

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

Action to be taken	Estimated implementation date	Action to be taken	Estimated implementation date
Receipt of Controlled Drug stock		<i>(Dispensing/supply of Controlled Drugs, continued)</i>	
Wholesaler delivery note signed and copy retained for Schedule 2 CDs	Current good practice	Patient's NHS number on all prescriptions (not just CDs)	Expected early 2006
All Schedule 2 CDs stored in locked CD receptacle and unauthorised access prevented	Current legal requirement	Only 28/30 days' supply of CD prescribed	Future good practice. Policy expected early 2006
Record made of Schedule 2 CDs received in CD register	Current legal requirement	CD prescriptions valid for 28/30 days (currently 13 weeks)	Expected early 2006
Temazepam, flunitrazepam, buprenorphine and diethylpropion stored in locked CD receptacle, over and above all Schedule 2 CDs	Current legal requirement	Identity of person collecting CD recorded for Schedule 2 CDs	Expected early 2006
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)	Will be mandatory once IT systems are in place and electronic CD registers are in common use. Planned for late 2006–07	Persons collecting Schedule 3 and 4 CDs required to sign prescription form	Expected early 2006
		Prescriber's unique identifying number to be included on prescription and recorded	Expected early 2006; recording likely to be mandatory from late 2006/07
		Pharmacist supplying CD to sign and date CD register record	Current good practice but likely to become mandatory once electronic CD registers in place, probably in 2007
			Once electronic software in place — could be up to 2008
			Expected early 2006
Recording in Controlled Drugs register (Schedule 2 CDs only)			
Receipt and supply of Schedule 2 CDs recorded in CD register	Current legal requirement	Date and time of issue and supply of prescription captured	Once electronic software in place — could be up to 2008
Record made in CD register in accordance with requirements of Misuse of Drugs legislation	Current legal requirement	Where prescriber's intentions are clear, pharmacists allowed to amend CD prescriptions for technical errors in accordance with Regulations and good practice guidance	Expected early 2006
Running balances to be recorded	Current good practice. Home Office has issued a "letter of comfort" allowing recording of running balances and the Society has published guidance to help pharmacist 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).	Printing and completion of patient drug record card (PDR)	Depends on results of pilot studies in 2006 — if positive, results could be latter part of 2006–07.
		Information about restrictions on prescribing rights cascaded to pharmacists	Expected 2006
		Information on CDs given to patients as part of shared decision making	Expected 2005–06
Electronic registers allowed	Proposed to be allowed from end of 2005, but probably not mandatory until 2007	Pharmacists and nurses who are qualified as supplementary prescribers allowed to prescribe CDs in accordance with a clinical management plan	April 2005
Additional information recorded (prescriber's ID number, name and ID of person collecting CD and pharmacist supplying CD)	Expected to be mandatory from 2006–07, Regulations should be amended later this year to allow additional recordings		
Registers kept for at least 11 years (current legal requirement is to keep registers for two years)	Likely to be mandatory once electronic CD registers become mandatory (probably in 2007)	Patient-returned Controlled Drugs	
		All unused or unwanted CDs to be returned to pharmacies	Current good practice
		Records made of all returned Schedule 2 CDs in accordance with good practice requirements	Current good practice — legal requirement probably in 2006–07
		Destruction of these CDs witnessed by another member of staff and signed against	Current good practice — future legal requirement, probably in 2006–07
Storage of Controlled Drugs		Destruction of Controlled Drug stock	
Storage requirements in accordance with Safe Custody Regulations 1973 or with any exemptions granted	Current legal requirement	Expired Schedule 2 CDs to be destroyed only in the presence of an authorised witness in accordance with Department of Health guidance	Current legal requirement
Tamper-evident manufacturer seals to be left intact on receipt of CD and only opened at time of supply	Current good practice	CDs to be destroyed in accordance with guidance in 'Medicines, ethics and practice: a guide for pharmacists'	Current good practice. Being discussed with Department of the Environment, Food and Rural Affairs
Regular stock checks carried out (weekly recommended)	Current good practice	Discussions around broadening the range of people able to act as authorised witness	Expected early 2006
CD registers should not be stored in CD receptacle	Current good practice		
Standard operating procedures in place for CD stock held on premises	Expected early in 2006	Inspection of pharmacies*	
		Routine inspections carried out by Society inspectors (no current duty for inspectors to inspect or monitor CDs)	Current good practice
		Inspection process by Society involves a duty to carry out CD inspection	Possibly 2006 — still under discussion with Department of Health
		Chemist inspecting officers carry out regular inspections in community pharmacies in most areas	Current good practice — in future may not be done on a regular basis
		Members of the primary care organisation carry out inspections (random rather than routine)	Expected in 2006 (potentially only in England)
		Annual formal clinical governance review of pharmacies carried out by primary care organisations	Expected in 2006 (potentially only in England)
		Professionals asked to notify the Society of any convictions or cautions, including CDs, as part of annual retention form	Current requirement
		Audit of fitness-to-practise decisions made at the Society	Expected 2006

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