The existing handwriting requirements should not be repealed until Government is satisfied, by the conduct of pilot schemes, that the arrangements for computer generation and/or transmission of controlled drug prescriptions are sufficiently secure.</p>	<p>We disagree. Special pads would seriously inconvenience prescribers and risk "borrowing" of pads, thus negating the purpose of tighter control. The special character of controlled drug prescriptions could be marked in other ways eg by overprinting a controlled drug watermark.</p> <p>We disagree. The Government does not regard it as feasible or desirable to make such a rigid distinction between prescribers who do and who do not ever need to prescribe controlled drugs (see para 3.3).</p> <p>We agree. We accept that this is necessary in the short term. However, the Government proposes to move as quickly as feasible to electronic generation of controlled drug prescriptions (see below).</p> <p>We disagree. The advantages seem small and any discrepancies between the computer generated and handwritten information could result in delays for patients in getting the medicines they need. An alternative might be to ask prescribers to initial each individual controlled drug item on the prescription.</p> <p>We agree in part. Computerised systems can be designed to have an inbuilt audit trail/footprint and additional security features. The Government will seek further assurance that existing systems have adequate security features before allowing electronic transmission of prescriptions. Security is a paramount feature in the design of the system for electronic transmission of prescriptions.</p>

Inquiry recommendation	Proposed action
<p>10 The special form should be in such format as will enable the Prescription Pricing Authority (PPA) to scan the prescribing information into its database so as to permit subsequent analysis and monitoring.</p>	<p>We agree in principle. The current standard prescription form is already suitable for scanning of additional information and this could form part of the shorter term IT solution. In the longer term, information will be captured from electronic transmission of prescriptions.</p>
<p>11 The special form should show the GMC registration number of the medical practitioner to whom the pad of forms has been issued.</p> <p>No other practitioner should be permitted to use it.</p> <p>The form should require the prescriber to indicate whether the prescription has been issued under the NHS or privately.</p> <p>Each prescription would have its own unique identification number.</p>	<p>We agree in principle. Future systems will use a special 12-digit code which will uniquely identify all prescribers, their practice and PCT. However, absence of the identifier (for handwritten prescriptions) should not make the prescription invalid.</p> <p>We agree. Controls on computer systems will normally prevent this.</p> <p>We agree. Private prescribers will be required to use a similar but distinct form.</p> <p>We agree in principle. Prescription forms already have distinct numbers, but capturing this information will depend on introducing scanning technology at PPA. Further work is need and to determine if existing prescription numbers would be suitable or if new systems for generating prescription identifiers would be required. The same identification numbers could be used for PDRCs for injectable Schedule 2 drugs to enhance the audit trail.</p> <p>In the longer term, ETP will generate a unique prescription number for each prescription.</p>
<p>12 The special form should provide the prescriber with a space in which to record a brief description of the condition for which the controlled drug has been prescribed.</p> <p>Prescribers should be expected, as a matter of good practice, to ask patients to consent to the provision of this information.</p>	<p>We disagree. The patient care record (an integral part of the National Programme for IT) will provide a better solution in the longer term.</p> <p>We agree in principle in the context of the patient care record, but there may be good reasons for patients to refuse consent and this must be respected.</p>
<p>13 Consideration should be given to requiring that the patient's NHS number or some other patient-specific identifier should be included on the special form.</p>	<p>We agree. Implementation should be straightforward once prescriptions for controlled drugs can be generated from the practice system.</p>
<p>14 The amount of a controlled drug that can be dispensed on a single prescription should be limited to a supply sufficient to last 28 days. This restriction would not apply to drugs in Schedule 5 to the MDR 2001.</p>	<p>We agree in principle, though in exceptional circumstances a supply of more than 28 days may be justified. The Government will work with professional bodies to develop good practice guidance.</p>

