What the Government’s response to recommendations of the fourth report of the Shipman Inquiry means in practice

This table, prepared in the Royal Pharmaceutical Society’s Fitness to Practise and Legal Affairs Directorate, provides a general outline of planned regulatory changes arising from the Government’s response to the recommendations in the fourth report of the Shipman Inquiry. The changes depend on a formal consultation, the outcome of which will inform changes in Regulations that will need to be laid before Parliament for its approval.

The Society, other pharmacy bodies and the Department of Health will issue guidance on various aspects outlined in the Table, such as common standards for inspections, guidance on prescribing obligations and restrictions, notifying regulatory body of convictions and cautions around CDs, guidance on amendments to prescription requirements, guidance on amending technical errors on CD prescriptions, guidance on recovery and safe disposal of CDs and promotion of electronic CD registers and running balances.

### Table: Changes arising from the Government’s response to the fourth report of the Shipman Inquiry

<table>
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<th>Action to be taken</th>
<th>Estimated implementation date</th>
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| **Receipt of Controlled Drug stock**  
Wholesaler delivery note signed and copy retained for Schedule 2 CDs  
All Schedule 2 CDs stored in locked CD receptacle and unauthorised access prevented  
Record made of Schedule 2 CDs received in record and electronically  
Temazepam, flunitrazepam, buprenorphine and diethylpropanone stored in locked CD receptacle, and above all Schedule 2 CDs  
Suppliers and prescribers keep all signed orders and requisitions and invoices for at least seven years (currently signed orders, requisitions and invoices kept for two years)  
Standardised forms used for all requisitions and private prescriptions and requisitions produced electronically  
Only actual amount supplied recorded in CD register at time  | Current good practice  
Current legal requirement  
Current legal requirement  
Current legal requirement  
Current legal requirement  
Will be mandatory once IT systems are in place and electronic CD registers are in common use. Planned for late 2006–07. |
| **Recording in Controlled Drugs register (Schedule 2 CDs only)**  
Receipt and supply of Schedule 2 CDs recorded in CD register  
Record made in CD register in accordance with requirements of Misuse of Drugs legislation  
Running balances to be recorded  
Electronic registers allowed  
Additional information recorded (prescriber’s ID number, name and ID of person collecting CD and pharmacist supplying CD)  
Registers kept for at least 11 years (current legal requirement to keep registers for two years)  | Current legal requirement  
Current good practice. Home Office has issued a “letter of comfort” allowing recording of running balances and the Society has published guidance to help pharmacists to do this. It is planned that the Regulations will be amended later this year to allow recording of running balances. This is likely to be mandatory once electronic CD registers become mandatory (probably 2007).  
Proposed to be allowed from end of 2005, but probably not mandatory until 2007. Regulations should be amended later this year to allow additional recordings  
Likely to be mandatory once electronic CD registers become mandatory (probably 2007).  |
| **Storage of Controlled Drugs**  
Storage requirements in accordance with Safe Custody Regulations 1973 or with any exemptions granted  
Tamper-evident manufacturer seals to be left intact on receipt of CD and only opened at time of supply  
Regular stock checks carried out (weekly recommended)  
CD registers should not be stored in CD receptacle  
Standard operating procedures in place for CD stock held on premises  | Current legal requirement  
Current good practice  
Current good practice  
Current legal requirement  
Expected early in 2006  |
| **Dispensing/supply of Controlled Drugs**  
Supplies of Schedule 2 CDs to be entered in CD record  
Prescriptions and signed orders for CDs to comply with legal requirements  
FP10(MDA) forms used if specified CDs need to be dispensed in installments  
Only actual amount supplied recorded in CD register at time of supply  
Owings to be recorded if and when they are supplied  
CD prescriptions and requisitions produced electronically  
Standardised forms used for all requisitions and private prescriptions for CDs  
CD requisitions and private prescriptions sent to Prescription Pricing Authority (England), Prescribing Services Unit (Wales) or Prescription Pricing Division (Scotland)  | Current legal requirement  
Current legal requirement  
Current legal requirement  
Current good practice  
Proposed to be allowed from end of 2005  
Expected early 2006  |
| **Patient returned Controlled Drugs**  
All unused or unwanted CDs to be returned to pharmacies  
Records made of all returned Schedule 2 CDs in accordance with good practice requirements  
Restrictions on disposal of these CDs witnessed by another member of staff and signed against  | Current good practice  
Expected early in 2006; recording likely to be mandatory once electronic CD registers become mandatory (probably in 2007)  |
| **Destruction of Controlled Drug stock**  
Expired Schedule 2 CDs to be destroyed only in the presence of an authorised witness in accordance with Department of Health guidance  
CDs to be destroyed in accordance with guidance in “Medicines, ethics and practice: a guide for pharmacists”  
Discussions around broadening the range of people able to act as authorised witness  | Current good practice  
Current good practice  
Expected early 2006  |
| **Inspection of pharmacies**  
Routine inspections carried out by Society inspectors (no current duty for inspectors to inspect or monitor CDs)  
Inspeciton process by Society involves a duty to carry out CD inspection  
Chemist inspecting officers carry out regular inspections in community pharmacies in most areas  
Members of the primary care organisation carry out inspections (random rather than routine)  
Annual formal clinical governance review of pharmacies carried out by primary care organisations  
Professionals asked to notify the Society of any convictions or cautions, including CDs, as part of annual retention form  | Current good practice  
Expected 2006 — if positive, results could be up to 2008  
Expected 2005–06  
Current good practice  
Current requirement  |

* The inspection process may vary in accordance with the Government’s response to the recommendations made in the fourth and fifth reports of the Shipman Inquiry.