

Council meeting 1 & 2 February 2005

OPEN BUSINESS

The Shipman Inquiry Fourth Report into the Regulation of Controlled Drugs in the Community): Implications for the Work of the Society

Purpose

To consider the implications of recommendations in the Government's Response to the Shipman Inquiry's Fourth Report.

Recommendations

Council is asked

- i) to note the Government's Implementation Plan (Appendix 1).
- ii) to note the Government's Summary of the Inquiry's Recommendations and Proposed Action (Appendix 2).
- iii) to agree proposed the action plan for the Society's future work on the 4th report (Appendix 3).

1. Background

- 1.1 The Fourth Report of the Shipman Inquiry - *The Regulation of Controlled Drugs in the Community* - was published on 15 July 2004. Following the recommendations of the Working Party chaired by Elizabeth Filkin, the RPSGB published a response to the Fourth Report on 5 November 2004. The Government's Response to the Fourth Report was published on 9 December 2004 when the Shipman Inquiry Fifth Report - *Safeguarding Patients : Lessons from the Past- Proposals for the future* - was published.
- 1.2 At the time of publication of the Fourth Report of the Inquiry in July 2004, the Department of Health in England wrote to a number of professional, patient, NHS and other organisations to say that Ministers, while welcoming the broad thrust of the report, had made clear that much detailed work would be needed to consider the individual recommendations in the Report in consultation with interested parties.
- 1.3 A number of working groups were established to give detailed consideration to the recommendations in the Report and to develop proposals for short-term and long-term improvements. The RPSGB participated in all four working groups, which met several times in September and October 2004. The four groups examined Inspection, audit, prescribing rights and information for patients. The RPSGB is also represented at, and has contributed to, meetings of the Shipman ACMD Sub Committee, which will be reporting to the Home Office's Advisory Council on the Misuse of Drugs on the implications of the recommendations in the Fourth Report.
- 1.4 The main focus of the Inquiry was on the means by which Shipman was able to divert substantial quantities of diamorphine, which he then used to murder patients. The Inquiry found that Shipman obtained most of his illicit supplies by either:

- Collecting diamorphine from pharmacies on behalf of patients but misappropriating all or some of the diamorphine for himself; or
- Taking possession of unused stocks of diamorphine prescribed for terminally ill patients after their deaths.

1.5 The Fourth Report makes 33 recommendations, which can be divided into the following groups (a full list of the recommendations is at Annex B):

- There should be an integrated, multidisciplinary inspection regime to monitor and inspect the use of controlled drugs for healthcare both in the NHS and in the private sector (Recommendation 1).
- There should be restrictions in certain circumstances on the right to prescribe controlled drugs, and on the length and currency of prescriptions (Recommendations 2-8 and 14-15).
- More robust measures should be put in place to ensure the safekeeping of controlled drugs and to provide a clear audit trail (Recommendations 9-13, 16-23, 25-27, 29, 30, 32, 33).
- Advice should be developed for the benefit of patients (and their representatives) about controlled drugs covering such issues as safekeeping and the need to return unused drugs to the pharmacy (Recommendation 28).

1.6 In the foreword to the Report, Dame Janet Smith stated that her main objective was:

‘To devise systems that would deter or detect the activities of any other dishonest healthcare professional who might seek to obtain controlled drugs for his/her own improper purposes or to allow supplies of controlled drugs to be diverted to the illicit drugs market’.

1.7 Dame Janet also acknowledged that it was important that the provision of healthcare to patients genuinely in need of controlled drugs should not be adversely affected by any measures recommended to prevent the abuse of such drugs.

1.8 It should be noted that whilst the Inquiry was advised of the systems in Northern Ireland, Scotland and Wales, its recommendations were confined to systems in England. The Government Response will be implemented in England and Wales. Scotland will also consider how the proposed changes should be implemented. Discussions are pending on the legislative scope.

2. Next Steps

There will be ongoing work with the officials in the Department of Health which is co-ordinating implementation of the Government’s response to the Fourth Report. The Working Party and Council will continue to be updated on progress.