Inquiry recommendation	Proposed action
15 The duration of validity of a prescription for controlled drugs should be limited to 28 days. This restriction would not apply to drugs in Schedule 5 to the MDR 2001.	We agree. A statutory 28 day limit will be introduced. Prescribers will however be allowed to extend the 28 day validity, for prescriptions of short duration of supply, by endorsing the prescription. Good practice guidance will define the (exceptional) circumstances in which this could be justified (see para 3.16).
16 When computer generated prescriptions are in general use for controlled drugs and when the electronic transmission of prescriptions is introduced, the software should be so designed as to ensure that both the time of issue of a prescription and the time at which it is dispensed are recorded.	We agree. The Government will in due course legislate to make this mandatory. In this context the “time of dispensing” should, if technically feasible, be taken to mean the time the prescription is handed over to the patient or representative, not the time the prescription is made up which could be significantly earlier.
17 The purchase of all stocks of controlled drugs for practice use should follow a procedure that is capable of being monitored. The same form which I have recommended for use when prescribing controlled drugs should also be used when ordering controlled drugs on requisition. The forms should be sent to the PPA for entry into its database so that all purchases of controlled drugs by any doctor can be monitored.	We agree, subject to further work on feasibility and cost. In the longer term the information could be transferred electronically.
18 GPs who keep a stock of Schedule 2 controlled drugs should be required (as now) to keep a CDR and to observe existing safe custody requirements.	We agree in principle. The Government fully accepts the importance of ensuring that all GP practices, and other providers of primary care services, should maintain a controlled drug register if they keep stocks of controlled drugs for practice use. Primary care providers will be required to make an annual declaration to the PCT as to whether they keep stocks of controlled drugs, and of any special circumstances.
They should be permitted to keep the CDR in electronic form.	We agree. The Government sees electronic controlled drug registers as a key part of the new audit trail (see para 4.14). The Government will therefore amend the Misuse of Drugs Regulations 2001 to allow electronic controlled drug registers and will work with professional organisations to promote their use through professional guidance. Once electronic controlled drug registers are in common use, and subject to consultation at the time, use of electronic controlled drug registers will become mandatory.

Inquiry recommendation	Proposed action
<p>The CDR should provide for the keeping of a running stock balance for each drug stocked.</p>	<p>We agree. The Government will amend the Misuse of Drugs Regulations 2001 accordingly.</p>
<p>Each GP who is either a principal in or employed by a practice that keeps controlled drugs for practice use should be under a legal obligation to comply with the terms of a standard operating procedure (SOP) devised or approved either by the PCT with which the practice contracts or, if and when a controlled drugs inspectorate is set up, by that body.</p>	<p>We agree. All healthcare providers holding stocks of controlled drugs should comply with an agreed SOP and will work with the Healthcare Commission to issue model SOPs for use both in the NHS and in the private sector. SOPs for NHS primary care providers will be agreed by the relevant Named Officer in the PCT in which the provider is located, for secondary care providers by the Trust's Proper Officer, for private providers by the Healthcare Commission as part of their registration processes.</p>
<p>The SOP should specify, among other things, the frequency with which the stock must be checked.</p>	<p>We agree. The content of SOPs will be informed by best current practice but will at a minimum include arrangements for checks on stocks/reconciliation against the running balance in the controlled drug register; arrangements for safe custody of controlled drug registers and access by practice/provider staff; and rules for transport of controlled drug registers by healthcare professionals.</p>
<p>Adherence to such SOPs should be mandatory and should be subject to regular inspection.</p>	<p>We agree in part. Adherence to SOPs will be monitored as part of the monitoring and inspection procedures described in Chapter 2 and reinforced through normal clinical governance processes.</p>
<p>Any doctor working as a locum should be under an obligation either to comply with the practice SOP or to make his/her personal arrangements to provide Schedule 2 drugs and to accept responsibility for keeping the necessary CDR.</p>	<p>We agree. As a general rule, the Government considers that locum doctors should adopt the procedures of the practice/provider in which they are working. Where this is not practicable (eg where a locum works across several practices) the PCT on whose Supplementary List the locum is registered should be responsible for supervision. This principle, and any exceptions, will be covered in the good practice guidance referred to above.</p>
<p>I suggest that the Healthcare Commission (or, if it comes into being, the controlled drugs inspectorate) should be responsible for approving SOPs for GPs in private practice and for ensuring compliance.</p>	<p>We agree. This will fall to the Healthcare Commission (see above).</p>
<p>Advice as to compliance and best practice should be issued nationally and should also be available from PCT officers in the course of the annual clinical governance visit or review.</p>	<p>We agree in principle. Local arrangements in PCTs may vary.</p>
<p>19 When the new arrangements for the provision of out of hours services come into effect, PCTs should establish protocols governing responsibility for the provision of Schedule 2 drugs and for the keeping of any CDR. I recommend the use of an appropriate SOP.</p>	<p>We agree. Guidance on the new out of hours services is already in preparation and will include suitable reference to the need for safe management of controlled drugs and compliance with relevant legislation.</p>

