

RECOMMENDATIONS

This summary contains only a brief statement of each of my recommendations. To understand the reasoning behind each recommendation, the reader must refer to the Chapter(s) in which the evidence relating to it is described and the section(s) of Chapter Fourteen in which the issues are discussed. The relevant references accompany each recommendation.

Inspection Arrangements

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 (CDRs) 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.
(Chapter Five, Chapter Nine, paragraphs 14.182–14.205 and paragraphs 14.256–14.257)

Prescribing Rights of Medical Practitioners

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.
(Chapter Four and paragraphs 14.8–14.17)
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.
(Chapter Four and paragraphs 14.18–14.32)
4. When a general practitioner (GP) has members of his/her immediate family on his/her list (which should happen only vary 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. (Chapter Four and paragraphs 14.18–14.32)

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. (Chapter Four and paragraphs 14.18–14.32)
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. (Chapter Four and paragraphs 14.37–14.46)
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. (Chapter Four and paragraphs 14.37–14.46)
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. (Chapter Four and paragraphs 14.37–14.46)

Prescriptions

9. A special printed form should be introduced for use when prescribing a controlled drug, whether within the NHS or on a private basis. Pads of such forms should be supplied only to doctors who need to prescribe such drugs in the course of their clinical practice. For the time being, these forms should be completed by hand, to the extent required by the Misuse of Drugs Regulations 2001 (MDR 2001). 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. 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. (Chapter Six and paragraphs 14.56–14.79)
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. (Chapter Six and paragraphs 14.56–14.79)
11. The special form should show the GMC registration number of the medical practitioner to whom the pad of forms has been issued. No other practitioner should be permitted to use

it. The form should require the prescriber to indicate whether the prescription has been issued under the NHS or privately. Each prescription would have its own unique identification number.

(Chapter Six, paragraphs 14.69–14.79 and paragraphs 14.83–14.92)

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. Prescribers should be expected, as a matter of good practice, to ask patients to consent to the provision of this information.
(Chapter Seven, Chapter Thirteen and paragraphs 14.109–14.118)
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.
(Chapter Four, Chapter Thirteen, paragraph 14.36 and paragraph 14.76)
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. (Chapter Four and paragraphs 14.93–14.99)
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.
(Chapter Six and paragraphs 14.100–14.102)
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. (Chapter Seven and paragraphs 14.80–14.82)

Safe Custody and Record Keeping for General Practitioners

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.
(Chapter Five, paragraph 14.127 and paragraph 14.133)
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. They should be permitted to keep the CDR in electronic form. The CDR should provide for the keeping of a running stock balance for each drug stocked. 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. The SOP should specify, among other things, the frequency with which the stock must be checked. Adherence to such SOPs should be mandatory and should be subject to regular inspection. 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. 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. 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.

(Chapter Six and paragraphs 14.119–14.133)

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.

(Chapter Six and paragraphs 14.128–14.133)

Controlled Drugs in the Pharmacy

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.

(Chapter Seven and paragraphs 14.103–14.108)

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.

(Chapter Seven and paragraphs 14.139–14.149)

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.

(Chapter Seven and paragraphs 14.139–14.149)

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.

(Chapter Seven and paragraphs 14.139–14.149)

24. Pharmacies should be permitted to keep their CDRs in electronic form.

(Chapter Seven and paragraphs 14.150–14.154)

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. (Chapter Seven and paragraphs 14.161–14.171)
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. (Chapter Seven and paragraphs 14.172–14.178)
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. (Chapter Seven and paragraphs 14.179–14.181)
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. (Chapter Seven, paragraphs 14.209–14.218 and paragraphs 14.245–14.253)

Controlled Drugs in the Community

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. (Chapter Eight and paragraphs 14.219–14.234)
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. The destruction of any unused Schedule 2 injectable drugs should be recorded on the PDRC, wherever it takes place. 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. (Chapter Eight and paragraphs 14.219–14.234)
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. (Chapter Eight and paragraphs 14.241–14.244)
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. 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.

(Chapter Eight and paragraphs 14.250–14.254)

33. It should be the responsibility of PCTs to ensure that suitable arrangements are in place for the disposal of controlled drugs. (Chapter Eight and paragraphs 14.239–14.253)