3. Risk implications

In discussions with Government about changes resulting from the Shipman Fourth Report, especially in relation to provision of services by the Inspectorate, a detailed risk analysis will be completed and considered.

4. Resource implications

- 4.1 A number of recommendations in the Fourth Report have implications for the Society; the Government's Implementation Plan is set out in Annex A.
- 4.2 The developments anticipated in the implementation of the Government's plan will impact upon resources. The Resource Management Committee (RMC) and Council will be kept up to date on developments.

Recommendations

Council is asked

- i) to note the Government's Implementation Plan (Appendix 1).
- ii) to note the Government's Summary of the Inquiry's Recommendations and Proposed Action (Appendix 2).
- iii) to agree the proposed action plan for the Society's future work on the 4th report (Appendix 3).

Mandie Lavin
Director Fitness to Practise & Legal Affairs

Appendix 1

Government Implementation Plan

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).

Appendix 2

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

No.	INQUIRY RECOMMENDATION	PROPOSED ACTION
1	<p>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 co-ordinate 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>It could be responsible for the supervised destruction of controlled drugs.</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>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>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>It might be responsible for the issue of special controlled drug prescription pads.</p>	<p>We disagree. This will not be needed (see Recommendation 9).</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>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>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. Partners in local networks will agree protocols for sharing of intelligence and for access to information needed for investigations.</p>
2	<p>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>

No.	INQUIRY RECOMMENDATION	PROPOSED ACTION
3	<p>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>
4	<p>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>
5	<p>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>
6	<p>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>
7	<p>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>
8	<p>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>

No.	INQUIRY RECOMMENDATION	PROPOSED ACTION
9	<p>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 repeated 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 e.g. 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 hand-written 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> <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>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 hand-written 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 needed 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>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>
10	<p>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>	
11	<p>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>	
12	<p>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>	

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	Prescribers should be expected, as a matter of good practice, to ask patients to consent to the provision of this information.	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.
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.	We agree. Implementation should be straightforward once prescriptions for controlled drugs can be generated from the practice system.
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.	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.
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.
	The CDR should provide for the keeping of a running stock balance for each drug stocked.	We agree. The Government will amend the Misuse of Drugs Regulations 2001 accordingly.

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	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.	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.
	The SOP should specify, among other things, the frequency with which the stock must be checked.	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.
	Adherence to such SOPs should be mandatory and should be subject to regular inspection.	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.
	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.	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 (e.g. 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.
	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.	We agree. This will fall to the Healthcare Commission (see above).
	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.	We agree in principle. Local arrangements in PCTs may vary.
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.	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.
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	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. 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,

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	<p>the prescription, to correct the technical defect and to dispense the drugs.</p>	<p>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>
21	<p>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>
22	<p>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>
23	<p>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.</p>	<p>We agree. Further consideration is needed on how to achieve an equivalent result when electronic transmission of prescriptions (ETP) is introduced.</p>
24	<p>Pharmacies should be permitted to keep their CDRs in electronic form.</p>	<p>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.</p>

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25	<p>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.</p>	<p>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.</p>
26	<p>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.</p>	<p>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.</p>
27	<p>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.</p>	<p>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.</p>
28	<p>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.</p>	<p>We agree in principle. The Government intends to mount a major campaign about the need for safe storage and safe disposal of all 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).</p>
29	<p>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>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>
30		

No.	INQUIRY RECOMMENDATION	PROPOSED ACTION
	<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>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 "targeted" 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>
31	<p>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>
32	<p>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>

No.	INQUIRY RECOMMENDATION	PROPOSED ACTION
33	<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>It should be the responsibility of PCTs to ensure that suitable arrangements are in place for the disposal of controlled drugs.</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 (e.g. a pharmacist from another company) and should be professionally accountable for their actions.</p> <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>