Inquiry recommendation	Proposed action
<p>20 There should be some relaxation of the strict requirement that a pharmacist is not permitted to dispense a controlled drug prescription unless there is full compliance with every technical requirement of the MDR 2001. Where the defect is only technical and the pharmacist is confident that the intention of the prescriber is clear, and is willing to accept professional responsibility for dispensing the prescription in the form in which it is presented, s/he should have the discretion to amend the prescription, to correct the technical defect and to dispense the drugs.</p>	<p>We agree. This principle has been strongly supported by pharmacy and patient organisations. The Government will amend the Misuse of Drugs Regulations 2001 to allow the pharmacist or dispenser to amend the prescription where there is a technical error and where the prescriber's intention is clear, in the light of all the information available to the dispenser.</p> <p>Working Group 3 suggested that the principle should if possible be extended to cover cases in which the intention is not fully clear but the dispenser can make a supply which in his/her judgement is safe and consistent with the underlying therapeutic intention. The Government agrees that every effort should be made to enable patients to get access to the drugs they need provided this does not put their safety at risk, and will explore this suggestion further in discussion with relevant stakeholders.</p>
<p>21 In the case of a controlled drug supply that must be recorded in the pharmacy CDR, a pharmacist should be required to ask the name and address of the person collecting the drugs, unless that information is already known to him/her. If the pharmacist does not know the person, s/he should also ask the person collecting the drugs to produce some form of personal identification. The name and address and a note of the form of identification provided should be recorded in the CDR, unless the collector is personally known to the pharmacist, in which case s/he should record that fact. If no identification is provided, the pharmacist should have discretion to supply or withhold the drugs and, if the drug is supplied, should record the fact that no identification was provided.</p>	<p>We agree. The Government will amend the Misuse of Drugs Regulations 2001 to require dispensers (including pharmacy or dispensing assistants) to ask for this information; the amendment will make clear that a dispenser who uses his/her discretion to make a supply in the absence of identification is not committing an offence. The Department of Health will issue guidance on what forms of identification would be acceptable.</p>
<p>22 Any healthcare professional, acting in his/her professional capacity, presenting a prescription or requisition for a controlled drug, the supply of which must be recorded in the pharmacy CDR, should, if not known to the pharmacist, be required to provide identification, preferably his/her professional registration card. The relevant information should be recorded in the CDR.</p>	<p>We agree. The Government will amend the Misuse of Drugs Regulations 2001 to require dispensers to seek this information and (in the case of drugs in Schedule 2) to require it to be recorded in the dispenser's controlled drug register. The Department of Health will, after discussion with the relevant professional organisations, issue good practice guidance requiring healthcare professionals to provide identification in these circumstances and advising on what forms of professional identification would be acceptable. If the healthcare professional is unable to provide formal ID, the pharmacist should have discretion to supply the controlled drug after seeking any corroborative information.</p>

Inquiry recommendation	Proposed action
23 Any person collecting controlled drugs in Schedules 3 and 4 from the pharmacy should be required to write and sign his/her name on the back of the prescription form.	We agree. Further consideration is needed on how to achieve an equivalent result when electronic transmission of prescriptions (ETP) is introduced.
24 Pharmacies should be permitted to keep their CDRs in electronic form.	We agree. Pharmacies should be allowed to keep their controlled drug registers in electronic form, and sees this as a key step to completing the audit trail. The Government will therefore amend the Misuse of Drugs Regulations 2001 to this effect at the earliest opportunity and will give notice that electronic controlled drug registers will in due course become mandatory. Once electronic controlled drug registers are in common use, pharmacies will be required at regular intervals to transmit information from the controlled drug register to a central data repository for reconciliation with information from suppliers.
25 The keeping of a running balance in pharmacy CDRs should henceforth be regarded as good practice. The Home Office should make its view on this clear to pharmacists, and the Royal Pharmaceutical Society of Great Britain (RPSGB) should publicise the new position. When electronic CDRs have come into general use, the keeping of such a balance should be made obligatory.	We agree. The Government will clarify or amend the Misuse of Drugs Regulations 2001 to make clear that controlled drug registers may include a running balance, and will invite the RPSGB and other pharmacy professional organisations to issue appropriate advice. The Government will also give notice of its intention to make a further amendment to the Misuse of Drugs Regulations 2001 in due course to make the inclusion of a running balance a mandatory requirement.
26 The name and professional registration number of the prescriber should be entered in the CDR, as should the name of the pharmacist responsible for supplying controlled drugs to a patient or his/her representative.	We agree in principle. In the short term the Government will clarify or amend the Misuse of Drugs Regulations 2001 to make clear that this information may be included in the controlled drug register, and will invite the RPSGB to promote it as good practice. It will further amend the Misuse of Drugs Regulations 2001 to make this mandatory once ETP, which will allow for automatic capture of information on the prescriber, is in common use.
27 The current requirement that a pharmacy CDR be kept for two years should be amended and the period should be extended to seven or, possibly, ten years. When electronic records are used, it should be possible (and it may be desirable) for CDRs to be kept even longer.	We agree in principle. Once electronic controlled drug registers are in common use, the Government will require pharmacies and dispensing practices to keep secure copies for up to 11 years.
28 The RPSGB should provide guidance to its members as to the information and advice to be given to patients and their representatives when receiving a supply of a controlled drug. This should usually comprise an accurate description of the controlled drug prescribed and advice about the need to keep the drug safe because of the risk of diversion. Patients and their representatives should be advised to return unused drugs to the pharmacy. This information and advice should be given both orally and in writing.	We agree in principle. The Government intends to mount a major campaign about the need for safe storage and safe disposal of <u>all</u> medicines. Specific information about controlled drugs should be given in the context of an informed dialogue between patients and healthcare professionals; the Government will promote this through guidance, education and provision of suitable materials (see Chapters 5 and 6).

Inquiry recommendation	Proposed action
<p>29 Pharmacists should be required to prepare a statutory patient drug record card (PDRC) to accompany every supply of injectable Schedule 2 drugs leaving the pharmacy. This should record the form and amount of the drug prescribed, the form and amount of the drug dispensed and the dosage instructions as they appear on the prescription.</p> <p>30. The healthcare professionals who administer such Schedule 2 injectable drugs should be obliged to enter every administration and new supply of such a drug on a master PDRC and should keep a running balance of the remaining stock.</p>	<p>We agree in principle. There is a need for closer audit of the use of injectable Schedule 2 controlled drugs in the community, and will pilot a system based on the Inquiry's proposals. The Government does not however see the need for a "master" PDRC, but considers that it would be more practicable for healthcare professionals to maintain a running balance on the PDRC relating to each separate supply of injectable Schedule 2 controlled drugs. When each supply is fully used up, the responsible healthcare professional should complete the PDRC and return it to the central data repository.</p>
<p>The destruction of any unused Schedule 2 injectable drugs should be recorded on the PDRC, wherever it takes place.</p>	<p>We agree in principle. The Government considers that it is good practice for healthcare professionals to return controlled drugs to pharmacists/dispensing surgeries for destruction rather than to destroy them in situ (see below). Where destruction in the home is considered necessary, the Government will require the destruction to be witnessed in the PDRC by a second signatory (but not necessarily an "authorised" signatory as defined in the current Misuse of Drugs Regulations).</p>
<p>After the death of the patient or when the time has come when injectable drugs are no longer required by him/her, the completed PDRC should be sent to the PCT to which the patient's GP is contracted. The PDRCs should be examined for anomalies and then married up with the patient's GP records. The controlled drugs inspectorate (if and when there is one) might carry out an occasional audit of PDRCs.</p>	<p>We agree in part. The Government agrees that the completed PDRC should be returned for analysis and reconciliation, but considers that this should be carried out centrally rather than by the PCT. The Department of Health will issue guidance to the NHS asking each PCT to establish procedures to ensure that the PDRC is recovered from the patient's home – wherever this can be done without causing undue distress – and returned to a central data repository for completion of the audit trail (see Recommendation 33 below).</p>
	<p>In the first instance, PCTs would be responsible for following up any discrepancies in the PDRCs. Information from the PDRC reconciliation would also be available for any subsequent "targetted" inspections undertaken on behalf of the PCT (see Chapter 2, especially para 2.15). The Healthcare Commission would be responsible for ensuring that PCTs had suitable arrangements in place for carrying out these investigations, but would not itself audit individual PDRCs.</p>