Appendix 3

Shipman Inquiry 4th Report- Onward Work plan

4 th Report Recommendation	Government Response	Implementation Plan	Action By Society	Lead Directorate
<p>1. Inspection Arrangements</p>	<ul style="list-style-type: none"> • Strengthen and co-ordinate existing monitoring and inspection arrangements. • Each NHS & private healthcare organisation to be responsible for monitoring use and management of CDs by the health professionals they employ or contract. A 'proper officer' within the organisation will have statutory responsibility to carry out these functions. • Statutory duty of collaboration between police, inspectorates and local agencies • Support unit based in Healthcare commission for overall quality assurance and leadership • Inspection regime will cover all sectors. Intensity of inspection will depend on assessment of relevant risk. • RPSGB inspectors to be responsible for inspecting CDs in community pharmacies. • RPSGB inspectors to have power (but not duty) to inspect secondary care. • Commission study on best ways of sharing intelligence on controlled drug issues. • Further work to apply inspection and monitoring principals to other settings e.g. dental services, educational establishments, prisons etc 	<p>Jan 2005- August 2005</p> <ul style="list-style-type: none"> • Draft legislation to impose statutory responsibility on healthcare organisations and statutory duty of collaboration between agencies. • Issue guidance on new inspection arrangements. • Reach agreement with RPSGB over CD inspection of community pharmacies. • Set up arrangements for training of inspectors and support to PCTs. <p>September 2005- March 2006</p> <ul style="list-style-type: none"> • Legislative changes to impose statutory responsibility on healthcare organisations and statutory duty of collaboration between agencies. • Feasibility study on national controlled drug intelligence database. 	<ul style="list-style-type: none"> • Determine inspection methods, standards and resource implications via ongoing work with DoH inspection subgroup & RPSGB inspector's scoping exercise. • Consider implications of extension of RPSGB inspectors role i.e. <ul style="list-style-type: none"> - Recruitment issues - Benchmarking and assessment standards - Appeal mechanisms - Publication of results • Discuss with proposed extension of RPSGB inspectors role with DoH • Prepare for statutory duty of collaboration. • Agree MOI with relevant organisations. • Consider training and performance management arrangements for inspectorate. • Respond to consultation papers on legislative changes. • Communicate new arrangements to membership. 	<p>FTP</p>

4 th Report Recommendation	Government Response	Implementation Plan	Action By Society	Lead Directorate
<p>2. Prescribing rights of medical practitioners</p>	<ul style="list-style-type: none"> Prescribers need licence to practise Professional ethical guidance to make clear that -treatment should be based on thorough history taking and examination -there should be genuine clinical need for treatment -prescriber should not prescribe beyond experience and competence -if the prescriber not patients normal GP they should seek patient consent to inform the GP of the consultation 	<p>September 2005-March 2006</p> <ul style="list-style-type: none"> Professional organisations to issue good practice guidance. 	<ul style="list-style-type: none"> Guidance on verifying a prescribers licence to practise. CoE requirement for pharmacist to be satisfied of prescribers licence to practise Update pharmacists on changes to information available via GMC on-line register. Develop CoE standards and guidance for pharmacist prescribers based on principals detailed in response. Consider issue of same pharmacist being responsible for prescribing and dispensing. 	PQI
<p>3. self-prescribing/ administration of CD by doctor</p>	<ul style="list-style-type: none"> Strengthen current ethical guidance to make clear that it is inappropriate for prescribers to self-prescribe/self-administer except in genuine emergency. Guidance to make clear what self-treatment is permissible in an emergency To be enforced through professional regulation 	<p>September 2005-March 2006</p> <ul style="list-style-type: none"> Professional organisations to issue good practice guidance. 	<p>Advise on practitioners professional requirements RE; self prescribing/ administration</p> <p>Guidance on what to do if a practitioner is self-prescribing</p> <p>Consider similar CoE requirement and supporting guidance for pharmacists once independent prescribing permissible</p>	PQI
<p>4. Prescribing of CDs for family and friends</p>	<ul style="list-style-type: none"> Practitioners not to have members of immediate family on their list or prescribe schedule 2-4 for a family member not on their list. CHRE, professional regulators and NHS to develop guidance to define limited range circumstance that treatment would be acceptable. Enforce through NHS and professional good practice guidance. 	<p>September 2005-March 2006</p> <ul style="list-style-type: none"> Professional organisations to issue good practice guidance 	<p>Advise on practitioners professional requirements RE: prescribing for family and friends.</p> <p>Guidance on what to do if practitioner prescribing for family and friends</p> <p>Similar CoE requirement for pharmacists <i>(not an immediate issue for supplementary prescribing because of requirement for CMP to be agreed with independent prescriber but will be an issue when pharmacists able to prescribe independently).</i></p>	PQI
<p>5. Prescribing CDs when no genuine professional relationship</p>	<ul style="list-style-type: none"> Professional guidance to support this requirement. Guidance to define 'genuine professional relationship 	<p>September 2005-March 2006</p> <ul style="list-style-type: none"> Professional organisations to issue good practice guidance 	<p>Similar CoE requirement for pharmacists <i>(present legal restrictions would prevent supplementary pharmacist prescribers prescribing when no professional relationship but should consider</i></p>	PQI