Inquiry recommendation	Proposed action
<p>31 Consideration should be given to changing the law so that all controlled drugs would become the property of the Crown on the death of the patient for whom they were prescribed.</p>	<p>We disagree. The Government is not persuaded that this change in the law is either necessary or would (as the Inquiry intended) make it easier for healthcare professionals to remove unwanted controlled drugs after the death of a patient. Under current legislation, no patient or carer is entitled to possess a controlled drug once there is no longer a clinical need. It would seem easier to rely on this argument than to attempt to persuade a grieving relative that they no longer “owned” the medicines in question – this might be particularly difficult in the case of a privately dispensed controlled drug.</p>
<p>32 There should be increased formality attaching to the destruction of injectable Schedule 2 controlled drugs dispensed for administration in the community. Their destruction and their removal from the home of the patient should be properly recorded and witnessed.</p>	<p>We agree. The Government will amend the Misuse of Drugs Regulations 2001 to require healthcare professionals to record on the PDRC, and have witnessed, any supply of injectable controlled drugs which they remove from the patient’s home or destroy at the end of a course of treatment. As noted above, good practice guidance will promote removal from home for destruction by a local pharmacy rather than destruction on the spot. The Government will also amend the Misuse of Drugs Regulations to make clear that healthcare professionals may lawfully remove unwanted controlled drugs; the healthcare professions should then ensure that this is reflected in their professional guidance.</p>
<p>The classes of person lawfully entitled to undertake or witness destruction should include doctors, pharmacists, nurses, suitably trained law enforcement officers or PCT officers, and inspectors of any new controlled drugs inspectorate.</p>	<p>We agree in principle. The Government will review the classes of person entitled to undertake or witness destruction. Working Group 3 strongly recommended that the authority to witness destruction of controlled drugs returned by patients should not be limited to a small number of “authorised signatories” but should be sufficiently broadly drawn so as not to interfere with the delivery of patient care at pharmacies and dispensaries. The critical requirement is that the witness should be professionally independent of the person carrying out the destruction (eg a pharmacist from another company) and should be professionally accountable for their actions.</p>

Inquiry recommendations	Proposed action
33 It should be the responsibility of PCTs to ensure that suitable arrangements are in place for the disposal of controlled drugs.	<p>We agree in principle. The Government agrees with this recommendation so far as it applies to the NHS. The Department of Health will issue guidance requiring PCTs to make suitable arrangements to ensure that any unwanted controlled drugs, and associated PDRCs in the case of injectable Schedule 2 controlled drugs, are recovered from patient's homes after the patient's death or the end of the treatment and returned to a community pharmacy or dispensing practice dispensary where the returned quantities will be entered on the controlled drug register. In general, a member of the clinical team responsible for the patient's care immediately before death (or the end of treatment) is likely to be the most appropriate person to carry out this task. PCTs should also ensure that pharmacies and dispensaries have arrangements for disposing of controlled drug waste which minimise the risk of diversion and comply with waste regulation.</p> <p>For the private sector, the Government will amend the Misuse of Drugs Regulations 2001 to make clear that the Registered Manager of each private healthcare establishment is responsible for ensuring the safe recovery and disposal of any controlled drugs unwanted at the end of a treatment or on the patient's death, and for recovering any associated PDRCs and returning them to the central data repository. The Government will ask the Healthcare Commission or Commission for Social Care Inspection, as appropriate, to enforce this requirement.</p>

Glossary

ACMD	Advisory Council on the Misuse of Drugs.
CDs	Controlled drugs: those drugs subject to controls on their prescribing, possession and supply. They are listed in one of the five Schedules to the Misuse of Drugs Regulations 2001. Those in Schedule 1 have no recognised clinical application.
CDR	controlled drug register
CHRE	The Council for Healthcare Regulatory Excellence (formerly the Council for Healthcare Regulatory Professions – CHRP); responsible for making the regulation of healthcare professionals more effective, protecting the public, ensuring consistency, and maintaining good practice.
CIOs	Chemist Inspection Officers; established police officers with a duty to inspect community pharmacies.
CPD	Continuing Professional Development
CSCI	The Commission for Social Care Inspection: single inspectorate for social care in England combining the work of the SSI, the SSI/Audit Commission Joint Review team and the social care work of the National Care Standards Commission.
CSM	Committee on Safety of Medicines. The CSM (and its subcommittees: Biologicals, Chemistry, Pharmacy and Standards, and Pharmacovigilance) is the body, appointed under Section 4 of the Medicines Act 1968, responsible for giving advice on safety, quality and efficacy in relation to human use of medicines. It is also responsible for collecting and investigating information relating to adverse drug reactions.
ETP	Electronic transfer of prescriptions
GDC	General Dental Council: regulates the dental profession, under the legal powers conferred by the Dentists Act 1984.
GMC	General Medical Council: regulates the medical profession, under the legal powers conferred by the Medical Act 1983.
GP	General (medical) practitioner
Healthcare Commission	The Healthcare Commission exists to promote improvement in the quality of healthcare in England and Wales. In England only this includes regulation of the independent healthcare sector.
MDA	The Misuse of Drugs Act 1971

MDR	Misuse of Drugs Regulations
NCAA	National Clinical Assessment Authority
NeLH	National Electronic Library for Health
NMC	The Nursing and Midwifery Council has replaced the UK Central Council and the four National Boards as the registration and regulatory body for nurses, midwives, and health visitors.
NPC	National Prescribing Centre
NPfIT	The National Programme for Information Technology focuses on changes to IT in the NHS that will improve patient experience. The programme has four particular goals: electronic appointment booking, an electronic care records service, electronic transmission of prescriptions, and fast, reliable underlying IT infrastructure.
NPSA	National Patient Safety Agency
PACT	Prescribing analysis and cost data (maintained by the PPA)
PCT	Primary Care Trust: the 302 PCTs cover all parts of England and receive their budgets directly from the Department
PDRC	patient drug record card
PPA	Prescription Pricing Authority
PSU	Prescribing Support Unit: an analytical team based in West Yorkshire SHA
RCGP	Royal College of General Practitioners
RCN	Royal College of Nursing
RMS	Regional Medical Service. A network of doctors, contracted with the former Regional Health Authorities to visit and report on general practices in their area. Abolished in 1991 and replaced with Regional Prescribing Advisors, comprising pharmacists as well as doctors.
RPSGB	The Royal Pharmaceutical Society of Great Britain regulates and inspects the profession of pharmacy in England, Scotland and Wales under legal powers conferred by section 60 of the Health Act 1999. It has been awarded a new supplemental Royal Charter (October 2004, operational from January 2005) that enlarges its flexibility in the use of these powers.
SchARR	Sheffield School of Health and Related Research
SHA	Strategic Health Authority: set up in April 2002, each covering an average population of 1.5 million. Their main functions include supporting PCTs and NHS Trusts and building capacity and supporting performance improvement across all their local healthcare agencies.
SOP	standard operating procedure

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