4 th Report Recommendation	Government Response	Implementation Plan	Action By Society	Lead Directorate
6. Medical practitioners to inform GMC about convictions/ cautions involving CDs.	<ul style="list-style-type: none"> Work with CHRE and professional regulators to follow the GMC in placing prescribers under professional obligation to notify them of CD related convictions or cautions within a reasonable time. 		<p><i>professional requirement in preparation for independent prescribing</i></p> <ul style="list-style-type: none"> Retention fee form now requires disclosure of cautions, convictions & fitness to practise proceedings by regulators or licensing bodies. Consider requirement to inform Society about criminal or fitness to practise proceeding in a timely manner (e.g. within 6 weeks). Guidance to reiterate that failure to inform the Society in timely manner may result in professional misconduct. 	PQI/ FTP
8. Information about prescribing restrictions to be available to pharmacists and others at all times.	<ul style="list-style-type: none"> Use established arrangements for cascading information about prescribers who have prescribing restrictions. In long term utilise IT tools and consider placing information on a secure intranet site accessible by all pharmacists. 	<p>April 2007 onwards</p> <ul style="list-style-type: none"> Consider feasibility of setting up secure intranet site listing those prescribers whose prescribing of CDs is restricted. 	<ul style="list-style-type: none"> Practice guidance on accessing information about doctors (and other prescribers) license to practice. Develop arrangements to convey information about restrictions on a pharmacist's fitness to practise e.g. via on-line register <i>(note- GMC intend to provide information about voluntary undertakings not to practise and Shipman 5 will also impact on this recommendation)</i> 	PQI/ FTP
9. Special CD prescription form.	<ul style="list-style-type: none"> NHS- overprint standard Rx forms. Private- standardised form (distinct from NHS). Move to computer generated Rx as soon as practical. Each CD item to be endorsed with prescriber's signature. 	<p>January 2005- August 2005</p> <ul style="list-style-type: none"> Amend legislation to allow computer generated CD prescriptions. <p>September 2005-March 2006</p> <ul style="list-style-type: none"> Regulations on mandatory use of standard forms for private prescribing. <p>April 2006-March 2007</p> <p>Set up systems to capture and analyse data on private prescribing.</p>	<p>Guidance for pharmacists on all new requirements for CD prescriptions. Update FTP factsheets 1 and 2 & MEP.</p>	PQI
11. CD Rx to show doctors GMC number. No other practitioner	<ul style="list-style-type: none"> Amend MoD Regulations to require unique prescriber ID (12 digit code) on NHS and private prescriptions. Absence of identifier should not 	<p>September 2005-March 2006 ?</p> <ul style="list-style-type: none"> Amend MoD Regulations to require prescriber ID on CD prescriptions. 	<p>Provide guidance on what to do if prescriber identifier missing i.e. -when to treat as technical breach, -what to do if prescribers repeatedly fail</p>	PQI

4 th Report Recommendation	Government Response	Implementation Plan	Action By Society	Lead Directorate
<p>to use this form. Each Rx to have unique identifier.</p>	<p>make Rx invalid. <ul style="list-style-type: none"> Discuss feasibility of a check that, for hand-written prescriptions, the signature matches the ID number. ETP will provide each prescription with a unique prescription number. </p>		<p>to comply.</p>	
<p>12. CD Rx to show details of condition being treated.</p>	<ul style="list-style-type: none"> Not supported- electronic patient-care record to provide better long-term solution. Professional Guidance to encourage prescribers to explain the advantages of sharing information about patient's condition within the clinical team, but patient's wish not to share information to be respected. 	<p>April 2007 onwards</p>	<p>Review CoE Confidentiality requirements and supporting guidance.</p>	<p>PQI</p>
<p>13. Patient NHS number (or similar) to be included on Rx.</p>	<p>Consult on amending MoD to require patient's NHS number on NHS and private controlled drug prescriptions.</p>	<p>September 2005-March 2006</p>	<p>Provide guidance on technical breaches.</p>	<p>PQI/ FTP</p>
<p>14. Maximum 28 days supply of CD to be prescribed on single Rx</p>	<ul style="list-style-type: none"> Enforce through good practice guidance. Max 28 days supply of schedule 2-4 CDs unless genuine clinical reasons for longer supply. Consult on amending MoD to allow repeat dispensing of CDs. PCT's to be informed of exceptions made. 	<p>September 2005-March 2006 Professional organisations to issue good practice guidance on the normal maximum amount of CDs to be prescribed.</p>	<ul style="list-style-type: none"> Guidance on what to do when more than 28 days supply prescribed. Guidance for pharmacist prescribers on amount to be prescribed. 	<p>PQI</p>
<p>15. CD Rx to only be valid for 28 days.</p>	<ul style="list-style-type: none"> Statutory 28 day validity for schedule 2-4 CD prescriptions. Prescribers may where clinically necessary, endorse and sign the prescription to extend its validity to 91 days. Professional guidance to detail circumstances in which extension is appropriate. 	<p>September 2005-March 2006 <ul style="list-style-type: none"> Regulation of the normal validity of CD prescriptions. Professional organisations to issue good practice guidance </p>	<p>Guidance on circumstances where extending the validity of the prescription would be appropriate.</p>	<p>PQI</p>
<p>16. Time of issue and time of dispensing prescription to be recorded.</p>	<p>Ensure ETP software captures time of issue and time prescription handed to the patient.</p>	<p>April 2007 onwards (once ETP and electronic CD registers in widespread use) <ul style="list-style-type: none"> Amend MoD regulations to make mandatory requirement. </p>	<p>Develop appropriate supporting guidance.</p>	<p>PQI</p>

4 th Report Recommendation	Government Response	Implementation Plan	Action By Society	Lead Directorate
<p>17. Purchase of CD stock for practice use to be monitored. CD Rx to be used to requisition stock. PPA to monitor.</p>	<ul style="list-style-type: none"> Amend MoD Regulations to require standard CD requisition form copy of requisition form to be sent to PPA electronic CD registers Assess cost and feasibility of legislating that information from electronic CD registers be sent to central data repository for reconciliation with information from suppliers. 	<p>September 2005-March 2006</p> <ul style="list-style-type: none"> Regulations on the mandatory use of standard GP requisition forms. <p>April 2006-March 2007</p> <ul style="list-style-type: none"> Set up systems to capture and analyse data from GP requisitions. <p>April 2007 onwards</p> <ul style="list-style-type: none"> Wholesalers, GPs and pharmacists to send information to central repository for analysis. 	<ul style="list-style-type: none"> Communicate interim and long-term arrangements. Consider confidentiality issues. 	PQI
<p>20. Pharmacist to have ability to amend technical defects.</p>	<ul style="list-style-type: none"> Amend MoD Regs to allow pharmacists to amend prescription where there is a technical error and the prescriber's intention is clear. Consider whether this principal should be extended to circumstances where prescribers intention not fully clear but pharmacists can make safe supply inline with underlying therapeutic intentions 	<p>September 2005-March 2006</p> <ul style="list-style-type: none"> Amend MOD Regulations to allow pharmacists to correct technical errors in CD prescriptions. 	<ul style="list-style-type: none"> Work with Home Office to determine what will constitute technical defect. Publicise guidance for pharmacists. Consider CoE requirements. 	PQI/ FTP
<p>21. Pharmacists to record name, address and type of ID provided by persons collecting Sch 2 CDs. If no ID, pharmacists to use professional discretion.</p>	<ul style="list-style-type: none"> Amend MoD regs to require name and ID of any person (including healthcare professionals) collecting Sch 2 CDs on behalf of a patient to be recorded. Pharmacist who uses his/her discretion to supply in absence of identification will not commit an offence. 	<p>September 2005- March 2006</p> <ul style="list-style-type: none"> Amend MoD Regulations to require pharmacists to seek and record relevant information. 	<p>Guidance on acceptable ID what to do if no ID provided. confidentiality issues. pharmacists providing on-line/mail order services.</p>	PQI
<p>22. Health professionals to provide ID when collecting CDs (unless their known to the pharmacist). Relevant details to</p>	<p>As above.</p>	<p>As above.</p>	<p>Guidance.</p>	PQI

4 th Report Recommendation	Government Response	Implementation Plan	Action By Society	Lead Directorate
<p>be recorded in CDR.</p> <p>23. Persons collecting Sch 3&4 CDs to write name and sign back of Rx form</p>	<p>Agreed but consideration needed on how to achieve equivalent result when ETP introduced.</p>	<p>September 2005-March 2006</p> <ul style="list-style-type: none"> Amend MoD regulations. 	<p>Guidance.</p>	<p>PQI</p>
<p>24. Pharmacists to keep CDR electronically.</p>	<ul style="list-style-type: none"> Amend MoD Regulations accordingly. Become mandatory requirement once ETP and electronic registers in common use. Electronic records to be kept for 11 years. Information from electronic CD registers to be sent to central repository. 	<p>January 2005- August 2005</p> <ul style="list-style-type: none"> Amend legislation to allow electronic controlled drug registers. <p>September 2005-March 2006</p> <ul style="list-style-type: none"> Guidance in collaboration with professional organisations to promote electronic CD registers. <p>April 2007 onwards</p> <ul style="list-style-type: none"> Mandatory requirement for electronic CD registers Information from CD registers to be sent to central repository for analysis. 	<p>Update guidance on information protection and security, especially regular back-up.</p> <p>Consider CoE requirements for confidentiality.</p> <p>Guidance on ability for electronic records to be monitored with minimal disruption to dispensing process and need for adequate back-up facilities.</p>	<p>PQI</p>
<p>25. Running balances to be maintained-initially good practice, obligatory one electronic CDRs in general use.</p>	<ul style="list-style-type: none"> Amend/clarify MoD Regs to make clear CD register may include running balances and work with pharmacy organisations to promote. 	<p>September 2005-March 2006</p> <ul style="list-style-type: none"> Amend/clarify MoD Regulations to permit running balances. Guidance in collaboration with professional organisations to promote running balances. <p>April 2007 onwards</p> <ul style="list-style-type: none"> Running balances to become mandatory requirement. 	<ul style="list-style-type: none"> In absence of legal requirement consider CoE requirement to ensure consistency (<i>if no professional or legal requirement pharmacists risk variation in practices</i>). Guidance to cover, issues such as how to maintain running balances, frequency of reconciliation, how to audit, what to do if discrepancies arise etc. 	<p>PQI</p>
<p>26. CDR to capture name and professional registration number of prescriber and responsible pharmacist.</p>	<ul style="list-style-type: none"> Amend MoD Regulations to make clear that CD registers may include name/professional number of dispensing pharmacist and work with pharmacy organisations to promote. Amend MoD Regs to make record of name/ ID number of prescriber and pharmacist a mandatory requirement once ETP and electronic CD registers are in widespread use. 	<p>September 2005-March 2006</p> <ul style="list-style-type: none"> Amend/clarify MoD regulations to permit recording of name/ID of pharmacist and prescriber. <p>April 2007 onwards</p> <ul style="list-style-type: none"> Mandatory requirement to record this information. 	<p>Guidance on accountability- i.e. 'responsible pharmacist' and maintaining verifiable audit trails</p>	<p>PQI/ FTP</p>
<p>28. RPSGB to issue</p>	<ul style="list-style-type: none"> Sustained programme of 	<p>September 2005-March 2006</p>	<ul style="list-style-type: none"> Work with DoH and other stakeholders 	<p>PAC/PQI</p>

4 th Report Recommendation	Government Response	Implementation Plan	Action By Society	Lead Directorate
<p>guidance on information & advice to be given to patients when supplying a CD. Patients to be advised orally and in writing to unused drugs to the pharmacy.</p>	<p>communications to advise people and carers of need for safe storage and destruction of all unwanted medicines.</p> <ul style="list-style-type: none"> • Prescribers and pharmacists to convey specific information about legal status of CDs in context of shared decision taking. • IT systems to facilitate sharing of information between clinical team. • Prescribers to explain the advantage of information sharing to the patient. • Review education requirements for health professionals in light of this. <p>Subject to pilots</p> <ul style="list-style-type: none"> • PDCR to be given with each separate supply of injectable schedule 2 CD. • PDCR to be sent to central repository e.g. PPA. • Work with professional organisations to issue good practice guidance. 	<ul style="list-style-type: none"> • Beginning of sustained programme of information to patients about the safe storage of all medicines and return of unwanted medicines to pharmacies. 	<p>to support campaign</p> <ul style="list-style-type: none"> • Guidance to help ensure patient confidentiality and privacy respected • Consider implications for undergraduate, pre-registration and post grad education. 	PQI
<p>29 & 30 PDRC</p>	<p>Subject to pilots</p> <ul style="list-style-type: none"> • PDCR to be given with each separate supply of injectable schedule 2 CD. • PDCR to be sent to central repository e.g. PPA. • Work with professional organisations to issue good practice guidance. 	<p>September 2005-March 2006</p> <ul style="list-style-type: none"> • An evaluated pilot study of use of PDCRs for Sch 2 injectable CDs. April 2006-March 2007 (subject to outcomes of feasibility study) • Legislate to require pharmacists and dispensing practices to prepare PDCRs for each issue of Sch 2 injectable CDs. • Set up systems to capture and analyse data from PDCRs. • Issue good practice guidance about the use of PDCRs. <p>September 2005-March 2006</p> <ul style="list-style-type: none"> • Guidance to PCTs on the recovery and safe disposal of unwanted CDs. 	<p>Guidance and changes to CoE once full details are confirmed.</p>	PQI
<p>32 & 33 Destruction and removal of CDs from patients home to be witnessed. PCTs to ensure suitable arrangements in place for disposal of CDs.</p>	<ul style="list-style-type: none"> • Review classes of persons entitled to undertake or witness CD destruction • PCT to agree local arrangements for recovery and disposal of CDs. • Healthcare professional responsible for patients care should generally take responsibility for recovering unwanted CDs & PDCR. • Unwanted CDs normally to be returned to pharmacy for audit and destruction rather than destroyed on spot. • Registered manager of private health 	<p>September 2005-March 2006</p> <ul style="list-style-type: none"> • Guidance to PCTs on the recovery and safe disposal of unwanted CDs. 	<p>Guidance on CD destruction to include</p> <ul style="list-style-type: none"> -record keeping requirements -authorised witnesses -requirements of waste management legislation 	OPQ/ FTP

4 th Report Recommendation	Government Response	Implementation Plan	Action By Society	Lead Directorate
<p>Training and professional development (no specific recommendation in 4th report)</p>	<p>or social care establishment to be responsible for recovery and disposal of CDs (and PDCR)</p> <ul style="list-style-type: none"> • Review extent to which undergraduate and postgraduate education for health professional provides basic training on safe use and handling of CDs. • Promote update training as part of CPD. • Ensure all health professionals who prescribe or use CDs have regular appraisal of extent to which they kept up to date with clinical or regulatory changes. • Promote uptake of NPC guidance in primary care. • Promote uptake of Duthie guidance in secondary care (NHS and Private) <p>Ensure suitable training available for staff involved in monitoring and inspection of CD arrangements.</p>	<p>September 2005-March 2006</p> <ul style="list-style-type: none"> • Review of arrangements for initial and continuing education of healthcare professionals in CD issues. 	<ul style="list-style-type: none"> • Review undergraduate and pre-registration training requirements. • Consider implications for CPD and revalidation. • Review current CD fact sheets and other resources provided by the Society. 	<p>Education & Registrat'n</p>